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 (KDPH).
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

Deputy Commissioner for Clinical Affairs, KY Department for Public Health

July 1, 2022
Date

Medical Director

Date

Local Health Department Name

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

Approved ECP method and dosing:

Initial

Date

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:

Name	Website
American Academy of Pediatric Dentistry	www.aapd.org
American Academy of Pediatrics	www.aap.org
American Cancer Society	www.cancer.org
American College of Nurse-Midwives	www.acnm.org
American College of Obstetrics and Gynecology	www.acog.org
American Diabetes Association	www.diabetes.org
American Dietetic Association	www.eatright.org
American Heart Association	www.americanheart.org
American Lung Association	www.lungusa.org
American Medical Association	www.ama-assn.org
American Nurses Association	www.nursingworld.org
Centers for Disease Control and Prevention	www.cdc.gov
March of Dimes Birth Defects Foundation	www.marchofdimes.com
National Breast & Cervical Cancer Early Detection Program	www.cdc.gov/cancer/

Other helpful websites and resources are:

Name	Website
Advisory Committee on Immunization Practices (ACIP)	https://www.cdc.gov/vaccines/acip/index.html
American Dental Association	www.ada.org
American Public Health Organization	www.apha.org
Arthritis Foundation	www.arthritis.org
Association of State & Territorial Health Organizations	www.astho.org
Dept. for Health and Human Services	www.os.dhhs.gov/
Department for Public Health Website	https://chfs.ky.gov/agencies/dph/Pages/default.aspx
Disease Links	www.nursing-links.com/diseases/
Environmental Protection Agency	www.epa.gov/enviro
First Candle/National SIDS Alliance	www.firstcandle.org
Food & Drug Administration (FDA)	www.fda.gov
Healthfinder	www.healthfinder.gov
Immunization Action Coalition	http://www.immunize.org/
Internet Drug List	www.rxlist.com
Johns Hopkins Medical Library	www.welch.jhu.edu/
Kids Health	http://kidshealth.org
KY Board of Nursing	www.kbn.ky.gov
Marchof Dimes	www.marchofdimes.com/
Mayo Clinic	www.mayohealth.org
Medicine Net	www.medicinenet.com
MedlinePlus Newborn Screening	www.nlm.nih.gov/medlineplus/newbornscreening.html
Morbidity and Mortality Weekly Report (MMWR)	www.cdc.gov/mmwr/
National Breast Cancer Foundation	www.nationalbreastcancer.org
National Cancer Institute (NCI)	www.nci.nih.gov
National Center for Infectious Diseases	www.cdc.gov/ncidod/
National Institutes of Health (NIH)	www.nih.gov
National Library of Medicine	www.nlm.nih.gov
National Newborn Screening & Genetics Resource	http://genes-r-us.uthscsa.edu/

Name	Website
National Organization for Rare Disorders	www.rarediseases.org/
Occupational Safety & Health Administration (OSHA)	www.osha.gov
Physicians' Desk Reference (PDR)	www.pdr.net
Proper Disposal of Prescription Drugs	http://www.whitehouse.gov/ondcp
Save Babies Through Screening Foundation	www.savebabies.org/
Taber's Online	www.tabers.com
UK Medical Center Library	https://libraries.uky.edu/libresources.php?lib_id=12
Vaccines for Foreign Travel	www.cdc.gov/travel/default.aspx
World Health Organization (WHO)	www.who.int

Clinical Service Guide Forms:

All Forms, Teaching Sheets, & QA tools for CSG are located on DPH Nursing Office Webpage.

HEALTH EQUITY

The Commonwealth faces many challenges in health outcomes, as evidenced by state health rankings, KyBRFS and disparities in health status between populations in Kentucky. The factors that contribute to Kentucky's overall health challenges are influenced by the conditions, in which we live, work and play know as social determinants of health (SDoH). These include education, physical and built environment, neighborhood, socioeconomic status, social connectedness, and access to health care. *Every facet of care provided by the local health department should include addressing and mitigating health inequities, SDoH, policies and processes and other barriers to care in efforts to improve linkage to resources and services to achieve optimal health for all Kentuckians.*

For more information, please contact Vivian Lasley-Bibbs, MPH, Director for the Office of Health Equity, Vivian.Lasley-Bibbs@ky.gov, 502-564-3970 ext. 4074.

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SECTION CONTACTS

1. Bronchodilator Rescue Inhaler	Michelle Malicote	502-229-5007
2. Cancer Screening/Follow-up	Colleen Toftness	502-564-3236 x4159
	Ellen Barnard	502-564-3236 x4157
3. Epinephrine Auto Injector Protocol	Michelle Malicote	502-229-5007
4. Family Planning	Shelley Wood	502-564-3236 x4169
5. Health Equity	Vivian Lasley-Bibbs	502-564-3970 x4074
6. Hepatitis C	Amanda Wilburn	502-564-3261 x4297
7. HIV	Tisha Johnson	502-564-6539 x4282
8. Immunizations	Amy Herrington	502-330-3071
9. Labatory Services	Robin Cotton	502-782-7711
10. Childhood Lead Poisoning Prevention	Trina Miller	502-564-1375
11. Naloxone Protocol	Ruth Willard	502-229-8922
	Michelle Malicote	502-229-5007
12. NBS & Metabolic Foods/Formula	Wanda Atha	502-564-1363
13. Oral Health	Julie McKee	502-564-3246 x4421
14. Pediatrics	Janice Bright	502-564-1366
15. Prenatal	Pauline Hayes	502-564-1370
16. Rabies	Kelly Giesbrecht	502-564-3418 x4313
17. Reportable Diseases	Carrell Rush	502-564-3261 x4240
18. STD	Sheri White	502-564-4804 x4301
19. TB	Emily Anderson	502-564-4276 x4298
	Michelle Stephens	502-564-4276 x4294

Minimal Requirements of a Cancer Screening Visit

Assessment	Initial Visit	Additional Visits
Note: KWCSP services (KWCSP-approved CPT codes) are now completely free to all KWCSP-eligible women.		
Comprehensive Health History to include: • Family history of breast/genital/colon-rectal cancers • LMP or date of menopause • Contraceptive method if childbearing age • Documentation of HRT or ERT, if menopausal • Date of last Pap/mammogram, and results • Previous abnormal Pap/HPV, diagnostics, treatments • Assessments: breast/cervical cancer risk factors/risk assessment, tobacco use	Required (Health History and Physical Examination Form)	Required (Interval Health History and Physical Examination Form)
Physical Examination to include: • Documentation of general appearance and mental status • Height/Weight/BMI • Blood pressure • Clinical breast exam (CBE) • Pelvic examination that includes visualization of the vulva, vagina, cervix/vaginal cuff, and thorough bimanual including adnexae • Other, as needed	Required Exceptions: Pelvic exams and CBE are not required for everyone	Required Exceptions: Pelvic exams and CBE are not required for everyone

Laboratory:
• Pap test and/or HPV test, as indicated by screening guidelines
• Fecal occult blood testing (i.e., FIT, Guaiac), beginning at age 45 for average-risk persons
  ○ Follow manufacturer's instructions
  ○ If positive, refer to M.D.
  ○ To inquire about the CRC Screening Program, contact Caisey at DPH: Caisy.ramseyjohnson@ky.gov , or call the KentuckyCancerLink navigator: 877-597-4655
• Hemoglobin, if indicated
• STD testing, if indicated by age/history/exam
	Required	Required

Referral for biennial mammogram (age ≥ 50) (annual mammograms as indicated; biennial mammograms for women under age 50, as indicated)	Required	Required
Counseling: (Documentation in medical record is required) • ACH-40, CSEM given/counseled and patient verbalized understanding • Breast Self-Awareness (optional teaching sheet) • Benefits/Risks of Mammography (optional teaching sheet) • Pap/Mammogram rescreening recommendations • Regular Exercise • Adequate diet (low fat, high fiber, 5 fruits/vegetables daily	Required	Required

• Osteoporosis/prevention and bone density testing • Risks/Benefits of HRT, if menopausal • Contraception, if needed • Smoking risks/cessation and referral • Immunization needs/updates • STD counseling, if indicated		
Ovarian Cancer Screening: Screening for ovarian cancer is not a recommended routine screening and is not a required part of the cancer screening visit. However, women with a family history or other women interested in being screened may be provided this phone number for finding a screening location and scheduling their own appointment: 1-800-766-8279		
Documentation of return clinic appointments	Required	Required
Follow-up of abnormal test results	Required	Required

Helpful Links:

Kentucky Wom**en's Cancer Screening Program**

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.

BREAST CANCER RISK FACTORS:

- Female age 40 or older; risk increases with age
- First degree relative (mother, sister, daughter) with a 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 section entitled "GENETIC COUNSELING/TESTING" for a definition of *close relative.*)
- Personal or family history of genetic syndromes such as Li-Fraumeni syndrome
- Personal history of breast cancer or a benign breast condition
- Dense breasts
- History of radiation treatments to the chest wall
- Early menarche (prior to age 12)
- Late menopause (after age 55)
- No pregnancies, or first pregnancy after age 30
- Hormone use: some oral contraceptives and combination (estrogen and progestin used together) hormone replacement therapy
- Use of the drug diethylstilbestrol (DES) or intrauterine exposure to it
- Overweight/Obese (especially after menopause)
- Lack of physical activity
- Alcohol consumption: risk increases with amount of alcohol consumed

BREAST SCREENING HISTORY

- Include dates and results of previous mammograms
- Elicit personal history of breast symptoms, including pain, tenderness, nipple discharge, palpable mass, or skin changes
- Document any personal history of breast cancer and previous biopsies or treatments
- Screen for risk factors (listed above)

BREAST SELF-AWARENESS, BREAST CANCER RISK ASSESSMENT, CLINICAL BREAST EXAMINATION AND MAMMOGRAPHY

- All females should be counseled on breast self-awareness (BSA) beginning at age 21. Counseling shall be documented in the medical record (e.g., "Breast Self-Awareness counseling provided").
- All women should undergo breast cancer risk assessment by age 25; update as needed.
- CBE:
    - A clinical breast exam (CBE) may be *offered** during the cancer screening visit to asymptomatic, average-risk women beginning at age 25 years (offered every 1-3 years for ages 25-39; offered annually to ages 40 and older).

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

  - A CBE should be performed annually on high-risk women or any woman who presents with symptoms.
  - 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.
  - The required method for performing the CBE is using the principles of positioning, three levels of palpation, and the vertical strip search pattern.
- 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.
- 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 ages 50-74 years of age should have biennial screening mammography.

  Note: 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.

- Trans-gender 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.
- Trans-gender 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 the consensus recommendations from The Center of Excellence for Transgender Health and the World Professional Association for Transgender Health

- 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.

- 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 surgical consult. These services can be reimbursed with KWCSP funds for eligible women.
- Screening of women at high-risk:
    - Women who are at high risk of developing breast cancer should be screened with both an annual mammogram and annual breast MRI, unless a provider orders a different screening.
    - Women assessed to be at high risk for breast cancer generally should begin screening at age 30, unless otherwise noted (below).
    - A woman is at 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

          Note: Risk assessment tools might not always be used to complete assessments, but as an option, a simple one can be found here .

        - ❖ She has a first-degree relative with pre-menopausal breast cancer (If no KNOWN family history of genetic mutations, begin screening 10 years younger than the age of the youngest family member when diagnosed, but not before age 30).
        - ❖ She has a KNOWN genetic mutation, such as BRCA 1 or BRCA 2 gene mutation, or is untested but has a first degree relative (mother, sister, daughter) with a KNOWN genetic mutation (This population should begin screening at age 25; ages 25-30 in this group should be referred to contracted gynecologist annually for assessment/consultation/screening orders.)

          Note: If the physician orders only a breast MRI for screening on a KWCSP-eligible woman, please contact KWCSP Nurse Consultant, Colleen Toftness: Colleen.Toftness@ky.gov .

        - ❖ She has a history of receiving radiation treatments to the chest wall between the ages of 10 and 30 years. (Begin annual screening 8 years after radiation was completed, but not younger than age 30)
        - ❖ She has a history of pre-cancer/cancer of the breast. (Post-mastectomy women will have a diagnostic mammogram of the opposite breast.)
- Any woman with an abnormal CBE should be referred for either a diagnostic mammogram (usually for women aged 30 and older) or ultrasound (often preferred for women 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).
- In menstruating women, the mammogram should be scheduled about 2 weeks after the LMP.

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 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. 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 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.

GENETIC COUNSELING/TESTING

Note: *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 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

**Note: "Close relative" means parent, sibling, or offspring (1st degree); grandparent, grandchild, uncle, aunt, nephew, niece, half-sibling (2nd degree); first cousin, great-grandparent, or great-grandchild (3rd 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.

PATIENT EDUCATION ON BREAST HEALTH

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. While the LHD staff will not

prescribe or refer women for risk-reducing medications, information should be provided to inform women of that option for some who are at increased risk for breast cancer. (An optional fact sheet from Komen.org can be found by clicking here , or one from the American Cancer Society can be found by clicking here.)

Patients with an abnormal CBE, mammogram, ultrasound, or MRI will have documented counseling done, as appropriate.

Breast Cancer Follow-up, Post Breast Cancer 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.

SURGICAL REFERRALS

- 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 the radiologist and found to be negative/benign. Thorough documentation by the radiologist shall be required.
- Any patient with a bloody nipple discharge (unilateral or bilateral) requires a referral to a surgeon for evaluation.
- Any patient with a spontaneous (without nipple stimulation) and/or unilateral nipple discharge requires a referral to a surgeon for evaluation.
- 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, phenothiazines, 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.
- If a patient presents with a "breast lump" that she has discovered herself, but both the CBE and mammogram (or other breast imaging) 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.
- 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 by sending an e-mail to Colleen.Toftness@ky.gov .
- 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 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.

TIMELY FOLLOW-UP

- 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.
- 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.
- Copies of results from consults and diagnostic procedures (including pathology reports) will be received and placed in the medical record within 30 days of the consult or diagnostic procedure.
- 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 chart. The NCM shall inform the patient of her next screening or diagnostic procedure that is ordered.
- 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.

TREATMENT FOR PRE-CANCER/CANCER OF THE BREAST

Patients that have been screened/diagnosed through the KWCSP, or a KWCSP-designated entity may be eligible for the Breast and Cervical Cancer Treatment Program (BCCTP) if diagnosed with pre-cancer or cancer of the breast. For more information and forms related to the BCCTP, please refer to their website here .

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 BCCTP. The NCM is responsible for initiating the BCCTP application.

Breast Pre-Cancerous Conditions:

- Lobular carcinoma-in-situ
- Atypical hyperplasia
- Benign Phylloides 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)”.

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 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 arrangements are made for the surgical consultation.

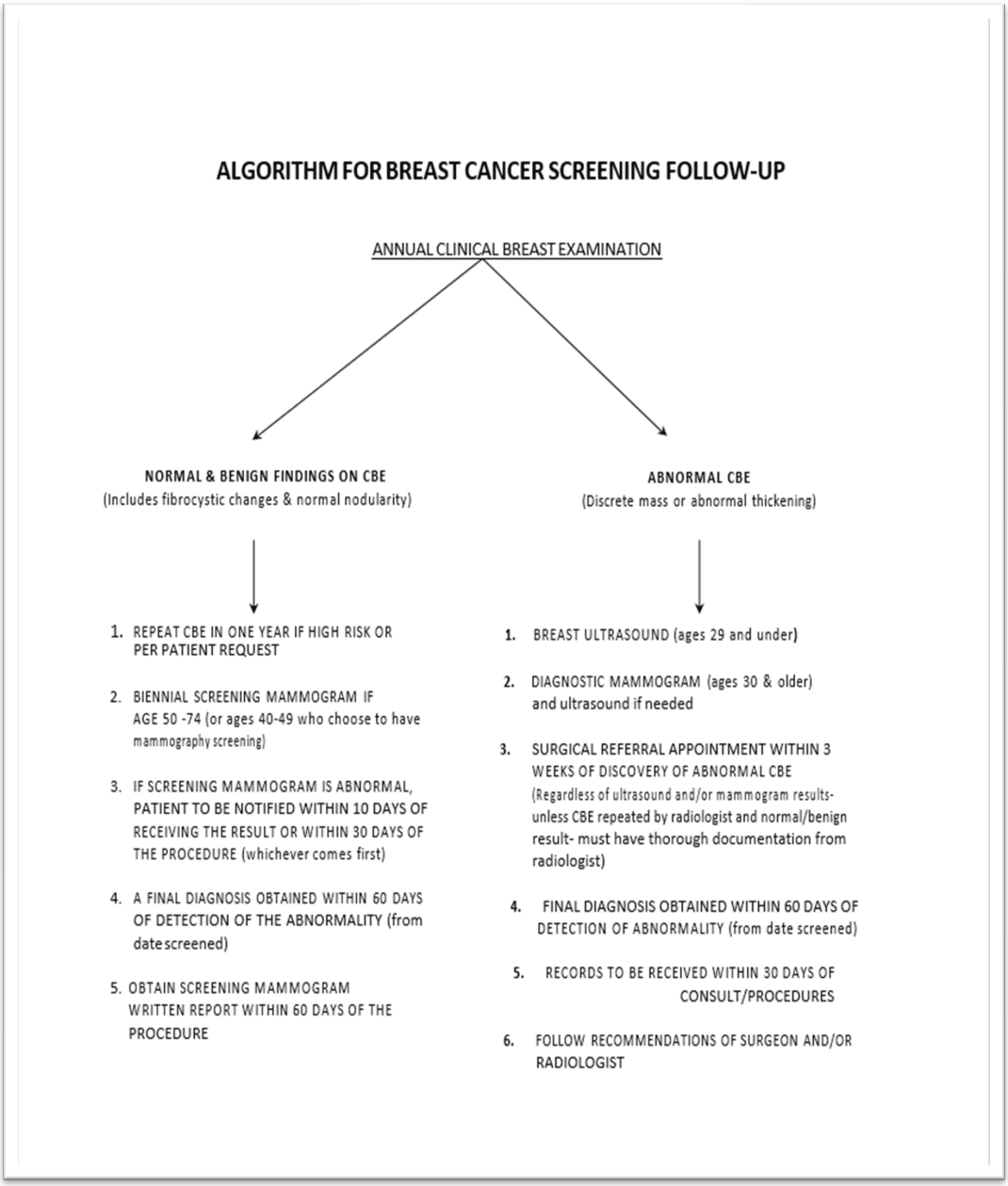
Category 6: Known Biopsy-Proven Malignancy; Appropriate Action Should Be Taken

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



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.

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.

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

CERVICAL CANCER SCREENING HISTORY

- Elicit date and result of last Pap/HPV test
- Determine if a previous history of an abnormal Pap and/or HPV
- Determine if history of a previous colposcopy and biopsy and/or treatment
- Screen for risk factors (listed above)
- Screen for history of abnormal bleeding patterns

PELVIC EXAMINATION

**Information in this section (Pelvic Examination) adapted from ACOG CommitteeOpinion Number 754, Oct. 2018; reaffirmed 2020)*

The pelvic examination consists of the following:

- Assessment of the external genitalia
- Internal speculum examination of the vagina and cervix
- Bimanual palpation of the adnexa, uterus and bladder
- May also include rectovaginal examination

A *screening* pelvic exam is one performed as a routine screening tool on an asymptomatic, non-pregnant woman. In 2018 the American College of Obstetricians and Gynecologists (ACOG) recommend that gynecologic care providers should counsel asymptomatic, non-pregnant women about the benefits, harms and lack of data for use of a screening pelvic exam. The patient and gynecologic care provider should then decide together if a pelvic examination will be performed.

During the cancer screening visit a screening pelvic exam is not required but may be performed after counseling the woman about the possible benefits/harms and the lack of supporting evidence for the

screening pelvic exam, and then affirming that the woman wishes for the pelvic exam to be performed.

Some possible *benefits* of a screening pelvic exam:

- Potential for early detection of treatable gynecologic conditions
- Allows an opportunity for the patient-provider conversation about normal/abnormal anatomy, symptoms, etc. and for the provider to answer any related questions the patient may have.

Some possible harms of a screening pelvic exam:

- Little evidence has been found as to the harms of the screening pelvic exam, such as fear/anxiety, pain/discomfort, or over-diagnosis, but neither is there sufficient evidence to support the use of a screening pelvic exam. In 2017, the USPSTF found only limited evidence of its ability to detect these specific gynecologic conditions: ovarian cancer, bacterial vaginosis, genital herpes. Studies show that pelvic examinations do not decrease ovarian cancer morbidity and mortality rates.

A (diagnostic) pelvic exam should be performed when indicated by medical history or symptoms. The following are some (but not all) indications for performing the pelvic exam:

- Abnormal bleeding
- Dyspareunia
- Pelvic pain
- Sexual dysfunction
- Vaginal dryness
- Vaginal bulge
- Urinary issues
- Inability to insert a tampon

RNs must refer any abnormal finding on the pelvic examination or any symptomatic woman to a mid-level or higher clinician or a contracted gynecologist for further evaluation. RNs may defer the pelvic exam on the symptomatic woman until she is seen by the higher-level clinician/gynecologist.

Note: For pelvic exam and follow-up protocol for the STD program see the STD section of the CSG.

CERVICAL CANCER SCREENING GUIDELINES

For average-risk women, the LHD will follow the cervical cancer screening guidelines recommended by the 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

Note: 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 may 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 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 contacted 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 the 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), 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. KWCSP 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. KWCSP funds can be used to reimburse for routine cervical cancer surveillance for 25 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 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 by sending an e-mail to Colleen.Toftness@ky.gov .

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, according to current ACS-ASCCP-ACOG guidelines.
- 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 (SPECIAL POPULATIONS). Vaginal/vulvar/labial Pap test 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 test 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 finding 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 age 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 25 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

Both the 2012 ASCCP management guidelines and the interim guidance later provided for management of abnormal results of the Primary HPV test have been replaced with the 2019 ASCCP Management Consensus Guidelines for abnormal cancer screening tests and cancer precursors. The risk-based management (free) web application can be accessed here:

https://app.asccp.org

You can also purchase (for approximately $10) the mobile app here:

https://www.asccp.org/mobile-app

Note: It has been suggested that the mobile app is the more user-friendly option.

When the clinical situation is such that these guidelines cannot be applied or do not provide guidance for the specific circumstance, or when the guidelines direct that clinical judgement must be used to make a decision, the RN must refer the case to a mid-level or higher clinician or to the contracted gynecologist to determine follow-up.

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 for KWCSP-eligible women 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 the 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 not received, the NCM must contact this provider to obtain an order. For additional information/guidance, see section "MANAGEMENT OF ANBORMAL PAP/HPV TEST RESULTS".

WOMEN WHO HAVE RECEIVED THE HPV VACCINE

Women who have received the HPV vaccine should continue to be screened according to the age-appropriate guidelines.

Cervical Cancer Follow-Up

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 ≥ 45 years)
- Epithelial cell abnormality: see Interpretation/Result (specify "squamous" or "glandular", as appropriate)

Interpretation/Result

- **Negative for Intraepithelial Lesion of 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 post-hysterectomy
- **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 ≥ 45 yrs.)
    (Also, specify if "negative for squamous intraepithelial lesion")
- **Epithelial Cell Abnormalities**
  - Squamous cell
    - Atypical squamous 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, CIN-3)
      - With features suspicious for invasion (if invasion is suspected)
    - Squamous cell carcinoma
  - 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
      - Extrauterine
      - 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)

PATIENT EDUCATION ON CERVICAL HEALTH

- 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.
- Counseling on the HPV vaccination shall be provided to the patient and the parent of minors when applicable.
- Patients must have documented counseling, as appropriate.

FOLLOW-UP

- Refer patient if abnormal cervix or polyps are visualized
- 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.
- 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 "first available" appointments
- 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.
- Results of referrals including colposcopy, biopsy pathology reports, cryotherapy, Loop electrosurgical excision procedure (LEEP) and pathology reports, Cold Knife Conization (CKC) procedure and pathology reports, and laser treatment documentation must be received within 30 days of the procedure
- The month and year the next Pap/HPV test is due shall 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 (e.g., verbal order, doctor's office note in chart, etc.) for the next screening or diagnostic procedure.

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 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). Currently two specific HPV tests have FDA approval for primary HPV screening, the Cobas HPV Test and the Onclarity HPV test; only the approved tests should be used for primary HPV screening.

MANAGEMENT OF ABNORMAL PAP/HPV TEST RESULTS

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.

Consult the 2019 ASCCP Risk-Based Management Consensus Guidelines (web-based or mobile app) for guidance in follow-up for any laboratory results for a Pap and/or HPV test. When the clinical situation is such that these guidelines cannot be applied or do not provide

guidance for the specific circumstance, or when the guidelines direct that clinical judgement must be used to make a decision, the RN must refer the case to a mid-level or higher clinician or to the contracted gynecologist to determine follow-up.

CYTOLOGY RESULTS AND GUIDANCE IN ADDITION TO THE 2019 ASCCP RISK-BASED MANAGEMENT CONSENSUS GUIDELINES

Below are the categories that correspond to the Bethesda 2014 System for reporting the result of a Pap Test.

#1 Satisfactory/Negative for Intraepithelial Lesion

#2 Atypical Squamous Cells of Undetermined Significance (ASC-US)

#3 Atypical Squamous Cells Cannot Exclude High Grade Lesions (ASC-H)

#4 Low Grade SIL (L-SIL, CIN-1, Mild Dysplasia, Including HPV Changes)

#5 High Grade SIL (H-SIL, CIN-2, CIN-3, Moderate-Severe Dysplasia, CIS)

#6 Squamous Cell Carcinoma

#7 Adenocarcinoma

#8 Adenocarcinoma-In-Situ (AIS)

#9 Unsatisfactory

#10 Atypical Glandular Cells of Undetermined Significance (AGC)

ADDITIONAL GUIDANCE FOR THE RN

In addition to the guidance for management of abnormal Pap results provided by the ASCCP guidelines, RNs are provided this additional guidance:

- Contact contracted provider if abnormal cervix or polyps visualized
- If EC/TZ is absent/insufficient, consult with a higher-level clinician/provider
- If presence of organisms or reactive cellular changes, consult with a higher-level clinician/provider
- If endometrial cells or glandular cells are present:
  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 the program will reimburse services on the approved CPT code list.
- Consult the 2019 ASCCP Risk-Based Management Consensus Guidelines (web-based or mobile app) for guidance in follow-up for any laboratory results for a Pap and/or HPV test. When the clinical situation is such that these guidelines cannot be applied or do not provide guidance for the specific circumstance, or when the guidelines direct that

clinical judgment must be used to make a decision, the RN must refer the case to a mid-level or higher clinician or to the contracted gynecologist to determine follow-up.

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 (e.g., gynecologist, colposcopist) 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 LEEP, or a cone biopsy, can be considered either a diagnostic or a 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.

TREATMENT FOR PRE-CANCER/CANCER OF THE CERVIX

Patients that have been screened or diagnosed through the 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 the cervix (includes endocervical). For more information and forms related to the BCCTP, please refer to their website by clicking here .

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 biopsy-confirmed diagnosis of pre-cancer or cancer of the breast or cervix, the NCM shall begin the application process for the BCCTP.

To be eligible for Medicaid's BCCTP, an applicant or recipient shall be a citizen of the United States, or a qualified legal alien who has not yet reached the age of 65 years (See also 907 KAR 20:005). When applying for Medicaid's BCCTP, the LHD shall verify patient's identity/citizenship (driver's license, birth certificate, patient statement/attestation), and shall obtain their social security number. For more information about eligibility and/or required documentation, visit the BCCTP website or contact the Department for Medicaid Services at: 1-800-635-2570.

To begin the application process, complete the Pre-Screening Eligibility Form, **MAP-813B**. (MAP-813B cannot be completed online.) Then complete the paper application, **MAP-813**. A signed and dated copy must be saved in the patient's chart, the information can be transferred to the online application, which is the one submitted to DMS. Once the online application is submitted, A BCCTP Confirmation page will appear. This should be printed and given to the client to serve as her BCCTP card. The original signed/dated paper application, Pre-Screening Eligibility Form, signed/dated copy of the electronic Confirmation Page, any proof of identity and citizenship that was provided, and social security number should all 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 BCCTP website.

During the initial BCCTP application process, the NCM shall inform the patient to contact the NCM two week 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 2 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 if 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 by sending an e-mail to: Colleen.Toftness@ky.gov .

Tracking and Follow-Up Requirements

The local health department (LHD) is accountable for tracking KWCSP 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 pre-natal. 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 KWCSP, the nurse must complete the following educational modules on TRAIN:

- **Utilizing Kentucky's Women's Cancer Screening and Treatment Programs (Course # 1095818)**
- **Utilizing Kentucky's Clinical Service Guide: Women's Cancer Screening (Course # 1095816)**
- **Nurse Case Management for Women's Cancer Screening Abnormal Results (Course # 1095819)**
- **Follow-up Documentation for Women's Cancer Screening Abnormal Results (Course # 1095817)**

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 KWCSP as soon as possible by sending an e-mail to Colleen.Toftness@ky.gov (preferred) or KWCSP@ky.gov . One-on-one training will be provided to each new NCM by a KWCSP Nurse Consultant. This training may be provided by webcast, 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 who is available to assume the NCM's role and responsibilities in the event the NCM is absent for more than 7 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 NCM 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 of the Progress Notes of the patient's medical chart. Administrative time is imperative 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 Case Management Form side of the WH-58 be used to assist staff with this required tracking and follow-up.

It is the responsibility of the KWCSP 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 all of part 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 in 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 LHD according to program guidelines. However, when a patient has a medical home, the patient may be referred to the primary care physician for follow-up management, after the patient is informed of the abnormal test result and need for follow-up. LHDs 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.

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 into the LHD 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 next section, "FOLLOW-UP FOR ABNORMAL TEST RESULTS").
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 LHD.
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 LHD.

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

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 LHD. The patient's medical home/PCP can be determined at registration.

Medical homes may include private physicians, Primary Care Centers, FQHCs 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.

FOLLOW-UP ARRANGEMENTS FOR KWCSP-ELIGIBLE PATIENTS

1. The NCM will schedule an appointment for the patient with a KWCSP 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 "Suspicious Abnormality" or "Highly Suggestive of Malignancy" mammogram (or other breast imaging) and cannot be contacted, the parent or guardian must be contacted. Minors shall be made aware of this policy at the screening visit.

FOLLOW-UP ARRANGEMENTS FOR PATIENTS WITH A MEDICAL HOME

1. The NCM will schedule an appointment for the patient with their Primary Care Provider (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 PCP 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 other breast imaging) 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 the PCP shall be documented in the patient's progress notes (CH3A).

OTHER SITUATIONS

Patients who are not KWCSP-eligible and do not have a medical home: LHDs 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.

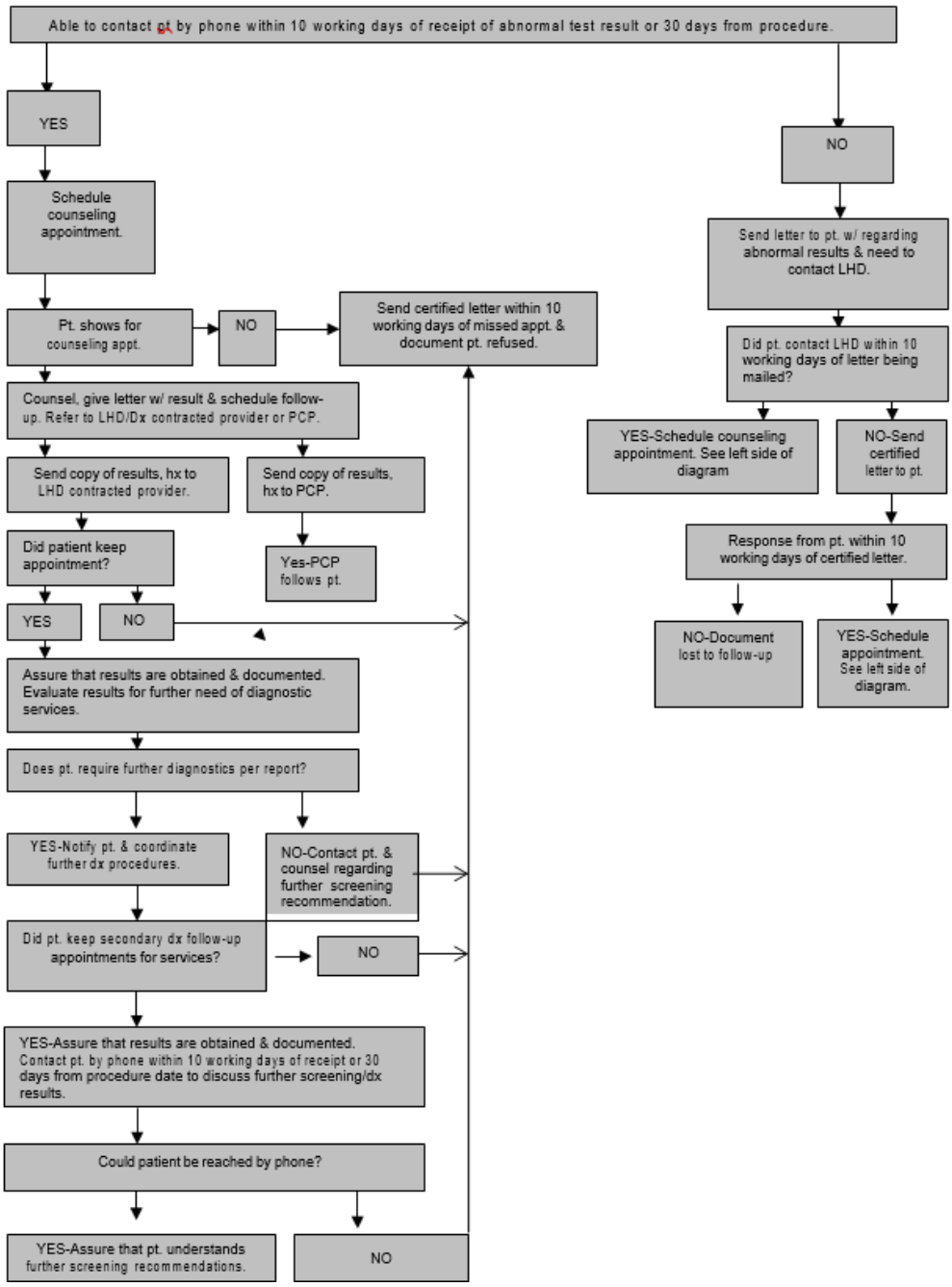
Work-up Refused: This occurs when a patient has been notified and counseled (by phone or in person) regarding an abnormal result and either fails to deep a referral appointment for diagnostics/treatment or verbalizes her desire not to seek follow-up. The date of final contact should be noted in the service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

Lost to Follow-up: This 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 the data collection form side of the WH-58.

Accepting Referrals/ Follow-up Referral Requirements

Healthcare providers should be encouraged to refer uninsured women to the LHD as soon as possible to determine eligibility for the 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 include CBE, pelvic exam and Pap test from another healthcare provider, the following are requirements of the KWCSP:

- The woman must meet the eligibility requirements of the program and provide consent for services.
- The patient is responsible for bringing her records at the time of the visit or having them sent to the LHD prior to the visit. This will enable the LHD provider to assess if all the minimum requirements were met. These records of the Pap test result as will 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).
- 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.
- If the physical examination portion of the visit was completed elsewhere (within the past 12 months) the nurse or clinician shall document on the physical exam form “See incoming records for the physical examination.”
- 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.
- 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.
YES
NO
Schedule counseling appointment.
Send letter to pt. w/ regarding abnormal results & need to contact LHD.
Pt. shows for counseling appt.
NO
Send certified letter within 10 working days of missed appt. & document pt. refused.
Did pt. contact LHD within 10 working days of letter being mailed?
Counsel, give letter w/ result & schedule follow-up. Refer to LHD/Dx contracted provider or PCP.
YES-Schedule counseling appointment. See left side of diagram
NO-Send certified letter to pt.
Send copy of results, hx to LHD contracted provider.
Send copy of results, hx to PCP.
Response from pt. within 10 working days of certified letter.
Did patient keep appointment?
Yes-PCP follows pt.
YES
NO
NO-Document lost to follow-up
YES-Schedule appointment. See left side of diagram.
Assure that results are obtained & documented. Evaluate results for further need of diagnostic services.
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?
NO
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

Emergencies

Table of Contents

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 must develop and maintain local policies 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 current in Basic Life Support (BLS).
- All staff should be offered the opportunity to participate in Basic Life Support (BLS) trainings.
- At a minimum, all staff must know their role in an emergency.
- 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*

(Latex-free equipment and supplies are recommended)

- AMBU bag-1 Adult and 1 Pediatric unit (Latex-free). Physical integrity checked monthly and replaced per manufacturer's recommendations.
- One-way masks-1 Adult and 1 Pediatric unit (Latex-free). One replacement piece for each mask.
- Sphygmomanometer, age appropriate, example: pediatric, adult, extra-large-serviced according to manufacturer's recommendations.
- Stethoscope
- Flashlight and extra batteries
- Oxygen tank with mask-monthly checks. Static checks and service per manufacturer's recommendations. See Hydrostatic Test Dates for Oxygen Cylinders below.
- Syringes and needles of various sizes, including filtered needles for use with glass ampules.
- Alcohol swabs or sponges
- Gloves of various sizes, Latex-free
- Aqueous epinephrine (1:1000); in either prefilled syringe, EpiPen® Auto-Injectors (0.3 mg) and EpiPen® Jr (0.15 mg) Auto-Injectors, or ampules; at least 4 but more for medically isolated clinics). DO NOT BUY 30mL vials of aqueous epinephrine.
- Diphenhydramine hydrochloride (HCL) (Benadryl® elixir) Liquid (Each 5 mL contains 12.5mg of Diphenhydramine HCL); Diphenhydramine hydrochloride (Benadryl® Injection) 50 mg/mL in ampules, disposable syringes, or vials, (a minimum of 4)
- Naloxone hydrochloride (NARCAN) Nasal Spray single-dose intranasal spray containing 2 mg or 4 mg of naloxone hydrochloride in 0.1 mL or Naloxone hydrochloride (NARCAN) auto injector 2 mg Injection: 2 mg/0.4 mL naloxone hydrochloride solution in a pre-filled auto-injector.
- 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, KY40202
  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 or LHD medical director

*A copy of the Emergency Equipment, Supplies, and Medication's 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).

CHECKING OXYGEN CYLINDERS

1. Identify which cylinder you have (Figure A or B below) and determine which directions you need to follow. Direction/step numbers pertain to numbers on the figures below.
2. Check to be certain regulator is hand-tight on neck of cylinder (Figure A only).
3. Adjust flowmeter dial to “0”. (If equipped with flowmeter dial.)
4. Open oxygen cylinder by turning toggle or key to the left (Figure A only). Figure B cylinder does not need to be opened.
5. Note the position of the indicator on the regulator dial. Just above or in the red area on the dial indicates the cylinder should be refilled. 500 psi or greater indicates sufficient oxygen for at least one patient use.
6. Record psi indication with date on a maintenance checklist (if available).
7. Close oxygen cylinder by turning toggle or key to the right (Figure A only).
8. Bleed pressure out of the regulator by turning the flowmeter dial to its highest possible setting (Figure A only).
9. Once the sound of pressure releasing is no longer heard, turn the flowmeter dial to “0” (Figure A only).

FIGURE A

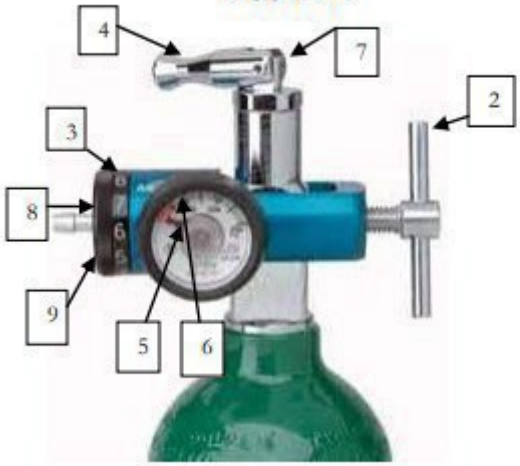
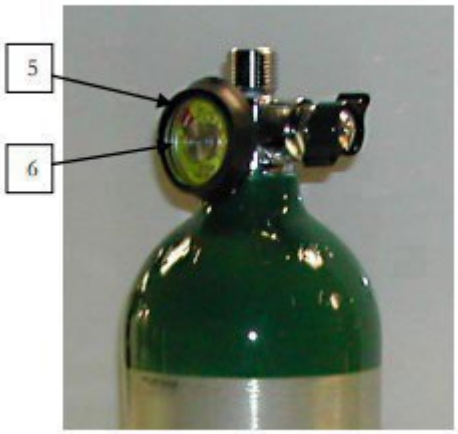


FIGURE B



(Shown without regulator)

Important Notes re: O2 cylinders:

- Oxygen cylinders should never be stored with pressure in the regulator or with the flowmeter set at any other value than “0”. If stored with pressure in the regulator, the integrity of the system may be compromised, and the tank could leak. A flowmeter storage value of other than “0” will also cause leakage.
- Connections to oxygen delivery devices should also be checked monthly.
- Always turn your oxygen cylinder on, check for adequate volume and properly prepare your delivery device before delivering oxygen to the patient!!

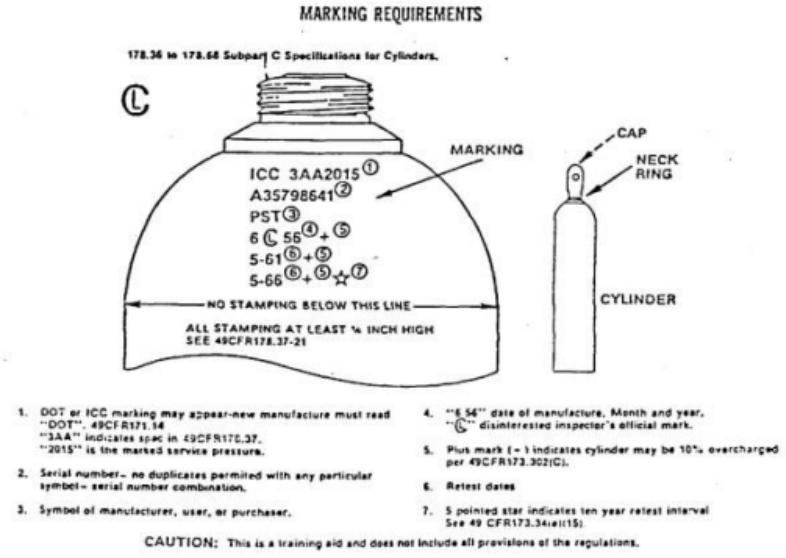
Oxygen Cylinder Markings

Oxygen cylinders are marked to designate the type of cylinder, maximum fill pressure, hydrostatic test date, inspector, manufacturer, and serial number. The marking is normally stamped into the shoulder of the cylinder. *The hydrostatic test date and inspector mark indicate when the cylinder was last tested and who tested the cylinder*. Most oxygen cylinders are required to be tested every 5 years. This test ensures the cylinder can safety hold the maximum fill pressure. There are two other markings which are sometimes found on these cylinders. The plus (+) sign located after the test date designates that the cylinder can be filled to 10% above the pressure stamped on the cylinder. The five-pointed star in the

same location designates that the hydrostatic test date has been extended an additional 5 years. A cylinder with a five-pointed star would need to be tested every 10 years.

Examples

Vertical Alignment:
DOT-3AA 2015
1234567
XY Corp
8 ® 08 +
Horizontal Alignment:
DOT-3AA 2015 1234567 XY Corp 8 ® 08 +
DOT = Department of Transportation
3AA = Seamless alloy-steel cylinder
2015 = 2015 psig fill pressure
1234567 = Serial number of cylinder
XY Corp = Manufacture of cylinder
8 ® 08 = Month and Year, in this example, August 2008, the symbol of the inspector is commonly placed between month and year (® used as example only)
+ = Cylinder maximum fill pressure can be 10% above 2015 psig or 2216.5 psig
= Cylinder may be tested every 10 years versus the standard 5 years



Figuire 1 Marking Requirements

Typical Oxygen Cylinder Markings Locations

Example Commercial Oxygen Cylinder Label

CGA Pamphlet C-9, Standard Color Marking of Compressed Gas Cylinders Intended for Medical Use states the color for oxygen cylinders is green. No other gas should be placed in a cylinder designated for oxygen. It is a safe practice to validate the contents of cylinders with an oxygen analyzer before use. This will validate both content and concentration. Most cylinders filled by commercial sources will also have a label indicating the contents and an oxidizer or fire warning. These labels should not be removed or covered by other labels or markings.

Oxygen Delivery Standards

Low-Flow Oxygen Delivery Standards		
Age	**Method**	**Flow Rate**
Adult	Nasal cannula	1-6 L/minute
	Simple face mask	6-10 L/minute
	Non-rebreather mask	15 L/minute
Children >2 years	Nasal cannula	0.125 -4 L/minute
	Simple face mask	4-10 L/minute
Children <2 years	Nasal cannula	0.125 -2 L/minute
	Simple face mask	4-10 L/minute

MEDICAL EMERGIENCIES 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 arrest or other life-threatening conditions.

Condition	Intervention
Syncope/Vasovagal Reaction “light-headed-fainting” Response to patient is usually immediate when measures are taken.	• ABC’s (Airway, Breathing, Circulation) • Place patient in supine position and loosen clothing • Elevate lower extremities 20 degrees • Monitor and record vital signs • Document all findings and actions in patient’s medical record • Question patient after episode about feelings prior to syncope and whether this is an isolated event or “usual response” to certain stimuli • Advise patient to report this to their primary care provider for further investigation

Suspected Severe, Acute Medical Condition including cardiac arrest, shock, hemorrhage, and/or aspiratory difficulties	• ABC’s (Airway, Breathing, Circulation)
	• Call for staff assistance
	• Maintain **AIRWAY**, provide **CPR** if necessary
	  ○ Place patient in supine position and loosen clothing
	  ○ Monitor and record vital signs
	• **Call 911** or local Emergency Medical Services immediately (preferably have someone not involved in direct patient care make the call)

*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.

Condition	Observation/Assessment	Intervention (Mild and Moderate Reactions)
MILD REACTION (May rapidly progress to a more server reaction)	• Generalized flush • Red, itchy, eyes • Itching at the injection site or other body sites • Localized to generalized urticaria (hive) • Vomiting, abdominal pain	• ABC's (Airway, Breathing, Circulation) • **Call 911** or local Emergency Medical Services immediately (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 per the low-flow oxygen deliver standards. ○ Special instructions** **for O_2, if given _____ (flow rate, lpm) • **FIRST-LINE TREATMENT**: GIVE AGE AND WEIGHT APPROPRIATED DOSES OF EPINEPHRINE, intramuscularly preferable 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, administration by name ○ Immediate therapy ○ Disposition of patient-transfer for further emergency care ASAP • Send copy of summary of emergency treatment with patient with written assessment of patient's condition at time of transfer • Document all measures taken in patient' medical record and place allergy label on front of patient's medical record if applicable. Advise patient (parent) about the drug or trigger that may have caused reaction. • Advise patient(parent) to report reaction to their 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 the Treatment of Anaphylactic Shock 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.
https://www.redcross.org/content/dam/redcross/uncategorized/6/CPro_PM_digital.pdf

PROTOCOL FOR TREATMENT OF ANAPHYLAXIS*

Condition	Observation/Assessment	Intervention (Severe Reactions)

SEVERE REATION	• 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 and rapid pulse
	• Hypotension
	• Shock
	• Unconsciousness
		• ABC's (Airway, Breathing, Circulation)
		• **Call 911** or local Emergency Medical Services immediately (preferably have someone not involved in direct patient care make the call)
		• Place patient in supine position and loosen clothing
		  ○ Elevate legs 20-30 degrees if tolerated
		  ○ Elevate head if breathing is difficult
		• Monitor pulse and respirations, mental status q1-2 minutes
		• Monitor BP if aged 3 years and older
		• Give OXYGEN by mask if any respiratory symptoms are present per the low-flow oxygen deliver standards.
		  ○ Special instructions** **for O_2, if given _____ (flow rate, lpm)**
		• **FIRST-LINE TREATMENT**: GIVE AGE AND WEIGHT APPROPRIATED DOSES OF EPINEPHRINE, intramuscularly preferable 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
		• Initiate cardiopulmonary resuscitation if necessary
		• Maintain accurate emergency flow sheet showing:
		  ○ Date
		  ○ Time of occurrence
		  ○ Vital signs
		  ○ Medication(s)-time, dosage, response, administration by name
		  ○ Immediate therapy
		  ○ Disposition of patient-transfer for further emergency care ASAP
		• Send copy of summary of emergency treatment with patient with written assessment of patient's condition at time of transfer
		• Document all measures taken in patient' medical record and place allergy label on front of patient's medical record if applicable.

*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.

**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.
https://www.redcross.org/content/dam/redcross/uncategorized/6/CPro_PM_digital.pdf

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.**

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

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 1-2mg/kg body weight**

	Age Group	Range of Weight (Pounds)*	Range of Weight (Kilograms)*	**Diphenhydramine HCL Dose 12.5 mg/5mL liquid**	
				mg	mL
Infants and Children	1-6 months	9-19 lbs.	4-8.5 kg	NA	NA
	7-36 months	20-32 lbs.	9-14.5 kg	10 mg-20 mg	4 mL-8 mL
	37-59 months	33-39 lbs.	15-17.5 kg	15 mg-30 mg	6 mL-12 mL
	5-7 years	40-56 lbs.	18-25.5 kg	20 mg-30 mg	8 mL-12 mL
	8-12 years	57-99 lbs.	26-45 kg	30 mg†	12 mL†
Teens	13-18 years	100+ lbs.	46+ kg	50 mg‡	20 mL‡
Adults	+> 19 years	100+ lbs.	46+ kg	50 mg‡	20 mL‡

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 3: Dosages for Diphenhydramine HCL (Benadryl)

Administered Intramuscularly--**The recommended dose of diphenhydramine HCL is 1-2 mg/kg body weight.**

	Age Group	Range of Weight (Pounds)*	Range of Weight (Kilograms)*	**Diphenhydramine HCL Dose 50 mg/mL injectable**	
				mg	mL
Infants and Children	1-6 months	9-19 lbs.	4-8.5 kg	NA	NA
	7-36 months	20-32 lbs.	9-14.5 kg	10 mg-20 mg	0.2 mL-0.4 mL
	37-59 months	33-39 lbs.	15-17.5 kg	15 mg-30 mg	0.3 mL-0.6 mL
	5-7 years	40-56 lbs.	18-25.5 kg	20 mg-30 mg	0.4 mL-0.6 mL
	8-12 years	57-99 lbs.	26-45 kg	30 mg†	0.6 mL†
Teens	13-18 years	100+ lbs.	46+ kg	50 mg‡	1 mL‡
Adults	+> 19 years	100+ lbs.	46+ kg	50 mg‡	1 mL‡

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 (Intramuscular/subcutaneous)*

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 but do not delay life-saving interventions.
- Call 911 to activate EMS immediately after administering the first dose of naloxone.

Signs and Symptoms of Opioid Overdose

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

- Extreme sleepiness (inability to awaken verbally or upon tactile stimulation)
- Slow to shallow respirations in drowsy or a patient that cannot be awakened
- Snoring or gurgling sounds (due to partial upper airway obstruction)
- Cyanosis of the lips/fingernails
- Extremely small “pinpoint” pupils
- Slow heart rate and/or low blood pressure

Signs of Overmedication (may progress to overdose)

- Unusual sleepiness
- Drowsiness or difficulty staying awake with loud verbal stimulus or tactile stimulation
- Mental confusion
- Slurred speech
- Intoxicated behavior
- Slow or shallow respirations
- Extremely small “pinpoint” pupils, although normal size pupils DO NOT exclude opioid overdose
- Slow heart rate
- Low blood pressure

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 aggressive verbal and tactile stimulation-ACT PROMPTLY!

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

Dosage and Intramuscular Administration:

- **Naloxone Intramuscular Injection 0.4mg/1mL single dose vial**:
  2 single dose vials and 2 syringes (3 mL syringe with 23- or 25-gauge 1-inch needles)
- **Naloxone Intramuscular Injection 1 mg/mL, 2 mL single dose disposable Luer-Jet™ Luer-Lock Prefilled Syringe**

Adult (> 17 years) Naloxone HCL 0.4mg/1mL-2 mg IM/SQ. May repeat every 3 minutes until desired response, breathing returns or EMS arrives. If no response is observed after 10 mg of naloxone hydrocholoride have been administered, question opioid toxicity.

Child/Adolescent (5-17 years; > 20 kg) 0.01mg/kg/dose IM/SQ. May repeat every 3 minutes until desired response, breathing returns, or EMS arrives.
Infants and Children (< 5 years; < 20 kg) 0.1 mg/kg/dose IM/SQ; may require repeated doses to prevent recurrent apnea. FDA-approved labeling recommends 0.01 mg/kg/dose IM, or subcutaneously every 2 to 3 minutes until the desired response is obtained, breathing returns, or EMS arrives.

Preparing naloxone in a vial:

1. Remove cap from the vial (do not touch the rubber stopper on the top of the vial).
2. Remove the cap from the syringe (be careful not to touch the needle).
3. Insert the needle into the vial and turn the vial upside down.
4. Pull the entire contents of the vial into the syringe.
5. Take the syringe out of the vial (carefully – do not touch the needle). Attempt to remove all of the large air bubbles from the syringe.
6. Wipe chosen injection site with alcohol swab prior to needle insertion.
7. Syringe should be inserted at a 90-degree angle.
8. Inject the contents of the syringe into the upper arm or thigh.
9. Carefully pull needle from the site. Some syringes have a safety covering that can shield the needle to prevent an accidental needle stick.
10. Never recap the needle.
11. Dispose of used syringe properly (sharps container or hard plastic container).
    a. Other option for disposal – give used syringe and vial to EMS when they arrive.
12. **May repeat every 3 minutes until breathing returns or EMS arrives.** When person begins to breathe, wake up, or vomit, place person on his/her side in the recovery position. Make sure to put space between you and the individual to protect yourself.

Preparing naloxone in pre-filled syringe:

1. Open the box and pull out the pre-filled 1mL syringe
2. Attach the 1-1 ½ inch needle to the syringe
3. Remove the safety cap on the needle
4. Quickly push the needle straight down into the outer mid-thigh muscle, through the clothes if necessary
5. Inject the contents of the syringe into the muscle
6. Carefully pull needle from the site. Some syringes have a safety covering that can shield the needle to prevent an accidental needle stick.
7. Never recap the needle.
8. Dispose of used syringe properly (sharps container or hard plastic container).
9. Other option for disposal – give used syringe and vial to EMS when they arrive.
10. **May repeat every 3 minutes until breathing returns or EMS arrives.** When person begins to breathe, wake up, or vomit, place person on his/her side in the recovery position. Make sure to put space between you and the individual to protect yourself.

ASSURE 911 HAS BEEN CALLED and that EMS has been activated.
STAY WITH THE PERSON AND MONITOR AND INTERVENE FOR RESPIRATORY DISTRESS.
Provide rescue breathing as necessary if 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. If they are breathing on their own, place them in the recovery position, on their side and support the body with one bent knee with the face turned to the side.
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.

Contraindications

Naloxone HCL 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.

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 sharp's 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 for the naloxone used in their facility and store naloxone hydrochloride according to the individual manufacturer's direction

*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 naloxone protocols may be developed locally for products not covered in this protocol.

ZIMHI (High Dose Naloxone HCL Intramuscular/subcutaneous)*

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 but do not delay life-saving interventions.
- Call 911 to activate EMS immediately after administering the first dose of naloxone.

Signs and Symptoms of Opioid Overdose

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

- Extreme sleepiness (inability to awaken verbally or upon tactile stimulation)
- Slow to shallow respirations in drowsy or a patient that cannot be awakened
- Snoring or gurgling sounds (due to partial upper airway obstruction)
- Cyanosis of the lips/fingernails
- Extremely small “pinpoint” pupils
- Slow heart rate and/or low blood pressure

Signs of Overmedication (may progress to overdose)

- Unusual sleepiness
- Drowsiness or difficulty staying awake with loud verbal stimulus or tactile stimulation
- Mental confusion
- Slurred speech
- Intoxicated behavior
- Slow or shallow respirations
- Extremely small “pinpoint” pupils, although normal size pupils DO NOT exclude opioid overdose
- Slow heart rate
- Low blood pressure

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 aggressive verbal and tactile stimulation-ACT PROMPTLY!

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

Dosage and Intramuscular Administration:

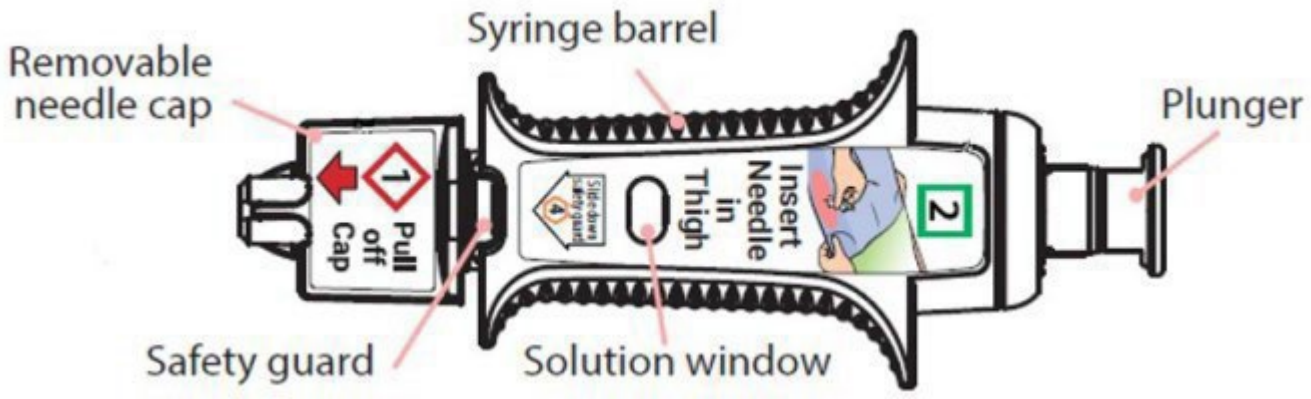
ZIMHI Naloxone HCL Injection 5 mg/0.5 mL single-dose, one prefilled syringe per case

Adult/Pediatric; Naloxone HCL 5mg/0.5 mL IM/SQ. May repeat every 3 minutes until desired response, breathing returns or EMS arrives.

Dosing in Pediatric Patients under Age One Year: In pediatric patients under the age of age, pinch the thigh muscle while administering ZIMHI.

ZIMHI is intended to be *administered by individuals 12 years of age or older.* Younger individuals or those with limited hand strength may find the device difficult to use.

ZIMHI is light sensitive. Store ZIMHI in the outer case provided to protect it from light.
Do not attempt to reuse ZIMHI. Each ZIMHI contains a single dose of naloxone hydrochloride for single-dose injection.



Administer ZIMHI according to the Instructions for Use and the printed instructions on the device label:

1. Place the patient in the supine position.
2. Inject ZIMHI intramuscularly or subcutaneously into the anterolateral aspect of the thigh with the needle facing downwards. Inject through clothing if necessary.
3. Embed the needle completely before transferring the thumb to the syringe plunger.

4. Immediately after injection, using one hand with fingers behind the needle, slide the safety guard over the needle. Do not use two hands to activate the safety guard.

5. <u>Never put thumb, fingers, or hand over the exposed needle. Failure to follow these instructions may result in a needlestick injury. If an accidental needlestick occurs, get medical help immediately [see Warnings and Precautions.</u>

6. Do NOT attempt to re-cap the needle with the needle cap once it has been removed.
7. Place the patient in the lateral recumbent position (recovery position).
8. ZIMHI must be used and/or properly disposed of as described below once the protective cap covering the needle is removed.
9. Put the used syringe into the blue case, close the case, and proper disposal.

https://zimhi.com/wp-content/uploads/2022/05/ZIMHI_Instructions-for-Use.pdf

ASSURE 911 HAS BEEN CALLED and that EMS has been activated.
STAY WITH THE PERSON AND MONITOR AND INTERVENE FOR RESPIRATORY DISTRESS.
Provide rescue breathing as necessary if 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. If they are breathing on their own, place them in the recovery position, on their side and support the body with one bent knee with the face turned to the side.
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.

Contraindications

ZIMHI 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

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.

Storage and Handling

- Store naloxone at controlled room temperature 20°C to 25°C (68°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 sharp's 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 for the naloxone used in their facility and store naloxone hydrochloride according to the individual manufacturer's direction

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Naloxone (Intranasal)*

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 but do not delay life-saving interventions.
- Call 911 to activate EMS immediately after administering the first dose of naloxone.

Signs and Symptoms of Opioid Overdose

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

- Extreme sleepiness (inability to awaken verbally or upon tactile stimulation)
- Slow to shallow respirations in drowsy or a patient that cannot be awakened
- Snoring or gurgling sounds (due to partial upper airway obstruction)
- Cyanosis of the lips/fingernails
- Extremely small “pinpoint” pupils
- Slow heart rate and/or low blood pressure

Signs of Overmedication (may progress to overdose)

- Unusual sleepiness
- Drowsiness or difficulty staying awake with loud verbal stimulus or tactile stimulation
- Mental confusion
- Slurred speech
- Intoxicated behavior
- Slow or shallow respirations
- Extremely small “pinpoint” pupils, although normal size pupils DO NOT exclude opioid overdose
- Slow heart rate
- Low blood pressure

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 aggressive verbal and tactile stimulation-ACT PROMPTLY!

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

Dosage and Intranasal Administration

Kloxxado/Naloxone Hydrochloride/Narcan Nasal Spray: 8mg / 0.1ml, 0.4mg / mL, 2mg/2mL, 4mg / 0.1mL in carton containing two blister packages each with a single Kloxxado, Naloxone or Narcan nasal spray.

Intranasal dosage Narcan nasal spray-

Adults: 1 spray (4mg) intranasally; repeat every 2-3 minutes alternating nostrils until desired response, breathing returns or EMS arrives. Each devise contains a single dose.

Infants, Children & Adolescents: 1 spray (4 mg) intranasally; repeat every 2-3 minutes alternating nostrils until desired response, breathing returns or EMS arrives. Each devise contains a single dose.

Intranasal dosage Kloxxado nasal spray-

Adults: 1 spray (8 mg) intranasally; repeat every 2-3 minutes alternating nostrils until desired response, breathing returns or EMS arrives. Each devise contains a single dose.

Infants, Children & Adolescents: 1 spray (8 mg) intranasally; repeat every 2-3 minutes alternating nostrils until desired response, breathing returns or EMS arrives. Each devise contains a single dose.

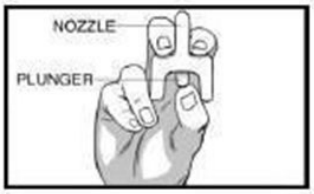
Intranasal NARCAN or Kloxxado administration:

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.



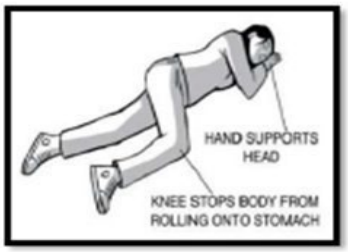
Step 4. Tilt the person's head back and provide support under the neck with your hand. Gently insert the tip of the nozzle into **one nostril** until your fingers on either side of the nozzle are against the bottom of the person's nose.

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.

ASSURE 911 HAS BEEN CALLED and that EMS has been activated.
STAY WITH THE PERSON AND MONITOR AND INTERVENE FOR RESPIRATORY DISTRESS.
Provide rescue breathing as necessary if 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. If they are breathing on their own, place them in the recovery position, on their side and support the body with one bent knee with the face turned to the side.
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.

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

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 sharp's 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 for the naloxone used in their facility and store naloxone hydrochloride according to the individual manufacturer's direction

*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 naloxone protocols may be developed locally for products not covered in this protocol.

Family Planning Clinical Service Guide
TABLE OF CONTENTS

CONTRACEPTIVES

Educate client of the types of contraceptives available, so client can be informed to choose which method of contraception will work best for them. Inability to pay should not serve as a barrier to access to contraceptive. Client's choice of contraceptive must be voluntary and without coercion. The FPEM-19 may be utilized as an overview between each type of contraceptive; and may assist client to determine which contraceptive method is best for him/her.

Effectiveness of any contraceptive is optimal with consistent use according to manufacturer recommendations. See CDC chart to compare effectiveness of family planning methods.

Manufacturer recommendations located on package inserts of specific products are the best sources for the following information: indications and usage, dosage and administration, contraindications, warnings, and precautions, adverse reactions, drug interactions, use in specific populations such as pregnancy, postpartum, breastfeeding, pediatric, etc., storage and handling, and specific patient counseling information. **Package insert for specific manufacturer recommendations** are best to screen for contraindications to specific methods based on client condition, client, and family medical history, and known risk factors.
The CDC Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use is also available as a quick reference to determine contraindications. The following categories on the summary chart help determine the safety for a client. See below for the definition of the different categories utilized in the summary chart:

- Category 1: No restriction for the use of contraceptive method
- Category 2: Advantages of using the method generally outweigh the theoretical or proven risks
- ***Category 3**: The theoretical or proven risks usually outweigh the advantages of using the method
- ***Category 4**: Represents an unacceptable health risk if the contraceptive method is used

***Do not initiate** family planning method under standing orders.

For patient safety, teachings should be client centered and performed for the specific product used for contraception. Information for counseling for specific products are located on the package insert. Additional recommended resources for contraceptive methods are available:

- Specific manufacturer websites
- KDPH Family Planning website (forms and teaching sheets)
- Medline Plus for Spanish and English teaching sheets
- American College of Obstetricians and Gynecologists ACOG Frequently Asked Questions

FAMILY PLANNING REQUIREMENTS MATRIX

Document Medical History on Adult H&P-14

very FP visit should include assessments for exploitation, nicotine use, vital signs, height/weight/BMI, STI risk factors (test as indicated per TI Matrix and HIV Clinical Protocols), gonorrhea and chlamydia annual test per CDC recommendations (sexually active women under 25 ears of age, or age 25 years and older, if at increased risk), pregnancy status (test as indicated), general appearance, mental health, and eproductive life plan.

	Contraceptive Service Visit				
	Initial/Annual	**Supply/ Follow-up**	**ECP**	**Pregnancy Testing**	**STI Testing**
Physical Assessment	• Pelvic exam as indicated				• Per STI Matrix • Per HIV Clinical Protocols
Laboratory	**Labs per STI Matrix and/or HIV Clinical Protocols for all family planning visits**				
				• Urine Pregnancy Test	
Education and Counseling	**All family planning visits will get the following education and counseling:** • Benefits of family planning • Family planning contraceptive methods • Specific method of contraceptive chosen by client • **Adolescent client counseling:** sexual abstinence, of parental involvement, coercion and consent • Resources for mental health and/or substance abuse • Follow up visit, as indicated • How to use a condom, as indicated • Client-centered preconception health counseling to include STI/HIV prevention, routine pap, other topics as indicated				
		• Individualize for each client needs	• Refer to deferred exam if client wants contraception	Negative: • Refer to deferred exam if client wants contraception • Benefits of planned pregnancy • Compliance with current contraceptive Positive: • Provide neutral, factual information and nondirective client-centered counseling on prenatal care and delivery, infant and foster care or adoption, and pregnancy termination, and other social services (e.g., HANDS, WIC, local pregnancy centers, DCBS, etc.); except with respect to any option(s) the client indicates they do not wish to receive information. (Abortion cannot be referred, promoted or supported as method of birth control. (45 CFR 59.5)	• Per STI Matrix, in addition to condoms for pregnancy prevention
Provide	**All family planning visits will get the following once a year, and more often as indicated:** • ACH-40 as indicated • Adolescents: FPEM-3 • Follow-up visit date for contraceptives or referral, as indicated • 24 hour emergency number • Contraceptive method of choice **unless contraindicated** (if not available provide RX or referral to provider as requested) • FPEM-19 or appropriate teaching sheets as indicated • Appropriate referrals as indicated (HANDS, Dietary, etc.)				
				Positive: • Referral to prenatal provider, upon request • List of resources including prenatal providers and social services not limited to, HANDS, WIC, local pregnancy, centers, DCBS, etc.	• Follow-up visit date (test results and treatment) • Treatment per STI Clinical Protocol (client and partner) • HIV-link to services as indicated • Condoms for pregnancy and STI prevention

HORMONAL ORAL CONTRACEPTION

Estrogen, Progesterone, or
Progestin Oral Contraceptive (POP, or mini-pill), or
Combined (Estrogen and Progestin) Oral Contraceptive (COC)

Contraindications/Precautions

- See package insert for contraindications
- Risk factors for VTE
- Postpartum <42 days with other risk for VTE
- Breastfeeding <42 days for CHCs only (POPs are considered safe)
- Breastfeeding, crosses into milk and can decrease milk production
- Per CDC, no adverse health outcomes or manifestations have been demonstrated in breastmilk; however, studies have been inadequately designed to determine whether a risk for either serious or subtle long-term effects exists
- Certain drug interactions

This is not a complete list of contraindications. Nurses should consult with provider prior to administration if any contraindication is present. Use CDC Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use, U.S. Medical Eligibility Criteria for Contraceptive Use **and package insert for specific manufacturer recommendations** to screen for contraindications to specific methods, based on client and family medical history and risk factors.

QUICK START for any hormonal oral contraceptive (COCs or POPs)
The preferred method of starting pills is to start the pill in the office regardless of time of cycle. Provide 7-day backup method.

- Intended for those who are reliable to succeed at daily administration, with consideration of affordability, access, and privacy concerns
- Use of COCs or POPs is often decided with consideration of a balance of benefits and side effects
- POPs may be a good option for those who should avoid use of estrogen (i.e., > 35 years old smoker, breastfeeding, history, or thrombosis, DVT, or PE; recent postpartum, HTN, CAD or CVD, lupus)

Indications, Usage, Counsel and Evaluate

- Provide 3-4 cycles of pills to new users. Provide the rest of remainder of practitioner's orders at follow-up visit, to include a blood pressure check
- Provide package insert, review, and counsel
    - Indications and usage, benefits, risks, and potential side effects,
    - Dosage and administration, including consistent timing of daily administration and what to do if there is a missed dose
    - Contraindications, warnings, and precautions to include signs for blood clots and a possible increased risk of breast cancer
    - Adverse reactions
    - Drug interactions and overdosage
    - Use in specific populations such as pregnancy, postpartum, breastfeeding, pediatric, etc.
    - Storage and handling
    - Patient counseling information including menses cycle disruptions, when to use back up method, possible increased risks of breast cancer, no protection against HIV, warnings and other precautions
    - Smoking cessation
    - Use after administration of ECPs
    - Use of barrier method

- When to report to a health care provider including for any development of severe mood swings, depression, jaundice, two missed periods, or any signs of pregnancy
- When to report to the emergency department and potentially serious side effects

Also, counsel any client choosing hormonal method of contraception, regarding potentially serious side effects. Potentially serious side effects can be referred as the acronym ACHES. These side effects include, but not limited to the following:

Abdominal pain (stomach pain, vomiting, weakness)
Chest pain (left arm or shoulder pain, coughing, or shortness of air
Headaches (severe), sudden intellectual impairment
Eye problems (blurred vision, complete or partial loss of vision, tunnel vision) and/or
Swelling and/or aching, redness, tenderness in the legs or thighs

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

DEPO-PROVERA (DMPA)

Contraindications/Precautions

- See package insert
- Some brands do not recommend as a long-term (i.e., longer than 2 years) birth control method unless other options are considered inadequate.
- Allergic to any medroxyprogesterone acetate or any other ingredient in DMPA
- Breastfeeding - crosses into milk and does not affect milk production
- Postpartum – certain brand indicates only give DMPA at sixth week postpartum if exclusively breastfeeding, otherwise may give within the first five days of postpartum
- Per CDC, most studies have found that women lose bone mineral density, BMD, during DMPA use but recover BMD after discontinuation. It is unclear whether adult women with long durations of DMPA use can regain BMD. Studies generally find no effect of POCs other than DMPA on BMD.

This is not a complete list of contraindications. Nurses should consult with provider prior to administration if any contraindication is present. Use CDC Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use, U.S. Medical Eligibility Criteria for Contraceptive Use **and package insert for specific manufacturer recommendations** to screen for contraindications to specific methods, based on client and family medical history and risk factors.

Indications, Usage, Counsel, and Evaluation

- Provide the package insert after review, and counsel
  - Indications and usage – not recommended as a long-term method unless other options are inadequate
  - Administration – every 13 weeks, and when switching from other methods
  - Benefits, risks, and potential side effects
  - Contraindications, warnings, and precautions including reduced bone mineral density with prolonged use
  - Adverse reactions: weight gain >10 pounds at 24 months
  - Drug interactions
  - Use in specific populations such as pregnancy, breastfeeding, pediatric, etc.
  - Storage and handling
  - Patient counseling information to include menses disruption, weight gain, possible increased risk of breast cancer, use of barrier method, use of back-up method, warnings and precautions, safety of DMPA if given during early stage of pregnancy
- The efficacy of Depo depends on adherence to the dosage schedule of administration

DMPA Injections
For initial injection or injection more than 13 weeks since previous injection

- Ensure the patient is not pregnant
    - Give during the first 5 days of a normal menstrual period, or
    - Postpartum – give during the first 5 days postpartum if not breastfeeding exclusively, or
    - Postpartum – exclusive breastfeeding, give at six weeks postpartum

Switching from other methods of contraception

- Should be given in a manner that ensures continuous contraceptive coverage based on the mechanism of action of both methods (e.g., clients switching from oral contraceptives should have the first DMPA injection on the day after the last active tablet or at the latest, on the day following the final inactive tablet)

Depo-Provera CI may be given at other times than those listed above

- Negative pregnancy test prior to administration, and
- May offer additional ECP if client reports unprotected sex within 5 days, and
    - Note: if client chose ECP then client may need to return to clinic for an additional pregnancy test in three weeks if no menses cycle has occurred
- Need to provide 7-day backup method

EMERGENCY CONTRACEPTIVE PILLS (ECPs)

Contraindications/Precautions

- See package insert
- Breast milk should be discarded for 24 hours after administration
- Some brands indicate higher failure rates for obese clients may be four times higher than women of BMI less than 25

This is not a complete list of contraindications. Nurses should consult with provider prior to administration if any contraindication is present. Use CDC Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use, U.S. Medical Eligibility Criteria for Contraceptive Use **and package insert for specific manufacturer recommendations** to screen for contraindications to specific methods, based on client and family medical history and risk factors.

Start ECPs as soon as possible after client presents with a history of unprotected or inadequately protected sexual intercourse. ECPs are most effective if taken within 12 hours of sexual encounter. For more information, see the specific package insert.

Obtain and document history including LMP, compliance with contraceptive use, history of sexual assault and/or possible STD exposure. Pregnancy testing is useful when concerned if client is pregnant from a prior sexual intercourse.

Performing a urine pregnancy test

- Optional if patient had a menstrual period within 21 days
- If patient has not had a menstrual period within 21 days, advise patient to have test

If pregnancy test result is

- Positive pregnancy test – Do Not Give ECP (no benefit, no danger) - Refer to pregnancy test matrix
- Negative or no pregnancy test – Counsel patient on potential side effects and need for reliable, consistent, contraception

Follow standing order for RNs on the signature page of the CSG
Return to clinic in three weeks for a pregnancy test if client has not started menses

Indications, Usage, Counsel and Evaluation

- Provide package insert after review and counsel
    - Indications and use (when, how, why to take the ECPs)
    - Dosage and administration
    - Contraindications, warnings, and precautions
    - Adverse reactions
    - Use in specific populations such as pregnancy, breastfeeding, pediatric, etc.
    - Storage and handling
    - Management of nausea and vomiting - routine use of antiemetics is not recommended, pretreatment may be considered
    - Specific patient counseling information
- Return to clinic for pregnancy test if menses is missed
- Provide method of birth control of client choice or provide a prescription for a birth control method or make client a same-day referral to obtain and begin a preferred birth control method.

HORMONAL (PROGESTIN) IMPLANT

Contraindications/Precautions

- See package insert
- Allergy to local anesthetic used for procedure to insert implant
- Breastfeeding - crosses into milk, and can decrease milk production
- Unexplained abnormal vaginal bleeding
- Menstrual cycle disturbances, including menstrual irregularities. If bothersome may provide several cycles of low dose pills, patch, or ring

This is not a complete list of contraindications. Nurses should consult with provider prior to administration if any contraindication is present. Use CDC Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use, U.S. Medical Eligibility Criteria for Contraceptive Use **and package insert for specific manufacturer recommendations** to screen for contraindications to specific methods, based on client and family medical history and risk factors.

Indications, Usage, Counsel, and Evaluation

- May be a good option for women who should avoid use of estrogen (i.e., > 35 years old smoker, breastfeeding, history, or thrombosis, DVT, or PE; recent postpartum, HTN, CAD or CVD, lupus).
- Implant is a single, thin rod that is inserted under the skin of the upper arm. The rod contains progestin that is gradually released into the body over three years.
- Insertion and removal shall be performed by a medical provider with special training per manufacturer recommendations.
- Implants are a hormonal method of contraception, refer back to the Hormonal Contraception section for additional information.
- Provide the package insert (prior to obtaining a consent for insertion), review and counsel
    - Indications and usage
    - Administration
    - Benefits, risks, and potential side effects
    - Contraindications, warnings, and precautions
    - Adverse reactions
    - Drug interactions
    - Use in specific populations such as pregnancy, breastfeeding, pediatric, etc.
    - Storage and handling
    - Patient counseling information
    - Location and feel of the implant under the skin
    - When to use back-up method after insertion
    - Wound care, dressing, with insertion or removal of implant
    - Complications and maintenance (palpate bead at insertion site)

- When to seek healthcare professional: Arm pain after insertion - rule out nerve damage or infection, check dressing to ensure not too tight, apply ice pack for 24 hours,

INTRAUTERINE DEVICE (IUD)

Contraindications/Precautions

- See package insert for specific contraindications and precautions
- Breastfeeding - crosses in breast milk
- Breastfeeding - some brands report a decrease in breast milk production
- Postpartum has an increased risk of perforation when inserted prior to complete involution of uterus
- Solid organ transplant
- Persistent enlarged ovarian follicles
- Per CDC, two randomized controlled trials found conflicting results on breastfeeding outcomes when LNG-IUDs were initiated immediately postpartum compared with 6–8 weeks postpartum. Initiation of LNG-IUDs immediately postpartum had no other harmful effect on infant health, growth, or development.

This is not a complete list of contraindications. Nurses should consult with provider prior to administration if any contraindication is present. Use CDC Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use, U.S. Medical Eligibility Criteria for Contraceptive Use **and package insert for specific manufacturer recommendations** to screen for contraindications to specific methods, based on client and family medical history and risk factors.

Potential problems with the use of IUDs can be referred as the acronym PAINS. These side effects include, but not limited to the following:

Period – late, spotting, or other abnormal vaginal bleeding
Abdominal pain or other type of pain, including pain with intercourse
Infection
Not feeling well
String missing

Indications, Usage, Counsel and Evaluation

- A pregnancy test performed on the day of insertion shall be negative
- If the retrieval threads cannot be visualized, the recommendation is to identify the location of the IUD by ultrasound; pregnancy, uterine perforation or expulsion should also be ruled out
- If a pregnancy occurs with an IUD, contact a medical provider for immediate treatment
- IUDs may be non-hormonal or hormonal and prevent pregnancy from 3-10 years, depending on the specific device and manufacturer
- Provide the package insert after review, and counsel
    - Indications and usage, how to use
    - Administration, insertion, and removal procedures
    - Benefits, risks, and potential side effects
    - Contraindications, warnings, and precautions
    - Maintenance of contraception, how and when to check strings
    - Adverse reactions
    - Drug interactions
    - Use in specific populations such as pregnancy, breastfeeding, pediatric, etc.
    - Storage and handling, disposal
    - When to use backup method
    - Use of barrier method
- Make an appointment in 4-6 weeks after new IUD insertion to follow-up and re-evaluate. Reexamine once a year after the initial follow-up visit; more frequently if clinically indicated.

- If dizziness or cramping during or after insertion does not pass, then notify healthcare provider for possible removal or replacement.
- Vasovagal reaction may occur with removal of the IUD.

HORMONAL PATCH (TRANSDERMAL)

Contraindications/Precautions

- See package insert for contraindications
  - Some brands are contraindicated with BMI greater than 25 kg/m2
  - Women who should avoid estrogen. Women are exposed to more estrogen with the patch than with the standard oral contraceptive.
  - Breastfeeding - crosses into milk, and can decrease milk production
  - No adverse health outcomes or manifestations have been demonstrated in breastmilk; however, studies have been inadequately designed to determine whether a risk for either serious or subtle long-term effects exists.

This is not a complete list of contraindications. Nurses should consult with provider prior to administration if any contraindication is present. Use CDC Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use, U.S. Medical Eligibility Criteria for Contraceptive Use **and package insert for specific manufacturer recommendations** to screen for contraindications to specific methods, based on client and family medical history and risk factors.
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Indications, Usage, Counsel, and Evaluation

- Only wear one patch at a time. Keep a replacement patch available.
- Provide the package insert after review and counsel
  - Indications and usage, how to use, placement of patch, frequency and change of patch, maintenance of patch
  - Administration, when to begin use – with or without previous method, restart after a patch-free interval
  - Benefits, risks, and potential side effects
  - Contraindications, warnings, and precautions
  - Adverse reactions
  - Drug interactions
  - Use in specific populations such as pregnancy, postpartum, breastfeeding, pediatric, etc.
  - Storage and handling, disposal
  - When to use backup method
  - Use of barrier method
    - Patient counseling information

HORMONAL VAGINAL RING

Contraindications/Precautions

- See package insert for contraindications
- Women with pronounced pelvic relaxation or prolapse
- Breastfeeding, crosses into milk, and can decrease milk production
- Per CDC, no adverse health outcomes or manifestations have been demonstrated in breastmilk; however, studies have been inadequately designed to determine whether a risk for either serious or subtle long-term effects exists.

This is not a complete list of contraindications. Nurses should consult with provider prior to administration if any contraindication is present. Use CDC Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use, U.S. Medical Eligibility Criteria for Contraceptive Use **and package insert for**

specific manufacturer recommendations to screen for contraindications to specific methods, based on client and family medical history and risk factors.

Indications, Usage, Counsel, and Evaluation

- Each vaginal ring is a combination hormonal method of contraception. Therefore, refer to the combined hormonal oral contraceptives guidance for additional information.
- There is no daily fluctuation of hormone levels with use of vaginal rings
- Hormonal vaginal rings vary in diameter, placed into the vagina for a specified number of days, then disposed of or washed and stored according to the manufacturer's recommendations.
- Provide the package insert after review and counsel
    - Indications and usage, how to use
    - Administration, insertion, and removal procedures
    - Benefits, risks, and potential side effects
    - Contraindications, warnings, and precautions
    - Adverse reactions
    - Drug interactions
    - Use in specific populations such as pregnancy, postpartum, breastfeeding, pediatric, etc.
    - Storage and handling, disposal
    - When to use backup method
    - Use of barrier method
- What to do if ring is left in place for longer than intended use
- Avoid douching, but topical therapies are allowed
- The ring is left in place for intercourse; it is small and flexible. Most women will not feel pressure or discomfort; and it is also comfortable for a partner

STERILIZATION

Sterilization of persons in federally assisted family planning projects must meet the requirements of Title 42 Chapter 1 Subchapter D Part 50 Subpart B 50.201 through 50.209 of the Public Health Service Act.

Federally required consent forms:
English: https://opa.hhs.gov/sites/default/files/2022-07/consent-for-sterilization-english-2025.pdf
Spanish: https://opa.hhs.gov/sites/default/files/2022-07/consent-for-sterilization-spanish-2025.pdf

Programs or projects to which this subpart applies shall perform or arrange for sterilization procedure of an individual if all requirements have been met. Requirements are that individual must be: mentally competent, at least 21 years of age at the time consent is obtained, has voluntarily given his/her informed consent, AND

- 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 sterilization. In the case of premature delivery, 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, or
    - 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 irreversible
- A thorough explanation of the specific procedure to be performed
- 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.
- Advise that the sterilization will be performed for at least 30 days except under the circumstances above.

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

An interpreter must be provided to assist the individual to be sterilized if he or she does not understand the language used on the consent form or the language used by the person obtaining the consent.

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.

PRECONCEPTION HEALTHCARE

Educate clients about the importance of pregnancy planning and spacing to reduce adverse pregnancy outcomes. A reproductive life plan (RLP) may reduce unintended pregnancy. RLP is a set of personal goals regarding if, when, and how to have children based on individual priorities, resources, and values. Take advantage of each family planning visit to assess each client's short and long-term reproductive plans. Reproductive Health National Training Center has a Preconception Counseling Checklist which includes guidance per ACOG recommendations.

Preconception interventions may include the following:

- Discuss reproductive life plan, readiness, and desire for pregnancy
- Evaluate overall health and opportunities to improve health
- Refer for clinical breast exam and/or PAP screening per KWCSP recommendations
- Explain that a healthy diet and lifestyle can reduce gestational diabetes
- Studies show that taking folic acid (0.4 mg of folic acid per day) before getting pregnant and for 3 months after conception can reduce the risk of neural tube disorders, such as spina bifida by up to 70%

- Immunizations – assess need for boosters or other immunization needs such as rubella, tetanus, chicken pox, HBV, HPV if applicable
- Control chronic and acute medical health conditions, such as diabetes, HTN, infections, asthma, or seizure disorders. Control of medical conditions before and during pregnancy reduces the risk of miscarriage and stillbirths, and other health problems for the infant
- Review prescriptions for teratogenic medications
- Screen for infectious disease as applicable
- Educate client to avoid use of alcohol, nicotine, and drug use. During pregnancy, these behaviors can increase risk for SIDS, preterm birth, fetal alcohol spectrum disorders, and neural tube disorders
- Strive to reach a healthy weight before pregnancy. Obesity can make it more difficult to become pregnant, and may result in additional complications during pregnancy, such as HTN, preeclampsia, gestational diabetes, stillbirth, and increase risk of cesarean delivery
- Assess a family history for intellectual disabilities, or genetic disorders such as sickle cell anemia, cystic fibrosis, or neural tube defects
- Discuss any issues with anxiety, depression, domestic violence, history of PTSD, financial issues, and support issues (including readiness for parenthood)

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 of pregnancy related risk factors to 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 concerns – positive family history of diseases may indicate need for additional screening
- STDs—early treatment decreases the risk of transmission to the fetus, and preterm delivery
- Vaccination history (Refer to Immunizations Section)
- Chronic medical conditions such as, hypertension, diabetes, obesity, epilepsy, DVT, depression
- Screen for alcohol, tobacco, other drugs (ATOD)
- Domestic violence
- Exercise and Nutrition

References for all contraceptives:

Center for Disease Control and Prevention. (2022). Contraception, birth control methods. https://www.cdc.gov/reproductivehealth/contraception/index.htm.

Center for Disease Control and Prevention. (2014). Providing quality family planning services. Recommendations of CDC and the U.S. Office of Population Affairs, 2014. Morbidity and Mortality Report. (MMWR). (63)(4). https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf

Center for Disease Control and Prevention. (2016). U.S. medical eligibility criteria for contraceptive use, 2016. Morbidity and Mortality Weekly Report. (MMWR). (65)(3). DOI: http://dx.doi.org/10.15585/mmwr.rr6503a1.

Center for Disease Control and Prevention. (2016). U.S. selected practice recommendations, 2016. https://www.cdc.gov/reproductivehealth/contraception/mmwr/spr/injectables.html

Code of Federal Regulations. (2022). Subpart b: sterilization of persons in federally assisted family planning projects. https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-50#sp42.1.50.b

Hatcher, R.A., Zieman, M., Lathrop, E., Haddad, L., & Allen, A. (15th ed.) (2019). Managing contraception for your pocket. Managing Contraception LLC.

Follow-up / Internal Tracking / Referral

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Follow-up Measures to Ensure Continuity of Care

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

- Patients who have abnormal test results
- Patients who have been referred to other providers
- Patients who have missed return appointments
- 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).
- 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 the patient's medical records. "No Show" should be documented in the medical record when a patient is noncompliant in keeping appointments.

This documentation should include:

- The reason for the call
- Any problems discussed by the patient/provider
- Any action taken and advice or instructions given
- The date and time of the call

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 at the end of this sections).

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 the report of the abnormal result.

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

- Initial contact may be made by telephone if the number is available, and the patient has permitted home contact.
- The second contact should be a regular mailed letter with directions for the patient to contact the LHD for follow-up.
- The third should be a certified or registered letter with directions for the patient to contact the LHD for follow-up.
- If the patient cannot be contacted by the above measures, a home visit is strongly recommended for results that are potentially life threatening.
- 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.
- 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 KWCSP's follow-up guidelines. See the KWCSP's Screening/Follow-up section for specific requirements.

Note: For particular conditions such as abnormal PAP tests results, mammograms, newborn screening, and communicable diseases, i.e., TB, HIV, and Hepatitis B, see section program guidelines for required follow-up. Program regulations and guidelines will supersede these requirements.

REFERRALS

Referrals are made to assist patients in obtaining services not available on-site. LHDs 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 seek 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 Diethystil-besterol-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)
- Woman who wants an FDA approved contraceptive not available on site
- 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 a guide for referral sources. Include other resources that may be available in the local area.

Sources	Phone Numbers
Kentucky Health Care Access Line	1-800-633-8100
Kentucky Prescription Assistance Program	1-800-633-8100
Poison Control Hotline	1-800-222-1222
Kentucky Dental Association	1-502-459-5373
Statewide First Step Program	1800-442-0087
Social Services	Local
Social Insurance	Local
Social Security	Local
Mental Health	Local
Division of Adult and Child Health	1-800-462-6122

Kentucky Hepatitis C Virus (HCV) Antibody Screening and Confirmation with HCV RNA Testing

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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 treatment referral to all at-risk patients, all pregnant persons, and all adults, regardless of risk, for a one-time screening. Please routinely offer HCV screening and testing services during healthcare encounters when persons are identified as being at risk.

Hepatitis C, a blood-borne disease, is now primarily spread through intravenous drug use; however, HCV can be contracted in other ways from contaminated blood. Hepatitis C is typically a chronic viral infection with few early symptoms, and health complications may not appear for decades. Ultimately, patients may suffer liver disease, liver cancer, and/or liver failure.

HCV is transmitted primarily through large or repeated percutaneous (i.e., passage through the skin) exposures to infectious blood. Populations and risks identified for potential HCV infections include persons who inject drugs (PWID), persons living with HIV; persons with sexual contact with an infected person; sharing personal items contaminated with infectious blood, such as razors or toothbrushes; 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

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. Prior, resolved HCV infection does not protect against later reinfection, regardless of genotype. There is no HCV vaccine. There are effective direct-acting antiviral treatments 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. Current estimates suggest there are over 80,000 Kentuckians living with chronic HCV infection.

Testing and Diagnosis

Find testing recommendations for Hepatitis C infection here: https://www.cdc.gov/hepatitis/hcv/guidelinesc.htm.

Testing for HCV infection begins with a laboratory-conducted assay for HCV antibody in blood or a rapid antibody test. See the Kentucky Adult HCV Screening, Testing and Referral Guidance. KDPH recommends that Local Health Departments (LHD) use venipuncture to obtain a specimen for HCV Antibody (anti-HCV) testing. HCV Rapid testing is most appropriate for offsite HCV Outreach Programs or in Syringe Exchange programs but can be used as a tool within LHDs as long as appropriate follow-up is assured. Refer to Appendix 3, 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 antibody result indicates one of the following: 1) current HCV infection, 2) past HCV infection that has resolved or been treated, or 3) false positivity. A reactive result should be followed by an 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 (DLS).

If HCV RNA is detected, that indicates current HCV infection. If HCV RNA is not detected, that indicates either a resolved/treated 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.

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 six 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:

- Local Health Departments seeking to participate in the Kentucky HCV antibody Screening and Testing with HCV RNA Quantitative Confirmation Program should email the Viral Hepatitis 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

- KDPH recommends HCV Rapid tests for offsite HCV Outreach Programs or in Syringe Exchange Programs. Training on the HCV Rapid can be arranged by contacting the rapid test manufacturer. Contact the Viral Hepatitis Program for the contact information. HCV Rapid testing should not start until this training has occurred. Test kits and controls have a defined shelf life and should not be used beyond their expiration dates. The rapid tests have defined storage and temperature guidelines that must be followed.
- 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.
- Identify HCV screening, educating, and testing healthcare personnel at your LHD who will provide HCV screening and testing services. The Viral Hepatitis Program is available to provide HCV Introductory Training upon request. The HCV Introductory Training will include screening, collection and handling, reporting, and appropriate counseling messages, with referral and linkage to care guidance.
- LHD 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 and referral.

Referral for HCV Management and Treatment

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

HCV-positive persons should be linked to care by referral or telehealth to a physician or mid-level clinician who treats hepatitis C.

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, or any primary care provider who has been trained to evaluate and treat hepatitis C.

Counseling Patients

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

- Sharing equipment used to inject drugs, not limited to syringes, can potentially spread HCV to others.
- 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.
- 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

Prior to it being a CDC recommendation, Kentucky amended SB 250 KRS 214.160 in 2018 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 Appendix 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

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 Appendix 3 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 Viral Hepatitis Program.

HCV Testing Provided at LHDs

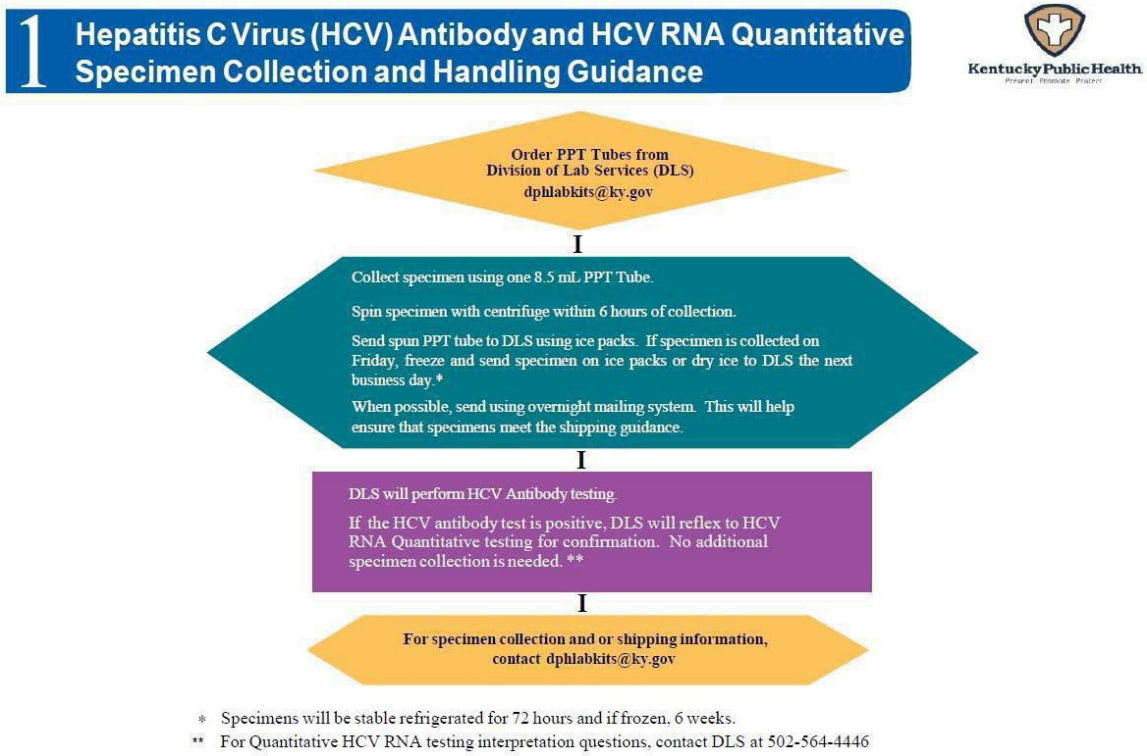
Perform HCV high risk screening and offer HCV testing to individuals identified high risk by LHD personnel. LHDs should refer an individual identified with HCV risk factors whose health insurance coverage will cover the cost of HCV testing to a private provider for HCV testing and follow up. If the individual 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 Appendix 3, the 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.

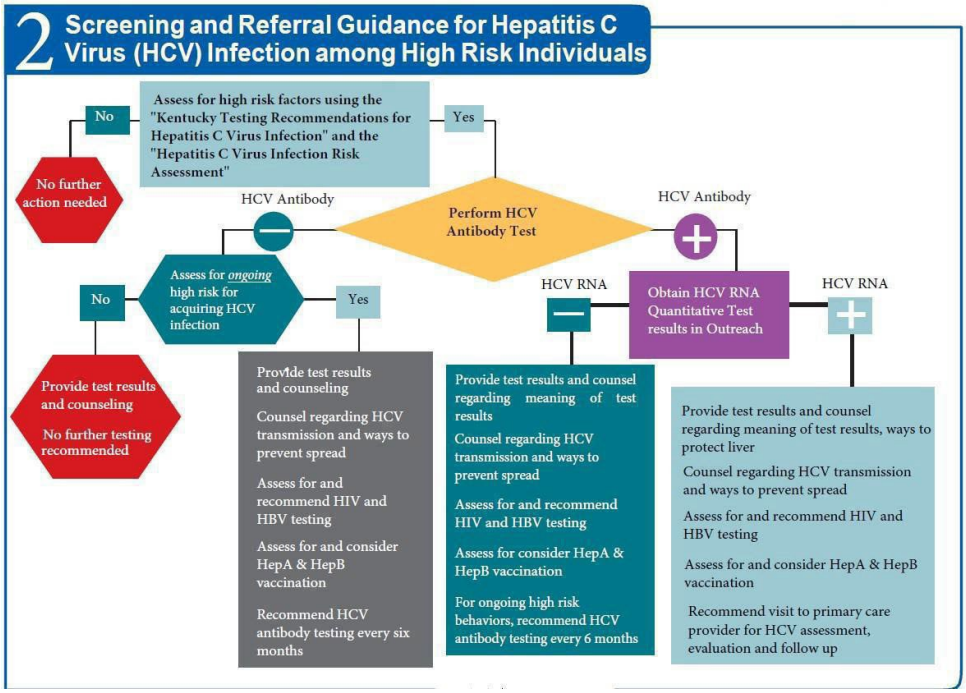
SpecimenCollection and Handling



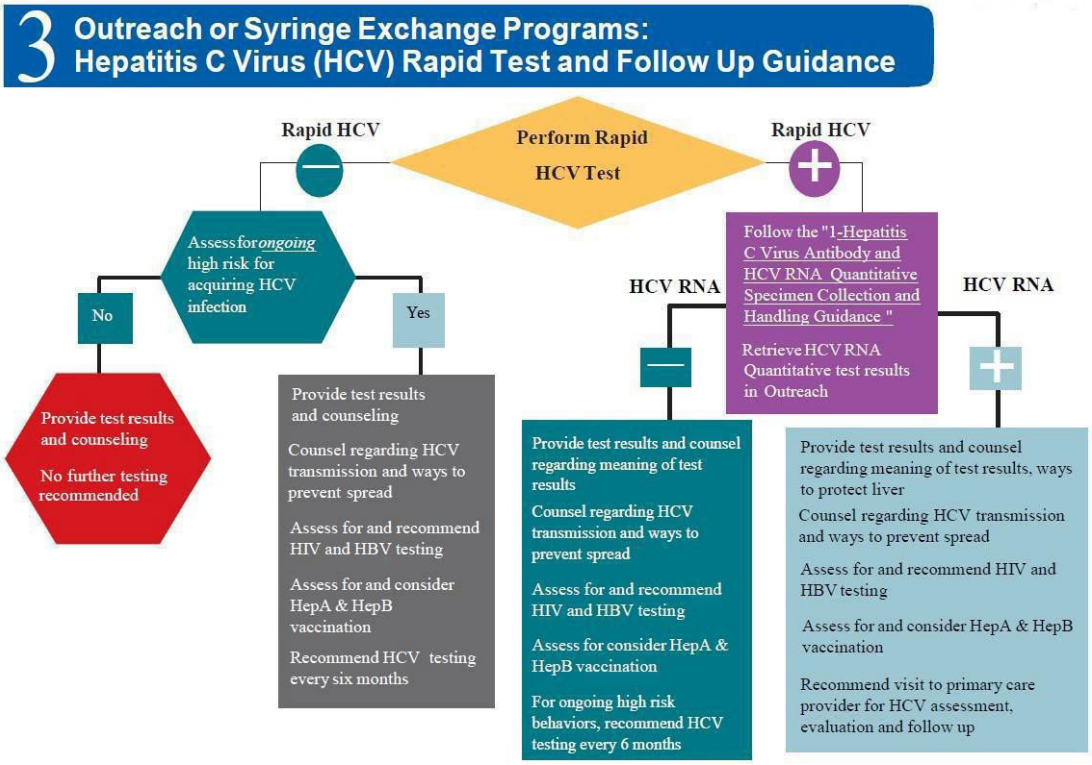
* Specimens will be stable refrigerated for 72 hours and if frozen, 6 weeks.

** For Quantitative HCV RNA testing interpretation questions, contact DLS at 502-564-4446

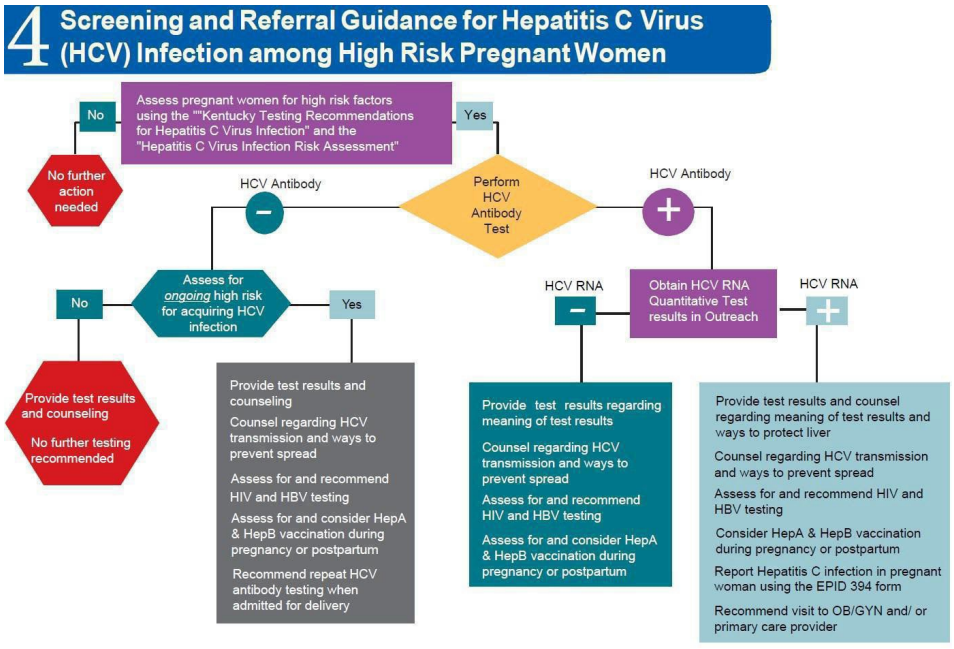
Screening and Referral Guidance



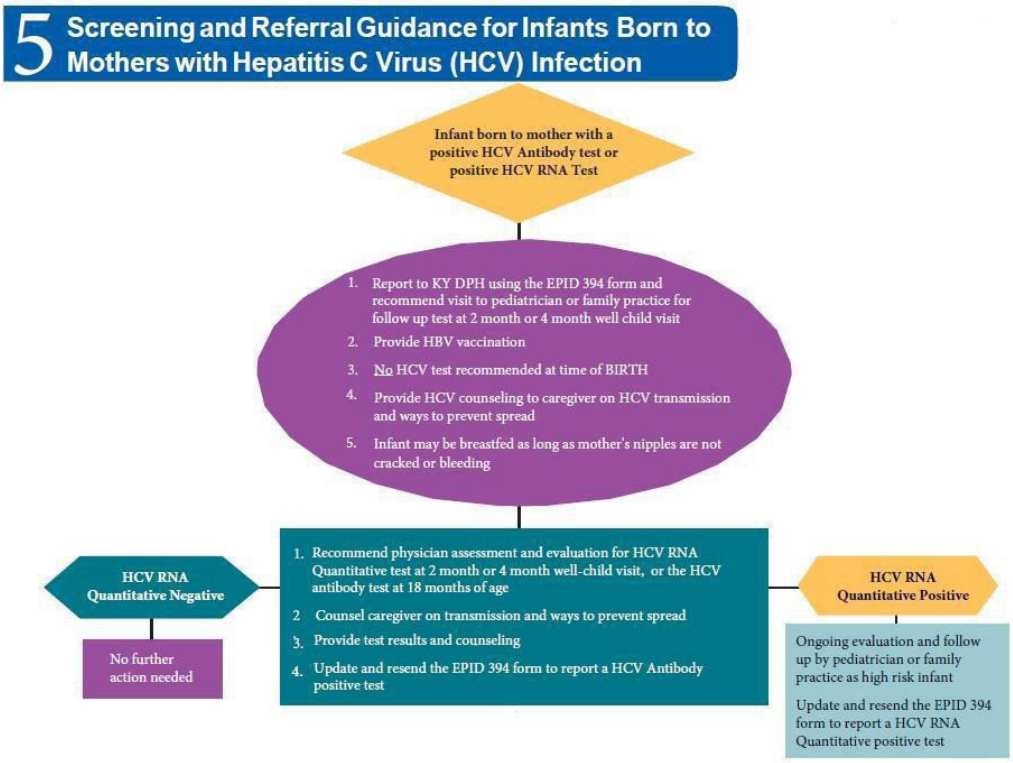
Outreachand Syringe Exchange Programs



Screening and Referral Guidance for Hepatitis C Virus Infection among High Risk Pregnant Women



Screening and Referral Guidance for Infants Born to Mothers with HCV Infection



ADMINISTRATIVE REFERENCE SECTION

Coding on the HCV Screening and Testing Record & Coding on the Patient Encounter Form (PEF), refer to Appendix 3, the 6-Kentucky Hepatitis C Virus (HCV) Local Health Department Screening and Testing Billing Codes.

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 use 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: https://kbml.ky.gov/prescribing-substance-abuse/Documents/Resources%20SA%20Kentucky%20Opioid%20Treatment%20Programs.pdf

Kentucky HCV Screening, Testing and Referral Guidance

Identify Individuals	HCV Pre-Test Counseling	HCV Testing	HCV RNA Confirmation & Referral
<u>Identify Individuals for Testing-See KDPH Hepatis C virus (HCV) Risk Assessment Form:</u> 1. Baby boomers (born between 1945 and 1965) 2. Pregnant Women 3. High Risk Factors Identified: Currently or ever injected drugs, including those who injected/ intranasal once or a few times many years ago Unregulated body piercing and/ or tattoos Household contact with a known HCV-positive person History of high-risk sexual behavior History of sexually transmitted infection History of incarceration 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	Pre-test HCV counseling 1. Discuss CDC testing recommendations 2. Provide HCV disease and transmission overview: a. Prevalence b. Ways to prevent spread c. Prognosis: Curable disease with appropriate management 3. Assess for, and if needed, recommend HIV and HBV testing 4. Assess for, and if needed, recommend Hep A & Hep B vaccinations 5. Discuss HCV testing process and timing: **Option 1:** HCV antibody test **Option 2**: HCV rapid test **If positive results: HCV RNA Quantitative confirmation**	Option 1- Local Health Department HCV <u>Antibody Test for Screening Individuals</u> A. Conduct antibody test using the" HCV Antibody and HCV RNA Quantitative Specimen Collection and Handling Guidance" B. Receive test results **HCV Antibody Test Result Notification** If Positive HCV antibody results: A. DLS will automatically reflex specimen for HCV RNA Quantitative testing B. Receive lab results from lab C. Provide test results and counseling **If Negative HCV antibody results:** A. Provide test results and counseling B. Counsel regarding meaning of test results C. Counsel regarding transmission and ways to prevent spread <u>Option 2- Syringe Exchange Programs-</u>HCV Rapid Test for Screening Individuals A. Conduct onsite rapid HCV test B. Receive test results **HCV Rapid test** **If Positive HCV antibody results**: A. Provide on-site rapid test results and counseling	**HCV RNA Quantitative Test Results** <u>HCV RNA Quantitative Test Results-</u> If positive HCV RNA Quantitative results: A. Provide HCV RNA test results. Counsel regarding meaning of test results, avoiding transmission to others and next steps of follow up B. Recommend follow up to either: a. Primary care provider b. HCV Provider Specialist c. Hepatologist d. Gastroenterologist e. Infectious Disease Specialist **If negative HCV RNA Quantitative results:** A. Provide test results and counseling B. Counsel regarding meaning of test results C. Counsel regarding HCV transmission and ways to prevent spread **If positive HCV RNA Quantitative results:** A. Provide HCV RNA test results. Counsel regarding meaning of test results, avoiding transmission to others and next steps of follow up B. Recommend follow up to either: a. Primary care provider

		B. 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" C. Receive lab results from lab **If Negative HCV rapid results:** A. Provide test results and counseling B. Counsel regarding meaning of test results C. Counsel regarding HCV transmission and ways to prevent spread	b. HCV Provider Specialist c. Hepatologist d. Gastroenterologist e. Infectious Disease Specialist **If negative HCV RNA Quantitative results:** A. Provide test results and counseling B. Counsel regarding meaning of test results and C. Counsel regarding HCV transmission and ways to prevent spread

HIV Non-Clinical and Clinical Protocols

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HIV Testing – Non-Clinical Settings

Non-Clinical Settings: Rapid Testing Finger Stick

TRAIN courses 1103422, 1103534, and 1103535 are encouraged for clinical providers performing rapid testing.

Pre-results Steps

Step 1: Introduce and orient client to session

- Introduce yourself and describe your role
- Provide a brief session overview including:
  - How long the session will take
  - Process for conducting the test
  - How the results are returned (same session)
- Obtain concurrence to proceed with the session

Step 2: Conduct brief risk screening

- Ask how the client decided to be tested; listen and probe for previous testing history and indicators of increased risk including:
  - Potential exposure in last 24–72 hours (to indicate need for non-occupational post-exposure prophylaxis [nPEP])
  - Potential exposure in last 3 months (to indicate need for acute infection testing, retesting 3 months after last exposure, condoms)
  - Symptoms (to indicate need for acute infection testing [venipuncture] and accessing medical care)
  - Ongoing risk behavior or key population (men who have sex with men [MSM], persons who inject drugs [PWID], partner with unknown or known HIV-positive status, transgender woman)
- Address indicators of increased risk and make immediate referrals to other services (i.e., nPEP, acute infection testing, or medical care) as indicated
- Assess the client's knowledge of HIV transmission, provide accurate information as needed
- Prepare for possible test results

Step 3: Prepare for and conduct initial instant HIV test (~1 minute read time)

- Explain the process of conducting the HIV test, including:
  - Type of test used (instant, HIV-1/HIV-2 antibody test, INSTI)
  - Sample collected (fingerstick blood; do not use oral fluid as tests conducted with blood are more sensitive for early infection)
  - Time until test results are ready (~1 minute)
- Explain the meaning of HIV-negative and HIV-positive test results, including:
  - Need for retesting if HIV-negative
  - Need for and process of conducting confirmatory testing if HIV-positive
  - Possibility of invalid result
- Obtain consent to test (oral or written)
- Distribute test kit information booklet (required for CLIA-waived tests)
- Collect specimen and conduct instant HIV test

Post-results steps

Step 4: Provide results of initial instant HIV test and conduct confirmatory testing if needed

- Confirm readiness to receive results
- Provide a clear explanation of results
  - NON-REACTIVE (HIV-NEGATIVE)
  - REACTIVE (HIV-POSITIVE): Confirmatory testing
  - INVALID (RARE): Repeat testing

Step 5: Develop care, treatment, and prevention plan based on results

NON-REACTIVE (HIV-NEGATIVE)

- Explore client's reaction to result
- Discuss need for retesting based on window period of test used and client's risk
- Emphasize key risk reduction strategies that will help the client remain HIV-negative:

- Choose less risky sexual behaviors
- Get tested for HIV together with partner(s)
- Use condoms consistently and correctly
- Reduce number of sex partners
- Talk to doctor about PrEP as indicated (according to PrEP screening indicators)
- Talk to doctor about nPEP as indicated (within 3 days following a specific exposure to HIV)
- Get tested and treated for other STDs and encourage partners to do the same
- If partner is HIV-positive, encourage partner to get and stay on treatment

- Provide condoms and refer to Syringe Service Programs (SSPs) as appropriate

REACTIVE (HIV-POSITIVE)

- Explore client's reaction to result
- Advise on next steps for follow-up testing
- The Kentucky Department for Public Health supported HIV testing in nonclinical settings employ option #2. For clinical sites, #1 and #2 are options for follow-up.
  1. Collect a specimen to send to DLS for confirmatory testing after the initial reactive instant test result; discuss the importance of returning to the agency to get the test result; and schedule a day and time for the client to return to the agency to get the result of the follow-up test.
  2. Collect a specimen and run a second rapid test using a different rapid test to confirm the result. If the second test is also reactive, proceed with steps 5 and 6. For a nonreactive confirmatory result, refer the client to a clinical provider or collect a sample to send to DLS.
- Discuss disclosure and inform about processes for partner services
- Advise to access care and treatment for HIV
  - Treatment can help people with HIV live long, healthy lives and prevent transmission
  - Other health issues can be addressed
- Emphasize key risk reduction strategies that will prevent transmission
  - Choose less risky sexual and drug-using behaviors
  - Get tested together with their partners
  - Use condoms consistently and correctly
  - Reduce number of sex partners
  - Encourage partners to be tested
- Provide condoms

Step 6: Refer and link with medical care, social and behavioral services

- Identify necessary medical, social, and behavioral referral services
- Make referrals as indicated, including to SSPs as appropriate
- Track linkage to HIV medical care

Complete and submit EvaluationWeb HIV Test form for all state-sponsored HIV tests within 2 weeks.

HIV Testing – Clinical Settings

Clinical Settings: Laboratory Testing/Venipuncture

- If possible, persons at highest risk should be tested for acute infection.
- If a client is concerned about a recent exposure or reports symptoms of acute HIV infection such as persistent fever, swollen throat or lymph nodes, or other severe flu-like symptoms, they should undergo laboratory testing.
- The need for using protection until acute infection can be ruled out should be emphasized.
- If testing immediately for acute infection is not an option, then the client should be tested using the non-clinical site protocol above and then retested 3 months after their potential exposure.
- In general, tests used for acute infection will be antigen/antibody combination tests used with blood specimens collected from the vein.
- The Department of Laboratory Services (DLS) screening test is Bio-Rad HIV Combo Ag/Ab EIA. A positive screening test is confirmed with the Bio-Rad Geenius HIV 1/2 Supplemental Assay.
- Schedule a follow-up appointment for test results ideally with the same provider.

- If negative, advise retest 3 months from last exposure and make appropriate referrals (PrEP, SSP, vaccinations, etc.). Offer screening services for other STI and condoms.
- If positive, refer to HIV care through HIV Care Coordinator program, with a goal of linking HIV positive persons to care within 7 days. Advise patient will be contacted by Partner Services to identify and notify sexual partners and syringe sharing partners of need for testing. Encourage those who tested anonymously to agree to confidential services. Offer screening services for other STI and TB, provide condoms, offer vaccinations, and advise on SSP.

Complete and submit EvaluationWeb HIV Test form for all state-sponsored HIV tests within 2 weeks after giving results to patient. If patient does not return within 2 months for results, complete and submit form to the HIV/AIDS Section. Retain the original copy at the local site for at least one year in case the patient returns (in which case, update and resubmit form).

How to collect sample and send to State Lab (DLS)

- Enter patient demographics into Outreach. Print labels from Outreach and fix to specimen tube.
- Collect and submit 7-10 ml red stopper tube of whole blood to the Virology Section of DLS. Two unique patient identifiers must be present on the tube and the label from Outreach.
- Confidential Test: Two unique patient identifiers on lab form and specimen tube. (preferred)
- Anonymous Test: ID number only on lab form and specimen tube.
- Court-Ordered Test: Name and ID number or another patient identifier must be on lab form and specimen tube. Send the most recent version of the Administrative Order of the Courts Form 499 to DLS with the specimen.

HIV Testing Non-Clinical and Clinical Sites

Confidential tests are preferred over anonymous tests.

Positive results must be reported to the Kentucky Department for Public Health within 5 business days. For reporting requirements, see https://chfs.ky.gov/agencies/dph/dehp/hab/Pages/reportsstats.aspx. Once reported, a Disease Intervention Specialist (DIS) will provide partner services for persons diagnosed with HIV disease and are available statewide.

For Kentucky HIV Care Coordinator locations, please see: https://chfs.ky.gov/agencies/dph/dehp/hab/Pages/services.aspx.

For Kentucky HIV/AIDS Prevention Programs and EvaluationWeb HIV testing form go to https://chfs.ky.gov/agencies/dph/dehp/hab/Pages/prevention.aspx. All state sponsored HIV tests (positive and negative) must have a completed EvaluationWeb form.

CDC recommends that all adolescents and adults get tested at least once for HIV as a routine part of medical care, and that MSM and others at high risk for HIV infection be tested at least annually. In addition, MSM and other persons participating in high risk activities might benefit from more frequent screening, such as every 3 to 6 months.

Reporting HIV/AIDS Cases

Report either by phone or mail. When mailing, place case forms inside **2** sealed envelopes, both marked **CONFIDENTIAL.**

Adult and pediatric case report forms can be downloaded from the website at: HIV/AIDS Reporting and Statistics - Cabinet for Health and Family Services (ky.gov). Please use the adult and pediatric case report forms when mailing in case reports. Do not fax any confidential information.

Reporting by phone:
HIV Surveillance staff at (866) 510-0008.

Reporting by mail:
Kentucky Department for Public Health
ATTN: Surveillance
275 East Main Street, HS2E-C
Frankfort, KY 40621

Kentucky Department for Public Health follows the provisions of 902 KAR 2:020 §16. Reportable Disease Surveillance (section 16, page 12).

Additional Resources

HIV Testing in Nonclinical Settings | Diagnose | Effective Interventions | HIV/AIDS | CDC

Post-Exposure Prophylaxis (PEP) | HIV Risk and Prevention | HIV/AIDS | CDC

Pre-Exposure Prophylaxis (PrEP) | HIV Risk and Prevention | HIV/AIDS | CDC

Learn About PrEP | Preventing New HIV Infections | Clinicians | HIV | CDC

HIV - STI Treatment Guidelines (cdc.gov)

About HIV/AIDS | HIV Basics | HIV/AIDS | CDC

Testing | HIV Basics | HIV/AIDS | CDC

Types of HIV Tests | Testing | HIV Basics | HIV/AIDS | CDC

Immunizations
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CLINICAL PROTOCOLS

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/, 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.

- The American College of Nurse-Midwives has been added to the list of organizations that approve the child and adolescent immunization schedule.
- Trademark symbols (®) were added to all vaccine trade names.

GENERAL COVID-19 VACCINE RECOMMENDATIONS

- COVID-19 vaccination is recommended for everyone aged 6 months and older in the United States for the prevention of COVID-19. However, the age groups approved under FDA, BLA or authorized under EUA to receive vaccination vary by vaccine product. CDC has issued recommendations for primary series, additional primary doses, and booster doses of COVID-19 vaccines, refer to the individual protocols for those products.

- Children aged less than six months (<6mths) should **not receive any** COVID-19 vaccine doses (either standard or partial doses) at this time unless part of a clinical trial.

- **Terminology for COVID-19 Vaccine Dosing**

- **Primary series:** Two (2)-dose series of an mRNA COVID-19 vaccine (Pfizer-BioNTech and Moderna) or a single dose of Janssen vaccine

- **Additional primary dose**: a subsequent dose of vaccine administered to people who likely did not mount a protective immune response after initial vaccination. An additional primary mRNA COVID-19 vaccine dose is recommended for moderately and severely immunocompromised people who received a two (2)-dose mRNA vaccine primary series.

- **Booster dose:** a subsequent dose of vaccine administered to enhance or restore protection by the primary vaccination which might have waned over time.

- **Homologous booster dose**: a subsequent dose of vaccine that is the same product as the primary series

- **Heterologous booster dose (mix-and-match booster)**: a subsequent dose of vaccine that is a different product than the primary series.

- **Fully Vaccinated:** a person has received their primary series of COVID-19 vaccines.

- **Up to Date:** a person has received all recommended COVID-19 vaccines, including any booster dose(s) when eligible.

People who received COVID-19 vaccine outside the United States

- Individuals who have received either all doses of an FDA-approved/FDA-authorized COVID-19 vaccine or WHO-EUL COVID-19 vaccine;
    - **Are considered fully vaccinated** and
    - **Do not** need any subsequent primary series doses.
- Individuals who have received the first dose of a two (2)-dose *FDA-approved/FDA-authorized mRNA COVID-19 vaccine:*
    - **Do not need to restart** the vaccine series.
    - Should receive the second dose as close to the recommended time as possible
    - **After completing the two (2)-dose primary series are considered fully vaccinated.**

- Individuals who were vaccinated in countries where only a single mRNA COVID-19 vaccine dose is administered:
    - **Are not considered fully vaccinated** in the United States.
    - Should receive an age-appropriate second dose of an mRNA vaccine (i.e., Pediatric Pfizer- BioNTech COVID-19 Vaccine formulation for persons aged five (5) through eleven (11) years [orange cap and label with orange border]; COMIRNATY; Pfizer- BioNTech COVID- 19 formulation for persons greater than or equal to twelve (≥12) years old [purple cap and label with purple border]; or Moderna for persons greater than or equal to eighteen (≥18) years to complete the two (2)-dose primary series.
    - **Upon completion, they are considered full-vaccinated**.

The minimum interval between receipt of the non-FDA-approved/authorized vaccine and initiation of the FDA-approved/authorized COVID -19 vaccine primary series is at least twenty-eight (28) days.

People vaccinated outside the United States who received a full primary mRNA series, should receive a COVID-19 vaccine booster dose or an additional primary dose per the recommendations for that individual based on their age https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines- us.html#people-vaccinated-outside-us.

People who completed all of the recommended doses of an WHO-EUL COVID-19 vaccine[4] not approved or authorized by FDA, or people who completed a heterologous (mix and match) series composed of any combination of FDA-approved, FDA-authorized, or WHO-EUL COVID-19 vaccines:

- Are considered fully vaccinated.
- Under the EUI, moderately or severely immunocompromised people aged ≥ 1 2 years should receive an additional primary dose of Pfizer-BioNTech COVID-19 vaccine (30 µg formulation [purple cap]) at least 28 days after receiving the second vaccine dose of their primary series as detailed in Considerations for COVID-19 vaccination in moderately or severely immunocompromised people.

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#considerations-covid19-vax-immunocopromised

- Under the EUI, people aged ≥ 18 years (including moderately or severely immunocompromised people who received an additional primary dose) are eligible to receive a single booster dose of Pfizer-BioNTech COVID- 19 vaccine (30 µg formulation [purple cap]) at least 3 months after completing their primary series, as detailed in Considerations for use of a COVID-19 vaccine booster dose.

People who received only the first dose of a multidose WHO-EUL COVID-19 primary series[4] that is not FDA-approved or FDA-authorized, or who received all or some of the recommended doses of a COVID-19 vaccine primary series that is not listed for emergency use by WHO:

- Should be offered primary vaccination with an FDA-approved or FDA-authorized COVID-19 vaccine (i.e., 2-dose mRNA series or single Janssen dose), with a minimum interval of at least 28 days since receipt of the last dose of a non-FDA-approved/authorized vaccine.
- After completion of primary vaccination with an FDA-approved or FDA-authorized COVID-19 vaccine, these individuals are considered fully vaccinated and are not recommended to receive an additional primary or booster dose at this time.

Currently, there is no data to support safety and efficacy of COVID-19 vaccination in persons who have received monoclonal antibodies or convalescent plasma treatment. There is no need to defer vaccination after monoclonal antibodies or convalescent plasma treatment.

Moderna COVID-19 Vaccine Bivalent
Standing orders for Administering Vaccine
6 months to 5 years old
(Dark Blue Cap with Gray Label OR Dark Pink Cap-Yellow (Border)

Vaccine	Diluent	Dosage (amount)/Route
6 months through 5 years old (DARK BLUE CAP WITH GRAY LABEL	DO NOT DILUT	0.25Ml (25mcq) IM Injections
6 months through 5 years old Bivalent (Pink cap with Yellow border label)	DO NOT DILUTE	0.2mL(10mcq) IM injection

Purpose

- To reduce morbidity and mortality from coronavirus disease 2019 (COVID-19) by vaccinating persons who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy

- Where authorized under state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess and vaccinate persons who meet the criteria in the "Procedure" section below without the need for clinician examination or direct order from the attending provider at the time of the interaction.
- **Review package insert prior to administration and confirm storage and handling guidance.**

Procedure

- Assess persons 6 months-5 years old for Moderna COVID-19 Vaccine based on the following criteria:

*Children who **ARE NOT** moderately or severely immunocompromised*

- If the recipient has never received a COVID-19 vaccine, administer dose 1 (one) of Moderna bivalent COVID-19 vaccine and dose 2 (two), 4-8 weeks later (DARK BLUE CAP WITH GRAY LABEL 0.25 ML)
- If the recipient has received 1 (one) previous dose of Moderna monovalent COVID-19 vaccine, administer 1 (one) dose of the bivalent COVID-19 vaccine at least 4–8 weeks after the receipt of the monovalent vaccine (DARK BLUE CAP WITH GRAY LABEL 0.25 ML)
- If the recipient has received 2 (two) doses on the monovalent Moderna COVID-19 vaccine, administer 1 (one) dose of the bivalent COVID-19 vaccine at least 8 weeks after the last monovalent vaccine. (DARK PINK CAP WITH YELLOW LABEL 0.2 ML)
- If the recipient has received 2 (two) doses of the monovalent Moderna COVID-19 vaccine and 1 (one) dose of the bivalent vaccine, no additional doses are recommended.

*Children who **ARE** moderately or severely immunocompromised*

- If the recipient has never received a COVID-19vaccine, administer dose 1 (one) of Moderna bivalent COVID-19 vaccine and dose 2 (two) at least 4 weeks later and dose 3 (three) at least 4 weeks later (DARK BLUE CAP WITH GRAY LABEL 0.25 ML)
- If the recipient has received 1(one) previous dose of Moderna monovalent COVID-19 vaccine, administer 1(one) dose of the bivalent COVID-19 vaccine at least 4 weeks after the receipt of the monovalent vaccine and dose 2 (two) at least 4 weeks later (DARK BLUE CAP WITH GRAY LABEL 0.25 ML)
- If the recipient has received 2 (two) doses of the monovalent Moderna COVID-19 vaccine, administer 1 (one) dose of the bivalent COVID-19 vaccine at least 4 weeks after the last monovalent vaccine. (DARK BLUE CAP WITH GRAY LABEL 0.25 ML)
- If the recipient has received 3 (three) doses of the monovalent Moderna COVID-19 vaccine, administer 1 (one) dose of the bivalent COVID-19 vaccine at least 8 weeks after last

monovalent dose (DARK PINK CAP WITH YELLOW LABEL 0.2 ML)

- If the recipient has received 2 (two) doses of the monovalent Moderna COVID-19 vaccine and 1 (one) dose of the bivalent vaccine, 1 additional dose of a homologous bivalent mRNA vaccine at least 2 months following the last recommended bivalent mRNA COVID-19 vaccine dose. For Moderna, 0.2mL/10 ug (dark pink cap and label with a yellow boarder) is recommended; 0.25/25 ug (dark blue cap and label with a gray border) is also authorized.
- If the recipient has received 3 (three) doses of the monovalent Moderna COVID-19 vaccine and 1 (one) dose of the bivalent vaccine, 1 additional dose of a homologous bivalent mRNA vaccine at least 2 months following the last recommended bivalent mRNA COVID-19 vaccine dose For Moderna, 0.2mL/10 ug (dark pink cap and label with a yellow boarder) is recommended; 0.25/25 ug (dark blue cap and label with a gray border) is also authorized.

NOTE: In addition to the above recommendations, further additional homologous bivalent dose(s) may be administered, informed by the clinical judgement of a healthcare provider and personal preference and circumstances. Any further additional doses should be administered at least 2 months after the last COVID-19 vaccine dose

Children with a history of myocarditis or pericarditis:

- If history is prior to COVID-19 vaccination, may receive Moderna COVID-19 vaccine formulation 6 months through 5 years of age after the episode of myocarditis or pericarditis has completely resolved.

If myocarditis or pericarditis occurred after the first dose of an mRNA vaccine, experts advise no additional doses of any COVID-19 vaccine. If, after a risk assessment. a decision is made to administer a subsequent dose of COVID-19 vaccine, vaccine should not be administered until the myocarditis or pericarditis has resolved. Clinical considerations can be found at www.cdc.gov/vaccines/ covid-19/clinical- considerations/covid-19-vaccines-us.html#considerations-pfizer-biontech-moderna

Additional Clinical Considerations

- For children who received a COVID-19 vaccine that is not currently authorized or approved in the United States, guidance can be found at: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#not-authorized-vaccines
- Moderna COVID-19 Vaccine may be co-administered with other vaccines without regard to timing, including simultaneous administration.
- For recommendations for COVID-19 vaccination and SARS-CoV-2 infection, see https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

Screen for Contraindications

- Do not administer Moderna COVID-19 Vaccine to individuals with known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Moderna COVID-19 Vaccine (see Full EUA Prescribing Information).

Precautions

- Most people determined to have a precaution to a COVID-19 vaccine at their appointment can and should be administered vaccine.
- History of:
  - Immediate allergic reaction‡ to any non-COVID-19 or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies [excluding subcutaneous immunotherapy for allergies, i.e., “allergy shots”])
  - Immediate (within 4 hours after vaccination) non-severe, allergic reaction to a previous dose of the COVID-19 vaccine
  - Moderate to severe acute illness
  - History of MIS-C or MIS-A
  - Myocarditis or pericarditis after a dose of an mRNA COVID-19 vaccine

Vaccine Administration

- Prepare to administer vaccine by IM injection.
    - Needle gauge and length: Use a 22–25-gauge, 1 inch
    - For children:
        - 6 months through 2 years: Vastus lateralis muscle in the anterolateral thigh
        - 2 through 5 years: Deltoid muscle in the upper arm

- See guidance provided above for dosing and schedule regimen
- Document vaccination.
    - COVID-19 vaccination providers must document vaccine administration in their medical record systems within 24 hours of administration and use their best efforts to report administration data to the relevant system (e.g., immunization information system) for the jurisdiction as soon as practicable and no later than 72 hours after administration.
    - Document each recipient's vaccine administration information:
        - Medical record: The vaccine and the date it was administered, manufacturer, lot number, vaccination site and route, name and title of the person administering the vaccine
        - Vaccination record card: Date of vaccination, product name/manufacturer, lot number, and name/location of the administering clinic or healthcare professional. Give to the vaccine recipient.
        - Immunization information system (IIS): Report the vaccination to the appropriate state/local IIS.

Post Vaccination Monitoring
Be prepared to manage medical emergencies.

- Vaccination providers should observe patients after vaccination to monitor for the occurrence of immediate adverse reactions, including syncope:
    - **30 minutes;** Persons with a history of:
        - A contraindication to another type of COVID-19 vaccine product.
        - Immediate (within 4 hours of exposure) non-severe allergic reaction to a COVID-19 vaccine.
        - Immediate allergic reaction of any severity to a non- COVID-19 vaccine or injectable therapies
        - Anaphylaxis due to any cause.
    - **15 minutes:** All other persons

Warnings

Management of Acute Allergic Reactions

- Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the Moderna COVID-19 Vaccine.
- Monitor Moderna COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention (CDC) guidelines (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html)

Myocarditis and Pericarditis

- Post marketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose. The observed risk is highest in males 18 through 24 years of age. Although some cases required intensive care support, available data from short-term follow-up suggest that most individuals have had resolution of symptoms with conservative management. Information is not yet available about potential long-term sequelae. The CDC has

published considerations related to myocarditis and pericarditis after vaccination, including for vaccination of individuals with a history of myocarditis or pericarditis (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html)

Syncope

- Syncope (fainting) may occur in association with administration of injectable vaccines, in adolescents. Procedures should be in place to avoid injury from fainting.

Altered Immunocompetence

- Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Moderna COVID-19 Vaccine.

Adverse Reactions

Adverse Reactions in Clinical Trials

- Adverse reactions in individuals 6 months through 23 months of age following administration of the primary series included irritability/crying, pain at the injection site, sleepiness, loss of appetite, fever, swelling at the injection site, erythema at the injection site, and axillary (or groin) swelling/tenderness. (See Full EUA Prescribing Information)
- Adverse reactions in individuals 24 months through 36 months of age following administration of the primary series included pain at the injection site, irritability/crying, sleepiness, loss of appetite, fever, erythema at the injection site, swelling at the injection site, and axillary (or groin) swelling/tenderness. (See Full EUA Prescribing Information)
- Adverse reactions in individuals 37 months through 5 years of age following administration of the primary series included pain at the injection site, fatigue, headache, myalgia, fever, chills, nausea/vomiting, axillary (or groin) swelling/tenderness, arthralgia, erythema at the injection site, and swelling at the injection site. (See Full EUA Prescribing Information)

Adverse Reactions in Post-Authorization Experience

- Anaphylaxis and other severe allergic reactions, myocarditis, pericarditis, and syncope have been reported following administration of the Moderna COVID-19 Vaccine outside of clinical trial

Report adverse events to the Vaccine Adverse Event Reporting System (VAERS). While this vaccine is under Emergency Use Authorization (EUA) (https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization), healthcare professionals are required to report to VAERS:

- Vaccine administration errors (whether associated with an adverse event [AE] or not)
- Serious AEs (irrespective of attribution to vaccination)
  » Multisystem inflammatory syndrome (MIS) in adults (https://www.cdc.gov/mis-c/mis-a.html) or children (https://www.cdc.gov/mis-c/index.html)
- Cases of COVID-19 that result in hospitalization or death
  » Any additional AEs and revised safety requirements per the Food and Drug Administration's (https://www.https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization) conditions for use of an authorized vaccine throughout the duration of the EUA
- Healthcare professionals are encouraged to report to VAERS (https://vaers.hhs.gove/):
  - Clinically important adverse events that occur after vaccination, even if you are not sure whether the vaccine caused the adverse event

Moderna Bivalent
Standing orders for Administering Vaccine

6 years through 11 years old Dark Blue Cap-Gray Label Border

Vaccine	Diluent	Dosage (amount)/Route
Bivalent Booster (Dark Blue Cap-Gray Label Border)	DO NOT DILUTE	0.25mL/(25mcq) IM injections

Purpose

- To reduce morbidity and mortality from coronavirus disease 2019 (COVID-19) by vaccinating persons who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy

- Where authorized under state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess and vaccinate persons who meet the criteria in the "Procedure" section below without the need for clinician examination or direct order from the attending provider at the time of the interaction.
- **Review package insert prior to administration and confirm storage and handling guidance.**

Procedure

- Assess persons 6 years through 11 years old for Moderna COVID-19 Vaccine based on the following criteria:

*Children who **ARE NOT** moderately or severely immunocompromised*

- Recipients who are unvaccinated should receive 1 (one) dose of Moderna bivalent vaccine
- Recipients who have received 1 (one) or more doses of monovalent mRNA should receive 1 (one) dose of Moderna bivalent at least 8 weeks after last monovalent
- Recipients who have received 2 (two) or more doses monovalent mRNA and 1 (one) bivalent mRNA, no additional doses are recommended
- Any recipients who have received a bivalent, no additional doses are recommended

*Children who **ARE** moderately or severely immunocompromised*

- If the recipient has never received a COVID-19 vaccine, administer dose 1 (one) of Moderna bivalent COVID-19 vaccine and dose 2 (two) at least 4 weeks later and dose 3 (three) at least 4 weeks later
- If the recipient has received 1(one) previous dose of Moderna monovalent COVID-19 vaccine, administer 1(one) dose of the bivalent COVID-19 vaccine at least 4 weeks after the receipt of the monovalent vaccine and dose 2 (two) at least 4 weeks later
- If the recipient has received 2 (two) doses of the monovalent Moderna COVID-19 vaccine, administer 1 (one) dose of the bivalent COVID-19 vaccine at least 4 weeks after the last monovalent vaccine
- If the recipient has received 3 (three) doses of the monovalent Moderna COVID-19 vaccine, administer 1 (one) dose of the bivalent COVID-19 vaccine at least 8 weeks after last monovalent dose
- If the recipient has received 3 (three) doses of the monovalent Moderna COVID-19 vaccine and 1 (one) dose of the bivalent vaccine, have the option to receive 1 additional dose of Moderna COVID-19 Vaccine (0.25mL/25 ug; dark blue cap and label with a gray border)

NOTE: In addition to the above recommendations, further additional homologous bivalent dose(s) may be

administered, informed by the clinical judgement of a healthcare provider and personal preference and circumstances. Any further additional doses should be administered at least 2 months after the last COVID-19 vaccine dose

Children with a history of myocarditis or pericarditis:

- If history is prior to COVID-19 vaccination, may receive Moderna COVID-19 vaccine formulation 6 through 11 years of age after the episode of myocarditis or pericarditis has completely resolved.
- If myocarditis or pericarditis occurred after the first dose of an mRNA vaccine, experts advise no additional doses of any COVID-19 vaccine. If, after a risk assessment. a decision is made to administer a subsequent dose of COVID-19 vaccine, vaccine should not be administered until the myocarditis or pericarditis has resolved. Clinical considerations can be found at www.cdc.gov/vaccines/ covid-19/clinical-considerations/covid-19-vaccines-us. html#considerations-pfizer-biontech-moderna

Additional Clinical Considerations

- For children who received a COVID-19 vaccine that is not currently authorized or approved in the United States, guidance can be found at: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations. html#not-authorized-vaccines
- Moderna COVID-19 Vaccine may be co-administered with other vaccines without regard to timing, including simultaneous administration.
- For recommendations for COVID-19 vaccination and SARS-CoV-2 infection, see https://www.cdc.gov/vaccines/ covid-19/clinical-considerations/covid-19-vaccines-us. html#CoV-19-vaccination
- **For children who transition from a younger to older protocol** https://www.cdc.gov/vaccines/covid-19/downloads/Moderna-Child-Age-Transition-508.pdf

Screen for Contraindications

- Do not administer Moderna COVID-19 Vaccine to individuals with known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Moderna COVID-19 Vaccine (see Full EUA Prescribing Information).
- Do not administer the monovalent vaccine (used for the primary series) for a booster dose
- Do not administer the bivalent vaccine (used for the booster) for the primary series

Precautions

- Most people determined to have a precaution to a COVID-19 vaccine at their appointment can and should be administered vaccine.
- History of:
    - Immediate allergic reaction‡ to any non-COVID-19 or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies [excluding subcutaneous immunotherapy for allergies, i.e., “allergy shots”])
    - Immediate (within 4 hours after vaccination) non-severe, allergic reaction to a previous dose of the COVID-19 vaccine
    - Moderate to severe acute illness
    - History of MIS-C or MIS-A
    - Myocarditis or pericarditis after a dose of an mRNA COVID-19 vaccine

Vaccine Administration

- Prepare to administer vaccine (dark blue cap-purple label border) by IM injection.
    - Needle gauge and length: Use a 22–25-gauge, 1 inch
- See guidance provided above for dosing and schedule regimen
    - Document vaccination.
        - COVID-19 vaccination providers must document vaccine administration in their medical record systems within 24 hours of administration and use their best efforts to report

administration data to the relevant system (e.g., immunization information system) for the jurisdiction as soon as practicable and no later than 72 hours after administration.

- Document each recipient's vaccine administration information:
  - Medical record: The vaccine and the date it was administered, manufacturer, lot number, vaccination site and route, name and title of the person administering the vaccine
  - Vaccination record card: Date of vaccination, product name/manufacturer, lot number, and name/location of the administering clinic or healthcare professional. Give to the vaccine recipient.
  - Immunization information system (IIS): Report the vaccination to the appropriate state/local IIS.

Post Vaccination Monitoring

- Be prepared to manage medical emergencies.
- Vaccination providers should observe patients after vaccination to monitor for the occurrence of immediate adverse reactions, including syncope:
  - **30 minutes;** Persons with a history of:
    - A contraindication to another type of COVID-19 vaccine product.
    - Immediate (within 4 hours of exposure) non-severe allergic reaction to a COVID-19 vaccine.
    - Immediate allergic reaction of any severity to a non- COVID-19 vaccine or injectable therapies
    - Anaphylaxis due to any cause.
  - **15 minutes:** All other persons

Warnings

Management of Acute Allergic Reactions

- Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the Moderna COVID-19 Vaccine.
- Monitor Moderna COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention (CDC) guidelines (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html)

Myocarditis and Pericarditis

- Post marketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose. The observed risk is highest in males 18 through 24 years of age. Although some cases required intensive care support, available data from short-term follow-up suggest that most individuals have had resolution of symptoms with conservative management. Information is not yet available about potential long-term sequelae. The CDC has published considerations related to myocarditis and pericarditis after vaccination, including for vaccination of individuals with a history of myocarditis or pericarditis (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html)

Syncope

- Syncope (fainting) may occur in association with administration of injectable vaccines, in adolescents. Procedures should be in place to avoid injury from fainting.

Altered Immunocompetence

- Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Moderna COVID-19 Vaccine.

Adverse Reactions

Adverse Reactions in Clinical Trials

- Adverse reactions in individuals 6 years through 11 years following administration of the

primary series included pain at the injection site, fatigue, headache, myalgia, chills, nausea/vomiting, axillary swelling/tenderness, fever, erythema at the injection site, swelling at the injection site, and arthralgia. (See Full EUA Prescribing Information)

Adverse Reactions in Post-Authorization Experience

- Anaphylaxis and other severe allergic reactions, myocarditis, pericarditis, and syncope have been reported following administration of the Moderna COVID-19 Vaccine outside of clinical trials.
- Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Moderna COVID-19 Vaccine.

Report adverse events to the Vaccine Adverse Event Reporting System (VAERS). While this vaccine is under Emergency Use Authorization (EUA) (https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization), healthcare professionals are required to report to VAERS:

- Vaccine administration errors (whether associated with an adverse event [AE] or not)
- Serious AEs (irrespective of attribution to vaccination)
  » Multisystem inflammatory syndrome (MIS) in adults (https://www.cdc.gov/mis-c/mis-a.html) or children (https://www.cdc.gov/mis-c/index.html)
- Cases of COVID-19 that result in hospitalization or death
  » Any additional AEs and revised safety requirements per the Food and Drug Administration's (https://www.https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization) conditions for use of an authorized vaccine throughout the duration of the EUA
- Healthcare professionals are encouraged to report to VAERS (https://vaers.hhs.gove/):
  - Clinically important adverse events that occur after vaccination, even if you are not sure whether the vaccine caused the adverse event

Moderna COVID-19 Bivalent Vaccine
Standing Orders for Administering Vaccine
12 Years of Age and Older: Dark Blue Cap and Grey Label Border

Vaccine	Dosage (amount)/Route
Moderna-Bivalent (12 years old and older)	**0.5mL (50 mcq)/IM injections**

Purpose

- To reduce morbidity and mortality from coronavirus disease 2019 (COVID-19) by vaccinating persons who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy

- Where authorized under state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess and vaccinate persons who meet the criteria in the "Procedure" section below without the need for clinician examination or direct order from the attending provider at the time of the interaction.
- **Review package insert prior to administration and confirm storage and handling guidance.**

Procedure

- Assess persons 12 years of age and older for vaccination with Moderna COVID-19 Vaccine based on the following criteria:

Persons who ARE NOT moderately or severely immunocompromised*

- If the recipient has never received a COVID-19 vaccine, administer 1 (one) dose of Moderna bivalent COVID-19 Vaccine.
- If the recipient has received 1 (one) or more previous dose/s of mRNA monovalent vaccines and no bivalent doses, administer 1 bivalent dose at least 8 weeks after last monovalent doses
- If the recipient has ever received 1(one) dose bivalent mRNA (regardless of monovalent vaccine history) no additional doses are recommended
- *Recipients 65 or older who have received a bivalent mRNA, have the option to receive 1 additional bivalent mRNA vaccine dose at least 4 months after the first dose of a bivalent mRNA*

Person who ARE moderately or severely immunocompromised*

- If the recipient has never received a COVID-19 vaccine, administer dose 1 (one) of Moderna bivalent COVID-19 vaccine and dose 2 (two) at least 4 weeks later and dose 3 (three) at least 4 weeks later
- If the recipient has received 1(one) previous dose of Moderna monovalent COVID-19 vaccine, administer 1(one) dose of the bivalent COVID-19 vaccine at least 4 weeks after the receipt of the monovalent vaccine and dose 2 (two) at least 4 weeks later
- If the recipient has received 2 (two) doses of the monovalent Moderna COVID-19 vaccine, administer 1 (one) dose of the bivalent COVID-19 vaccine at least 4 weeks after the last monovalent vaccine
- If the recipient has received 3 (three) doses of the monovalent Moderna COVID-19 vaccine, administer 1 (one) dose of the bivalent COVID-19 vaccine at least 8 weeks after last monovalent dose
    - People ages 12 years and older who are moderately or severely immunocompromised have the option to receive 1 additional dose of Moderna COVID-19 Vaccine (0.5 mL/50 ug; dark blue cap and label with a gray border)

at least 2 months following the last recommended bivalent COVID-19 vaccine dose

- If the recipient has received 3 (three) doses of the monovalent Moderna COVID-19 vaccine and 1 (one) dose of the bivalent vaccine, see guidance below
    - People ages 12 years and older who are moderately or severely immunocompromised have the option to receive 1 additional dose of Moderna COVID-19 Vaccine (0.5 mL/50 ug; dark blue cap and label with a gray border) at least 2 months following the last recommended bivalent COVID-19 vaccine dose

NOTE: In addition to the above recommendations, further additional homologous bivalent dose(s) may be administered, informed by the clinical judgement of a healthcare provider and personal preference and circumstances. Any further additional doses should be administered at least 2 months after the last COVID-19 vaccine dose.

- For persons who received a COVID-19 vaccine:
    - Outside of the United States
    - Not currently authorized/approved in the United States
    - See clinical guidance, including Bivalent booster dose recommendations, at https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19- vaccines-us.
- Moderna COVID-19 vaccine may be co-administered with other vaccines without regard to timing, including simultaneous administration.
- For recommendations for COVID-19 vaccination and SARS-CoV-2 infection, see https://www.cdc.gov/vaccines/ covid-19/clinical-considerations/covid-19-vaccines-us. html#CoV-19-vaccination

* Inform recipients, especially males 12 through 29 years of age and their parents/legal representative (when relevant) of the possibility of myocarditis or pericarditis following receipt of mRNA COVID-19 vaccines and the need to seek care if symptoms of myocarditis or pericarditis develop after vaccination. Educational materials are available at https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myocarditis.html

- Screen for Contraindications and Precautions
    - Contraindications:
        - History of a:
            - Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine
            - Known diagnosed allergy to a component of the COVID-19 vaccine (see https://www.cdc.gov/vaccines/ covid-19/clinical-considerations/covid-19-vaccines-us. Appendix-C for a list of vaccine components)
    - Precautions:
        - Most people determined to have a precaution to a COVID-19 vaccine at their appointment can and should be administered vaccine.
        - Immediate allergic reaction† to any non-COVID-19 vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies [excluding subcutaneous immunotherapy for allergies, i.e., “allergy shots”])
            - This includes non-COVID-19 vaccines and therapies with multiple components and the component(s) that elicited the reaction is unknown
        - Immediate (within 4 hours after vaccination) non-severe, allergic reaction to a previous dose of the COVID-19 vaccine
        - Contraindication to one type of COVID-19 vaccine (mRNA) is a precaution to other types of COVID-19 vaccines (Janssen)‡
        - Moderate to severe acute illness, with or without fever
        - History of myocarditis or pericarditis after a dose of an mRNA COVID-19 vaccine

Sex and Weight of Patient	Needle Gauge	Needle Length	Injection Sites
Female or male fewer than 130 lbs.	22-25	5/8¶-1"	Deltoid muscle of arm
Female or male 130-152 lbs.	22-25	1"	Deltoid muscle of arm
Female 152-200 lbs.	22-25	1"– 1 ½"	Deltoid muscle of arm
Male 152-260 lbs.	22-25	1 ½"	Deltoid muscle of arm
Female 200+ lbs.	22-25	1 ½"	Deltoid muscle of arm
Male 260+ lbs.	22-25	1 ½"	Deltoid muscle of arm

- Provide all recipients with a copy of the current federal Emergency Use Authorization (EUA) Fact Sheet for Recipients and Caregivers.
- Prepare to administer the vaccine. Choose the correct needle gauge, needle length, and injection site for persons:
    - 12 years of age:
        - Needle gauge/length: 22-25 gauge, 1-inch.
        - Site: Deltoid muscle of arm.
    - 19 years of age and older: See chart.
- **Follow the manufacturer's guidance for storing/handling punctured vaccine vials.**
- Administer Moderna COVID-19 Vaccine by intramuscular (IM) injection
- See above for dose and vaccine schedule
- Document vaccination.
    - COVID-19 vaccination providers must document vaccine administration in their medical record systems within 24 hours of administration and use their best efforts to report administration data to the relevant system (e.g., immunization information system) for the jurisdiction as soon as practicable and no later than 72 hours after administration.
    - Document each recipient's vaccine administration information:
        - Medical record: The vaccine and the date it was administered, manufacturer, lot number, vaccination site and route, name and title of the person administering the vaccine
- Vaccination record card: Date of vaccination, product name/manufacturer, lot number, and name/location of the administering clinic or healthcare professional. Give to the vaccine recipient
- Be prepared to manage medical emergencies.
    - Vaccination providers should observe patients after vaccination to monitor for the occurrence of immediate adverse reactions, including syncope:
    - 30 minutes: persons with a history of:
        - A contraindication to another type of COVID-19 vaccine product.
        - Immediate (within 4 hours of exposure) non-severe allergic reaction to a COVID-19 vaccine.
        - Immediate allergic reaction of any severity to a non- COVID-19 vaccine or injectable therapies
        - Anaphylaxis due to any cause.
    - 15 minutes: All other persons
    - Syncope may occur in association with injectable vaccines, among adolescents. Procedures should be in place to avoid falling injuries and manage syncopal reactions.
    - For more information, please see:
        - **Interim Considerations: Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination at https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html**
        - **CDC's *General Best Practice Guidelines for Immunization*, "Preventing and Managing Adverse Reactions," at** https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/adverse-reactions.html
        - **Immunization Action Coalition's "Medical Management of Vaccine Reactions in Adults in a Community Setting" at** https://www.immunize.org/catg.d/p3082.pdf
- Report adverse events to the Vaccine Adverse Event Reporting System (VAERS).

- While this vaccine is under Emergency Use Authorization (EUA), (https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/ emergency-use-authorization) healthcare professionals are required to report to VAERS:
  - Vaccine administration errors (whether associated with an adverse event [AE] or not)
  - Serious AEs (irrespective of attribution to vaccination)
  - Multisystem inflammatory syndrome (MIS) in adults (https://www.cdc.gov/mis-c/mis-a.html) or children(https://www.cdc.gov/mis-c/index.html)

† An immediate allergic reaction is defined as any hypersensitivity-related signs or symptoms such as urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within 4 hours following exposure to a vaccine or medication.
‡ Consider consultation with an allergist-immunologist to help determine if a patient with a contraindication to an mRNA vaccine can safely receive the Janssen COVID-19 Vaccine. Healthcare providers and health departments may also request a consultation from the Clinical Immunization Safety Assessment COVIDvax project (https://www.cdc.gov/vaccinesafety/ensuringsafety/ monitoring/cisa/index.html). Vaccination of these individuals should only be done in an appropriate setting under the supervision of a healthcare provider experienced in the management of severe allergic reactions.
People with a contraindication to mRNA COVID-19 vaccines (including due to a known PEG allergy) have a precaution to Janssen COVID-19 vaccination. People who have previously received an mRNA COVID-19 vaccine dose should wait at least 28 days to receive Janssen COVID-19 Vaccine.

People with a contraindication to Janssen COVID-19 Vaccine (including due to a known polysorbate allergy) have a precaution to mRNA COVID-19 vaccination.
§ Alternately, the anterolateral thigh can be used. A 1.5-inch needle may be used if administering vaccine in this site.
¶ Some experts recommend a 5/8-inch needle for men and women who weigh less 130 pounds. If used, skin must be stretched tightly (**do not bunch subcutaneous tissue**).

Pfizer-BioNTech COVID-19 Bivalent Vaccine
Vaccine Standing orders for Administering Vaccine
6 months to 4 years old (Maroon Cap)

Vaccine	Diluent	Dosage (amount)/Route
6 months through 4 years old (Maroon cap with maroon border label)	Dilute with 2.2 mL sterile 0.9% Sodium Chloride Injection, USP prior to use	0.2mL/(3mcq) IM injection

*The vial labels may state "Age 2y to < 5y" or "Age 6m to < 5y" and carton labels may state "For age 2 years to < 5 years" or "For age 6 months to < 5 years". Vials with either printed age range can be used for individuals 6 months through 4 years of age

Purpose

- To reduce morbidity and mortality from coronavirus disease 2019 (COVID-19) by vaccinating persons who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy

- Where authorized under state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess and vaccinate persons who meet the criteria in the "Procedure" section below without the need for clinician examination or direct order from the attending provider at the time of the interaction.
- **Review package insert prior to administration and confirm storage and handling guidance.**

Procedure

- Assess persons 6 months-4 years old with Pfizer- BioNTech COVID-19 Vaccine based on the following criteria:
    - The Pfizer-BioNTech Bivalent COVID-19 Vaccine for individuals 6 months through 4 years of age is supplied in a multiple dose vial with a maroon cap and a label with a maroon border with "Bivalent". Please verify that you have the correct vial.

*Children who **ARE NOT** moderately or severely immunocompromised*

- Children who have not been previously vaccinated should receive:
    - Dose 1 and Dose 2 administered 3-8 weeks apart
    - Dose 2 and Dose 3 administered at least 8 weeks apart
- Children who have received 1 dose of monovalent Pfizer-BioNTech should receive:
    - Bivalent Dose 1 administered 3-8 weeks after the monovalent
    - Bivalent Dose 2 administered at least 8 weeks after Bivalent Dose 1
- Children who have received 2 doses of monovalent Pfizer-BioNTech should receive:
    - Bivalent Dose 1 administered at least 8 weeks after the last monovalent dose
- Children who have received 3 doses of monovalent Pfizer-BioNTech should receive:
    - Bivalent Dose 1 administered 8 weeks after receiving the last monovalent dose
- Children that have received 2 doses of monovalent Pfizer-BioNTech and 1 dose bivalent Pfizer BioNTech, no additional doses are recommended

*Children who **ARE** moderately or severely immunocompromised*

- Children who have not been previously vaccinated may receive:
    - Dose 1 and Dose 2 administered (three) 3 weeks apart

        - Dose 2 and Dose 3 administered at least 8 weeks apart
    - Children who have received 1 dose of monovalent Pfizer-BioNTech should receive:
        - Bivalent Dose 1 administered (three) 3 weeks after the monovalent
        - Bivalent Dose 2 administered at least 8 weeks after Bivalent Dose 1
    - Children who have received 2 doses of monovalent Pfizer-BioNTech should receive:
        - Bivalent Dose 1 administered at least 8 weeks after the last monovalent dose
    - Children who have received 3 doses of monovalent Pfizer-BioNTech should receive:
        - Bivalent Dose 1 administered (eight) 8 weeks after receiving the last monovalent dose
    - Children that have received 2 doses of monovalent Pfizer-BioNTech and 1 dose bivalent Pfizer BioNTech,
        - Have the option to receive 1 additional dose of a homologous bivalent mRNA vaccine at least 2 months following the last recommended bivalent mRNA COVID-19 vaccine dose.
    - Children that have received 3 doses of monovalent Pfizer-BioNTech and 1 dose bivalent Pfizer-BioNTech
        - Have the option to receive 1 additional dose of a homologous bivalent mRNA vaccine at least 2 months following the last recommended bivalent mRNA COVID-19 vaccine dose.

NOTE: In addition to the above recommendations, further additional homologous bivalent dose(s) may be administered, informed by the clinical judgement of a healthcare provider and personal preference and circumstances. Any further additional doses should be administered at least 2 months after the last COVID-19 vaccine dose

Individuals who will turn from 4 years old to 5 years old

- In general, CDC recommends that people receive the age-appropriate vaccine product and dosage based on their age on the day of vaccination. If a person moves to an older age group between vaccine doses, they should receive the vaccine product and dosage for the older age group for all subsequent doses with the following exception:
    - FDA EUA requires that children who receive the Pfizer-BioNTech COVID-19 Vaccine and transition from age 4 to 5 years during the 3-dose vaccination series **must complete the series they start** (i.e., receive the 0.2 mL/3 ug dosage supplied in vials with a maroon cap and label with a maroon border for all 3 doses).

Children with a history of myocarditis or pericarditis:

- If history is prior to COVID-19 vaccination, may receive Pfizer-BioNTech formulation 6 months through 4 years of age after the episode of myocarditis or pericarditis has completely resolved.
- If myocarditis or pericarditis occurred after the first dose of an mRNA vaccine, experts advise no additional doses of any COVID-19 vaccine. If, after a risk assessment. a decision is made to administer a subsequent dose of COVID-19 vaccine, vaccine should not be administered until the myocarditis or pericarditis has resolved. Clinical considerations can be found at www.cdc.gov/vaccines/ covid-19/clinical-considerations/covid-19-vaccines-us. html#considerations-pfizer-biontech-moderna

Additional clinical considerations

- For children who received a COVID-19 vaccine that is not currently authorized or approved in the United States, guidance can be found at: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations. html#not-authorized-vaccines
- Pfizer-BioNTech COVID-19 Vaccine may be co-administered with other vaccines without regard to timing, including simultaneous administration.
- For recommendations for COVID-19 vaccination and SARS-CoV-2 infection, see https://www.cdc.gov/vaccines/ covid-19/clinical-considerations/covid-19-vaccines-us. html#CoV-19-vaccination

Vaccine Administration

- Prepare to administer the appropriate vaccine by IM injection.
    - Needle gauge and length: Use a 22–25-gauge, 1 inch
    - For children:
        - 6 months through 2 years: Vastus lateralis muscle in the anterolateral thigh
        - 2 through 4 years: Deltoid muscle in the upper arm

- Administer 0.2 mL of Pfizer-BioNTech COVID-19 Bivalent Vaccine for children 6 months through 4 years of age as outlined above

Document vaccination.

- COVID-19 vaccination providers must document vaccine administration in their medical record systems within 24 hours of administration and use their best efforts to report administration data to the relevant system (e.g., immunization information system) for the jurisdiction as soon as practicable and no later than 72 hours after administration.
- Document each recipient's vaccine administration information:
    - Medical record: The vaccine and the date it was administered, manufacturer, lot number, vaccination site and route, name and title of the person administering the vaccine
    - Vaccination record card: Date of vaccination, product name/manufacturer, lot number, and name/location of the administering clinic or healthcare professional. Give to the vaccine recipient.
    - Immunization information system (IIS): Report the vaccination to the appropriate state/local IIS.

Post Vaccination Monitoring

- Be prepared to manage medical emergencies.
- Vaccination providers should observe patients after vaccination to monitor for the occurrence of immediate adverse reactions, including syncope:
    - **30 minutes;** Persons with a history of:
        - A contraindication to another type of COVID-19 vaccine product.
        - Immediate (within 4 hours of exposure) non-severe allergic reaction to a COVID-19 vaccine.
        - Immediate allergic reaction of any severity to a non- COVID-19 vaccine or injectable therapies
        - Anaphylaxis due to any cause.
    - **15 minutes:** All other persons

Contraindications

Do not administer Pfizer-BioNTech COVID-19 Vaccine to individuals with known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech COVID-19 Vaccine (see Full EUA Prescribing Information).

Warnings

Management of Acute Allergic Reactions

- Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of Pfizer-BioNTech COVID-19 Vaccine.
- Monitor Pfizer-BioNTech COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention (CDC) guidelines at https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html

Myocarditis and Pericarditis

- Post marketing data demonstrate increased risks of myocarditis and pericarditis,

particularly within 7 days following the second dose. The observed risk is highest in males 12 through 17 years of age.

Syncope

- Syncope (fainting) may occur in association with administration of injectable vaccines, in adolescents. Procedures should be in place to avoid injury from fainting.

Altered Immunocompetence

- Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Pfizer-BioNTech COVID-19 Vaccine.

Adverse Reactions in Post Authorization Experience

- Severe allergic reactions, including anaphylaxis, and other hypersensitivity reactions (e.g., rash, pruritus, urticaria, angioedema), diarrhea, vomiting, pain in extremity (arm), and syncope have been reported following administration of the Pfizer-BioNTech COVID-19 Vaccine.
- Myocarditis and pericarditis have been reported following administration of the Pfizer-BioNTech COVID-19 Vaccine.
- Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Pfizer-BioNTech COVID-19 Vaccine.

Adverse Reactions in Clinical Trials

- Adverse reactions in participants 6 through 23 months of age following administration of the Pfizer-BioNTech COVID-19 Vaccine included irritability, decreased appetite, tenderness at the injection site, injection site redness, fever, injection site swelling, and lymphadenopathy (see Full EUA Prescribing Information).
- Adverse reactions in participants 2 through 4 years of age following administration of the Pfizer-BioNTech COVID-19 Vaccine included pain at the injection site, fatigue, injection site redness, fever, headache, injection site swelling, chills, muscle pain, joint pain, and lymphadenopathy (see Full EUA Prescribing Information).

Report adverse events to the Vaccine Adverse Event Reporting System (VAERS).

- While this vaccine is under Emergency Use Authorization (EUA), (https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/ emergency-use-authorization) healthcare professionals are required to report to VAERS:
    - Vaccine administration errors (whether associated with an adverse event [AE] or not)
    - Serious AEs (irrespective of attribution to vaccination)
    - Multisystem inflammatory syndrome (MIS) in adults (https://www.cdc.gov/mis- c/mis-a.html) or children(https://www.cdc.gov/mis-c/index.html)

Pfizer-BioNTech COVID-19 Bivalent
Standing orders for Administering Vaccine
5 years through 11 years old Orange Cap-Orange Label Border

Vaccine	Diluent	Dosage (amount)/Route
Bivalent Booster (Orange Cap and Orange Label Border)	MUST DILUTE	0.2mL/(10mcq) IM injections

Purpose

- To reduce morbidity and mortality from coronavirus disease 2019 (COVID-19) by vaccinating persons who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy

- Where authorized under state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess and vaccinate persons who meet the criteria in the "Procedure" section below without the need for clinician examination or direct order from the attending provider at the time of the interaction.
- **Review package insert prior to administration and confirm storage and handling guidance.**

Procedure

- Assess persons 5 years through 11 years old for Pfizer COVID-19 Vaccine based on the following criteria:

*Children who **ARE NOT** moderately or severely immunocompromised*

- Children who have not been previously vaccinated should receive 1 (one) dose of bivalent Pfizer COVID-19
- Children who have received 1 (one) or more doses of a monovalent mRNA should receive 1 (one) dose of bivalent Pfizer COVID-19 vaccine
- Children who have received 2 (two) doses of a monovalent mRNA and 1 (one) dose of bivalent, no additional doses
- Children who have ever received a bivalent dose (regardless of monovalent history), no additional doses

*Children who **ARE** moderately or severely immunocompromised*

- Individuals who have not been previously vaccinated may receive:
  - Dose 1 and Dose 2 administered 3 weeks apart
  - Dose 2 and Dose 3 administered at least 4 weeks apart
- Individuals who have received 1 dose of monovalent Pfizer-BioNTech should receive:
  - Bivalent Dose 1 administered 3 weeks after the monovalent
  - Bivalent Dose 2 administered at least 4 weeks after Bivalent Dose 1
- Individuals who have received 2 doses of monovalent Pfizer-BioNTech should receive:
  - Bivalent Dose 1 administered at least 4 weeks after the last monovalent dose
- Individuals who have received 3 doses of monovalent Pfizer-BioNTech should receive:
  - Bivalent Dose 1 administered 8 weeks after receiving the last monovalent dose
- Individuals that have received 2 doses of monovalent Pfizer-BioNTech and 1 dose bivalent Pfizer BioNTech,
  - Bivalent Pfizer-BioNTech COVID-19 Vaccine (0.2 mL/10 ug; orange cap and label with an orange border) at least 2 months following the last recommended bivalent COVID-19 vaccine dose
- Individuals that have received 3 doses monovalent Pfizer-BioNTech and 1 dose bivalent mRNA
  - Bivalent Pfizer-BioNTech COVID-19 Vaccine (0.2 mL/10 ug; orange cap and label with an orange border) at least 2 months following the last recommended

bivalent COVID-19 vaccine dose

NOTE: In addition to the above recommendations, further additional homologous bivalent dose(s) may be administered, informed by the clinical judgement of a healthcare provider and personal preference and circumstances. Any further additional doses should be administered at least 2 months after the last COVID-19 vaccine dose

Additional Clinical Considerations

- For children who received a COVID-19 vaccine that is not currently authorized or approved in the United States, guidance can be found at: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#not-authorized-vaccines
- Pfizer COVID-19 Vaccine may be co-administered with other vaccines without regard to timing, including simultaneous administration.
- For recommendations for COVID-19 vaccination and SARS-CoV-2 infection, see https://www.cdc.gov/vaccines/ covid-19/clinical-considerations/covid-19-vaccines-us. html#CoV-19-vaccination
- **For children who transition from a younger to older protocol:** https://www.cdc.gov/vaccines/covid-19/downloads/Pfizer-Child-Age-Transition-508.pdf

Screen for Contraindications

- Do not administer Pfizer COVID-19 Vaccines to individuals with known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer COVID-19 Vaccine (see Full EUA Prescribing Information).
- Do not administer the monovalent vaccine (used for the primary series) for a booster dose
- Do not administer the bivalent vaccine (used for the booster) for the primary series

Precautions

- Most people determined to have a precaution to a COVID-19 vaccine at their appointment can and should be administered vaccine.
- History of:
    - Immediate allergic reaction‡ to any non-COVID-19 or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies [excluding subcutaneous immunotherapy for allergies, i.e., “allergy shots”])
    - Immediate (within 4 hours after vaccination) non-severe, allergic reaction to a previous dose of the COVID-19 vaccine
    - Moderate to severe acute illness
    - History of MIS-C or MIS-A
    - Myocarditis or pericarditis after a dose of an mRNA COVID-19 vaccine

Vaccine Administration

- Prepare to administer vaccine (dark blue cap-purple label border) by IM injection.
    - Needle gauge and length: Use a 22–25-gauge, 1 inch
- Follow dose and schedule regimen outlined above
- Document vaccination.
    - COVID-19 vaccination providers must document vaccine administration in their medical record systems within 24 hours of administration and use their best efforts to report administration data to the relevant system (e.g., immunization information system) for the jurisdiction as soon as practicable and no later than 72 hours after administration.
    - Document each recipient's vaccine administration information:
        - Medical record: The vaccine and the date it was administered, manufacturer, lot number, vaccination site and route, name and title of the person administering the vaccine
        - Vaccination record card: Date of vaccination, product name/manufacturer, lot number, and name/location of the administering clinic or healthcare professional. Give to the vaccine recipient.
        - Immunization information system (IIS): Report the vaccination to the appropriate state/local IIS.

Post Vaccination Monitoring

- Be prepared to manage medical emergencies.
- Vaccination providers should observe patients after vaccination to monitor for the occurrence of immediate adverse reactions, including syncope:
    - **30 minutes;** Persons with a history of:
        - A contraindication to another type of COVID-19 vaccine product.
        - Immediate (within 4 hours of exposure) non-severe allergic reaction to a COVID-19 vaccine.
        - Immediate allergic reaction of any severity to a non- COVID-19 vaccine or injectable therapies
        - Anaphylaxis due to any cause.
    - **15 minutes:** All other persons

Warnings

Management of Acute Allergic Reactions

- Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the Pfizer COVID-19 Vaccine.
- Monitor Pfizer COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention (CDC) guidelines (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html)

Myocarditis and Pericarditis

- Post marketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose. The observed risk is highest in males 18 through 24 years of age. Although some cases required intensive care support, available data from short-term follow-up suggest that most individuals have had resolution of symptoms with conservative management. Information is not yet available about potential long-term sequelae. The CDC has published considerations related to myocarditis and pericarditis after vaccination, including for vaccination of individuals with a history of myocarditis or pericarditis (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html)

Syncope

- Syncope (fainting) may occur in association with administration of injectable vaccines, in adolescents. Procedures should be in place to avoid injury from fainting.

Altered Immunocompetence

- Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Pfizer COVID-19 Vaccine.

Adverse Reactions

Adverse Reactions in Clinical Trials

- Adverse reactions in individuals 5 years through 11 years following administration of the primary series included pain at the injection site, fatigue, headache, myalgia, chills, nausea/vomiting, axillary swelling/tenderness, fever, erythema at the injection site, swelling at the injection site, and arthralgia. (See Full EUA Prescribing Information)

Adverse Reactions in Post-Authorization Experience

- Anaphylaxis and other severe allergic reactions, myocarditis, pericarditis, and syncope have been reported following administration of the Pfizer COVID-19 Vaccine outside of clinical trials.
- Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Pfizer COVID-19 Vaccine.

Pfizer- BioNTech Bivalent
Standing Orders for Administering Vaccine

12 years of Age and Older (Gray cap with Gray Label

Vaccine	Diluent	Dosage (amount)/Route
Pfizer- BioNTech **-Bivalent Booster (12 years old and older) (Gray Cap with Gray Label)**	**Do not dilute**	**0.3 mL(30 mcq)/IM injection**

Purpose

- To reduce morbidity and mortality from coronavirus disease 2019 (COVID-19) by vaccinating persons who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy

- Where authorized under state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess and vaccinate persons who meet the criteria in the "Procedure" section below without the need for clinician examination or direct order from the attending provider at the time of the interaction.
- **Review package insert prior to administration and confirm storage and handling guidance.**

Procedure

Assess persons 12 years of age and older who **are not** moderately or severely immunocompromised for vaccination with Pfizer- BioNTech COVID-19 Vaccine based on the following criteria:

- Unvaccinated individuals should receive 1 dose of bivalent Pfizer-BioNTech COVID-19 vaccine
- Recipients who have received 1 or more doses of a monovalent mRNA and no doses of bivalent should receive 1 dose of bivalent Pfizer-BioNTech COVID-19 vaccine
- Recipients between the ages 12 and 64 who have received a bivalent mRNA (regardless of monovalent history) no additional dose is recommended
- Recipients 65 or older who have received a bivalent mRNA, have the option to receive 1 additional bivalent mRNA vaccine dose at least 4 months after the first dose of a bivalent mRNA

Assess persons 12 years of age and older who **are** moderately or severely immunocompromised for vaccination with Pfizer- BioNTech COVID-19 Vaccine based on the following criteria:

- Individuals who have not been previously vaccinated may receive:
  - Dose 1 and Dose 2 administered 3 weeks apart
  - Dose 2 and Dose 3 administered at least 4 weeks apart
- Individuals who have received 1 dose of monovalent Pfizer-BioNTech should receive:
  - Bivalent Dose 1 administered 3 weeks after the monovalent
  - Bivalent Dose 2 administered at least 4 weeks after Bivalent Dose 1
- Individuals who have received 2 doses of monovalent Pfizer-BioNTech should receive:
  - Bivalent Dose 1 administered at least 4 weeks after the last monovalent dose
- Individuals who have received 3 doses of monovalent Pfizer-BioNTech should receive:
  - Bivalent Dose 1 administered 8 weeks after receiving the last monovalent dose
- Individuals that have received 2 doses of monovalent Pfizer-BioNTech and 1 dose bivalent Pfizer BioNTech
  - People ages 12 years and older who are moderately or severely immunocompromised have the option to receive 1 additional dose of Pfizer-BioNTech COVID-19 Vaccine (0.3 mL/30 ug; gray cap and label with a gray

border) at least 2 months following the last recommended bivalent COVID-19 vaccine dose

- Individuals that have received 3 doses monovalent Pfizer-BionNTech and 1 dose bivalent mRNA
  - People ages 12 years and older who are moderately or severely immunocompromised have the option to receive 1 additional dose of Pfizer-BioNTech COVID-19 Vaccine (0.3 mL/30 ug; gray cap and label with a gray border) at least 2 months following the last recommended bivalent COVID-19 vaccine dose

NOTE: In addition to the above recommendations, further additional homologous bivalent dose(s) may be administered, informed by the clinical judgement of a healthcare provider and personal preference and circumstances. Any further additional doses should be administered at least 2 months after the last COVID-19 vaccine dose

Preparation for Administration

- **Pfizer- BioNTech** COVID-19 Vaccine, Bivalent is supplied as a frozen suspension that does not contain a preservative and must be thawed prior to administration.
- Verify that the vial label states **Pfizer- BioNTech** COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5).
- Each multiple dose vial contains 6 doses of 0.3 mL. If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and contents.
- Screen for Contraindications and Precautions
  - Contraindications:
    - History of a:
      - Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine
      - Known diagnosed allergy to a component of the COVID-19 vaccine (see https://www.cdc.gov/vaccines/ covid-19/clinical-considerations/covid-19-vaccines-us. Appendix-C for a list of vaccine components)
  - Precautions:
    - Most people determined to have a precaution to a COVID-19 vaccine at their appointment can and should be administered vaccine.
    - Immediate allergic reaction† to any non-COVID-19 vaccine or injectable therapy (i.e., intramuscular, intravenous, or
    - subcutaneous vaccines or therapies [excluding subcutaneous immunotherapy for allergies, i.e., “allergy shots”])
      - This includes non-COVID-19 vaccines and therapies with multiple components and the component(s) that elicited the reaction is unknown
    - Immediate (within 4 hours after vaccination) non-severe, allergic reaction to a previous dose of the COVID-19 vaccine
    - Contraindication to one type of COVID-19 vaccine (mRNA) is a precaution to other types of COVID-19 vaccines (Janssen)‡
    - Moderate to severe acute illness, with or without fever
    - History of myocarditis or pericarditis after a dose of an mRNA COVID-19 vaccine

Sex and Weight of Patient	Needle Gauge	Needle Length	Injection Sites
Female or male fewer than 130 lbs	22-25	5/8¶-1”	Deltoid muscle of arm
Female or male 130-152 lbs	22-25	1”	Deltoid muscle of arm
Female 152-200 lbs	22-25	1” – 1 ½”	Deltoid muscle of arm
Male 152-260 lbs	22-25	1 ½”	Deltoid muscle of arm
Female 200+ lbs	22-25	1 ½”	Deltoid muscle of arm
Male 260+ lbs	22-25	1 ½”	Deltoid muscle of arm

- Provide all recipients with a copy of the current federal Emergency Use Authorization (EUA) Fact Sheet for Recipients and Caregivers.
- Prepare to administer the vaccine. Choose the correct needle gauge, needle length, and injection site for persons:
    - 12 years of age:
        - Needle gauge/length: 22-25 gauge, 1-inch.
        - Site: Deltoid muscle of arm.
- **Follow the manufacturer's guidance for storing/handling punctured vaccine vials.**
- Administer Pfizer COVID-19 Vaccine by intramuscular (IM) injection
    - 0.3 mL mL to individuals per the dose and regimen outlined above:
    - Document vaccination.
    - COVID-19 vaccination providers must document vaccine administration in their medical record systems within 24 hours of administration and use their best efforts to report administration data to the relevant system (e.g., immunization information system) for the jurisdiction as soon as practicable and no later than 72 hours after administration.
    - Document each recipient's vaccine administration information:
        - Medical record: The vaccine and the date it was administered, manufacturer, lot number, vaccination site and route, name and title of the person administering the vaccine
        - Vaccination record card: Date of vaccination, product name/manufacturer, lot number, and name/location of the administering clinic or healthcare professional. Give to the vaccine recipient.
- Be prepared to manage medical emergencies.
    - Vaccination providers should observe patients after vaccination to monitor for the occurrence of immediate adverse reactions, including syncope:
    - 30 minutes: persons with a history of:
        - A contraindication to another type of COVID-19 vaccine product.
        - Immediate (within 4 hours of exposure) non-severe allergic reaction to a COVID-19 vaccine.
        - Immediate allergic reaction of any severity to a non- COVID-19 vaccine or injectable therapies
        - Anaphylaxis due to any cause.
    - 15 minutes: All other persons
    - Syncope may occur in association with injectable vaccines, among adolescents. Procedures should be in place to avoid falling injuries and manage syncopal reactions.
    - For more information, please see:
        - **Interim Considerations: Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination at** https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html
        - **CDC's *General Best Practice Guidelines for Immunization*, "Preventing and Managing Adverse Reactions," at** https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/adverse-reactions.html
        - **Immunization Action Coalition's "Medical Management of Vaccine Reactions in Adults in a Community Setting" at** https://www.immunize.org/catg.d/p3082.pdf
- Report adverse events to the Vaccine Adverse Event Reporting System (VAERS).
    - While this vaccine is under Emergency Use Authorization (EUA), (https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/ emergency-use-authorization) healthcare professionals are required to report to VAERS:
        - Vaccine administration errors (whether associated with an adverse event [AE] or not)
        - Serious AEs (irrespective of attribution to vaccination)
        - Multisystem inflammatory syndrome (MIS) in adults (https://www.cdc.gov/mis-c/mis-a.html) or children(https://www.cdc.gov/mis-c/index.html)

† An immediate allergic reaction is defined as any hypersensitivity-related signs or symptoms such as urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within 4 hours following exposure to a vaccine or medication.

‡ Consider consultation with an allergist-immunologist to help determine if a patient with a contraindication to an mRNA vaccine can safely receive the Janssen COVID-19 Vaccine. Healthcare providers and health departments may also request a consultation from the Clinical Immunization Safety Assessment COVIDvax project (https://www.cdc.gov/vaccinesafety/ensuringsafety/ monitoring/cisa/index.html). Vaccination of these individuals should only be done in an appropriate setting under the supervision of a healthcare provider experienced in the management of severe allergic reactions.

- People with a contraindication to mRNA COVID-19 vaccines (including due to a known PEG allergy) have a precaution to Janssen COVID-19 vaccination. People who have previously received an mRNA COVID-19 vaccine dose should wait at least 28 days to receive Janssen COVID-19 Vaccine.
- People with a contraindication to Janssen COVID-19 Vaccine (including due to a known polysorbate allergy) have a precaution to mRNA COVID-19 vaccination.

§ Alternately, the anterolateral thigh can be used. A 1.5-inch needle may be used if administering vaccine in this site.

¶ Some experts recommend a 5/8-inch needle for men and women who weigh less 130 pounds. If used, skin must be stretched tightly (**do not bunch subcutaneous tissue**).

NOVAVAX

Standing Orders for Administering Vaccine

Vaccine	Diluent	Dosage (amount)/Route
12 years old and older	DO NOT DILUTE	5mcq SARAS-CoV-2rs 50MCQ Matrix-M/0.5mL/IM

Purpose

- To reduce morbidity and mortality from novel coronavirus disease 2019 (COVID-19) by vaccinating persons who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy

- Where authorized under state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess and vaccinate persons who meet the criteria in the "Procedure" section below without the need for clinician examination or direct order from the attending provider at the time of the interaction.
- **Review package insert prior to administration and confirm storage and handling guidance.**

Procedure

- Assess persons 12 years old and older on the following criteria:

*Those who **ARE NOT** moderately or severely immunocompromised*

- Primary Series: If the recipient has never received a COVID-19 vaccine, administer 1 dose of Novavax COVID-19 Vaccine
- If the recipient has received 1 previous dose of Novavax COVID-19 Vaccine, administer the second dose at least 3-8 weeks after Dose 1.
- If the recipient has received 2 previous doses of Novavax COVID-19 Vaccine, administer a bivalent mRNA booster 2 months after the primary series is complete (See Moderna or Pfizer bivalent CSG)

*Those who **ARE** moderately or severely immunocompromised*

- Primary Series If the recipient has never received a COVID-19 vaccine, administer 1 dose of Novavax COVID-19 Vaccine
- If the recipient has received 1 previous dose of Novavax COVID-19 Vaccine, administer the second dose at least 3 weeks after Dose 1.
- If the recipient has received 2 previous doses of Novavax COVID-19 Vaccine, administer a bivalent mRNA booster 2 months after the primary series is complete (See Moderna or Pfizer bivalent CSG)

Booster doses

- A monovalent Novavax booster dose (instead of a bivalent mRNA booster dose) may be used in **limited situations** in people ages 18 years and older who completed any FDA-approved or FDA-authorized monovalent primary series, have not received any previous booster dose(s), and are unable to receive an mRNA vaccine (i.e., mRNA vaccine contraindicated or not available) or unwilling to receive an mRNA vaccine and would otherwise not receive a booster dose.
- People ages 18 years and older who completed primary vaccination using any COVID-19 vaccine **and have not received any previous booster dose(s)** may receive a monovalent Novavax booster dose **at least 6 months after completion of the primary series**

Additional Clinical Considerations

- The same vaccine product should be used for all doses in the primary series.
    - There are limited data on the safety and efficacy of a mixed primary series composed of any combination of Moderna, Novavax, and Pfizer-BioNTechCOVID-19 vaccines.
    - If a mixed primary series is inadvertently administered
        - The series is complete, and doses do not need to be repeated.
        - This is considered an error; report to the Vaccine Adverse Event Reporting System (VAERS)

- If a person starts but is unable to complete the primary series with the same COVID-19 vaccine due to a contraindication, any other age-appropriate COVID-19 vaccine may be administered to complete the series at a minimum interval of 4 weeks (28 days) from the last COVID-19 vaccine dose.
    - This would not need to be reported to VAERS.

Coadministration

- In general, COVID-19 vaccines may be administered without regard to timing of other vaccines. Routine administration of all age-appropriate doses of vaccines simultaneously is recommended for people for whom no specific contraindications exist at the time of the healthcare visit.

There are additional considerations for orthopoxvirus vaccines

- If orthopoxvirus vaccine administered first:
    - Might consider waiting 4 weeks before receiving a Moderna, Novavax, or Pfizer-BioNTech vaccine
- If Moderna, Novavax, or Pfizer-BioNTech administered first:
    - No minimum interval necessary before receiving orthopoxvirus vaccination for prophylaxis in the setting of an outbreak

Screen for Contraindications

- History of a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of Novavax COVID-19 Vaccine
- History of a known diagnosed allergy to a component of Novavax COVID-19 Vaccine
    - People with an allergy-related contraindication to one type of COVID-19 vaccine have a contraindication or precaution to the other type of COVID-19 vaccines
- People with a known allergy to polysorbate have a contraindication to both Novavax and Janssen
- In all other cases, an allergy-related contraindication to one type of COVID-19 vaccine is a precaution to the other types

Precautions

- Most people determined to have a precaution to a COVID-19 vaccine at their appointment can and should be administered vaccine.
- History of:
    - History of an immediate allergic reaction to any vaccine other than COVID-19 vaccine or to any injectable therapy
    - History of a non-severe, immediate (onset less than 4 hours) allergic reaction after a dose Novavax COVID-19 Vaccine
    - Moderate or severe acute illness, with or without fever
    - History of Multi Inflammatory Syndrome in Child (MIS-C) or Multi Inflammatory Syndrome in Adult (MIS-A)
    - History of myocarditis or pericarditis after a dose of an mRNA or Novavax COVID-19 vaccine

Vaccine Administration

- Prepare to administer vaccine by intramuscular injection.
    - Needle gauge and length: Use a 22–25-gauge, 1 inch
- Document vaccination.
    - COVID-19 vaccination providers must document vaccine administration in their medical record systems within 24 hours of administration and use their best efforts to report administration data to the relevant system (e.g., immunization information system) for the jurisdiction as soon as practicable and no later than 72 hours after administration.
    - Document each recipient's vaccine administration information:
        - Medical record: The vaccine and the date it was administered, manufacturer, lot number, vaccination site and route, name and title of the person administering the vaccine
        - Vaccination record card: Date of vaccination, product name/manufacturer, lot number, and

name/location of the administering clinic or healthcare professional. Give to the vaccine recipient.
- Immunization information system (IIS): Report the vaccination to the appropriate state/local IIS.

Post Vaccination Monitoring

- Be prepared to manage medical emergencies.
- Vaccination providers should observe patients after vaccination to monitor for the occurrence of immediate adverse reactions, including syncope:
  - **30 minutes**; Persons with a history of:
    - A contraindication to another type of COVID-19 vaccine product.
    - Immediate (within 4 hours of exposure) non-severe allergic reaction to a COVID-19 vaccine.
    - Immediate allergic reaction of any severity to a non-COVID-19 vaccine or injectable therapies.
    - Anaphylaxis due to any cause.
  - **15 minutes:** All other persons

Warnings

Management of Acute Allergic Reactions

Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the Novavax COVID-19 Vaccine, Adjuvanted.

Monitor the Novavax COVID-19 Vaccine, Adjuvanted recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control (CDC) and Prevention guidelines (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html).

Myocarditis and Pericarditis

Clinical trials data provide evidence for increased risks of myocarditis and pericarditis following administration of Novavax COVID-19 Vaccine, Adjuvanted (*see Full EUA Prescribing Information*).

Syncope

Syncope (fainting) may occur in association with administration of injectable vaccines. Procedures should be in place to avoid injury from fainting.

Altered Immunocompetence

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Novavax COVID-19 Vaccine, Adjuvanted.

ADVERSE REACTIONS

Adverse Reactions in Clinical Trials

Adverse reactions reported in clinical trials following administration of the Novavax COVID-19 Vaccine, Adjuvanted include injection site pain/tenderness, fatigue/malaise, muscle pain, headache, joint pain, nausea/vomiting, injection site redness, injection site swelling, fever, chills, injection site pruritus, hypersensitivity reactions, lymphadenopathy-related reactions, myocarditis, and pericarditis. (see *Full EUA Prescribing Information*).

Adverse Reactions Identified during Post-Authorization Use

Myocarditis, pericarditis, and anaphylaxis have been reported following administration of the Novavax COVID-19 Vaccine, Adjuvanted outside of clinical trials.

Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Novavax COVID-19 Vaccine, Adjuvanted.

Report adverse events to the Vaccine Adverse Event Reporting System (VAERS). While this vaccine is under Emergency Use Authorization (EUA) (https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization), healthcare professionals are required to report to VAERS:

- Vaccine administration errors (whether associated with an adverse event [AE] or not)
- Serious AEs (irrespective of attribution to vaccination)
- Cases of COVID-19 that result in hospitalization or death
- Any additional AEs and revised safety requirements per the Food and Drug Administration's (https://www. https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization) conditions for use of an authorized vaccine throughout the duration of the EUA
- Healthcare professionals are encouraged to report to VAERS (https://vaers.hhs.gove/):
    - Clinically important adverse events that occur after vaccination, even if you are not sure whether the vaccine caused the adverse event

STANDING ORDERS FOR
Administering Diphtheria, Tetanus, and Acellular Pertussis (DTaP) Vaccine to Children Younger Than Age 7 Years

Purpose

To reduce morbidity and mortality from tetanus, diphtheria, and pertussis by vaccinating all infants and children who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy

Where allowed by state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess the need for and vaccinate children and teens who meet any of the criteria below.

Procedure

1. **Assess Children in Need of Vaccination** against diphtheria, tetanus, and pertussis based on the following criteria:
   - Age 2 months through 6 years who have not completed a DTaP vaccination series

2. **Screen for contraindications and precautions** ***Contraindications***
   - Do not give DTaP vaccine to an infant or child who has experienced a serious reaction (e.g., anaphylaxis) to a prior dose of the vaccine or to any of its components. For information on vaccine components, refer to the manufacturers' package insert (www.immunize.org/packageinserts) or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.
   - Do not give any DTaP to an infant or child who has experienced encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures) not attributable to another identifiable cause within 7 days following a previous dose of DTaP.

   Precautions
   - Moderate or severe acute illness with or without fever
   - History of Guillain-Barré syndrome within 6 weeks of previous dose of tetanus toxoid-containing vaccine
   - History of an Arthus-type hypersensitivity reaction after a previous dose of DTaP; in such cases, defer vaccination until at least 10 years have elapsed since the last tetanus toxoid-containing vaccine
   - Progressive neurologic disorder (including infantile spasms), uncontrolled epilepsy, or progressive encephalopathy until a treatment regimen has been established and the condition has stabilized

3. **Provide Vaccine Information Statements**

   Provide all patients (or, in the case of minors, their parent, or legal representative) 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 www.immunize.org/vis. (For information about how to document that the VIS was given, see section 6 titled "Document Vaccination.")

4. Prepare to Administer Vaccine

Choose the needle gauge, needle length, injection site according to the following chart:

AGE OF INFANT/CHILD	NEEDLE GAUGE	NEEDLE LENGTH	INJECTION SITE
Younger than 12 months	22-25	1"	Anterolateral thigh muscle
12 through 35 months	22-25	5/8**-1" 1-1 ¼"	Anterolateral thigh muscle or deltoid muscle of arm*
3 through 10 years	22-25	5/8**-1" 1-1 ¼"	Anterolateral thigh muscle or deltoid muscle of arm*
11 through 18 years	22-25	5/8**-1" 1-1 ½"	Anterolateral thigh muscle or deltoid muscle of arm*

* Preferred site.
** A 5/8" needle may be used for children for IM injection in the deltoid muscle only if the skin is stretched tight, the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle.

5. Administer DTaP vaccine, 0.5 mL, via the intramuscular (IM) route, according to the following tables:

VACCINE AND DOSE NUMBER	RECOMMENDED AGE FOR THIS DOSE	MINIMUM AGE FOR THIS DOSE	RECOMMENDED INTERVAL TO NEXT DOSE	MINIMUM INTERVAL TO NEXT DOSE
DTaP #1	2 months	6 weeks	8 weeks	4 weeks
DTaP #2	4 months	10 weeks	8 weeks	4 weeks
DTaP #3	6 months	14 weeks	6-12 months [1]	6 months [1]
DTaP #4	15-18 months	15 months	3 years	6 months
DTaP #5	4-6 years	4 years		

1- If a child aged 12 months or older received dose #4 with an interval less than 6 months but more than 4 months, the dose does not need to be repeated.

NOTE: For individuals who failed to complete the schedule as stated above, do not start over. Simply follow the schedule below.

Schedule for catch-up vaccination:

NUMBER OF PRIOR DOCUMENTED DOSES	MINIMUM INTERVAL BETWEEN DOSES OF DTAP VACCINE STARTING FROM THE MOST RECENT DOSE GIVEN			
	DOSE 1 TO DOSE 2	DOSE 2 TO DOSE 3	DOSE 3 TO DOSE 4	DOSE 4 TO DOSE 5
Unknown	4 weeks	4 weeks	6 months[2]	6 months[3]
0	4 weeks	4 weeks	6 months[2]	6 months[3]
1	4 weeks	4 weeks	6 months[2]	6 months[3]
2		4 weeks	6 months[2]	6 months[3]
3			6 months[2]	6 months[3]
4				6 months[3]

2- Infants should be no younger than age 12 months when receiving dose #4.

3- Dose #5 should be given no younger than age 4 years. Dose #5 is not necessary if dose #4 was given after age
4 years.

6. Document Vaccination

Document each patient's vaccine administration information and follow-up in the following places:

Medical record: Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and address and, if appropriate, the title of the person administering the vaccine. You must also document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Note that medical records/charts should be documented and retained in accordance with applicable state laws and regulations. If vaccine was not administered, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal). Offer the vaccine to the patients at the next visit.

Personal immunization record card: Record the date of vaccination and the name/location of the administering clinic.

Immunization Information System (IIS) or "registry": Report the vaccination to the appropriate state/local IIS, if available.

7. Be Prepared to Manage Medical Emergencies

Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications. For IAC's "Medical Management of Vaccine Reactions in Children and Teens," go to www.immunize.org/catg.d/p3082a.pdf. For "Medical Management of Vaccine Reactions in Adult Patients," go to www.immunize.org/catg.d/p3082.pdf. To prevent syncope, vaccinate patients while they are seated or lying down and consider observing them for 15 minutes after receipt of the vaccine.

8. Report Adverse Events to VAERS

Report all adverse events following the administration of DTaP vaccine to the federal Vaccine Adverse Event Reporting System (VAERS). To submit a VAERS report online (preferred) or to download a writable PDF form, go to https://www.vaers.hhs.gov/report event.html. Further assistance is available at (800) 822-7967.

STANDING ORDER FOR

Diphtheria Tetanus Acellular Pertussis-Inactivated Poliovirus (DTaP-IPV) Combination Vaccine (KINRIX®)

Purpose

- To reduce mortality from diphtheria, tetanus, pertussis, and poliomyelitis as the fifth dose in the diphtheria, tetanus, and acellular pertussis (DTaP) vaccine series and the fourth dose in the inactivated poliovirus vaccine (IPV) series in children aged 4 through 6 years (prior to the 7th birthday) whose previous DTaP vaccine doses have been with INFANRIX and/or PEDIARIX for the first 3 doses and INFANRIX for the fourth dose by vaccinating all infants and children who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy

- Where allowed by state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess the need for and vaccinate children and teens who meet any of the criteria below.
- **Review the package insert prior to administration and confirm storage and handling guidance**

Procedure

- Single dose of KINRIX is indicated for active immunization against diphtheria, tetanus, pertussis, and poliomyelitis as the
    - fifth dose in the diphtheria, tetanus, and acellular pertussis (DTaP) vaccine series and the
    - fourth dose in the inactivated poliovirus vaccine (IPV) series in children aged 4 through 6 years (prior to the 7th birthday) whose previous DTaP vaccine doses have been with INFANRIX and/or PEDIARIX for the first 3 doses and INFANRIX for the fourth dose.

Screen for Contraindications and Precautions

- **Contraindications**
    - Severe allergic reaction (e.g., anaphylaxis) after a previous dose of any diphtheria toxoid-, tetanus toxoid-, pertussis- or poliovirus-containing vaccine, or to any component of KINRIX, including neomycin and polymyxin B.
    - Encephalopathy within 7 days of administration of a previous pertussis-containing vaccine.
    - Progressive neurologic disorders
- **Precautions**
    - If Guillain-Barré syndrome occurs within 6 weeks of receipt of a prior vaccine containing tetanus toxoid, the decision to give KINRIX should be based on potential benefits and risks.
    - The tip caps of the prefilled syringes contain natural rubber latex which may cause allergic reactions.
    - Syncope (fainting) can occur in association with administration of injectable vaccines, including KINRIX. Procedures should be in place to avoid falling injury and to restore cerebral perfusion following syncope.

- If temperature ≥105°F, collapse or shock-like state, or persistent, inconsolable crying lasting ≥3 hours have occurred within 48 hours after receipt of a pertussis-containing vaccine, or if seizures have occurred within 3 days after receipt of a pertussis-containing vaccine, the decision to give KINRIX should be based on potential benefits and risks.
- For children at higher risk for seizures, an antipyretic may be administered at the time of vaccination with KINRIX.

Provide Vaccine Information Statements

- Provide all patients (or, in the case of minors, their parent, or legal representative) 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 www.immunize.org/vis. (For information about how to document that the VIS was given, see section 6 titled "Document Vaccination.")

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.

Age of child	Needle length and gauge	Vaccine Site
4-6 years old	22-25 gauge 5/8th*-1 inch	Deltoid muscle of arm (preferred)

*If the skin is stretched tightly and the subcutaneous tissues are not bunched

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.**

Document Vaccination

- Document each patient's vaccine administration information and follow-up in the following

places:

- Medical record*:*
  - Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. You must also document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Note that medical records/charts should be documented and retained in accordance with applicable state laws and regulations. If vaccine was not administered, record the reason(s) for non-receipt of the vaccine (e.g., medical contra-indication, patient refusal). Discuss the need for vaccine with the patient at the next visit.
- Personal immunization record card:
  - Record the date of vaccination and the name/location of the administering clinic.
- Immunization Information System (IIS) or "registry*":*
  - Report the vaccination to the appropriate state/local IIS, if available.

Be Prepared to Manage Medical Emergencies

- Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications. For IAC's "Medical Management of Vaccine Reactions in Adult Patients in a Community Setting," go to www.immunize.org/catg.d/p3082.pdf. For "Medical Management of Vaccine Reactions in Children and Teens in a Community Setting," go to www.immunize.org/catg.d/p3082a.pdf.
- To prevent syncope, vaccinate patients while they are seated or lying down and consider observing them for 15 minutes after receipt of the vaccine.

Report Adverse Events to VAERS

- Report all adverse events following the administration of Hepatitis A vaccine to the federal Vaccine Adverse Event Reporting System (VAERS). To submit a VAERS report online (preferred) or to download a writable PDF form, go to https://vaers.hhs.gov/reportevent.html. Further assistance is available at (800) 822-7967.

Special Situations

- Wound management in children less than age 7 years with history of 3 or more doses of tetanus-toxoid-containing vaccine: For all wounds except clean and minor wounds, administer DTap if more than 5 years since last dose of tetanus-toxoid-containing vaccine. See: www.cdc.gov/mmwr/volumes/67/rr/rr6702a1.htm

STANDING ORDER FOR

Quadracel (Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed and Inactivated Poliovirus Vaccine)

Purpose

- To reduce mortality from tetanus, diphtheria, pertussis and polio for children 4 through 6 years old who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy

- Where allowed by state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess the need for and vaccinate children and teens who meet any of the criteria below.
- **Review the package insert prior to administration and confirm storage and handling guidance**

Procedure

- Quadracel is a vaccine indicated for active immunization against diphtheria, tetanus, pertussis and poliomyelitis.
  - A single dose of Quadracel is approved for use in children 4 through 6 years of age as a fifth dose in the diphtheria, tetanus, pertussis vaccination (DTaP) series, and
  - A fourth or fifth dose in the inactivated poliovirus vaccination (IPV) series, in children who have received 4 doses of Pentacel and/or DAPTACEL vaccine.

Screen for Contraindications and Precautions

- **Contraindications**
  - Severe allergic reaction (e.g., anaphylaxis) to any ingredient of Quadracel, or following any diphtheria toxoid, tetanus toxoid, pertussis-containing vaccine or inactivated poliovirus vaccine.
  - Encephalopathy within 7 days of a previous pertussis- containing vaccine with no other identifiable cause
  - Progressive neurologic disorder until a treatment regimen has been established and the condition has stabilized

- **Precautions**
  - Carefully consider benefits and risks before administering Quadracel to persons with a history of:
    - -hyporesponsive episode (HHE) or persistent, inconsolable crying lasting hours within 48 hours after a previous pertussis-containing vaccine.
    - seizures within 3 days after a previous pertussis-containing vaccine.
    - If Guillain-Barré syndrome occurred 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

Provide Vaccine Information Statements

- Provide all patients (or, in the case of minors, their parent, or legal representative) 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 www.immunize.org/vis. (For information about how to

document that the VIS was given, see section 6 titled “Document Vaccination.”)

Dosage and Route

- Administer Quadracel® vaccine 0.5 mL intramuscularly (IM) after reconstitution.

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.

Age	Needle Length and Gauge	Preferred Site
Children 4-6 years old	22-25 Gauge/1 Inch	Deltoid muscle of arm

Document Vaccination

- Document each patient’s vaccine administration information and follow-up in the following places:
    - Medical record*:*
        - Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. You must also document, in the patient’s medical record or office log, the publication date of the VIS and the date it was given to the patient. Note that medical records/charts should be documented and retained in accordance with applicable state laws and regulations. If vaccine was not administered, record the reason(s) for non-receipt of the vaccine (e.g., medical contra-indication, patient refusal). Discuss the need for vaccine with the patient at the next visit.
    - Personal immunization record card:
        - Record the date of vaccination and the name/location of the administering clinic.
    - Immunization Information System (IIS) or “registry*”:*
        - Report the vaccination to the appropriate state/local IIS, if available.

Be Prepared to Manage Medical Emergencies

- Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications. For IAC’s “Medical Management of Vaccine Reactions in Adult Patients in a Community Setting,” go to www.immunize.org/catg.d/p3082.pdf. For “Medical Management of Vaccine Reactions in Children and Teens in a Community Setting,” go to www.immunize.org/catg.d/p3082a.pdf.
- To prevent syncope, vaccinate patients while they are seated or lying down and consider observing them for 15 minutes after receipt of the vaccine.

Report Adverse Events to VAERS

- Report all adverse events following the administration of Hepatitis A vaccine to the federal Vaccine Adverse Event Reporting System (VAERS). To submit a VAERS report online (preferred) or to download a writable PDF form, go to https://vaers.hhs.gov/reportevent.html. Further assistance is available at (800) 822-7967.

STANDING ORDER for
DTaP-HepB-IPV Combination Vaccine (PEDIARIX®)

Purpose

- To reduce mortality from diphtheria, tetanus, pertussis, infection caused by all known subtypes of hepatitis B virus, and poliomyelitis. who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy

- Where allowed by state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess the need for and vaccinate children and teens who meet any of the criteria below.
- **Review the package insert prior to administration and confirm storage and handling guidance**

Procedure

- PEDIARIX is a vaccine indicated for active immunization against diphtheria, tetanus, pertussis, infection caused by all known subtypes of hepatitis B virus, and poliomyelitis.
- PEDIARIX is approved for use as a 3-dose series in infants born of hepatitis B surface antigen (HBsAg)-negative mothers.
- PEDIARIX may be given as early as 6 weeks of age through 6 years of age (prior to the 7th birthday).

Screen for Contraindications and Precautions

- **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

- **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 contain dry natural rubber latex that may cause allergic reactions in latex sensitive individuals.

Provide Vaccine Information Statements

- Provide all patients (or, in the case of minors, their parent, or legal representative) 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 www.immunize.org/vis. (For information about how to document that the VIS was given, see section 6 titled "Document Vaccination.")

Indications and Usage

- PEDIARIX is a vaccine indicated for active immunization against diphtheria, tetanus, pertussis, infection caused by all known subtypes of hepatitis B virus, and poliomyelitis.
- PEDIARIX is approved for use as a 3-dose series in infants born of hepatitis B surface antigen (HBsAg)-negative mothers. PEDIARIX may be given as early as 6 weeks of age through 6 years of age (prior to the 7th birthday).

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.

Dose	Minimum Age	Minimum Interval from Previous Dose
1	6 weeks	-
2	10 weeks	6 weeks
3	24 weeks	8 weeks*

*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.

Document Vaccination

- Document each patient's vaccine administration information and follow-up in the following places:
    - Medical record*:*
        - Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. You must also document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Note that medical records/charts should be documented and retained in accordance with applicable state laws and regulations. If vaccine was not administered, record the reason(s) for non-receipt of the vaccine (e.g., medical contra-indication, patient refusal). Discuss the need for vaccine with the patient at the next visit.
    - Personal immunization record card:
        - Record the date of vaccination and the name/location of the administering clinic.
    - Immunization Information System (IIS) or "registry*":*
        - Report the vaccination to the appropriate state/local IIS, if available.

Be Prepared to Manage Medical Emergencies

- Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications. For IAC's "Medical Management of Vaccine Reactions in Adult Patients in a Community Setting," go to www.immunize.org/catg.d/p3082.pdf. For "Medical Management of Vaccine Reactions in Children and Teens in a Community Setting," go to www.immunize.org/catg.d/p3082a.pdf.
- To prevent syncope, vaccinate patients while they are seated or lying down and consider observing them for 15 minutes after receipt of the vaccine.

Report Adverse Events to VAERS

- Report all adverse events following the administration of Hepatitis A vaccine to the federal Vaccine Adverse Event Reporting System (VAERS). To submit a VAERS report online (preferred) or to download a writable PDF form, go to https://vaers.hhs.gov/reportevent.html. Further assistance is available at (800) 822-7967.

STANDING ORDER FOR

Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Inactivated Poliovirus and *Haemophilus* b Conjugate (Tetanus Toxoid Conjugate) Vaccine DTaP-IPV/Hib Combination Vaccine (Pentacel®)

Purpose

- To reduce mortality from diphtheria, tetanus, pertussis, and poliomyelitis and invasive disease due to Haemophilus influenzae type b for infant and children who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy

- Where allowed by state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess the need for and vaccinate children and teens who meet any of the criteria below.
- **Review the package insert prior to administration and confirm storage and handling guidance**

Procedure

- Pentacel is a vaccine indicated for active immunization against diphtheria, tetanus, pertussis, poliomyelitis and invasive disease due to Haemophilus influenzae type b. Pentacel is approved for use as a four-dose series in children 6 weeks through 4 years of age (prior to 5th birthday

Screen for Contraindications and Precautions

- **Contraindications**
  - Severe allergic reaction (eg, anaphylaxis) after a previous dose of Pentacel, any ingredient of Pentacel, or any other diphtheria toxoid, tetanus toxoid, pertussis-containing vaccine, inactivated poliovirus vaccine or H.influenzae type b vaccine.
  - Encephalopathy within 7 days of a previous pertussis-containing vaccine with no other identifiable cause.
  - Progressive neurologic disorder until a treatment regimen has been established and the condition has stabilized.
- **Precautions**
  - Carefully consider benefits and risks before administering Pentacel to persons with a history of:
    - fever ≥40.5°C (≥105°F)
    - hypotonic-hyporesponsive episode (HHE) or
    - persistent, inconsolable crying lasting ≥3 hours within 48 hours after a previous pertussis-containing vaccine.
    - seizures within 3 days after a previous pertussis-containing vaccine.
  - If Guillain-Barré syndrome occurred within 6 weeks of receipt of a prior vaccine containing tetanus toxoid, the risk for Guillain-Barré syndrome may be increased following Pentacel.
    - For infants and children with a history of previous seizures, an antipyretic may be administered (in the dosage recommended in its prescribing information) at the time of vaccination with Pentacel and for the next 24 hours.
    - Apnea following intramuscular vaccination has been observed in some infants born prematurely. The decision about when to administer an intramuscular vaccine, including Pentacel, to an infant born prematurely

should be based on consideration of the individual infant's medical status and the potential benefits and possible risks of vaccination.

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

Administration of Pentacel®, DTaP-IPV/Hib		
Dose	**Minimum Age**	**Minimum Interval to the Next Dose**
One(1),or any dose	6 weeks*	**4 weeks** (dose 1 to dose 2)
Two (2)	10 weeks	**4 weeks** (dose 2 to dose 3)
Three (3)	14 weeks	**6 months** (dose 3 to dose 4, determined by DTaP and IPV component);
Four (4)	**12 months**	Note that both the minimum interval **AND** age must be met for the fourth dose of DTaP, Hib (for Pentacel or any other formulation) to be counted as valid**;** **DTaP dose 5 IS NOT given as Pentacel vaccine**.

*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.

Dose	**Maximum age for Pentacel Administration**
Any Dose	4 years, 364 days (i.e., do not administer at age 5 years or older.)

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).

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

Document Vaccination

- Document each patient's vaccine administration information and follow-up in the following places:
    - Medical record*:*
        - Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. You must also document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Note that medical records/charts should be documented and retained in accordance with applicable state laws and regulations. If vaccine was not administered, record the reason(s) for non-receipt of the vaccine (e.g., medical contra-indication, patient refusal). Discuss the need for vaccine with the patient at the next visit.
    - Personal immunization record card:
        - Record the date of vaccination and the name/location of the administering clinic.

- Immunization Information System (IIS) or "registry*":*
  - Report the vaccination to the appropriate state/local IIS, if available

Be Prepared to Manage Medical Emergencies

- Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications. For IAC's "Medical Management of Vaccine Reactions in Adult Patients in a Community Setting," go to www.immunize.org/catg.d/p3082.pdf. For "Medical Management of Vaccine Reactions in Children and Teens in a Community Setting," go to www.immunize.org/catg.d/p3082a.pdf.
- To prevent syncope, vaccinate patients while they are seated or lying down and consider observing them for 15 minutes after receipt of the vaccine.

Report Adverse Events to VAERS

- Report all adverse events following the administration of Hepatitis A vaccine to the federal Vaccine Adverse Event Reporting System (VAERS). To submit a VAERS report online (preferred) or to download a writable PDF form, go to https://vaers.hhs.gov/reportevent.html. Further assistance is available at (800) 822-7967.

Standing Orders for Administering Hepatitis A Vaccine to Children and Teens

Purpose

To reduce morbidity and mortality from hepatitis A virus (HAV) by vaccinating all children and teens who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy

Where allowed by state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess the need for and vaccinate children and teens who meet any of the criteria below.

Procedure

1. **Assess Children and Teens in Need of Vaccination** against HAV infection based on the following criteria:
    - age 12–23 months and lacking documentation of at least 1 dose of hepatitis A vaccine (HepA)
    - age 2 through 18 years who are unvaccinated or have not completed a HepA series
    - age 6 months and older with anticipated travel to a country with intermediate or high endemicity for hepatitis A (i.e., all except Canada, Japan, Australia, New Zealand, and parts of Western Europe) *(Note: A dose given at age 6–11 months does not count toward the routine 2-dose series given after the first birthday.)*

2. **Screen for contraindications and precautions**

    Contraindications

    - Do not give HepA to a child or teen who has experienced a serious reaction (e.g., anaphylaxis) to a prior dose of the vaccine or to any of its components. For information on vaccine components, refer to the manufacturers' package insert (www.immunize.org/fda) or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.

    Precautions

    - Moderate or severe acute illness with or without fever

3. **Provide Vaccine Information Statements**
    - Provide all patients (or, in the case of minors, their parent, or legal representative) 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 www.immunize.org/vis. (For information about how to document that the VIS was given, see section 6 titled "Document Vaccination.")

4. Prepare to Administer Vaccine

Choose the needle gauge, needle length, and injection site according to the following chart

Age of Infant/Child/Teen	Needle Gauge	Needle Length	Injection Site
Infants (6-11 months)	22-25	1"	Anterolateral thigh muscle
Toddlers (1-2 years)	22-25	5/8*-1" 1-1 ¼"	Anterolateral thigh muscle** Deltoid muscle of arm
Children (3-10 years)	22-25	5/8*-1" 1-1 ¼"	Deltoid muscle of arm** Anterolateral thigh muscle
Adolescents and Teens (11-18 years)	22-25	5/8*-1" 1-1 ½ "	Deltoid muscle of arm** Anterolateral thigh muscle

* A 5/8" needle may be used for children for IM injection in the deltoid muscle only if the skin is stretched tight, the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle.
** Preferred site.

5. Administer Hep A vaccine, 0.5 mL for patients aged 6 months (6–11 months for international travel) through 18 years and 1.0 mL for patients aged 19 years and older, via the intramuscular (IM) route, according to the following tables:

Schedule for routine vaccination

Vaccine Dose and Number	Recommended Age for Dose	Minimum Age for Dose	Recommended Interval to Next Dose	Minimum Interval to Next Dose
HepA #1	12–23 months	12 months	6– 18 months	6 months
HepA #2	>18 months	18 months		

Schedule for catch-up vaccination

Age	Dose 1 to Dose 2
12 months to & years	6 months
7-18 years	6 months

Schedule for travelers to countries with intermediate or high endemicity for HAV

Age of Traveler	Health Status	Hepatitis A Vaccine	Immune Globulin
Younger than age 6 months	Healthy	No	0.1 or 0.2 mL/kg[1]
6 through 11	Healthy	1 dose[2]	None
1 through 18 years	Healthy & not previously vaccinated	1 dose	None
All ages >12 months	Immunocom-promised & not previously vaccinated	1 dose	0.1 or 0.2 mL/kg[1]

FOOTNOTES

1 Infants younger than age 6 months and older children for whom vaccine is contraindicated should be given IG at a dose of 0.1 mL/kg for travel of up to 1 month's time. For travel of 2 months or longer, they should be given IG 0.2 mL/kg and repeat dose of 0.2 mL/kg for every 2 months that travel continues.

2 A dose given at age 6–11 months does not count toward the routine 2-dose series given after the first birthday.

6. Document Vaccination

- Document each patient's vaccine administration information and follow-up in the following places:
- ***Medical record:*** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. You must also document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Note that medical records/charts should be documented and retained in accordance with applicable state laws and regulations. If vaccine was not administered, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal). Discuss the need for vaccination with the patient (or, in the case of a minor, their parent or legal representative) at the next visit.
- Personal immunization record card: Record the date of vaccination and the name/location of the administering clinic.
- Immunization Information System (IIS) or "registry": Report the vaccination to the appropriate state/local IIS, if available.

7. Be Prepared to Manage Medical Emergencies

- Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications. For IAC's "Medical Management of Vaccine Reactions in Children and Teens in a Community Setting," go to www.immunize.org/catg.d/p3082a.pdf. For "Medical Management of Vaccine Reactions in Adult Patients in a Community Setting," go to www.immunize.org/catg.d/p3082.pdf. To prevent syncope, vaccinate patients while they are seated or lying down and consider observing them for 15 minutes after receipt of the vaccine.

8. Report Adverse Events to VAERS

- Report all adverse events following the administration of Hepatitis A vaccine to the federal Vaccine Adverse Event Reporting System (VAERS). To submit a VAERS report online (preferred) or to download a writable PDF form, go to https://vaers.hhs.gov/reportevent.html. Further assistance is available at (800) 822-7967.

Standing Order for Administration of Hepatitis A Vaccine to Adults

Purpose

- To reduce morbidity and mortality from hepatitis A virus (HAV) by vaccinating all adults who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy

- Where allowed by state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess the need for and vaccinate adults who meet any of the criteria below.
- **Review the package insert prior to administration and confirm storage and handling guidance.**

Procedure

- **Assess Adults in Need of Vaccination** against HAV infection based on the following criteria:
    - anticipated travel to a country with intermediate or high endemicity for hepatitis A (i.e., all except Canada, Japan, Australia, New Zealand, and parts of Western Europe)
    - a male who has sex with other males
    - users of street drugs (injecting and non-injecting)
    - homelessness or living in temporary housing (such as a shelter)
    - diagnosis of chronic liver disease (including hepatitis B, hepatitis C, cirrhosis, fatty liver disease, alcoholic liver disease, autoimmune hepatitis, alanine aminotransferase [ALT], or aspartate aminotransferase [AST] level greater than twice the upper limit of normal)
    - diagnosis of HIV infection
    - anticipated close personal contact with an international adoptee from a country of high or intermediate endemicity during the first 60 days after the arrival of the adoptee in the United States
    - employment in a research laboratory requiring work with HAV or HAV-infected primates
    - recent possible exposure to HAV (e.g., within previous two weeks) *(Note: For adults older than age 40 years with recent exposure to HAV, immune globulin [IC; 0.1 mL/kg] may also be administered depending on the provider's risk assessment [see https://stacks.cdc.gov/view/cdc/59777]).*
    - any other adult who wants to be protected from hepatitis A
        - *Note: In settings where a high proportion of people have risk factors for hepatitis A infection, assume that unvaccinated adults age 19 years and older are at risk without individual risk-factor screening. Such settings include a) healthcare settings targeting services to injection or non-injection drug users and b) group homes or nonresidential daycare facilities for developmentally disabled persons.*

Screen for Contraindications and Precautions

- **Contraindications**
    - Do not give Hep A to an adult who has experienced a serious reaction (e.g., anaphylaxis) to a prior dose of the vaccine or to any of its components. For information on vaccine components, refer to the manufacturers' package insert

(www.immunize.org/fda), or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.

- **Precautions**
  - Moderate or severe acute illness with or without fever

Provide 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 www.immunize.org/vis. (For information about how to document that the VIS was given, see section 6 titled "Document Vaccination.")

Prepare to Administer Vaccine

Choose the needle gauge, needle length, and injection site according to the following chart

Gender and Weight of Patients	**Needle Gauge**	**Needle Length**	**Injection Site****
Female or male less than 130 lbs.	22–25	5/8*–1"	Deltoid muscle of arm
Female or male 130–152 lbs.	22–25	1"	Deltoid muscle of arm
Female 152–200 lbs.	22–25	1–11/2"	Deltoid muscle of arm
Male 153–260 lbs.	22–25	1–11/2"	Deltoid muscle of arm
Female 200+ lbs.	22–25	11/2"	Deltoid muscle of arm
Male 260+ lbs.	22–25	11/2"	Deltoid muscle of arm

* A 5/8" needle may be used for children for IM injection in the deltoid muscle only if the skin is stretched tight, the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle.
** Alternatively, the anterolateral thigh also can be used.

Administer Hep A Vaccine

0.5 mL for patients younger than age 19 years and 1.0 mL for patients age 19 years and older, via the intramuscular (IM) route, according to the following tables:

History of Previous Hep A Vaccination	**Dose and Schedule for Administration of Hep A**
0 documented doses, or none known	Give Hep A as dose #1. Give dose 2 at least 6 months later.
1 previous dose of Hep A	Give dose #2 of Hep A at least 6 months after dose #1.

Notes:

- *For HIV-infected people, Hep A vaccination may be less protective. CDC recommends HIV-positive people receive immune globulin (0.1 mL/kg) within 2 weeks of a high-risk exposure to hepatitis A virus (e.g., household contact or sexual partner), regardless of vaccination status.*
- *For travelers needing pre-exposure protection against hepatitis A:*
- *If healthy and age 40 years or younger, 1 dose of Hep A before departure will provide adequate protection.*
- *If age 41 years or older, immunocompromised, having chronic liver disease or other chronic medical condition, and departure is anticipated within the next 2 weeks, administer the initial dose of Hep A vaccine. Immune globulin (0.1 mL/kg for travel up to 1 month; 0.2 mL/kg for*

- *travel up to 2 months; 0.2 mL/kg every 2 months for travel of >2 months duration) may also be administered simultaneously at a separate site.*

Document Vaccination

- Document each patient's vaccine administration information and follow-up in the following places:
    - Medical record*:*
        - Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. You must also document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Note that medical records/charts should be documented and retained in accordance with applicable state laws and regulations. If vaccine was not administered, record the reason(s) for non-receipt of the vaccine (e.g., medical contra-indication, patient refusal). Discuss the need for vaccine with the patient at the next visit.
    - Personal immunization record card:
        - Record the date of vaccination and the name/location of the administering clinic.
    - Immunization Information System (IIS) or "registry*":*
        - Report the vaccination to the appropriate state/local IIS, if available.

Be Prepared to Manage Medical Emergencies

- Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications. For IAC's "Medical Management of Vaccine Reactions in Adult Patients in a Community Setting," go to www.immunize.org/catg.d/p3082.pdf. For "Medical Management of Vaccine Reactions in Children and Teens in a Community Setting," go to www.immunize.org/catg.d/p3082a.pdf. To prevent syncope, vaccinate patients while they are seated or lying down and consider observing them for 15 minutes after receipt of the vaccine.

Report Adverse Events to VAERS

- Report all adverse events following the administration of Hepatitis A vaccine to the federal Vaccine Adverse Event Reporting System (VAERS). To submit a VAERS report online (preferred) or to download a writable PDF form, go to https://vaers.hhs.gov/reportevent.html. Further assistance is available at (800) 822-7967.

STANDING ORDER FOR

Hepatitis A/B Vaccine (TWINRIX®)

Purpose

- To reduce morbidity and mortality from against disease caused by hepatitis A virus and infection by all known subtypes of hepatitis B virus by vaccinating individuals over the age of 18 who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy

- Where allowed by state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess the need for and vaccinate children and teens who meet any of the criteria below.
- **Review the package insert prior to administration and confirm storage and handling guidance**

Procedure

- TWINRIX is a vaccine indicated for active immunization against disease caused by hepatitis A virus and infection by all known subtypes of hepatitis B virus.
- TWINRIX is approved for use in persons 18 years of age or older.

Screen for Contraindications and Precautions

- **Contraindications**
  - Severe allergic reaction (e.g., anaphylaxis) after a previous dose of any hepatitis A-containing or hepatitis B-containing vaccine, or to any component of TWINRIX, including yeast and neomycin.
  -
- **Precautions**
  - The tip caps of the prefilled syringes contain natural rubber latex which may cause allergic reaction.
  - Syncope (fainting) can occur in association with administration of injectable vaccines, including TWINRIX. Procedures should be in place to avoid falling injury and to restore cerebral perfusion following syncope

Provide Vaccine Information Statements

- Provide all patients (or, in the case of minors, their parent, or legal representative) 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 www.immunize.org/vis. (For information about how to document that the VIS was given, see section 6 titled "Document Vaccination.")

Indications and Usage

- 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

- 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**.**
- 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

- 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.

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.

Document Vaccination

- Document each patient's vaccine administration information and follow-up in the following places:
  - Medical record*:*
    - Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. You must also document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Note that medical records/charts should be documented and retained in accordance with applicable state laws and regulations. If vaccine was not administered, record the reason(s) for non-receipt of the vaccine (e.g., medical contra-indication, patient refusal). Discuss the need for vaccine with the patient at the next visit.
  - Personal immunization record card:
    - Record the date of vaccination and the name/location of the administering clinic.
  - Immunization Information System (IIS) or "registry*":*
    - Report the vaccination to the appropriate state/local IIS, if available.

Be Prepared to Manage Medical Emergencies

- Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications. For IAC's "Medical Management of Vaccine Reactions in Adult Patients in a Community Setting," go to www.immunize.org/catg.d/p3082.pdf. For "Medical Management of Vaccine Reactions in Children and Teens in a Community Setting," go to www.immunize.org/catg.d/p3082a.pdf.
- To prevent syncope, vaccinate patients while they are seated or lying down and consider observing them for 15 minutes after receipt of the vaccine.

Report Adverse Events to VAERS

- Report all adverse events following the administration of Hepatitis A vaccine to the federal Vaccine Adverse Event Reporting System (VAERS). To submit a VAERS report online (preferred) or to download a writable PDF form, go to https://vaers.hhs.gov/reportevent.html. Further assistance is available at (800) 822-7967.

STANDING ORDERS FOR
Administering Hepatitis B Vaccine to Children and Teens

Purpose

To reduce morbidity and mortality from hepatitis B virus (HBV) by vaccinating all children and teens who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy

Where allowed by state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess the need for and vaccinate children and teens who meet any of the criteria below.

Procedure

1. **Assess Children and Teens in Need of Vaccination** against HBV infection based on the following criteria:
   - Lack of documentation of at least 3 doses of hepatitis B vaccine (Hep B) with the third dose given at least 16 weeks after the first dose, at least 8 weeks after the second dose, and when no younger than age 24 weeks

2. **Screen for contraindications and precautions** ***Contraindications***
   - Do not give Hep B to a child or teen who has experienced a serious reaction (e.g., anaphylaxis) to a prior dose of the vaccine or to any of its components. For information on vaccine components, refer to the manufacturers' package insert (www.immunize.org/packageinserts) or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.
   - Do not give any Hep B to a child or teen who has experienced hypersensitivity to yeast.

   Precautions
   - Moderate or severe acute illness with or without fever

3. **Provide Vaccine Information Statements**
   Provide all patients (or, in the case of minors, their parent, or legal representative) 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 www.immunize.org/vis. (For information about how to document that the VIS was given, see section 6 titled "Document Vaccination.")

4. **Prepare to Administer Vaccine**
   Choose the needle gauge, needle length, and injection site according to the following chart

AGE OF INFANT/CHILD/TEEN	NEEDLE LENGTH	INJECTION SITE
Newborns (1st 28 days)	Vs*	Anterolateral thigh muscle
Infants (1-12 months)	1"	Anterolateral thigh muscle
Toddlers (1-2 years)	Vs*-1" 1-1 ¼ "	Anterolateral thigh muscle** Deltoid muscle of arm
Children (3-10 years)	Vs*-1" 1-1 ¼ "	Deltoid muscle of arm** Anterolateral thigh muscle
Adolescents and Teens (11-18 years)	Vs*-1" 1-1 ½ "	Deltoid muscle of arm** Anterolateral thigh muscle

* A Vs" needle may be used for children for IM injection in the deltoid muscle only if the skin is

stretched tight, the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle.
** Preferred site.

5. **Administer Hep B vaccine,** 0.5 mL, via the intramuscular (IM) route, according to the following tables:

Schedule for routine vaccination

VACCINE AND DOSE NUMBER	RECOMMENDED AGE FOR THIS DOSE	MINIMUM AGE FOR THIS DOSE	RECOMMENDED INTERVAL TO NEXT DOSE	MINIMUM INTERVAL TO NEXT DOSE
Hep B #1	Birth	Birth	4 weeks–4	4 weeks
Hep B #2	1–2 months	4 weeks	8 weeks–17	8 weeks
Hep B #3	6–18 months	24 weeks		

NOTES
1 Children ages 11 through 15 years may be given an alternative 2-dose adult formulation using Recombivax HB. Dose 2 must be given 4–6 calendar months after dose 1.
2 Dose 3 must not be given earlier than age 24 weeks.

Schedule for catch-up vaccination

NUMBER OF PRIOR DOCUMENTED DOSES	MINUMUM AGE FOR DOSE 1	MINUMUM INTERVAL BETWEEN DOSES OF HEPB STARTING FROM THE MOST RECENT DOSE GIVEN	
		DOSE 1 TO DOSE 2	DOSE 2 TO DOSE 3
None or unknown[1]	Birth	4 weeks	8 weeks and at least 16 weeks
1		4 Weeks	8 weeks and at least 16 weeks
2			8 weeks and at least 16 weeks between Dose 1 and Dose 2

6. **Document Vaccination**

Document each patient's vaccine administration information and follow-up in the following places:
Medical record: Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. You must also document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Note that medical records/charts should be documented and retained in accordance with applicable state laws and regulations. If vaccine was not administered, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal). Offer the vaccine to the patient at the next visit.
Personal immunization record card: Record the date of vaccination and the name/location of the

administering clinic. ***Immunization Information System (IIS) or "registry":*** Report the vaccination to the appropriate state/local IIS, if available.

7. **Be Prepared to Manage Medical Emergencies**

   Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications. For IAC's "Medical Management of Vaccine Reactions in Children and Teens," go to www.immunize.org/catg.d/p3082a.pdf. For "Medical Management of Vaccine Reactions in Adult Patients," go to www.immunize.org/catg.d/p3082.pdf. To prevent syncope, vaccinate patients while they are seated or lying down and consider observing them for 15 minutes after receipt of the vaccine.

8. **Report Adverse Events to VAERS**

   Report all adverse events following the administration of Hepatitis B vaccine to the federal Vaccine Adverse Event Reporting System (VAERS). To submit a VAERS report online (preferred) or to download a writable PDF form, go to https://vaers.hhs.gov/reportevent.html. Further assistance is available at (800) 822-7967.

STANDING ORDERS FOR

Administering Hepatitis B Vaccine to Adults

Purpose

- To reduce morbidity and mortality from hepatitis B virus (HBV) by vaccinating all adults who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Policy

- Where allowed by state law, standing orders enable eligible nurses, pharmacists, and other health care professionals to assess the need for vaccination and to vaccinate adults who meet any of the criteria below.
- **Review the package insert prior to administration and confirm storage and handling guidance.**

Procedure

- **Assess Adults for Need of Vaccination** against HBV infection[1,2,3] according to the following criteria:
    - All adults age 19 through 59 years
    - All adults age 60 or older with risk factors for HBV infection due to:
        - Sexual exposure risk
            - sex partners of hepatitis B surface antigen [HBsAg]-positive people
            - sexually active people not in monogamous relationships
            - people seeking treatment for a sexually-transmitted infection
        - men who have sex with men
    - Percutaneous or mucosal exposure to blood:
        - current or recent injection-drug use
        - household contacts of HBsAg-positive people
        - residents and staff of facilities for developmentally disabled people
        - healthcare and public safety workers with risk for exposure to blood or blood-contaminated body fluids
        - hemodialysis, peritoneal dialysis, home dialysis, and predialysis patients
        - patients with diabetes at the discretion of the treating clinician
    - Other factors
        - anticipated travel to countries with high or intermediate endemic hepatitis B
        - people with hepatitis C infection
        - chronic liver disease (including, but not limited to people with cirrhosis, fatty liver disease, alcoholic liver disease, autoimmune hepatitis, and an alanine aminotransferase [ALT] or aspartate aminotransferase [AST] level greater than twice upper limit of normal)
        - HIV infection
        - incarceration
        - Any adult age 60 or older who does not meet the risk-based recommendations above may be vaccinated.

Notes:

1. In general, people who have documented completion of a Hep B series at any point or who have *a history of previous HBV infection should not receive additional Hep B vaccine, although there is no evidence that additional vaccination is harmful.*
2. *Revaccination may be indicated for certain high-risk adults, including healthcare workers who are documented non-responders to an initial Hep B series, and certain dialysis patients. For revaccination guidance, see the 2018 ACIP recommendations for the prevention of hepatitis B at www.cdc.gov/mmwr/volumes/67/rr/pdfs/ rr6701-H.pdf (pages 23-24).*
3. *In settings where the patient population has a high rate of previous HBV infection, prevaccination testing, which may be performed at the same visit when the first dose of vaccine is administered, might reduce costs by avoiding complete vaccination of people who are already immune. However, prevaccination testing is not required and should not create a*

barrier to vaccination

Screen for Contraindications and Precautions

- ***Contraindications***
  - Do not give hepatitis B vaccine to a person who has experienced a serious systemic or anaphylactic reaction to a prior dose of the vaccine or to any of its components. For a list of vaccine components, refer to the manufacturer's package insert (www.immunize.org/fda) or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/ excipient-table-2.pdf.
- ***Precautions***
  - Moderate or severe acute illness with or without fever
  - ***Pregnancy***
    - Pregnancy testing is not needed before vaccination; however, data on Heplisav-B and PreHevbrio are currently insufficient to reach any conclusions concerning vaccine-associated risks in pregnancy. Thus, providers should vaccinate pregnant people needing Hep B vaccination with Engerix-B, Recombivax HB, or Twinrix.

Provide 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 www.immunize.org/vis. (For information about how to document that the VIS was given, see section 6 titled "Document Vaccination.")

Prepare to Administer Vaccine

Choose the needle gauge, needle length, and injection site according to the following chart:

Gender and Weight Of Patient	Needle Gauge	Needle Length	Injection Site
Female or male less than 130 lbs.	22–25	5/8"*–1"	Deltoid muscle of arm
Female or male 130–152 lbs.	22–25	1"	Deltoid muscle of arm
Female 153–200 lbs.	22–25	1–1'h"	Deltoid muscle of arm
Male 153–260 lbs.	22–25	1–1'h"	Deltoid muscle of arm
Female 200+ lbs.	22–25	1'h"	Deltoid muscle of arm
Male 260+ lbs.	22–25	1'h"	Deltoid muscle of arm
Female or male, any weight	22–25	1"*–1'h"	Anterolateral thigh

Alternative needle lengths may be used for IM injections if the skin is stretched tight, the subcutaneous tissue is not bunched, and the injections is made at the 90-degree angle to the skin as follows:

- 5/8" need for patients weigh les than 130 lbs. (<60 kg)
- 1" needle for administration in the thigh muscle for adults of any weight

Administer Hepatitis B Vaccine according to the criteria and guidance in the tables below:

TYPE OF VACCINE	AGE GROUP	DOSE	ROUTE
Heplisav-B (Dynavax)	18 yrs. & older	0.5 mL	Intramuscular (IM)
Pediatric formulation of Engerix-B (GSK) or Recombivax HB (Merck)	19 yrs. & younger	0.5 mL	Intramuscular (IM)
Adult formulation of Engerix-B (GSK) or Recombivax HB (Merck)	20 yrs. & older	1.0 mL	Intramuscular (IM)
PreHevbrio (VBI Vaccines)	18 yrs. & older	1.0 mL	Intramuscular (IM)

Schedules for Vaccination

HISTORY OF PREVIOUS VACCINATION	For patients whose previous brand of vaccine is known, continue with the same brand as shown below. If brand is not known or is not available, continue with a 3-dose schedule as indicated in the right-hand column	
	Schedule for administration of Heplisav-B1,2	Schedule for administration of Engerix-
None or unknown	Give a 2-dose series at 0 and 1 month.	Give a 3-dose series at 0, 1, and 6 mos.
1 dose	Give dose #2 at least 4 wks. after dose #1 to complete the series.	Give dose #2 at least 4 wks. after #1; then, give dose #3 at least 8 wks. after dose #2 and at least 16 wks. after dose #1.
2 doses		Give dose #3 at least 8 wks. after dose #2 and at least 16 wks. after dose #1.

NOTES:

1. For patients receiving hemodialysis or with other immunocompromising conditions, use one of the following alternative dosing schedules: (a) Recombivax HB: series of 3 doses (1 mL each) of 40 mcg/mL at 0, 1, and 6 mos., OR (b) Engerix-B: series of 4 doses (2 mL each) as a single 2-mL dose or as two 1-mL doses on a 0-, 1-2.
2. The hepatitis B vaccine series does not need to be restarted, regardless of the time that has elapsed between doses.

Information on Certain Risk Groups

- For persons born in Asia, the Pacific Islands, Africa, or other countries identified as having high rates of HBV infection, see www.cdc.gov/mmwr/PDF/rr/rr5416.pdf (page 25), ensure that they have also been tested for hepatitis B surface antigen (HBsAg) to find out if they are chronically infected. If test is performed on same visit, administer hepatitis B vaccine after the blood draw. Do not delay initiating hepatitis B vaccination while waiting for test results. If patient is found to be HBsAg-positive, appropriate medical follow-up should be provided; no further doses of hepatitis B vaccine are indicated.
- Certain people need testing for immunity (anti-HBs) 1–2 months following vaccination. Check ACIP recommendations for details at www.cdc.gov/mmwr/volumes/67/rr/pdfs/rr6701-H.pdf (page 25).

Document Vaccination

- Document each patient's vaccine administration information and follow up in the following places:
- Medical record: Document the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. You must also document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Note that medical records/charts should be documented and retained in accordance with applicable state laws and regulations. If vaccine was not administered, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal); discuss the need for vaccine with the patient at the next visit.
- Personal immunization record card: Record the date of vaccination and the name/location of the administering clinic.
- Immunization Information System (IIS) or "registry": Report the vaccination to the appropriate state/local IIS, if available.

- Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications. For Immunize.org's "Medical Management of Vaccine Reactions in Adult Patients," go to www.immunize.org/catg.d/p3082.pdf. To prevent syncope, vaccinate patients while they are seated or lying down and consider observing them for 15 minutes after receipt of the vaccine.

Report All Adverse Events to VAERS

- Report all adverse events following the administration of hepatitis B vaccine to the federal Vaccine Adverse Event Reporting System (VAERS). To submit a VAERS report online (preferred) or to download a writable PDF form, go to http://vaers.hhs.gov/reportevent.html. Further assistance is available at (800) 822-7967.

STANDING ORDERS FOR
Administering *Haemophilus influenzae* Type B Vaccine to Children & Teens

Purpose

To reduce morbidity and mortality from *Haemophilus influenzae* type B disease by vaccinating all children and teens who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy

Where allowed by state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess the need for and vaccinate children and teens who meet any of the criteria below.

Procedure

1. **Assess children and teens in need of vaccination against Hib disease based on the following criteria:**
   a. Age 6 weeks through 59 months without prior Hib vaccination or who did not complete the series
   b. Age 6 weeks through 59 months with immunoglobulin deficiency, early component complement deficiency, or are receiving chemotherapy or radiation therapy
   c. Age 6 weeks through 18 years with human immunodeficiency virus (HIV) infection
   d. Age 6 weeks or older (including adults) with anatomic or functional asplenia (including sickle cell disease) or who are undergoing elective splenectomy
   e. Age 6 weeks or older (including adults) and a recipient of hematopoietic stem cell transplant

2. **Screen for contraindications and precautions *Contraindication***

   Do not give Hib vaccine to a child or teen who has experienced a serious systemic or anaphylactic reaction to a prior dose of Hib vaccine or to any of its components. For information on vaccine components, refer to the manufacturers' package insert (www.immunize.org/fda) or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/ appendices/B/excipient-table-2.pdf.

   Precaution

   Moderate or severe acute illness with or without fever

3. **Provide Vaccine Information Statements**

   Provide all patients (or, in the case of minors, their parent, or legal representative) 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 www.immunize.org/vis. (For information about how to document that the VIS was given, see section 6 titled "Document Vaccination.")

4. **Prepare to Administer Vaccine**

   Choose the needle gauge, needle length, and injection site according to the following

Age of Infant/Child/Teen	Needle Gauge	Needle Length	Injection Site
Infants (6-11 months)	22-25	1"	Anterolateral thigh muscle
Toddlers (1-2 years)	22-25	5/8*-1" 1-1 ¼"	Anterolateral thigh muscle** Deltoid muscle of arm
Children (3-10 years)	22-25	5/8*-1" 1-1 ¼"	Deltoid muscle of arm** Anterolateral thigh muscle

Adolescents and Teens (11-18 years)	22-25	5/8*-1” 1-1 ½ “	Deltoid muscle of arm** Anterolateral thigh muscle

* Preferred site.

** A 5/8” needle may be used for children for IM injection in the deltoid muscle only if the skin is stretched tight, the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle.

5. Administer Hib vaccine, 0.5 mL, via the intramuscular (IM) route, according to the following tables:

a. Schedule for routine vaccination

VACCINE AND DOSE NUMBER	RECOMMENDED AGE FOR THIS DOSE	MINIMUM AGE FOR THIS DOSE	RECOMMENDED INTERVAL TO NEXT DOSE	MINIMUM INTERVAL TO NEXT DOSE
Hib #1	2 months	6 weeks	8 weeks	4 weeks
Hib #2	4 months	10 weeks	8 weeks	4 weeks
Hib #3[1]	6 months	14 weeks	6–9 months	8 weeks
Hib #4	12–15 months	12 months		

b. Schedule for catch-up vaccination of healthy children

NUMBER OF PRIOR DOCUMENTED DOSES	AGE GROUP	SCHEDULE FOR ADMINISTRATION OF HIB VACCINE
0 documented doses, or none	Younger than age 1 year	Follow schedule as per above.
0 documented doses, or none	12 through 59 months	Give dose #1, followed by final dose in 8 weeks. (no
1 dose before age 1 year		Give dose #2 at least 8 weeks after dose #1.
2 doses before age 1 year		Give dose #3 at least 8 weeks after dose #2.

c. Schedule for catch-up vaccination of children with certain medical conditions[2]

MEDICAL CONDITION OR PROCEDURE	AGE AND VACCINATION HISTORY		
	CHILDREN AGE 12–59 MONTHS WHO ARE UN-VACCINATED[2] OR HISTORY OF ONLY 1 DOSE	CHILDREN AGE 12–59 MONTHS WITH HIS-TORY OF 2 OR MORE DOSES	CHILDREN AGE 5 YEARS OR OLDER WHO ARE UNVACCINATED[2]
Functional or anatomic asplenia	Give 2 doses, 8 weeks apart.	Give 1 dose at least 8 weeks after previous	Give 1 dose
HIV-infected	Give 2 doses, 8 weeks apart.	Give 1 dose at least 8 weeks after previous	Give 1 dose
Immunoglobulin defi-ciency, early component	Give 2 doses, 8 weeks apart.	Give 1 dose at least 8 weeks after previous	
Chemotherapy or radiation therapy[3]	Give 2 doses, 8 weeks apart.[3]	Give 1 dose at least 8 weeks after previous dose.[3]	
Hematopoietic stem cell transplant	Give 3 doses (at least 4 weeks apart) beginning 6–12 months after transplant, regardless of Hib vaccination history.		
Elective splenectomy	For unvaccinated[2] children age 15 months or older, give 1 dose, preferably at least 14 days before procedure		

Note: 1 PRP-OMP (Pedvax-Hib, Merck) is given as a 2-dose primary series (age 2 and 4 mos) with a booster at age 12–15 mos. PRP-T vaccines (ActHib, Sanofi and HibrixGSK) are given as a 3-dose primary series (age 2, 4, and 6 mos) with a booster at age 12–15 mos. PedvaxHIB is preferred for Ameri- can Indian/Alaska Native infants.

2 Children who have not received a primary series and booster or at least 1 dose of Hib vac- cine at age 15 months or older are considered unvaccinated.

3 Children who were vaccinated within 14 days of starting immunosuppressive therapy should be revaccinated at least

3 months after completion of therapy.Children younger than age 12 months with special medical conditions should follow routine Hib vaccination recommendations (see 5a above).

6. Document Vaccination

Document each patient's vaccine administration information and follow-up in the following places:

Medical record: Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. You must also document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Note that medical records/charts should be documented and retained in accordance with applicable state laws and regulations. If vaccine was not administered, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal). Offer the vaccine to the patient at the next visit.

Personal immunization record card: Record the date of vaccination and the name/location of the administering clinic.

Immunization Information System (IIS) or "registry": Report the vaccination to the appropriate state/local IIS, if available.

7. Be Prepared to Manage Medical Emergencies

Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications. For IAC's "Medical Management of Vaccine Reactions in Children and Teens," go to www.immunize.org/catg.d/p3082a.pdf. For "Medical Management of Vaccine Reactions in Adult Patients," go to www.immunize.org/catg.d/p3082.pdf. To prevent syncope, vaccinate patients while they are seated or lying down and consider observing them for 15 minutes after receipt of the vaccine.

8. Report Adverse Events to VAERS

Report all adverse events following the administration of Hib vaccine to the federal Vaccine Adverse Event Reporting System (VAERS). To submit a VAERS report online (preferred) or to download a writable PDF form, go to https://vaers.hhs.gov/reportevent.html. Further assistance is available at (800) 822-7967.

STANDING ORDER FOR

***Haemophilus influenzae* Type b (Hib) Tetanus Toxoid Conjugate Vaccine - HIBERIX®**

Purpose

- To reduce mortality from tetanus and Haemophilous Influenzae Type b for children 6 weeks through 4 years old who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy

- Where allowed by state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess the need for and vaccinate children and teens who meet any of the criteria below.
- **Review the package insert prior to administration and confirm storage and handling guidance**

Procedure

- A 4-dose series (0.5-mL each) given by intramuscular injection
  - Primary series: One dose each at 2, 4, and 6 months of age. The first dose may be given as early as 6 weeks of age.
  - Booster: One dose at 15 through 18 months of age

Screen for Contraindications and Precautions

- **Contraindications**
  - 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 HIBERIX

- **Precautions**
  - If Guillain-Barré syndrome has occurred within 6 weeks of receipt of a prior vaccine containing tetanus toxoid, the decision to give HIBERIX should be based on potential benefits and risks.
  - Syncope (fainting) can occur in association with administration of injectable vaccines, including HIBERIX. Procedures should be in place to avoid falling injury and to restore cerebral perfusion following syncope.
  - 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.

Provide Vaccine Information Statements

- Provide all patients (or, in the case of minors, their parent, or legal representative) 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 www.immunize.org/vis. (For information about how to document that the VIS was given, see section 6 titled "Document Vaccination.")

Indications and Usage

- HIBERIX is indicated for active immunization for the prevention of invasive disease caused by Haemophilus influenzae (H. influenzae) type b. HIBERIX is approved for use in children aged 6 weeks through 4 years (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.
    - Primary series (3 doses): One dose each at 2, 4, and 6 months of age.
    - 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.

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.

Age	Needle Length and Gauge	Preferred Site
Infants Ages 2-3	22-25 Gauge/1 Inch	Vastus Lateralis Muscle of Anterolateral Thigh
Toddler 1-2 years	22-25 gauge/ 1-1.25 inch	Vastus Lateralis Muscle of Anterolateral Thigh (Preferred)
Children 3-4	22-25 Gauge/1 Inch	Deltoid muscle of arm (Preferred)

Document Vaccination

- Document each patient's vaccine administration information and follow-up in the following places:
    - Medical record:
        - Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. You must also document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Note that medical records/charts should be documented and retained in accordance

with applicable state laws and regulations. If vaccine was not administered, record the reason(s) for non-receipt of the vaccine (e.g., medical contra-indication, patient refusal). Discuss the need for vaccine with the patient at the next visit.

- Personal immunization record card:
  - Record the date of vaccination and the name/location of the administering clinic.
- Immunization Information System (IIS) or "registry"***:***
  - Report the vaccination to the appropriate state/local IIS, if available.

Be Prepared to Manage Medical Emergencies

- Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications. For IAC's "Medical Management of Vaccine Reactions in Adult Patients in a Community Setting," go to www.immunize.org/catg.d/p3082.pdf. For "Medical Management of Vaccine Reactions in Children and Teens in a Community Setting," go to www.immunize.org/catg.d/p3082a.pdf.
- To prevent syncope, vaccinate patients while they are seated or lying down and consider observing them for 15 minutes after receipt of the vaccine.

Report Adverse Events to VAERS

- Report all adverse events following the administration of Hepatitis A vaccine to the federal Vaccine Adverse Event Reporting System (VAERS). To submit a VAERS report online (preferred) or to download a writable PDF form, go to https://vaers.hhs.gov/reportevent.html. Further assistance is available at (800) 822-7967.

Standing Orders For

Administering *Haemophilus Influenzae* Type B Vaccine to Adults

Purpose

- To reduce morbidity and mortality from *Haemophilus influenzae* type B disease by vaccinating all adults who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy

- Where allowed by state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess the need for and vaccinate adults who meet any of the criteria below.

Procedure

- **Assess adults in need of vaccination against Hib disease based on the following criteria:**
  - Diagnosis of anatomic or functional asplenia (e.g., sickle cell disease) and no prior documented history of Hib vaccination
  - Planning an elective splenectomy and no prior documented history of Hib vaccination
  - Recipient of hematopoietic stem cell transplant

Screen for contraindications and precautions

- ***Contraindication***
  - Do not give Hib vaccine to an adult who has experienced a serious systemic or anaphylactic reaction to a prior dose of Hib vaccine or to any of its components. For information on vaccine components, refer to the manufacturers' package insert (www.immunize.org/packageinserts) or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/ appendices/B/excipient-table-2.pdf.
- ***Precaution***
  - Moderate or severe acute illness with or without fever

Provide Vaccine Information Statements

- Provide all adult 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 www.immunize.org/vis. (For information about how to document that the VIS was given, see section 6 titled "Document Vaccination.")

Prepare to Administer Vaccine

Choose the needle gauge, needle length, and injection site according to the following chart:

GENDER and Weight of Patient	Needle Gauge	Needle Length	Injection Site
Female or male less than 130 lbs.	22–25	5/8*–1"	Deltoid muscle of arm
Female or male 130–152 lbs.	22–25	1"	Deltoid muscle of arm
Female 153–200 lbs.	22–25	1–11/2"	Deltoid muscle of arm
Male 153–260 lbs.	22–25	1–11/2"	Deltoid muscle of arm
Female 200+ lbs.	22–25	11/2"	Deltoid muscle of arm
Male 260+ lbs.	22–25	11/2"	Deltoid muscle of arm

* Preferred site.
** A 5/8" needle may be used for IM injection in the deltoid muscle only if the skin is stretched tight, the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle.

Administer Hib Vaccine

0.5 mL, via the intramuscular (IM) route, according to the following tables:

MEDICAL CONDITION	HIB VACCINE GUIDANCE
Elective splenectomy	If unvaccinated, give 1 dose at least 14 days before splenectomy
Functional or anatomic asplenia	If unvaccinated, give 1 dose.
Recipients of hematopoietic stem cell transplant	Administer 3 doses in at least 4-week intervals 6–12 months after transplant, regardless of Hib vaccine history.

Document Vaccination

- Document each patient's vaccine administration information and follow-up in the following places:
    - Medical record: Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. You must also document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Note that medical records/charts should be documented and retained in accordance with applicable state laws and regulations. If vaccine was not administered, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal). Offer the vaccine to the patient at the next visit.
    - Personal immunization record card: Record the date of vaccination and the name/location of the administering clinic.
    - Immunization Information System (IIS) or "registry": Report the vaccination to the appropriate state/local IIS, if available.
    -

Be Prepared to Manage Medical Emergencies

- Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and

medications. For “Medical Management of Vaccine Reactions in Adult Patients,” go to www.immunize.org/catg.d/p.3082.pdf. For IAC’s “Medical Management of Vaccine Reactions in Children and Teens,” go to www.immunize.org/catg.d/p3082a.pdf. To prevent syncope, vaccinate patients while they are seated or lying down and consider observing them for 15 minutes after receipt of the vaccine.

Report Adverse Events to VAERS

- Report all adverse events following the administration of Hib vaccine to the federal Vaccine Adverse Event Reporting System (VAERS). To submit a VAERS report online (preferred) or to download a writable PDF form, go to https://vaers.hhs.gov/reportevent.html. Further assistance is available at (800) 822-7967.

STANDING ORDERS FOR

Administering Human Papillomavirus Vaccine to Children and Teens

Purpose

To reduce morbidity and mortality from human papillomavirus (HPV) infection by vaccinating all children and teens who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy

Where allowed by state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess the need for and vaccinate children and teens who meet any of the criteria below.

Procedure

1. Assess children and teens for need of vaccination against human papillomavirus infection based on the following criteria:

- Age 11 years and older who have not completed an HPV vaccination series
- Age 9 years and older with any history of sexual abuse or assault
- Age 9 through 10 years, without a specific risk factor, whose parent/guardian wishes to have them vaccinated

2. Screen for contraindications and precautions

Contraindication

Do not give HPV vaccine to an child or teen who has experienced a serious systemic or anaphylactic reaction to a prior dose of HPV vaccine or to any of its components (e.g., yeast). For information on vaccine components, refer to the manufacturers' package insert (www.immunize.org/fda) or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.

Precaution

- Moderate or severe acute illness with or without fever
- Pregnancy; delay vaccination until after completion of the pregnancy

3 Provide Vaccine Information Statements

Provide all patients (or, in the case of minors, their parent, or legal representative) 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 www.immunize.org/vis. (For information about how to document that the VIS was given, see section 6 titled "Document Vaccination.")

4 Prepare to Administer Vaccine

Choose the needle gauge, needle length, and injection site according to the following chart:

AGE OF INFANT/CHILD	NEEDLE GAUGE	NEEDLE LENGTH	INJECTION SITE
9 through 10 years	22-25	5/8**-1" 1-1 ¼ "	Deltoid muscle of arm* Anterolateral thigh muscle
11 through 18 years	22-25	5/8**-1" 1-1 ½ "	Deltoid muscle of arm* Anterolateral thigh muscle

* Preferred site.

**A 5/8" needle may be used for children for IM injection in the deltoid muscle only if the skin is stretched tight, the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle.

5. Administer HPV vaccine, 0.5 mL, via the intramuscular (IM) route, according to the following tables: ***Schedule for routine vaccination***

TYPE OF VACCINE	AGE WHEN FIRST DOSE IS ADMINISTERED	DOSE	SCHEDULE
HPV (Gardasil 9)	9 through 14 years	0.5 mL	Two doses, 6–12 months apart[2]
	15 years or older	0.5 mL	Three doses at 0, 1–2, and 6 months

Note: For individuals who failed to complete either the 2-dose or 3-dose schedule as stated above, do not start over. Simply follow the schedule shown below.

Schedule for catch-up vaccination

HISTORY OF PREVIOUS HPV VACCINATION	SCHEDULE FOR ADMINISTRATION OF HPV VACCINE
0 documented doses, or none known	Follow schedule as per above table.
1 previous dose when younger than age	Give dose #2 with minimum interval of 5 months[2]
2 previous doses given less than 5 months apart and dose #1 given when younger than age 15 years	Give dose #3 with minimum interval of 12 weeks after dose #2 and at least 5 months after dose #1.
1 previous dose when age 15 or older	Give dose #2 at least 4 weeks after dose #1, then give dose #3 at least 12 weeks after dose #2 and at least 5 months after dose #1.
2 previous doses when age 15 or older	Give dose #3 at least 12 weeks after dose #2 and at least 5 months after dose #1.

[1] Only two doses are recommended for anyone who begins the schedule before the 15th birthday, regardless of age at series completion.
[2] Immunocompromised persons, including those with HIV infection, should receive a 3-dose series at 0, 1–2, and 6 months, regardless of age at vaccine initiation.

6. Document Vaccination

Document each patient's vaccine administration information and follow-up in the following places: ***Medical record:*** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. You must also document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Note that medical records/charts should be documented and retained in accordance with applicable state laws and regulations. If vaccine was not administered, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal). Discuss the need for vaccine with the patient (or, in the case of a minor, their parent or legal representative) at the

next visit.

Personal immunization record card: Record the date of vaccination and the name/location of the administering clinic.

Immunization Information System (IIS) or "registry": Report the vaccination to the appropriate state or local IIS, if available.

7. Be Prepared to Manage Medical Emergencies

Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications. For IAC's "Medical Management of Vaccine Reactions in Children and Teens," go to www.immunize.org/catg.d/p3082a.pdf. For "Medical Management of Vaccine Reactions in Adult Patients," go to www.immunize.org/catg.d/p3082.pdf. To prevent syncope, vaccinate patients while they are seated or lying down and consider observing them for 15 minutes after receipt of the vaccine.

8. Report Adverse Events to VAERS

Report all adverse events following the administration of HPV vaccine to the federal Vaccine Adverse Event Reporting System (VAERS). To submit a VAERS report online (preferred) or to download a writable PDF form, go to https://www.vaers.hhs.gov/reportevent.html. Further assistance is available at (800) 822-7967.

STANDING ORDERS FOR

Administering Human Papillomavirus Vaccine to Adults

Purpose

To reduce morbidity and mortality from human papillomavirus (HPV) infection by vaccinating all adults who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy

Where allowed by state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess the need for and vaccinate adults who meet any of the criteria below.

Procedure

1. **Assess adults for need of vaccination against human papillomavirus infection based on the following criteria:**
   - Adults, age 26 years or younger
   - Adults, age 27 through 45 years, based on shared clinical decision making. *(Note: Although many adults ages 27–45 years have prior exposures to 1 or more HPV types, most have not been exposed to all 9 HPV types that are contained in the vaccine. Also, at any age, having a new sex partner is a risk factor for being exposed to a new HPV infection.)*

2. **Screen for contraindications and precautions *Contraindication***

   Do not give HPV vaccine to an adult who has experienced a serious systemic or anaphylactic reaction to a prior dose of HPV vaccine or to any of its components (e.g., yeast). For information on vaccine components, refer to the manufacturers' package insert (www.immunize.org/fda), or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf or www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states. ***Precaution***

   - Moderate or severe acute illness with or without fever
   - Pregnancy; delay vaccination until after completion of the pregnancy

3. **Provide 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 www.immunize.org/vis. (For information about how to document that the VIS was given, see section 6 titled "Document Vaccination.")

4. **Prepare to Administer Vaccine**

   Choose the needle gauge, needle length, and injection site according to the following chart:

GENDER AND WEIGHT OF PATIENT	NEEDLE GAUGE	NEEDLE LENGTH	INJECTION SITE
Female or male less than 130 lbs	22–25	5/8* –1"	Deltoid muscle of arm

Female or male 130–152 lbs	22–25	1"	Deltoid muscle of arm
Female 153–200 lbs	22–25	1–11/2"	Deltoid muscle of arm
Male 153–260 lbs	22–25	1–11/2"	Deltoid muscle of arm
Female 200+ lbs	22–25	11/2"	Deltoid muscle of arm
Male 260+ lbs	22–25	11/2"	Deltoid muscle of arm

* A 5/8" needle may be used in patients weighing less than 130 lbs (<60 kg) for IM injection in the deltoid muscle only if the skin is stretched tight, the subcutaneous tissue is not bunched, and the injection is made at a 90° angle to the skin.

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5. **Administer HPV vaccine,** 0.5 mL, via the intramuscular (IM) route, according to the following table:

HISTORY OF PREVIOUS HPV VACCINATION[1]	SCHEDULE FOR ADMINISTRATION OF HPV VACCINE
0 documented doses, or none known	Give 3 doses at 0, 1–2, and 6 months.
1 previous dose given before 15th birthday	Give dose #2 at least 5 months after dose #1; no further doses are indicated.2
1 previous dose given at 15 years or older	Give the 2nd dose 1–2 months (minimum of 4 weeks) after dose #1, then give the 3rd dose 6 months after dose 1 (minimum of 12 weeks after dose #2 and at least 5 months after dose #1).
2 previous doses with dose #1 given before 15th birth- day and dose #2 given at least 5 months after dose #1	No further doses are indicated.[2]
1 previous dose given before 15th birthday and dose #2 given 5 months later, after 15th birthday	No further doses are indicated.[2]
2 previous doses given at 15 years or older	Give the 3rd dose 6 months after dose #1 (minimum of 12 weeks after dose #2 and at least 5 months after dose #1).

1. All previously administered doses of HPV vaccine (regardless of brand) count as valid doses if given at appropriate intervals.
2. Immunocompromised persons, including those with HIV infection, should receive a 3-dose schedule at 0, 1–2, and 6 months, regardless of age at vaccine initiation.

6. **Document Vaccination**

Document each patient's vaccine administration information and follow-up in the following places:

Medical record: Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. You must also document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. If vaccine was not administered, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal). Discuss the need for vaccine with the patient at the next visit.

Personal immunization record card: Record the date of vaccination and the name/location of the administering clinic.

Immunization Information System (IIS) or "registry": Report the vaccination to the appropriate state/local IIS, if available.

7. **Be Prepared to Manage Medical Emergencies**

Be prepared for management of a medical emergency related to the administration of vaccine by having a

written emergency medical protocol available, as well as equipment and medications. For IAC's "Medical Management of Vaccine Reactions in Adult Patients in a Community Setting," go to www.immunize.org/catg.d/p3082.pdf. To prevent syncope, vaccinate patients while they are seated or lying down and consider observing them for 15 minutes after receipt of the vaccine.

8. **Report Adverse Events to VAERS**

   Report all adverse events following the administration of HPV vaccine to the federal Vaccine Adverse Event Reporting System (VAERS). To submit a VAERS report online (preferred) or to download a writable PDF form, go to https://vaers.hhs.gov/reportevent.html. Further assistance is available at (800) 822-7967.

Administering Influenza Vaccine to Adults 18 years and older

Purpose

To reduce morbidity and mortality from influenza by vaccinating all adults who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Policy

Where allowed by state law, standing orders enable eligible nurses, pharmacists, and other healthcare professionals to assess the need for vaccination and to vaccinate adults who meet any of the criteria below.

Procedure

- **Assess Adults for Need of Vaccination against Influenza**
  - All adults 18 years and older are recommended to receive influenza vaccination each year.
  - Adults age 65 and older should preferentially receive any one of the following higher dose or adjuvanted influenza vaccines: **quadrivalent high-dose inactivated influenza vaccine (HD-IIV4), quadrivalent recombinant influenza vaccine (RIV4), or quadrivalent adjuvanted IIV (aIIV4, Fluad**). If none of these three vaccines is available, then any other age-appropriate influenza vaccine should be used.
  - Adults who are or will be pregnant during the influenza season. Administer any recommended, age-appropriate quadrivalent IIV (IIV4) or RIV4 to pregnant people in any trimester.
  - Adults who do not recall whether they received influenza vaccine in the current vaccination season should be vaccinated.
  - Adults who recently received or are planning to receive COVID-19 vaccine may be administered influenza vaccine either simultaneously (on the same day, at separate anatomic sites) or at any time before or after COVID-19 vaccine. Interim clinical considerations and detailed current guidance for the use of COVID-19 vaccines are available at www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html. Information on coadministration of all vaccines can be found at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/timing.html and information on giving 2 or more intramuscular vaccines can be found at https://www.immunize.org/catg.d/p2030.pdf

- **Screen for Contraindications and Precautions**
  - Contraindications for use of all influenza vaccines
    - Do not give any egg-based IIV4 to a person who has experienced a serious systemic or anaphylactic reaction to any component of the vaccine (except egg), or to a prior dose of any influenza vaccine (i.e., egg-based IIV, cell culture-based IIV [ccIIV], RIV, or live attenuated influenza vaccine [LAIV]).
    - Do not give ccIIV4 to a person who has experienced a serious systemic or anaphylactic reaction to any component of ccIIV4 or to a prior dose of any ccIIV.
    - Do not give any RIV4 to a person who has experienced a serious systemic or anaphylactic reaction to any component of RIV4 or to a prior dose of any RIV.
    - Do not give any LAIV4 to a person who has experienced a serious systemic or anaphylactic reaction to any component of LAIV4 or to a prior dose of any influenza vaccine (egg-based IIV, ccIIV, RIV, or LAIV).
    - For a list of vaccine components, refer to the manufacturer's package insert (www.immunize.org/fda) or go to www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states.

  - **Additional contraindications for use of LAIV4 only**
    - Do not give LAIV4 to a person who:
      - is pregnant
      - has functional or anatomic asplenia, cochlear implant, or is immunocompromised due to any cause (including immunosuppression caused by medications or HIV infection)

- has active communication between CSF and the oropharynx, nose, or ear or any other cranial CSF leak
- is age 50 years or older
- received influenza antivirals before scheduled vaccination (zanamivir or oseltamivir within 48 hours; peramivir within 5 days; baloxavir within 17 days). If any of these antiviral drugs are taken within 14 days after LAIV4, revaccinate with IIV4 or RIV4.
- is a close contact for a severely immunosuppressed person who requires a protected environment

- **Precautions for use of all influenza vaccines**
  - Moderate or severe acute illness with or without fever
  - History of Guillain-Barré syndrome within 6 weeks of a previous influenza vaccination

  - **Precautions for use of ccIIV4 and RIV4**
    - History of a serious systemic or anaphylactic reaction to a previous dose of any egg-based IIV, LAIV, or RIV is a precaution to use of ccIIV4.
    - History of a serious systemic or anaphylactic reaction to a previous dose of any egg-based IIV, ccIIV, or LAIV, is a precaution to use of RIV4.

Influenza vaccine contraindications and precautions for persons with a history of serious systemic or anaphylactic reaction to a previous dose of an influenza vaccine are summarized in the table below.

Vaccine Associated with Previous Serious or Anaphylactic Reaction	Available 2022–23 Influenza Vaccines		
	Egg-Based IIV4s And LAIV4	**cciiV4**	**RIV4**
Any egg-based IIV or LAIV	Contraindication	Precaution*	Precaution*
Any ccIIV	Contraindication	Contraindication	Precaution*
Any RIV	Contraindication	Precaution	Contraindication
Unknown influenza vaccine	Allergist consultation recommended		

* Use of ccIIV4 and RIV4 in such instances should occur in an inpatient or outpatient medical setting under the supervision of a healthcare provider (HCP) who can recognize and manage severe allergic reaction. HCPs may consider consulting with an allergist to help identify the vaccine component responsible for the reaction.

- **Precautions for use of LAIV4 only**
  - Asthma
  - Other chronic medical conditions that might predispose the person to complications of influenza infection (e.g., other chronic pulmonary, cardiovascular [excluding isolated hypertension], renal, hepatic, neurologic, hematologic, or metabolic disorders [including diabetes mellitus])

Note regarding egg allergy: *People with egg allergy of any severity can receive any recommended and age-appropriate influenza vaccine (i.e., any IIV4, RIV4, or LAIV4) that is otherwise appropriate for their health status. Most influenza vaccines (except RIV4 and cell-cultured IIV4) are egg-cultured and may have trace amounts of egg protein. If a vaccine other than ccIIV4 or RIV4 is used, people with a history of severe allergic reaction to egg involving any symptom other than hives (e.g., angioedema or swelling, respiratory distress, lightheadedness, or recurrent emesis), or who required epinephrine or another emergency medical intervention, the selected vaccine should be administered in a medical setting (e.g., health department or physician office).*
Vaccine administration should be supervised by a healthcare provider who is able to recognize and manage severe allergic reactions.

- **Provide 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 https://www.immunize.org/vis/ (For information about how to

document that the VIS was given, see section 6 titled “Document Vaccination.”)

- **Prepare to Administer Vaccine**

For vaccine that is to be administered intramuscularly, choose the needle gauge, needle length, and injection site according to the following chart:

Gender And Weight of Patient	Needle Gauge	Needle Length	Injection Site
Female or male less than 130 lbs	22–25	⅝"†–1"	Deltoid muscle of arm
Female or male 130–152 lbs	22–25	1"	Deltoid muscle of arm
Female 153–200 lbs	22–25	1–1½"	Deltoid muscle of arm
Male 153–260 lbs	22–25	1–1½”	Deltoid muscle of arm
Female 200+ lbs	22–25	1½”	Deltoid muscle of arm
Male 260+ lbs	22–25	1½”	Deltoid muscle of arm
Female or male, any weight	22–25	1½”	Anterolateral thigh muscle

† A **⅝"** needle may be used in patients weighing less than 130 lbs (<60 kg) for IM injection in the deltoid muscle only if the skin is stretched tight, the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle to the skin.

For LAIV, which is administered intranasally, prepare the vaccine according to directions in the package insert.

Administer Influenza Vaccine to adults according to the criteria and guidance in the table below:

Type Of Vaccine	Vaccine Name	Adult Age Group	Dose	Route	Instructions‡
Inactivated influenza vaccine (IIV4)	*Afluria-Quad *Flurix-Quad *FluLaval-Quad *Fluzone Quad	All adults	0.5 mL	Intramuscular (IM)	Administer vaccine in deltoid muscle.
IIV4-high dose *(preferred age 65+§)*	FluzoneHD-Quad	65 years and older	0.7 mL	Intramuscular (IM)	Administer vaccine in deltoid muscle.
Adjuvanted inactivated influenza vaccine¶ (aIIV4) *(preferred age 65+§)*	Fluad-Quad	65 years and older	0.5 mL	Intramuscular (IM)	Administer vaccine in deltoid muscle.
Recombinant influenza vaccine (RIV4) *(preferred age 65+§)*	Flubloc-Quad	18 years and older	0.5 mL	Intramuscular (IM)	Administer vaccine in deltoid muscle.
Cell Culture-based IIV4 (ccIIV4)	*Flucelvax-quad	All adults	0.5 mL	Intramuscular (IM)	Administer vaccine in deltoid muscle.
Live attenuated influenza vaccine (LAIV4)	*FluMist	Healthy, younger than age 50 years (except if pregnant)	0.2 mL (0.1 mL into each nostril)	Intranasal spray (NAS)	Spray half of vaccine into each nostril while the patient is in an upright position.

‡For complete instructions on how to administer influenza vaccine, see “How to Administer Intramuscular and Intranasal Influenza Vaccines” at www.immunize.org/catg.d/p2024.pdf .

§ Adults age 65 and older should receive an adjuvanted (aIIV4) or higher dose (IIV4-HD or IV4) influenza vaccine. If none is available, any age-appropriate influenza vaccine may be used.

¶ Because of the limited data on the safety of simultaneous administration of two or more vaccines containing nonaluminum adjuvants (i.e., Fluad, Heplisav-B, Shingrix) and the availability of nonadjuvanted influenza vaccine options, selection of a nonadjuvanted influenza vaccine may be considered in situations in which influenza vaccine and another vaccine containing a nonaluminum adjuvant are to be administered concomitantly. However, vaccination should not be delayed if a specific product is not available.

***Vaccines provided via 317**

- **Document Vaccination**
    - Document each patient's vaccine administration information and follow up in the following places:
    - **Medical record:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and address and, if appropriate, the title of the person administering the vaccine. You must also document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Note that medical records/charts should be documented and retained in accordance with applicable state laws and regulations. If vaccine was not administered, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal); discuss the need for vaccine with the patient (or, in the case of a minor, their parent or legal representative) at the next visit.
    - **Personal immunization record card:** Record the date of vaccination and the name/location of the administering clinic.
    - **Immunization Information System (IIS) or "registry":** Report the vaccination to the appropriate state/local IIS.
- **Be Prepared to Manage Medical Emergencies**
    - Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications. Report All Adverse Events to VAERS
    - Report all adverse events following the administration of influenza vaccine to the federal Vaccine Adverse Event Reporting System (VAERS). To submit a VAERS report online (preferred) or to download a writable PDF form, go to https://vaers.hhs.gov/reportevent.html. Further assistance is available at (800) 822-7967.

Administering Influenza Vaccine to Children and Adolescent

Purpose

To reduce morbidity and mortality from influenza by vaccinating all children and adolescents who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy

Where allowed by state law, standing orders enable eligible nurses, pharmacists, and other healthcare professionals to assess the need for vaccination and to vaccinate children and adolescents who meet any of the criteria below.

Procedure

- **Assess Children and Adolescents for Need of Vaccination against Influenza**
    - All people 6 months of age and older are recommended to receive influenza vaccination each year.
    - A second dose of influenza vaccine is recommended 4 weeks or more after the first dose for children age 6 months through 8 years if they have not or don't know if they have received 2 doses in prior years (not necessarily in the same season).
    - A second dose is needed for a 9-year-old child who received one dose in the current season when they were age 8 years, if they have not or don't know if they have received 2 doses in prior years.
    - Children and teens who recently received or are planning to receive COVID-19 vaccine may be administered influenza vaccine either simultaneously (on the same day) or at any time before or after COVID-19 vaccine. Interim clinical considerations and detailed current guidance for the use of COVID-19 vaccines are available at www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html Information on coadministration of all vaccines can be found at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/timing.html.

- **Screen for Contraindications and Precautions**
    - **Contraindications for use of all influenza vaccines**
        - Do not give any egg-based inactivated influenza vaccine (IIV4) to a child or teen who has experienced a serious systemic or anaphylactic reaction to any component of the vaccine (except egg), or to a prior dose of any influenza vaccine (i.e., egg-based IIV, cell culture-based IIV [ccIIV], recombinant influenza vaccine [RIV], or live attenuated influenza vaccine [LAIV]).
        - Do not give ccIIV4 to a child or teen who has experienced a serious systemic or anaphylactic reaction to any component of ccIIV4 or to a prior dose of any ccIIV.
        - Do not give any RIV4 to a teen age 18 years or older who has experienced a serious systemic or anaphylactic reaction to any component of RIV4 or to a prior dose of RIV.
        - Do not give any LAIV4 to a child or teen who has experienced a serious systemic or anaphylactic reaction to any component of LAIV4 or to a prior dose of any influenza vaccine (egg-based IIV, ccIIV, RIV, or LAIV).
        - For a list of vaccine components, refer to the manufacturer's package insert (www.immunize.org/fda) or go to www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states .
    - **Additional contraindications for use of LAIV only**
        - Do not give LAIV4 to a child or adolescent who
            - is pregnant
            - is age 2 through 4 years who has received a diagnosis of asthma or who has experienced wheezing or asthma within the past 12 months, based on a healthcare provider's statement or medical record
            - has functional or anatomic asplenia, or a cochlear implant
            - has active communication between CSF and the oropharynx, nose, or ear or any other cranial CSF leak

- is immunocompromised due to any cause (including immunosuppression caused by medications or HIV infection)
- is age 6 months through 17 years and is receiving aspirin- or salicylate-containing medicine
- received influenza antivirals *before* scheduled vaccination (zanamivir or oseltamivir within 48 hours; peramivir within 5 days; baloxavir within 17 days). If any of these antiviral drugs are taken within 14 days *after* LAIV4, revaccinate with IIV4 or RIV4.
- is a close contact of a severely immunosuppressed person who requires a protected environment

- **Precautions for use of all influenza vaccines**
  - Moderate or severe acute illness with or without fever
  - History of Guillain-Barré syndrome within 6 weeks of a previous influenza vaccination

- **Precautions for use of ccIIV and RIV**
  - History of a serious systemic or anaphylactic reaction to a previous dose of any egg-based IIV, LAIV, or RIV is a precaution to use of ccIIV4.
  - History of a serious systemic or anaphylactic reaction to a previous dose of any egg-based IIV, ccIIV, or LAIV, is a precaution to use of RIV4.

Influenza vaccine contraindications and precautions for children and teens with a history of serious systemic or anaphylactic reaction to a previous dose of an influenza vaccine are summarized in the table below.

Vaccine Associated with Previous Serious or Anaphylactic Reaction	Available 2022–23 Influenza Vaccines		
	Egg-Based IIV4s and LAIV4	cciiv4	RIV4
Any Egg-Based IIV Or LAIV	Contraindication	Precaution*	Precaution*
Any ccIIV	Contraindication	Contraindication	Precaution
Any RIV	Contraindication	Precaution*	Contraindication
Unknown Influenza Vaccine	Allergist Consultation Recommended		

* Use of ccIIV4 and RIV4 in such instances should occur in an inpatient or outpatient medical setting under the supervision of a healthcare provider (HCP) who can recognize and manage severe allergic reaction. HCPs may consider consulting with an allergist to help identify the vaccine component responsible for the reaction.

- **Precautions for use of LAIV4 only**
  - Age 5 years or older with asthma
  - Other chronic medical conditions that might predispose the person to complications of influenza infection (e.g., other chronic pulmonary, cardiovascular [excluding isolated hypertension], renal, hepatic, neurological/ neuromuscular, hematologic, or metabolic disorders [including diabetes mellitus])

Note regarding patients with egg allergy: *People with egg allergy of any severity can receive any recommended and age-appropriate influenza vaccine (i.e., any IIV4, RIV4, or LAIV4) that is otherwise appropriate for their health status. Most influenza vaccines (except RIV4 and cell cultured IIV4) are egg cultured and may have trace amounts of egg protein. If a vaccine other than ccIIV4 or RIV4 is used, children and teens with a history of reactions to egg involving any symptom other than hives (e.g., angioedema or swelling, respiratory distress, lightheadedness, or recurrent emesis), or who required epinephrine or another emergency medical intervention, the selected vaccine should be administered in a medical setting (e.g., health department or physician office).*
Vaccine administration should be supervised by a healthcare provider who is able to recognize and manage severe allergic conditions.

- **Provide Vaccine Information Statements**
  - Provide all patients (or, in the case of minors, their parent, or legal representative) 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 www.immunize.org/vis. (For information about how to document that the VIS was given, see section 6 titled “Document Vaccination.”)

- **Prepare to Administer Vaccine**

For vaccine that is to be administered intramuscularly, choose the needle gauge, needle length, and injection site according to the following chart:

Age of Child	Needle Gauge	Needle Length	Injection Site
Infants age 6 through 11 months	22–25	1"	Anterolateral thigh muscle
Age 1 through 2 years	22–25	1–1¼"	Anterolateral thigh muscle†
		5/8‡–1"	Deltoid muscle of arm
Age 3 through 10 years	22–25	5/8‡–1”	Deltoid muscle of arm†
		1–1¼"	Anterolateral thigh muscle
Age 11 years and older	22–25	5/8‡–1"	Deltoid muscle of arm†
		1–1½"	Anterolateral thigh muscle

† Preferred site.

‡ A 5/8" needle may be used in patients weighing less than 130 lbs (<60 kg) for IM injection in the deltoid muscle only if the skin is stretched tight, the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle to the skin.

For LAIV4, which is administered intranasally, prepare the vaccine according to directions in the package insert.

Administer Influenza Vaccine according to the age of patient and desired route of vaccination described below:

Type Of Vaccine	Age Group	Dose	Route	Instructions §
Inactivated influenza vaccine (IIV4)	6–35 months	Afluria: 0.25 mL Fluarix: 0.5 mL *Flucelvax: 0.5 mL (cell culture based)* FluLaval: 0.5 mL Fluzone: 0.25 or 0.5 mL	Intramuscular (IM)	Administer vaccine in anterolateral thigh muscle; alternatively, children age 12 through 35 months may receive injection in deltoid muscle.
Inactivated influenza vaccine (IIV4) • Afluria • Fluarix • *Flucelvac-cell cultured based* • FluLaval • Fluzone	3 years and older	0.5 mL	Intramuscular (IM)	Administer vaccine in deltoid muscle or, alternatively, in anterolateral thigh muscle.
Recombinant influenza vaccine (RIV4)-Flubloc	18 years and older	0.5 mL	Intramuscular (IM)	Administer vaccine in deltoid muscle.
Live attenuated influenza vaccine (LAIV4)-FluMist	Healthy, age 2 years and older (except if pregnant)	0.2 mL (0.1 mL into each nostril)	Intranasal spray (NAS)	Spray half of vaccine into each nostril while the patient is in an upright position.

Note: For children age 6 months through 8 years who 1) are receiving influenza vaccine for the first time, 2) have had fewer than two prior doses of influenza vaccine in all previous years, or 3) don’t know their influenza vaccine history, administer two doses separated by at least 4 weeks.

§ For complete instructions on how to administer influenza vaccine, see “How to Administer Intramuscular and Intranasal Influenza Vaccines” at www.immunize.org/catg.d/p2024.pdf

- **Document Vaccination**
    - Document each patient's vaccine administration information and follow up in the following places:
        - ***Medical record:*** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and address and, if appropriate, the title of the person administering the vaccine. You must also document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient (parent/legal representative). Note that medical records/charts should be documented and retained in accordance with applicable state laws and regulations. If vaccine was not administered, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal); discuss the need for vaccine with the patient (or, in the case of a minor, their parent or legal representative) at the next visit.
        - ***Personal immunization record card:*** Record the date of vaccination and the name/location of the administering clinic.
        - ***Immunization Information System (IIS) or "registry":*** Report the vaccination to the appropriate state/local IIS.
- **Be Prepared to Manage Medical Emergencies**
    - Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications. To prevent syncope in older children, vaccinate patients while they are seated or lying down and consider observing them for 15 minutes after receipt of the vaccine.
- **Report All Adverse Events to VAERS**
    - Report all adverse events following the administration of influenza vaccine to the federal Vaccine Adverse Event Reporting System (VAERS). To submit a VAERS report online (preferred) or to download a writable PDF form, go to https://vaers.hhs.gov/reportevent.html. Further assistance is available at (800) 822-7967.

STANDING ORDERS FOR
Administering Inactivated Poliovirus Vaccine to Children and Teens

Purpose

To reduce morbidity and mortality from poliomyelitis by vaccinating all children and teens who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy

Where allowed by state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess the need for and vaccinate children and teens who meet any of the criteria below.

Procedure

1. **Assess Children in Need of Vaccination** against poliomyelitis based on the following criteria:
   - Age 2 months through 17 years who have not completed an inactivated poliomyelitis vaccine (IPV) series
   - IPV is not routinely recommended for U.S. residents age 18 years or older

2. **Screen for contraindications and precautions**

   Contraindications
   - Do not give IPV to an infant or child who has experienced a serious reaction (e.g., anaphylaxis) to a prior dose of the vaccine or to any of its components. For information on vaccine components, refer to the manufacturers' package insert (www.immunize.org/fda) or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.

   Precautions
   - Moderate or severe acute illness with or without fever
   - Pregnancy

3. **Provide Vaccine Information Statements**

   Provide all patients (or, in the case of minors, their parent, or legal representative) 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 www.immunize.org/vis. (For information about how to document that the VIS was given, see section 6 titled "Document Vaccination.")

4. **Prepare to Administer Vaccine**

   IPV may be administered either intramuscularly or subcutaneously.

   If vaccine is to be administered by the **intramuscular route**, choose the needle gauge, needle length, and injection site according to the following chart:

Age of Infant/Child/Teen	Needle Gauge	Needle Length	Injection Site
Younger than 12 months	22-25	1"	Anterolateral thigh muscle
12 through 35 months	22-25	5/8*-1" 1-1 ¼"	Anterolateral thigh muscle** Deltoid muscle of arm
Children (3-10 years)	22-25	5/8*-1" 1-1 ¼"	Deltoid muscle of arm** Anterolateral thigh muscle
Adolescents and Teens (11-18 years)	22-25	5/8*-1" 1-1 ½ "	Deltoid muscle of arm** Anterolateral thigh muscle

* Preferred site.

** A 5/8" needle may be used for children for IM injection in the deltoid muscle only if the skin is stretched tight,

the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle.

If vaccine is to be administered by the **subcutaneous route**, use the needle gauge, needle length, and injection site according to the following chart:

NEEDLE GAUGE	NEEDLE LENGTH	INJECTION SITE
23–25	5/8"	Fatty tissue over triceps or fatty tissue over anterolateral thigh

5. Administer IPV vaccine, 0.5 mL, via the intramuscular (IM) route or subcutaneous (Subcut) route, according to the following tables:

Schedule for routine vaccination

VACCINE AND DOSE NUMBER	RECOMMENDED AGE FOR THIS DOSE	MINIMUM AGE FOR THIS DOSE	RECOMMENDED INTERVAL TO NEXT DOSE	MINIMUM INTERVAL TO NEXT
IPV #1	2 months	6 weeks	8 weeks	4 weeks
IPV #2	4 months	10 weeks	8 weeks–14	4 weeks
IPV #3	6–18 months	14 weeks	6–12 months	6 months
IPV #4[2,3]	4–6 years	4 years		

NOTE: For individuals who failed to complete the schedule as stated above, do not start over. Simply follow the schedule in section #5.

Schedule for catch-up vaccination

NUMBER OF PRIOR DOCUMENTED DOSES	MINIMUM INTERVAL[1] BETWEEN DOSES OF IPV STARTING FROM THE MOST RECENT DOSE GIVEN		
	DOSE 1 TO DOSE 2	DOSE 2 TO DOSE 3	DOSE 3 TO DOSE 4
Unknown	4	4 weeks	6 months
0	4	4 weeks	6 months
1	4	4 weeks	6 months
2		4 weeks	6 months
3			6 months

NOTES

1 In the first 6 months of life, use minimum ages and intervals only for travel to a polio-endemic region or during an outbreak.

2 If a child received 4 or more doses before the 4th birthday (e.g., in a combination vaccine), an additional dose is still necessary after the 4th birthday and at least 6 months after the previous dose.

3 If a child or teen has received a 3rd dose at age 4 years or older, a 4th dose is not necessary as long as there is a 6-month interval between doses 2 and 3.

6. Document Vaccination

Document each patient's vaccine administration information and follow-up in the following places:
Medical record: Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and address and, if appropriate, the title of the person administering the vaccine. You must also document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Note that medical records/charts should be documented and retained in accordance with applicable state laws and regulations. If vaccine was not administered, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal). Discuss the need for vaccine with the patient (or, in the case of a minor, their parent or legal representative) at the next visit.

Personal immunization record card: Record the date of vaccination and the name/location of the administering clinic.

Immunization Information System (IIS) or "registry": Report the vaccination to the Kentucky Immunization Registry (KYIR)

7. Be Prepared to Manage Medical Emergencies

Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications. For IAC's "Medical Management of Vaccine Reactions in Children and Teens," go www.immunize.org/catg.d/p3082a.pdf. For "Medical Management of Vaccine Reactions in Adult Patients," go to www.immunize.org/catg.d/p3082.pdf. To prevent syncope, vaccinate patients while they are seated or lying down and consider observing them for 15 minutes after receipt of the vaccine.

8. Report Adverse Events to VAERS

Report all adverse events following the administration of IPV to the federal Vaccine Adverse Event Reporting System (VAERS). To submit a VAERS report online (preferred) or to download a writable PDF form, go to https://www.vaers.hhs.gov/report event.html. Further assistance is available at (800) 822-7967.

Protocol for JYNNEOS of Intradermal Administration
Adults (≥18 years of age) in the General Population

Vaccine	Dosage (Amount) Route
JYNNEOS	**0.1mL INTRADERMAL 2 doses 28 days apart May be administered for 1st and/or 2nd dose**

Purpose

- To reduce morbidity and mortality from smallpox and monkeypox by vaccinating persons who meet the criteria established by the Centers for Disease Control and Prevention (CDC).

Policy

- Where authorized under state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess and vaccinate persons who meet the criteria in the "Procedure" section below without the need for clinician examination or direct order from the attending provider at the time of the interaction.
- **Review the package insert prior to administration and confirm storage and handling guidance.**

Procedure

- **Assess Persons for Need of Vaccination** against smallpox and monkeypox based on current guidance provided by CDC and state or local public health authorities. Refer to www.cdc.gov/poxvirus/ monkeypox/considerations-for-monkeypox-vaccination.html for current CDC guidance for the 2022 Monkeypox Outbreak. Healthcare professionals must monitor this website for updates and comply with any such posted updates.
- **Screen for Contraindications and Precautions**
    - Contraindications:
        - Severe allergic reaction (e.g., anaphylaxis) after a previous dose of JYNNEOS vaccine.
    - Precautions:
        - History of severe allergic reaction (e.g., anaphylaxis) to gentamicin or ciprofloxacin.
        - History of severe allergic reaction (e.g., anaphylaxis) to chicken or egg protein AND currently avoiding all chicken and egg products.
        - After discussing risks and benefits with the patient, persons with a precaution to vaccination may be vaccinated with a 30-minute observation period or referred for allergist-immunologist consultation prior to vaccination.

Preparation and Administration

- Assess Persons for Vaccine Dose and Route.
    - JYNNEOS vaccine can be administered either subcutaneously or intradermally.
    - Intradermal (ID) administration is recommended for persons **18 years of age and older who do not have a history of keloid scars.**
    - Please note that this document addresses intradermal administration only.
- Provide Vaccine Information Statement (VIS).
    - Provide all recipients with a copy of the FDA EUA Fact Sheet for Recipients and Caregivers. You may offer the current VIS at www.cdc.gov/vaccines/
    - hcp/vis/vis-statements/smallpox-monkeypox.html
    - For the Spanish version, refer to the Language Index at www.immunize.org/vis. www.cdc.gov/vaccines/hcp/vis/vis-statements/smallpox-monkeypox.html.

- Prepare to Administer Vaccine
    - Allow JYNNEOS vaccine to thaw and reach room temperature before use.
    - When thawed, JYNNEOS is a milky, light yellow to pale white colored suspension.
    - Swirl the vial gently for at least 30 seconds.
      Withdraw dose of **0.1 m**L using 25-28 gauge, ¼" to ½' needle with a short bevel into a tuberculin syringe.
- Administer Vaccine
    - Vaccine Schedule: Administer two doses of JYNNEOS (0.1 mL each) 28 days apart
        - For more details on the dosing interval, refer to www.cdc.gov/poxvirus/monkeypox/considerations-for-monkeypox-vaccination.html
    - Select and cleanse vaccination site 2-4 inches below the antecubital fossa (elbow) on the volar surface of the forearm.
        - If the volar surface of the forearm cannot be used, administer vaccine subcutaneous per the Jynneos Subcutaneous Administration Protocol.
    - Administer JYNNEOS intradermally into the volar surface of the forearm:
        - While pulling the skin taut, position the needle bevel facing up and insert the needle at a 5-to 15-degree angle into the dermis.
        - Slowly inject 0.1mL intradermally. This should produce a noticeable pale elevation of the skin (wheal).
        - **Do not massage the site**
        - A bandage may be placed over the injection site as needed.
        - A person who presents for their second JYNNEOS vaccine dose who is still experiencing erythema or induration at the site of intradermal administration of the first vaccine dose (e.g., the forearm) may have the second dose administered intradermally in the contralateral forearm.
- Observe Patients after Vaccination
    - Vaccination providers should observe patients after vaccination to monitor for the occurrence of immediate adverse reactions, including syncope:
        - **30 minutes**: Persons with a history of anaphylaxis to gentamicin, ciprofloxacin, chicken, or egg protein (AND who are currently avoiding exposure to all chicken or egg products)
        - **15 minutes**: Can consider for all other persons
- **Vaccine administration complications or concerns see** https://www.cdc.gov/poxvirus/monkeypox/interim-considerations/errors-deviations.html

Document Vaccination

- Vaccination providers must document vaccine administration in their medical record systems upon administration and use their best efforts to report administration data to the relevant system (e.g., immunization information system) for the jurisdiction as soon as practicable and no later than 72 hours after administration.
- Document each recipient's vaccine administration information:
    - Medical record: The vaccine and the date it was administered, manufacturer, lot number, vaccination site and route, name and title of the person administering the vaccine
    - Vaccination record: Date of vaccination, product name/manufacturer, lot number, and name/location of the administering clinic or healthcare professional. Give to the vaccine recipient.

Be Prepared to Manage Medical Emergencies

- Vaccine providers should be familiar with identifying immediate allergic reactions, including anaphylaxis, and be prepared to treat these events at the time of vaccine administration.
    - Providers should also have a plan in place to contact emergency medical services immediately in the event of a severe acute vaccine reaction. Because anaphylaxis may recur after patients begin to recover, monitoring in a medical facility for several hours is advised, even after complete resolution of symptoms and signs.

For more information: https://www.cdc.gov/poxvirus/monkeypox/considerations-for-monkeypox-vaccination.html

Protocol for JYNNEOS Subcutaneous Administration
Adults with Certain Medical Conditions and Children

Vaccine	Dosage (Amount) Route
JYNNEOS	**0.5mL subcutaneous 2 doses 28 days apart** **May be used for 1st and/or 2nd dose**

Purpose

- To reduce morbidity and mortality from smallpox and monkeypox by vaccinating persons who meet the criteria established by the Centers for Disease Control and Prevention (CDC).

Policy

- Where authorized under state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess and vaccinate persons who meet the criteria in the "Procedure" section below without the need for clinician examination or direct order from the attending provider at the time of the interaction.
- **Review the package insert prior to administration and confirm storage and handling guidance.**

Procedure

- **Assess Persons for Need of Vaccination** against smallpox and monkeypox based on current guidance provided by CDC and state or local public health authorities. Refer to www.cdc.gov/poxvirus/ monkeypox/considerations-for-monkeypox-vaccination.html for current CDC guidance for the 2022 Monkeypox Outbreak. Healthcare professionals must monitor this website for updates and comply with any such posted updates.
- **Screen for Contraindications and Precautions**
    - Contraindications:
        - Severe allergic reaction (e.g., anaphylaxis) after a previous dose of JYNNEOS vaccine
    - Precautions:
        - History of severe allergic reaction (e.g., anaphylaxis) to gentamicin or ciprofloxacin
        - History of severe allergic reaction (e.g., anaphylaxis) to chicken or egg protein AND currently avoiding all chicken and egg products
        - After discussing risks and benefits with the patient, persons with a precaution to vaccination may be vaccinated with a 30-minute observation period or referred for allergist-immunologist consultation prior to vaccination

Preparation and Administration

- Assess Persons for Vaccine Dose and Route
    - JYNNEOS vaccine can be administered either subcutaneously or intradermally depending on the person's age and presence of certain medical conditions. **All persons less than 18 years of age and persons 18 years of age and older who have a history of keloid scars should receive JYNNEOS vaccination subcutaneously.**
    - Please note that this document addresses subcutaneous administration only.

- Provide Vaccine Information Statement (VIS)
    - Provide persons younger than age 18 with a copy of the FDA EUA Fact sheet for Recipients and Caregivers.
    - Provide persons 18 years of age and older with a copy of the current VIS at www.cdc.gov/vaccines/hcp/vis/vis-statements/smallpox-monkeypox.html.
    - For the Spanish version, refer to the Language Index at www.immunize.org/vis.

- Prepare to Administer Vaccine
    - Allow JYNNEOS vaccine to thaw and reach room temperature before use.
    - When thawed, JYNNEOS is a milky, light yellow to pale white colored suspension
    - Swirl the vial gently for at least 30 seconds
    - Withdraw dose of 0.5 mL using a 23–25 gauge, 5/8" needle into a sterile syringe for injection

- Administer Vaccine
    - Vaccine Schedule:
        - Administer two doses of JYNNEOS (0.5 mL each) 28 days apart
        - For persons >12 months of age: Administer JYNNEOS subcutaneously by pinching up fatty tissue over the triceps area in the upper arm and insert the needle at a 45-degree angle.
            - Secondary site is the front and outer side of the upper thigh.
        - For infants <12 months of age: Administer JYNNEOS subcutaneously by pinching up fatty tissue over the anterolateral thigh and insert the needle at a 45-degree angle.
            - For infants <6 months of age, discuss with pediatrician prior to vaccination.
        - Vaccines inadvertently administered intramuscularly (IM) can be considered valid doses and do not need to be repeated. IM doses need to be reported to the manufacturer at drug.safety@bavarian-nordic.com.

    - **Vaccine administration complications or concerns see** https://www.cdc.gov/poxvirus/monkeypox/interim-considerations/errors-deviations.html

- Observe Patients after Vaccination
    - Vaccination providers should observe patients after vaccination to monitor for the occurrence of immediate adverse reactions, including syncope:
        - **30 minutes**: Persons with a history of anaphylaxis to gentamicin, ciprofloxacin, chicken, or egg protein (AND who are currently avoiding exposure to all chicken or egg products)
        - **15 minutes**: Can consider for all other persons

Document Vaccination

- Vaccination providers must document vaccine administration in their medical record systems upon administration and use their best efforts to report administration data to the relevant system (e.g., immunization information system) for the jurisdiction as soon as practicable and no later than 72 hours after administration.
- Document each recipient's vaccine administration information:
    - Medical record: The vaccine and the date it was administered, manufacturer, lot number, vaccination site and route, name and title of the person administering the vaccine
    - Vaccination record: Date of vaccination, product name/manufacturer, lot number, and name/location of the administering clinic or healthcare professional. Give to the vaccine recipient.

Be Prepared to Manage Medical Emergencies

- Vaccine providers should be familiar with identifying immediate allergic reactions, including anaphylaxis, and be prepared to treat these events at the time of vaccine administration.
    - Providers should also have a plan in place to contact emergency medical services immediately in the event of a severe acute vaccine reaction. Because anaphylaxis may recur after patients begin to recover, monitoring in a medical facility for several hours is advised, even after complete resolution of symptoms and signs.

For more information: https://www.cdc.gov/poxvirus/monkeypox/considerations-for-monkeypox-vaccination.html

For information on administration errors: https://www.cdc.gov/poxvirus/monkeypox/interim-considerations/errors-deviations.html

STANDING ORDERS FOR
Administering Measles, Mumps, and Rubella Vaccine to Children and Teens

Purpose

To reduce morbidity and mortality from measles, mumps, and rubella by vaccinating all children and teens who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Policy

Where allowed by state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess the need for vaccination and to vaccinate children and teens who meet any of the criteria below.

Procedure

1. **Assess Children and Teens for Need of Measles, Mumps, and Rubella (MMR) Vaccination** based on the following criteria:

   - Age 12 months or older with no documentation of MMR vaccine
   - Age 4 years or older with no documentation of two doses of MMR vaccine
   - Age 6 months or older with pending international travel
   - Age 12 months or older with documentation of only 1 dose of MMR vaccine given when younger than age 12 months
   - History of two previous doses of MMR and identified by public health as being at increased risk during a mumps outbreak

2. **Screen for Contraindications and**

   Precautions *Contraindications*

   - Do not give MMR vaccine to a child or teen who has experienced a severe allergic reaction (e.g., anaphylaxis) to a previous dose of MMR vaccine or to any of its components. For a list of vaccine components, refer to the manufacturer's package insert (www.immunize.org/packageinserts) or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.
   - Do not give MMR vaccine to a child or teen who is pregnant or may become pregnant within 1 month (pregnant teens should be vaccinated upon completion or termination of pregnancy).
   - Do not give MMR vaccine to a child or teen having known severe immunodeficiency (e.g., from hematologic and solid tumors, receipt of chemotherapy, congenital immunodeficiency, long-term immunosuppressive therapy).
   - Do not give MMR vaccine to a child or teen receiving prolonged (14 days or longer) high-dose steroid therapy, or severely immunocompromised from HIV infection. *(HIV infection is not a contraindication to MMR for those children and teens who are not severely immunocompromised [i.e., CD4+ T-lymphocyte counts greater than or equal to 200 cells per microliter for 6 months or more].)*
   - Do not give MMR vaccine to a child or teen with a family history of congenital or hereditary immuno- deficiency in first-degree relatives (e.g., parents, siblings) unless the immune competence of the potential vaccine recipient has been clinically substantiated or verified by a laboratory.

Precautions

- Moderate or severe acute illness with or without fever
- History of recent (within the past 11 months) receipt of antibody-containing blood product (specific interval depends on product)
- History of thrombocytopenia or thrombocytopenic purpura
- Need for tuberculin skin testing (TST) or interferon-gamma release assay (IGRA) testing. If active tuberculosis is suspected, MMR should be delayed. Measles vaccination might suppress tuberculin reactivity temporarily. The TST should be administered either any time before, simultaneously with, or at least 4–6 weeks after the measles-containing vaccine (e.g., MMR, MMRV).

3. Provide 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 www.immunize.org/vis. (For information about how to document that the VIS was given, see section 6 titled "Document Vaccination.")

4. Prepare to Administer Vaccine

Choose the needle gauge, needle length, and injection site according to the following chart:

NEEDLE GAUGE	NEEDLE LENGTH	INJECTION SITE
23–25	5/8"	Fatty tissue over triceps or fatty tissue over anterolateral

5. Administer Measles, Mumps, and Rubella Vaccine (MMR), 0.5 mL, via the subcutaneous (Subcut) route, according to the following criteria and schedule:

HISTORY OF PREVIOUS MMR VACCINATION	AGE GROUP	SCHEDULE FOR ADMINISTRATION OF MMR VACCINE
0 documented doses, or none known	12 months to 4 years	Give dose #1.
0 documented doses, or none known	4 years and older	Give dose #1. Give dose #2 at least 4 weeks later.
1 previous dose given before age 12 months	12 months and older	Give dose #1. Give dose #2 at least 4 weeks later.
1 previous dose of MMR given at age 12 months or older	4 years and older	Give dose #2 at least 4 weeks after dose #1.
2 previous doses of MMR and identified by public health to be at increased risk during a mumps outbreak	Any age	Give dose #3 at least 4 weeks after dose #2

6. Document Vaccination

Document each patient's vaccine administration information and follow up in the following places:

Medical record: Document the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. You must also document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Note that medical records/charts should be documented and retained in accordance with applicable state laws and regulations. If vaccine was not administered, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal). Offer this vaccine at the next visit.

Personal immunization record card: Record the date of vaccination and the name/location of the administering clinic.

Immunization Information System (IIS) or "registry": Report the vaccination to the appropriate state/local IIS, if available.

7. Be Prepared to Manage Medical Emergencies

Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications. For IAC's "Medical Management of Vaccine Reactions in Children and Teens," go to www.immunize.org/catg.d/p3082a.pdf. For "Medical Management of Vaccine Reactions in Adult Patients," go to www.immunize.org/catg.d/p3082.pdf. To prevent syncope, vaccinate patients while they are seated or lying down and consider observing them for 15 minutes after receipt of the vaccine.

8. Report All Adverse Events to VAERS

Report all adverse events following the administration of MMR vaccine to the federal Vaccine Adverse Event Reporting System (VAERS). To submit a VAERS report online (preferred) or to download a writable PDF form, go to https://vaers.hhs.gov/reportevent.html. Further assistance is available at (800) 822-7967.

STANDING ORDERS FOR

Administering Measles, Mumps, and Rubella Vaccine to Adults

Purpose

To reduce morbidity and mortality from measles, mumps, and rubella disease by vaccinating all adults who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Policy

Where allowed by state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess the need for vaccination and to vaccinate adults who meet any of the criteria below.

Procedure

1. Assess Adults for Need of Measles, Mumps, and Rubella (MMR) Vaccination

a. Identify adults **in need of initial MMR vaccination** who

- were born in the U.S. in 1957 or later, or
- are a healthcare worker of any age, and who do not meet evidence of immunity by having met any of the following criteria:
  - Documentation of receiving at least 1 dose of MMR vaccine
  - Laboratory evidence of immunity or laboratory confirmation of disease to measles, mumps, and rubella

b. Identify adults **in need of a second dose of MMR vaccine** who

- were born U.S. in 1957 or later and are planning to travel internationally,
- are a student in a college, university, technical, or vocational school, or
- are a healthcare worker born in 1957 or later

c. Identify adults who have been recommended to receive an additional dose of MMR because of their increased risk for mumps during a current mumps outbreak (resulting in either 2 or 3 total doses)

2. Screen for Contraindications and Precautions *Contraindications*

- Do not give MMR vaccine to a person who has experienced a severe allergic reaction (e.g., anaphylaxis) after a previous dose of MMR vaccine or to any of its components. For a list of vaccine components, refer to the manufacturer's package insert (www.immunize.org/packageinserts) or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.
- Do not give MMR vaccine to a woman who is pregnant or may become pregnant within 1 month (pregnant women should be vaccinated upon completion or termination of pregnancy).
- Do not give MMR vaccine to a person having known severe immunodeficiency (e.g., from hematologic and solid tumors, receipt of chemotherapy, congenital immunodeficiency, long-term immunosuppressive therapy).

- Do not give MMR vaccine to a person receiving high-dose systemic immunosuppressive therapy (e.g., two weeks or more of daily receipt of 20 mg or more [or 2 mg/kg body weight or more] of prednisone or equivalent).
- Do not give MMR vaccine to an adult with a family history of congenital or hereditary immunodeficiency in first-degree relatives (e.g., parents, siblings) unless the immune competence of the potential vaccine recipient has been clinically substantiated or verified by laboratory testing.

- Do not give MMR vaccine to an adult with human immunodeficiency virus (HIV) infection and CD4+ T-lymphocytes count <200 cells/µL. *(HIV infection is not a contraindication to MMR for adults who are not severely immunocompromised [i.e., CD4+ T-lymphocyte counts >200 cells/µL for 6 months or more.]) In circumstances where only counts or only percentages are available on the lab report, assessment can be based on the laboratory measure that is available (i.e., counts or percentages).*

Precautions

- Moderate or severe acute illness with or without fever
- History of recent (within the past 11 months) receipt of antibody-containing blood product (specific interval depends on product)
- History of thrombocytopenia or thrombocytopenic purpura
- Need for tuberculin skin testing or interferon-gamma release assay (IGRA) testing. If active tuberculosis is suspected, MMR should be delayed. Measles vaccination might suppress tuberculin reactivity temporarily. Measles-containing vaccine can be administered on the same day as tuberculin skin testing, or should be postponed for at least 4 weeks after the vaccination.

3. Provide 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 www.immunize.org/vis. (For information about how to document that the VIS was given, see section 6 titled “Document Vaccination.”)

4. Prepare to Administer Vaccine

Choose the needle gauge, needle length, and injection site according to the following chart:

NEEDLE GAUGE	NEEDLE LENGTH	INJECTION SITE
23–25	5/8"	Fatty tissue over triceps

Reconstitute the vaccine with the manufacturer-supplied diluent just prior to administration.

5. Administer MMR Vaccine, 0.5 mL, via the subcutaneous (Subcut) route, according to the following criteria and schedule:

HISTORY OF PREVIOUS MMR VACCINATION	DOSE AND SCHEDULE FOR ADMINISTRATION OF MMR
0 documented doses, or none known	Give 0.5 mL MMR as dose #1. If indicated, give dose #2 at least 4 weeks later.
1 previous dose of MMR	If indicated, give 0.5 mL MMR as dose #2 at least 4 weeks after dose #1.

6. Document Vaccination

Document each patient's vaccine administration information and follow up in the following places:

Medical record: Document the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. You must also document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Note that medical records/charts should be documented and retained in accordance with applicable state laws and regulations. If vaccine was not administered, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal). Offer this vaccine at the next visit.

Personal immunization record card: Record the date of vaccination and the name/location of the administering clinic.

Immunization Information System (IIS) or "registry": Report the vaccination to the appropriate state/local IIS, if available.

7. Be Prepared to Manage Medical Emergencies

Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications. For IAC's "Medical Management of Vaccine Reactions in Adults," go to www.immunize.org/catg.d/p3082.pdf. For "Medical Management of Vaccine Reactions in Children and Teens," go to www.immunize.org/catg.d/p3082a.pdf. To prevent syncope, vaccinate patients while they are seated or lying down and consider observing them for 15 minutes after receipt of the vaccine.

8. Report All Adverse Events to VAERS

Report all adverse events following the administration of MMR vaccine to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov. To submit a VAERS report online (preferred) or to download a writable PDF form, go to https://vaers.hhs.gov/reportevent.html. Further assistance is available at (800) 822-7967.

STANDING ORDER FOR
Measles, Mumps, Rubella and Varicella Combination (MMRV) Vaccine (ProQuad®)

Purpose

- To reduce mortality from Measles Mumps, Rubella and Varicella all infants and children from 12 months older to 12 years old who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy

- Where allowed by state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess the need for and vaccinate children and teens who meet any of the criteria below.
- **Review the package insert prior to administration and confirm storage and handling guidance**

Procedure

- ProQuad is a vaccine indicated for active immunization for the prevention of measles, mumps, rubella, and varicella in children 12 months through 12 years of age

Screen for Contraindications and Precautions

- **Contraindications**
  - History of anaphylactic reaction to neomycin or hypersensitivity to gelatin or any other component of the vaccine.
  - Primary or acquired immunodeficiency states.
  - Family history of congenital or hereditary immunodeficiency.
  - Immunosuppressive therapy.
  - Active untreated tuberculosis or febrile illness (>101.3°F or >38.5°C).
  - Pregnancy.

- **Precautions**
  - Administration of ProQuad (dose 1) to children 12 to 23 months old who have not been previously vaccinated against measles, mumps, rubella, or varicella, nor had a history of the wild-type infections, is associated with higher rates of fever and febrile seizures at 5 to 12 days after vaccination when compared to children vaccinated with M-M-R® II and VARIVAX® administered separately.
  - Use caution when administering ProQuad to children with a history of cerebral injury or seizures or any other condition in which stress due to fever should be avoided.
  - Use caution when administering ProQuad to children with anaphylaxis or immediate hypersensitivity to eggs or contact hypersensitivity to neomycin.
  - Use caution when administering ProQuad to children with thrombocytopenia.
  - Avoid close contact with high-risk individuals susceptible to varicella since transmission of varicella vaccine virus may occur between vaccinees and susceptible contacts
  - Defer vaccination for at least 3 months following blood or plasma transfusions, or administration of immune globulins (IG).
  - Avoid using salicylates for 6 weeks after vaccination with ProQuad.

- Avoid pregnancy for 3 months following vaccination with measles, mumps, rubella, and/or varicella vaccines.

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. .
  - ACIP 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 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
    - should be 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.

Dosage and Route

- Administer 0.5 mL subcutaneously
- 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.

Age	Needle Length and Gauge	Preferred Site
Infants Ages 2-3	22-25 Gauge/1 Inch	Vastus Lateralis Muscle of Anterolateral Thigh
Toddler 1-2 years	22-25 gauge/ 1-1.25 inch	Vastus Lateralis Muscle of Anterolateral Thigh (Preferred)
Children 3-12	22-25 Gauge/1 Inch	Deltoid muscle of arm (Preferred)

Document Vaccination

- Document each patient's vaccine administration information and follow-up in the following places:
    - Medical record*:*
        - Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. You must also document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Note that medical records/charts should be documented and retained in accordance with applicable state laws and regulations. If vaccine was not administered, record the reason(s) for non-receipt of the vaccine (e.g., medical contra-indication, patient refusal). Discuss the need for vaccine with the patient at the next visit.
    - Personal immunization record card:
        - Record the date of vaccination and the name/location of the administering clinic.
    - Immunization Information System (IIS) or "registry*":*
        - Report the vaccination to the appropriate state/local IIS, if available.

Be Prepared to Manage Medical Emergencies

- Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications. For IAC's "Medical Management of Vaccine Reactions in Adult Patients in a Community Setting," go to www.immunize.org/catg.d/p3082.pdf. For "Medical Management of Vaccine Reactions in Children and Teens in a Community Setting," go to www.immunize.org/catg.d/p3082a.pdf.
- To prevent syncope, vaccinate patients while they are seated or lying down and consider observing them for 15 minutes after receipt of the vaccine.

Report Adverse Events to VAERS

- Report all adverse events following the administration of Hepatitis A vaccine to the federal Vaccine Adverse Event Reporting System (VAERS). To submit a VAERS report online (preferred) or to download a writable PDF form, go to https://vaers.hhs.gov/reportevent.html. Further assistance is available at (800) 822-7967.

Special situations

- **Pregnancy with no evidence of immunity to rubella**: MMR contraindicated during pregnancy; after pregnancy (before discharge from health care facility), 1 dose
- **Nonpregnant women of childbearing age with no evidence of immunity to rubella**: 1 dose
- **HIV infection with CD4 count ≥200 cells/µL for at least 6 months and no evidence of immunity to measles, mumps, or rubella**: 2-dose series at least 4 weeks apart; MMR contraindicated in HIV
- **Severe immunocompromising conditions**: MMR contraindicated
- **Students in postsecondary educational institutions, international travelers, and household or close, personal contacts of immunocompromised persons, with no evidence of immunity to measles, mumps, or rubella**: 2-dose series at least 4 weeks apart if previously did not receive any MMR or 1 dose if previously received 1 dose MMR
- **Health care personnel:**
    - **Born in 1957 or later with no evidence of immunity to measles, mumps, or rubella**: 2-dose series at least 4 weeks apart for measles or mumps or at least 1 dose MMR for rubella
    - **Born before 1957 with no evidence of immunity to measles, mumps, or rubella**: Consider 2-dose series at least 4 weeks apart for measles or mumps or 1 dose for rubella

STANDING ORDERS FOR

Administering Meningococcal ACWY Vaccine to Children and Teens

Purpose

To reduce morbidity and mortality from meningococcal disease caused by serotypes A, C, W, or Y by vaccinating all children and teens who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Policy

Where allowed by state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess the need for and vaccinate children and teens who meet any of the criteria below.

Procedure

Assess children and teens for need of vaccination against meningococcal disease according to the following criteria:

Routine meningococcal ACWY vaccination

- Age 11–12 years who have not received MenACWY at age 10 years or older
- As catch-up for ages 13–15 years who have not received MenACWY at age 10 years or older
- Age 16 years and in need of dose #2
- Ages 17 through 18 years and in need of dose #2 as catch-up
- As catch-up for all unvaccinated teens ages 16 through 18 years
- Consider catch-up for age 19 through 21 years with have not received a dose on or after their 16th birthday
- First-year college students living in a residential facility who were never vaccinated or who were last vaccinated when younger than age 16 years

Risk-based meningococcal ACWY vaccination

Children aged 2 months and older with

- Diagnosis of persistent complement component deficiency (an immune system disorder) or use of a complement inhibitor (Soliris [eculizumab] or Ultomiris [ravulizumab])
- Diagnosis of anatomic or functional asplenia (including sickle-cell disease)
- Diagnosis of infection with human immunodeficiency virus

Children aged 2 months and older who

- Are part of an outbreak attributable to a vaccine serogroup
- Anticipate travel to a country where meningococcal disease is hyperendemic or epidemic (e.g., the "meningitis belt" of sub-Saharan Africa), particularly if contact with the local population will be prolonged

Screen for contraindications and precautions

Contraindications – Do not give MenACWY vaccine to a child or teen who has a history of a serious allergic reaction (e.g., anaphylaxis) after a previous dose of meningococcal vaccine or to a meningococcal vaccine component. For information on vaccine components, refer to the manufacturer's package insert (www.immunize.org/fda) or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.

Precaution – Moderate or severe acute illness with or without fever

Provide Vaccine Information Statements

Provide all patients (or, in the case of a minor, their parent or legal representative) with a copy of

the most current federal Vaccine Information Statement (VIS) available at www.immunize.org/vis. You must document in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient (parent/legal representative). 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 www.immunize.org/vis.

Prepare to Administer Vaccine

Choose the needle gauge, needle length, and injection site according to the following chart:

AGE OF CHILD/TEEN	NEEDLE GAUGE	NEEDLE LENGTH	INJECTION SITE
Infants (2 through 11 months*)	22–25	1"	Anterolateral thigh
Toddlers (1 through 2 years)	22–25	1–11/4"	Anterolateral thigh
		5/8"–1"	Deltoid muscle of arm
Children (3 through 10 years)	22–25	5/8"–1"	Deltoid muscle of arm**
		1–11/4"	Anterolateral thigh
Adolescents and Teens (11 through 18 years)	22–25	5/8"–1"	Deltoid muscle of arm**
		1–11/2"	Anterolateral thigh muscle

*Only Menveo vaccine can be used for infants aged 2 through 23 months; MenQuadfi may be used beginning at age 2 years.
**Preferred site

stretched tight, the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle to the skin.

Administer 0.5 mL vaccine via the intramuscular (IM) route

AGE OF PATIENT	SCHEDULE
For preteens age 11 through 12 years	Give dose #1 of 2-dose series. (Dose #2 will be due at age 16
For teens age 13 through 15 years	Give catch-up dose #1 of 2-dose series. (Dose #2 will be due at age 16 through 18 years.)
For teens age 16 years	Give dose #2. Separate from dose #1 by at least 8 weeks.
For teens age 17 through 18 years	Give catch-up dose #2.
Catch-up for all teens age 16 through	If no history of prior vaccination, give 1 dose of MenACWY.
For first year college students living in a residential facility	If no history of prior vaccination, give 1 dose of MenACWY. If history of 1 dose of MenACWY given when younger than age 16 years, give dose #2 of MenACWY.

Schedule and criteria for routine vaccination with MenACWY

Schedule and criteria for MenACWY vaccination in people with underlying medical conditions or other risk factors

For children, adolescents, and teens with risk factors as identified in section 1 on the previous page, refer to "Meningococcal ACWY Vaccine Recommendations by Age and Risk Factor" found at www.immunize.org/catg.d/p2018.pdf.

Document Vaccination

Document each patient's vaccine administration information and any needed follow-up in the following places:

Medical record: Record the date the vaccine was administered, the manufacturer and lot number,

the vaccination site and route, and the name and address and, if appropriate, the title of the person administering the vaccine. You must also document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Note that medical records/charts should be documented and retained in accordance with applicable state laws and regulations. If vaccine was not administered, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal); discuss the need for vaccination with the patient (or, in the case of a minor, their parent or legal representative) at the next visit.

Personal immunization record card: Record the date of vaccination and the name/location of the administering clinic.

Immunization Information System (IIS) or "registry": Report the vaccination to the appropriate state/local IIS, if available.

Be Prepared to Manage Medical Emergencies

Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications. For IAC's "Medical Management of Vaccine Reactions in Children and Teens in a Community Setting,"go to www.immunize.org/catg.d/p3082a.pdf. For IAC's "Medical Management of Vaccine Reactions in Adults in a Community Setting,"go to www.immunize.org/catg.d/p3082.pdf. To prevent syncope in older children, vaccinate patients while they are seated or lying down and consider observing them for 15 minutes after receipt of the vaccine.

Report Adverse Events to VAERS

Report all adverse events to meningococcal vaccine to the federal Vaccine Adverse Event Reporting System (VAERS). To submit a VAERS report online (preferred) or to download a writable PDF form, go to https://www.vaers.hhs.gov/reportevent.html. Further assistance is available at (800) 822-7967.

Standing Orders For

Administering Meningococcal ACWY Vaccine to Adults

Purpose

- To reduce morbidity and mortality from meningococcal disease caused by serotypes A, C, W, or Y by vaccinating all adults who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Policy

- Where allowed by state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess the need for and vaccinate adults who meet any of the criteria below.
- **Review the package insert prior to administration and confirm storage and handling guidance.**

Procedure

- **Assess adults for need of vaccination against meningococcal disease according to the following criteria:**
    - ***Routine meningococcal ACWY vaccination***
        - First-year college students living in a residential facility who were never vaccinated, who were last vaccinated when younger than age 16 years, or who were vaccinated after their 16th birthday but more than 5 years earlier.
        - Adults aged 19 through 21 years who have not been vaccinated with a dose of MenACWY since their 16th birthday may be vaccinated.
    - ***Risk-based meningococcal ACWY vaccination***
        - Diagnosis of persistent complement component deficiency (an immune system disorder) or use of a complement inhibitor (Soliris [eculizumab] or Ultomiris [ravulizumab]).
        - Diagnosis of anatomic or functional asplenia (including sickle-cell disease)
        - Diagnosis of human immunodeficiency virus (HIV) infection
        - Part of an outbreak attributable to a vaccine serogroup
        - Anticipated travel to a country where meningococcal disease is hyperendemic or epidemic (e.g., the "meningitis belt" of sub-Saharan Africa), particularly if contact with the local population will be prolonged
        - Employment as a microbiologist with routine exposure to isolates of *N. meningitidis*

Screen for Contraindications and Precautions

- Contraindications
    - Do not give MenACWY vaccine to an adult who has experienced a serious systemic or anaphylactic reaction to a prior dose of the vaccine or to any of its components. For information on vaccine components, refer to the manufacturer's package insert (www.immunize.org/fda) or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.
- Precautions
    - Moderate or severe acute illness with or without fever

Provide Vaccine Information Statements

- Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS) available at www. immunize.org/vis. You must document in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. 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 www.immunize.org/vis.

Review the vaccination schedule and criteria for MenACWY

- For schedule of vaccination of adults with risk factors as identified in section 1 above, refer to "Meningococcal Vaccination Recommendations by Age and Risk Factor for Serogroups A, C, W, or Y Protection" found at www.immunize.org/catg.d/p2018.pdf.

Prepare to Administer Vaccine

- Choose the needle gauge, needle length, and injection site according to the following chart:

Gender and Weight Of Patient	Needle Gauge	Needle Length	Injection Site
Female or male less than 130 lbs.	22–25	5/8"*–1"	Deltoid muscle of arm
Female or male 130–152 lbs.	22–25	1"	Deltoid muscle of arm
Female 153–200 lbs.	22–25	1–11/2"	Deltoid muscle of arm
Male 153–260 lbs.	22–25	1–11/2"	Deltoid muscle of arm
Female 200+ lbs.	22–25	11/2"	Deltoid muscle of arm
Male 260+ lbs.	22–25	11/2"	Deltoid muscle of arm

* A 5/8" needle may be used in patients weighing less than 130 lbs. (<60 kg) for IM injection in the deltoid muscle only if the skin is stretched tight, the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle to the skin.

Administer MenACWY Vaccine

0.5 mL, IM, according to the table below:

History of Previous Menacwy Vaccination	Dose and Schedule For Administration Of Menacwy
0 documented doses, or none known	Give MenACWY Dose #1.
1 or more previous doses and in a risk group (see #1 on page 1)	Give an additional dose every 5 years if risk continues
A 1st year college student living in a residence hall with history of either a) no prior MenACWY vaccination, b) only 1 dose given and was younger than age 16 years, or c) most recent dose given after 16th birthday and more than 5 years have elapsed.	Give 1 dose

Document Vaccination

- Document each patient's vaccine administration information and any needed follow-up in the following places:
    - Medical record: Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and address and, if appropriate, the title of the person administering the vaccine. Note that medical records/charts should be documented and retained in accordance with applicable state laws and regulations. If vaccine was not administered, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal); discuss the need for vaccination with the

patient at the next visit.

- Personal immunization record card: Record the date of vaccination and the name/location of the administering clinic.
- Immunization Information System (IIS) or "registry": Report the vaccination to the appropriate state/local IIS, if available.

Be Prepared to Manage Medical Emergencies

- Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications. For IAC's "Medical Management of Vaccine Reactions in Adults in a Community Setting," go to www.immunize.org/catg.d/p3082.pdf. For IAC's "Medical Management of Vaccine Reactions in Children and Teens in a Community Setting," go to www.immunize.org/catg.d/p3082a.pdf. To prevent syncope, vaccinate patients while they are seated or lying down and consider observing them for 15 minutes after receipt of the vaccine.

Report Adverse Events to VAERS

- Report all adverse events following the administration of meningococcal vaccine to the federal Vaccine Adverse Event Reporting System (VAERS). To submit a VAERS report online (preferred) or to download a writable PDF form, go to https://vaers.hhs.gov/reportevent.html. Further assistance is available at (800) 822-7967.

STANDING ORDERS FOR
Administering Meningococcal B Vaccine to Adolescents and Adults

Purpose

To reduce morbidity and mortality from serogroup B meningococcal disease by vaccinating all adolescents and adults who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy

Where allowed by state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess the need for and vaccinate adolescents and adults who meet any of the criteria below.

Procedure

1. Assess adolescents and adults for need of vaccination against meningococcal serogroup B disease according to the following criteria:

- Age 16 through 23 years who want to be vaccinated based on the risks and benefits of the vaccine (also known as shared clinical decision-making). The ACIP-preferred age is 16 through 18 years.
- Age 10 years and older, including all adults, with
  - Diagnosis of persistent complement component deficiency (e.g., inherited chronic deficiencies in C3, C5–C9, properdin, factor D and factor H) or taking eculizumab (Soliris) or ravulizumab (Ultomiris)
  - Diagnosis of anatomic or functional asplenia (including sickle cell disease)
  - Risk of exposure due to an outbreak of meningococcal serogroup B disease
  - Microbiologists routinely exposed to isolates of *Neisseria meningitidis*

2. Screen for contraindications and precautions

Contraindication – Do not give meningococcal B vaccine to an adolescent or adult who has experienced a serious systemic or anaphylactic reaction to a prior dose of meningococcal B vaccine or to any of its components. For information on vaccine components, refer to the manufacturers' package insert (www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states) or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.

Precaution – Moderate or severe acute illness with or without fever; pregnancy

3. Provide Vaccine Information Statements

Provide all patients (or, in the case of minors, their parent, or legal representative) 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 www.immunize.org/vis.

4. Prepare to Administer Vaccine

Choose the needle gauge, needle length, and injection site according to the following chart:

AGE OF PATIENT	NEEDLE GAUGE	NEEDLE LENGTH	INJECTION SITE
10 years	22–25	5/8*–1" 1–11/4"	Deltoid muscle of arm** Anterolateral thigh muscle
11–18 years	22–25	5/8*–1" 1–11/2"	Deltoid muscle of arm** Anterolateral thigh muscle
Age 19 years and older			
• Female or male less than 130 lbs	22–25	5/8*–1"	Deltoid muscle of arm
• Female or male 130–152 lbs	22–25	1"	Deltoid muscle of arm
• Female 153–200 lbs	22–25	1–11/2"	Deltoid muscle of arm
• Male 153–260 lbs	22–25	1–11/2"	Deltoid muscle of arm
• Female 200+ lbs	22–25	11/2"	Deltoid muscle of arm
• Male 260+ lbs	22–25	11/2"	Deltoid muscle of arm

* A 5/8" needle may be used in patients weighing less than 130 lbs (<60 kg) for IM injection in the deltoid muscle only if the skin is stretched tight, the subcutaneous tissue is not bunched, and the injection is made at a 90° angle to the skin.
**Preferred site

5. **Administer MenB vaccine**, 0.5 mL, via the intramuscular (IM) route, according to the following tables:

- Adolescents and adults, age 16–23 years (preferred age 16–18 years) not at increased risk1 for meningococcal serogroup B disease, based on shared clinical decision-making

TYPE OF VACCINE	AGE GROUP	DOSE	SCHEDULE
Bexsero(MenB-4c, Glaxo- SmithKline)	10 years	0.5 mL	Two doses, 4 weeks apart
Trumenba(MenB-FHbp, Pfizer)	10 years and older	0.5 mL	Two doses at 0 and 6 months[2]
			Three doses at 0, 1–2, and 6 months

NOTE

The two brands of MenB vaccines are not interchangeable; the same vaccine product must be used for all doses, including booster doses. If vaccination is indicated and the brand of the previous dose or doses is unavailable or cannot be deter-mined, complete a primary series with the available brand.

Adolescents and adults at increased risk[1] for meningococcal serogroup B disease

TYPE OF VACCINE	AGE GROUP	DOSE	SCHEDULE	BOOSTER DOSES(S)
Bexsero(MenB-4c, Glaxo- SmithKline)	10 years	0.5 mL	Twodoses, 4 weeks	If risk is ongoing, give MenB booster 1 year[3] following completion of primary series, followed by boosters every 2–3 years thereafter.
Trumenba(MenB-FHbp, Pfizer)	10 years and older	0.5 mL	Threedoses at 0, 1–2, and 6 months	

1. People at increased risk include those who have anatomic or functional asplenia (including sickle cell disease) or persistent complement component deficiency, who use a complement inhibitor (eculizumab [Soliris] or ravulizumab [Ultomiris]), who are microbiologists routinely exposed to *Neisseria meningitidis*, or who are identified by local public health authorities as at risk due to an ongoing meningococcal B disease outbreak.
2. If Dose #2 of the 2-dose Trumenba series is administered earlier than 6 months after Dose #1, a third dose should be administered at least 4 months after Dose #2.
3. People at risk during an outbreak who have completed the MenB primary series may receive the first MenB booster dose as early as 6 months after completing the primary series, if recommended by public health authorities.

6. Document Vaccination

Document each patient's vaccine administration information and follow-up in the following places:
Medical record: Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. You must also document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Note that medical records/charts should be documented and retained in accordance with applicable state laws and regulations. If vaccine was not administered, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal); discuss the need for vaccination with any high-risk patient who refuses vaccination at the next visit.
Personal immunization record card: Record the date of vaccination and the name/location of the administering clinic.

Immunization Information System (IIS) or "registry": Report the vaccination to the appropriate state/local IIS, if available.

7. Be Prepared to Manage Medical Emergencies

Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications. For IAC's "Medical Management of Vaccine Reactions in Children and Teens in a Community Setting," go to www.immunize.org/catg.d/p3082a.pdf. For "Medical Management of Vaccine Reactions in Adult Patients in a Community Setting," go to www.immunize.org/catg.d/p3082.pdf. To prevent syncope, vaccinate patients while they are seated or lying down and consider observing them for 15 minutes after receipt of the vaccine.

Report Adverse Events to VAERS

Report all adverse events following the administration of meningococcal vaccine to the federal Vaccine Adverse Event Reporting System (VAERS). To submit a VAERS report online (preferred) or to download a writable PDF form, go to https://vaers.hhs.gov/reportevent.html. Further assistance is available at (800) 822-7967.

Administering Pneumococcal Conjugate Vaccine to Children

Purpose

To reduce morbidity and mortality from invasive pneumococcal disease by vaccinating all infants and children who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy

Where allowed by state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess the need for and vaccinate children and teens who meet any of the criteria below.

Procedure

1. **Assess Infants and Children in Need of Vaccination** against invasive pneumococcal disease based on the following criteria:

   Routine pneumococcal vaccination

   Pneumococcal conjugate vaccine (PCV13) should be administered routinely to all children ages 2 through 59 months.

   Risk-based pneumococcal vaccination

   - Age 2 years and older with chronic heart disease (particularly cyanotic congenital heart disease and cardiac failure); chronic lung disease (including asthma treated with high-dose oral corticosteroids); diabetes mellitus
   - Age 2 years and older with cerebrospinal fluid leak; candidate for or recipient of cochlear implant
   - Age 2 years and older with sickle cell disease and other hemoglobinopathies; anatomic or functional asplenia; congenital or acquired immunodeficiency; HIV infection; chronic renal failure; nephrotic syndrome; malignant neoplasms, leukemias, lymphomas, Hodgkin disease, and other diseases associated with treatment with immunosuppressive drugs or radiation therapy; solid organ transplantation, multiple myeloma

2. **Screen for contraindications and precautions**

   Contraindications

   - Do not give PCV13 to a child who has experienced a serious reaction (e.g., anaphylaxis) to a prior dose of the vaccine or to any of its components (including to any diphtheria toxoid-containing vaccine). For information on vaccine components, refer to the manufacturers' package insert (www.immunize.org/fda) or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.

   Precautions

   - Moderate or severe acute illness with or without fever

3. **Provide Vaccine Information Statements**

   Provide all patients (or, in the case of minors, their parent, or legal representative) 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 www.immunize.org/vis. (For information about how to document that the VIS was given, see section 6 titled "Document Vaccination.")

4. Prepare to Administer Vaccine

Choose the needle gauge, needle length, and injection site according to the following chart:

AGE OF CHILD/TEEN	NEEDLE GAUGE	NEEDLE LENGTH	INJECTION SITE
Younger than 12 months	22–25	1"	Anterolateral thigh
12 through 35 months	22–25	1–11/4" 5/8"–1"	Anterolateral thigh muscle** Deltoid muscle of arm
Children (3 through 10 years)	22–25	5/8"–1" 1–11/4"	Deltoid muscle of arm** Anterolateral thigh muscle
Adolescents and Teens (11 through 18 years)	22–25	5/8"–1" 1–11/2"	Deltoid muscle of arm** Anterolateral thigh muscle

* Preferred site.

**A 5/8" needle may be used for children for IM injection in the deltoid muscle only if the skin is stretched tight, the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle.

5. Administer pneumococcal conjugate vaccine (PCV13), 0.5 mL, via the intramuscular (IM) route, to all healthy children as well as children with a medical condition or other risk factor according to the guidance on page 4 ("Recommendations for Pneumococcal Vaccines Use in Children and Teens").

Table 1. Recommended Schedule for Administering Pneumococcal Conjugate Vaccine (PCV13)

Child's age now	Vaccination history of PCV13	Recommended PCV13 Schedule (For minimum interval guidance for catch-up vaccination, see * below)
2 through 6 months	0 doses	3 doses, 8 weeks* apart; 4th dose at age 12–15 months
	1 dose	2 doses, 8 weeks* apart; 4th dose at age 12–15 months
	2 doses	1 dose, 8 weeks* after the most recent dose; 4th dose at age 12–15 months
7 through 11 months	0 doses	2 doses, 8 weeks apart* and a 3rd dose at age 12–15 months
	1 or 2 doses before age 7 months	1 dose at age 7–11 months and a 2nd dose at age 12–15 months, at least 8 weeks after the most recent dose
	1 dose at age 7–11 months	2 doses: 1 dose at age 7–11 months and a 2nd dose at age 12–15 months, at least 8 weeks after the most recent dose
	2 doses at age 7–11 months	1 dose at age 12–15 months
12 through 23 months	0 doses	2 doses, at least 8 weeks apart
	1 dose before age 12 months	2 doses, at least 8 weeks apart

	1 dose at or after age 12 months	1 dose, at least 8 weeks after the most recent dose
	2 or 3 doses before age 12 months	1 dose, at least 8 weeks after the most recent dose
	2 doses at or after age 12 months	0 doses
24 through 59 months (healthy children)	0 doses	1 dose
	Any incomplete schedule**	1 dose, at least 8 weeks after the most recent dose
24 through 71 months (children with underlying medical condition as described in Table 3 below)	Unvaccinated or any incomplete schedule** of less than 3 doses	2 doses: 1st dose at least 8 weeks after most recent dose and a 2nd dose at least 8 weeks later
	Any incomplete schedule ** of 3 doses	1 dose, at least 8 weeks after the most recent dose
6 through 18 years with immunocompromising condition, functional or anatomic asplenia (see specific conditions in Table 3 below), cerebrospinal fluid leak, or cochlear implant	No history of PCV13	1 dose

Table 2. Recommended Schedule for Administering Pneumococcal Polysaccharide Vaccine (PPSV 23)

Risk Group	Schedule for	Revaccination with
Immunocompetent children and teens with underlying medical condition (see Table 3 at right)	Give 1 dose of PPSV23 at age 2 years or older and at least 8 weeks after last dose of PCV13	Not indicated
Children and teens with immunocompromising condition, functional or anatomic asplenia (see specific conditions in Table 3 at right)	Give 1 dose of PPSV23 at age 2 years or older and at least 8 weeks after last dose of PCV13	Give 1 additional dose of PPSV23 at least 5 years following the first PPSV23; the next recommended dose would be at age 65 years
Children and teens age 6 years & older with chronic liver disease, alcoholism	If no history of PPSV23, give 1 dose of PPSV23 at least 8 weeks after any prior PCV13 dose	Not indicated

Table 3. Medical Conditions and Other Risk Factors That Are Indications for PCV13 or PPSV23

Risk Group	Condition
Immunocompe- tent children and teens age 2 years & older with risk condition	Chronic heart disease (particularly cyanotic congenital heart disease and cardiac failure); chronic lung disease (including asthma if treated with prolonged high-dose oral corticosteroids); diabetes mellitus; cerebrospinal fluid leak; cochlear implant; for ages 6 years and older: chronic liver disease, alcoholism
Children and teens age 2 years & older with functional or anatomic asplenia	• Sickle cell disease and other hemoglobinopathies • Congenital or acquired asplenia, or splenic dysfunction
Children and teens age 2 years & older with immunocom - promising condition	• HIV infection • Chronic renal failure and nephrotic syndrome • Diseases associated with treatment with immunosuppressive drugs or radiation therapy (e.g., malignant neoplasms, leukemias, lymphomas, and Hodgkin disease; or solid organ transplantation) • Congenital immunodeficiency (includes B- [humoral] or T-lymphocyte deficiency; complement deficiencies, particularly C1, C2, C3, or C4 deficiency; and phagocytic disorders [excluding chronic granulomatous disease])

* Minimum interval between doses: For children younger than age 12 months: 4 weeks; for children age 12 months and older: 8 weeks.

** For information on completion of incomplete schedules, visit current "Recommended Immunization Schedule for Children and Adolescents Age 18 Years or Younger—United States" at www.cdc.gov/vaccines/schedules/hcp/child-adolescent.html.

6. Document Vaccination

Document each patient's vaccine administration information and follow-up in the following places:

Medical record: Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and address and, if appropriate, the title of the person administering the vaccine. You must also document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Note that medical records/charts should be documented and retained in accordance with applicable state laws and regulations. If vaccine was not administered, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal). Discuss the need for vaccine with the patient (or, in the case of a minor, their parent or legal representative) at the next visit.

Personal immunization record card: Record the date of vaccination and the name/location of the administering clinic.

Immunization Information System (IIS) or "registry": Report the vaccination to the appropriate state/local IIS, if available.

7. Be Prepared to Manage Medical Emergencies

Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications. For IAC's "Medical Management of Vaccine Reactions in Children and Teens in Community Settings," go to www.immunize.org/catg.d/p3082a.pdf. For "Medical Management of Vaccine Reactions in Adults in Community Settings," go to www.immunize.org/catg.d/p3082.pdf. To prevent syncope, vaccinate patients while they are seated or lying down and consider observing them for 15 minutes after receipt of the vaccine.

8. Report Adverse Events to VAERS

Report all adverse events following the administration of pneumococcal vaccine to the federal Vaccine Adverse Event Reporting System (VAERS). To submit a VAERS report online (preferred) or to download a writable PDF form, go to https://www.vaers.hhs.gov/report event.html. Further assistance is available at (800) 822-7967.

STANDING ORDERS FOR
Administering Pneumococcal Polysaccharide Vaccine (PPSV23) to Children and Teens

Purpose

To reduce morbidity and mortality from pneumococcal disease by vaccinating all children and teens who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy

Where allowed by state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess the need for and vaccinate children and teens who meet any of the criteria below.

Procedure

1. Assess Children and Teens in Need of Vaccination

a. CDC recommend 13-Valent Pneumococcal Conjugate Vaccine (PCV13) or 15-Valent Pneumococcal Conjugate Vaccine (PSV15) for all infants as a series of 4 doses

- Give 1 dose at 2 months, 4 months, 6 months and 12 through 15 months.
    - Children who miss their shots or start the series later than recommended should still get vaccinated. The number of doses recommended and the intervals between doses will depend on the child's age when vaccination begins

b. Children ages 2-4 years old without certain medical conditions

- CDC recommends PCV13 or PCV15 vaccination for children 2 through 4 years old who are unvaccinated or received an incomplete pneumococcal conjugate vaccine (either PCV13 or PCV15) series. PCV13 and PCV15 can be used interchangeably.
    - Give 1 dose of PCV13 or PCV15

c. CDC recommends pneumococcal vaccination for children 2 through 5 years old who have certain medical conditions that increase their risk of pneumococcal disease based on having any of the following conditions:

- chronic heart disease, particularly cyanotic congenital heart disease and cardiac failure
- chronic lung disease, including asthma if treated with high-dose oral corticosteroid therapy
- diabetes mellitus
- cerebrospinal fluid leak
- cochlear implant
    - Give 2 doses of a pneumococcal conjugate vaccine (either PCV13 or PCV15) if they are unvaccinated or received an incomplete pneumococcal conjugate vaccine series with <3 doses before 24 months of age. Give the second dose at least 8 weeks after the first.
    - Give 1 dose of PCV13 or PCV15 if they received 3 doses of a pneumococcal conjugate vaccine before 12 months but have not received their fourth booster dose.

- Give 1 dose of PPSV23 at least 8 weeks after the pneumococcal conjugate vaccine series is complete.

d. CDC recommends pneumococcal vaccination for children 2 through 5 years old who have certain medical conditions that increase their risk of pneumococcal disease based on having any of the following conditions
    - sickle cell disease and other hemoglobinopathies
    - anatomic or functional asplenia
    - congenital or acquired immunodeficiency
    - HIV infection
    - chronic renal failure or nephrotic syndrome
    - diseases associated with treatment with immunosuppressive drugs or radiation therapy, including malignant neoplasms, leukemias, lymphomas, and Hodgkin disease
    - solid organ transplantation
        - Give 2 doses of a pneumococcal conjugate vaccine (either PCV13 or PCV15) if they are unvaccinated or received an incomplete pneumococcal conjugate vaccine series with <3 doses before 24 months of age. Give the second dose at least 8 weeks after the first.
        - Give 1 dose of PCV13 or PCV15 if they received 3 doses of a pneumococcal conjugate vaccine before 12 months but have not received their fourth booster dose.
        - Give 2 doses of PPSV23 after the pneumococcal conjugate vaccine series is complete. Give the first dose at least 8 weeks after any prior pneumococcal conjugate vaccine dose, then give the second dose of PPSV23 at least 5 years after the first PPSV23 dose

e. CDC recommends pneumococcal vaccination for children 6 through 18 years old who have certain medical conditions that increase their risk of pneumococcal disease based on having any of the following conditions
    - Cerebrospinal fluid leak
    - Cochlear implant
        - Give 1 dose of a pneumococcal conjugate vaccine (either PCV13 or PCV15) if they have not received any doses of a pneumococcal conjugate vaccine. Administer PCV13 or PCV15 before giving any recommended doses of PPSV23.
        - Give 1 dose of PPSV23 (if not already given earlier in childhood) at least 8 weeks after PCV13 or PCV15.

f. CDC recommends pneumococcal vaccination for children 6 through 18 years old who have certain medical conditions that increase their risk of pneumococcal disease based on having any of the following conditions

    - Chronic renal failure or nephrotic syndrome
    - Congenital immunodeficiency
    - B- (humoral) or T-lymphocyte deficiency
    - Complement deficiency, particularly C1, C2, C3, or C4 deficiency
    - Phagocytic disorder, excluding chronic granulomatous disease
    - Congenital or acquired asplenia, or splenic dysfunction
    - Diseases associated with treatment of immunosuppressive drugs or radiation therapy
    - Hodgkin disease
    - Leukemia
    - Lymphoma
    - Malignant neoplasm
    - Solid organ transplant
    - HIV infection
    - Sickle cell disease or other hemoglobinopathies

- Give 1 dose of a pneumococcal conjugate vaccine (either PCV13 or PCV15) if they have not received any doses of a pneumococcal conjugate vaccine. Administer PCV13 or PCV15 before giving any recommended doses of PPSV23.
- Ensure the child receives 2 doses of PPSV23. The first dose of PPSV23 should be given at least 8 weeks after any prior pneumococcal conjugate vaccine dose, then the second dose of PPSV23 should be given at least 5 years after the first dose of PPSV23.

g. CDC recommends pneumococcal vaccination for children 6 through 18 years old who have certain medical conditions that increase their risk of pneumococcal disease based on having any of the following conditions
    - Chronic heart disease, particularly cyanotic congenital heart disease and cardiac failure
    - Chronic lung disease, including asthma if treated with prolonged high-dose oral corticosteroid therapy
    - Diabetes mellitus
        - Give 1 dose of PPSV23 (if not already given earlier in childhood).

2. Screen for contraindications and precautions *Contraindications*

▪ Do not give PPSV23 to a child or teen who has experienced a serious reaction (e.g., anaphylaxis) to a prior dose of the vaccine or to any of its components. For information on vaccine components, refer to the manufacturer's package insert (www.immunize.org/fda) or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.

Precautions

▪ Moderate or severe acute illness with or without fever

3. Provide Vaccine Information Statements

Provide all patients (or, in the case of minors, their parent, or legal representative) 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 www.immunize.org/vis. (For information about how to document that the VIS was given, see section 6 titled "Document Vaccination.")

4. Prepare to Administer Vaccine

PCV administered intramuscular (IM) or PPSV23 may be administered via either the intramuscular (IM) or subcutaneous (SC) route. The PCV and PPSV23 dosage is 0.5 mL.

If vaccine is to be administered by the **intramuscular route**, choose the needle gauge, needle length, and injection site according to the following chart

AGE OF CHILD/TEEN	NEEDLE GAUGE	NEEDLE LENGTH	INJECTION SITE
Younger than 12 months	22–25	1"	Anterolateral thigh
12 through 35 months	22–25	1–11/4" ⅝***–1"	Anterolateral thigh muscle** Deltoid muscle of arm
Children (3 through 10 years)	22–25	⅝***–1" 1–11/4"	Deltoid muscle of arm** Anterolateral thigh muscle
Adolescents and Teens (11 through 18 years)	22–25	⅝***–1" 1–11/2"	Deltoid muscle of arm** Anterolateral thigh muscle

* A 5/8" needle may be used for children for IM injection in the deltoid muscle only if the skin is stretched tight, the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle.

** Preferred site.

If vaccine is to be administered by the **subcutaneous route**, choose the needle gauge, needle length, and injection site according to the following chart:

NEEDLE GAUGE	NEEDLE LENGTH	INJECTION SITE
23–25	5/8"	Fatty tissue over triceps or fatty tissue over anterolateral thigh muscle

Additional vaccine information:

- PCV13 https://www.fda.gov/files/vaccines%2C%20blood%20%26%20biologics/published/Package-Insert----- Prevnar-13.pdf
- PCV 15 https://www.fda.gov/media/150819/download
- PPSV23 https://www.fda.gov/media/80547/download

5. Document Vaccination

Document each patient's vaccine administration information and follow-up in the following places:

Medical record: Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. You must also document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Note that medical records/charts should be documented and retained in accordance with applicable state laws and regulations. If vaccine was not administered, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal). Discuss the need for vaccine with the patient (or, in the case of a minor, their parent or legal representative) at the next visit.

Personal immunization record card: Record the date of vaccination and the name/location of the administering clinic.

Immunization Information System (IIS) or "registry": Report the vaccination to the appropriate state/local IIS, if available.

6. Be Prepared to Manage Medical Emergencies

Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications. For IAC's "Medical Management of Vaccine Reactions in Children and Teens," go to www.immunize.org/catg.d/p3082a.pdf. For "Medical Management of Vaccine Reactions in Adult Patients," go to www.immunize.org/catg.d/p3082.pdf. To prevent syncope, vaccinate patients while they are seated or lying down and consider observing them for 15 minutes after receipt of the vaccine.

7. Report Adverse Events to VAERS

Report all adverse events following the administration of PPSV23 vaccine to the federal Vaccine Adverse Event Reporting System (VAERS). To submit a VAERS report online (preferred) or to download a writable PDF form, go to https://vaers.hhs.gov/reportevent.html. Further assistance is available at (800) 822-7967.

STANDING ORDERS FOR
Administering Pneumococcal Vaccines (PCV15, PCV20, and PPSV23) to Adults

Purpose

To reduce morbidity and mortality from pneumococcal disease by vaccinating all adults who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Policy

Where allowed by state law, standing orders enable eligible nurses, pharmacists, and other healthcare professionals to assess the need for vaccination and to vaccinate adults who meet any of the criteria below.

Procedure

1. **Assess Adults for Need of Vaccination** against *Streptococcus pneumoniae* (pneumococcus) infection according to the following criteria:

   Routine Pneumococcal Vaccination

   Age 65 years or older

   Risk-Based Pneumococcal Vaccination

   Age 19 through 64 years with any of the following conditions:

   - **Non-immunocompromising conditions:** Chronic heart disease[1], chronic lung disease[2], diabetes mellitus, chronic liver disease, cirrhosis, cigarette smoking, alcoholism, cochlear implant, cerebrospinal fluid (CSF) leak
   - **Immunocompromising conditions:** Sickle cell disease, other hemoglobinopathy, congenital or acquired asplenia, congenital or acquired immunodeficiency[3], HIV, chronic renal failure, nephrotic syndrome, leukemia, lymphoma, multiple myeloma, generalized malignancy, Hodgkin's disease, solid organ transplant, iatrogenic immunosuppression[4]

   1. Chronic heart disease includes congestive heart failure and cardiomyopathies.

   2. Chronic lung disease includes chronic obstructive pulmonary disease, emphysema, and asthma.

   3. Congenital or acquired immunodeficiency includes B- (humoral) or T-lymphocyte deficiency, complement deficiencies (particularly C1, C2, C3, and C4 deficiencies), and phagocytic disorders (excluding chronic granulomatous disease).

   4. Iatrogenic immunosuppression includes diseases requiring treatment with immunosuppressive drugs, including long-term systemic corticosteroids, and radiation therapy.

2. **Screen for Contraindications and Precautions**

   Contraindications

   Do not give pneumococcal conjugate vaccine (PCV15, Vaxneuvance, Merck; PCV20, Prevnar20, Pfizer) or pneumococcal polysaccharide vaccine (PPSV23, Pneumovax 23, Merck) to a person who has experienced a serious systemic or anaphylactic reaction to a

prior dose of the vaccine or to any of its components. For a list of vaccine components, refer to the manufacturer's package insert (www.immunize.org/fda) or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.

Precautions

Moderate or severe acute illness with or without fever

3. Provide 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 www.immunize.org/vis. (For information about how to document that the VIS was given, see section 6 titled "Document Vaccination.")

4. Prepare to Administer Vaccine

PCV15 and PCV20 must be given IM. PPSV23 may be administered either intramuscularly (IM) or subcutaneously (Subcut).

For vaccine that is to be administered IM, choose the needle gauge, needle length, and injection site according to the following chart:

GENDER AND WEIGHT OF PATIENT	NEEDLE GAUGE	NEEDLE LENGTH	INJECTION SITE
Female or male less than 130 lbs	22–25	5/8"*–1"	Deltoid muscle of arm
Female or male 130–152 lbs	22–25	1"	Deltoid muscle of arm
Female 153–200 lbs	22–25	1–11/2"	Deltoid muscle of arm
Male 153–260 lbs	22–25	1–11/2"	Deltoid muscle of arm
Female 200+ lbs	22–25	11/2"	Deltoid muscle of arm
Male 260+ lbs	22–25	11/2"	Deltoid muscle of arm
Female or male, any weight	22–25	1"*–11/2"	Anterolateral thigh muscle

* Alternative needle lengths may be used for IM injections if the skin is stretched tight, the subcutaneous tissue is not bunched, and the injection is made at a 90° angle to the skin as follows: a) a 5/8" needle for patients weighing less than 130 lbs (<60 kg) or b) a 1" needle for administration in the thigh muscle for adults of any weight.

If you prefer Subcutaneous injection of PPSV23, choose a 23–25 gauge, 5/8" needle for injection into the fatty tissue overlying the triceps muscle.

5. Administer PCV15, PCV20, and PPSV23, 0.5 mL, according to the following schedules based on the recipient's history of pneumococcal vaccination:

- PCV15 and PCV20 must be administered by the IM route.
- PPSV23 may be administered either IM or Subcutaneous.

Recommendations for a) all adults age 65 years or older and b) all adults age 19 through 64 years with an indication for pneumococcal vaccination due to a medical condition or other risk factor:

For adults with no or unknown history of any pneumococcal vaccination: Select ***only*** one of the two options below

Option 1		Option 2
Administer PCV20	or	Administer PCV15, then Administer PPSV23 at least one year later (1)

1. For adults with an immunocompromising condition, cochlear implant, or CSF leak, a shorter interval of at least 8 weeks is recommended when administering PPSV23 (or PCV20 if PPSV23 is unavailable) following prior PCV13; an 8-week interval can be considered when PPSV23 is administered after PCV15.

For adults who have only received PPSV23: Select ***only*** one of the two options below.

Note: No further doses of PPSV23 are indicated because the patients have already had it.

Option 1		Option 2
Administer PCV20 at least 1 year after PPSV23	or	Administer PCV15 at least 1 year after PPSV23

For adults with a history of PCV13 vaccination with or without a history of PPSV23: Select option below based on patient's age

Table 1. Routine vaccination for all adults 65 and older

HISTORY OF PCV	HISTORY OF PPSV23	RECOMMENDED VACCINATION SCHEDULE
PCV13	0 or unknown	Administer PPSV23 at least 1 year after PCV13; if PPSV23 is unavailable,* administer 1 dose of PCV20. (1)
PCV13	PPSV23 at younger than 65 yrs	Administer PPSV23 at least 5 years after previous dose and at least 1 year after PCV13; if PPSV23 is unavailable,* administer 1 dose of PCV20. (1)
PCV13	PPSV23 at 65 yrs or older	No additional doses recommended

Table 2. Risk-based vaccination schedule for adults ages 19 through 64 years

HISTORY OF PCV	HISTORY OF PPSV23	RECOMMENDED VACCINATION SCHEDULE
PCV13	0 or unknown	Administer PPSV23 at least 1 year after PCV13; if PPSV23 is unavailable, * administer PCV20. (1,2)
PCV13	1 dose	No additional doses recommended when younger than age 65 years; however, for adults with an immunocompromising condition, administer PPSV23 #2 at least 5 years after PPSV23 dose #1 and at least 1 year after PCV13. (1,2)
PCV13	2 doses	No additional doses recommended when younger than age 65 yrs. (2)

*Unavailable = not in stock at time of vaccination visit

1. For adults with an immunocompromising condition, cochlear implant, or CSF leak, a shorter interval of at least 8 weeks is recommended when administering PPSV23 (or PCV20 if PPSV23 is unavailable) following prior PCV13; an 8-week interval can be considered when PPSV23 is administered after PCV15.

2. For adults age 19 through 64 years with an immunocompromising condition, administer PPSV23 #2 at least 5 years after PPSV23 #1. If PPSV23 #2 is also administered before age 65, administer PPSV23 #3 after the 65th birthday and at least 5 years after #2. If PCV20 is administered because PPSV23 is unavailable,* no additional doses of PPSV23 are indicated.

6. Document Vaccination

Document each patient's vaccine administration information and follow up in the following places:

Medical record: Document the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. You must also document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Note that

medical records/charts should be documented and retained in accordance with applicable state laws and regulations. If vaccine was not administered, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal). Discuss the need for vaccine with the patient at the next visit.

Personal immunization record card: Record the date of vaccination and the name/location of the administering clinic.

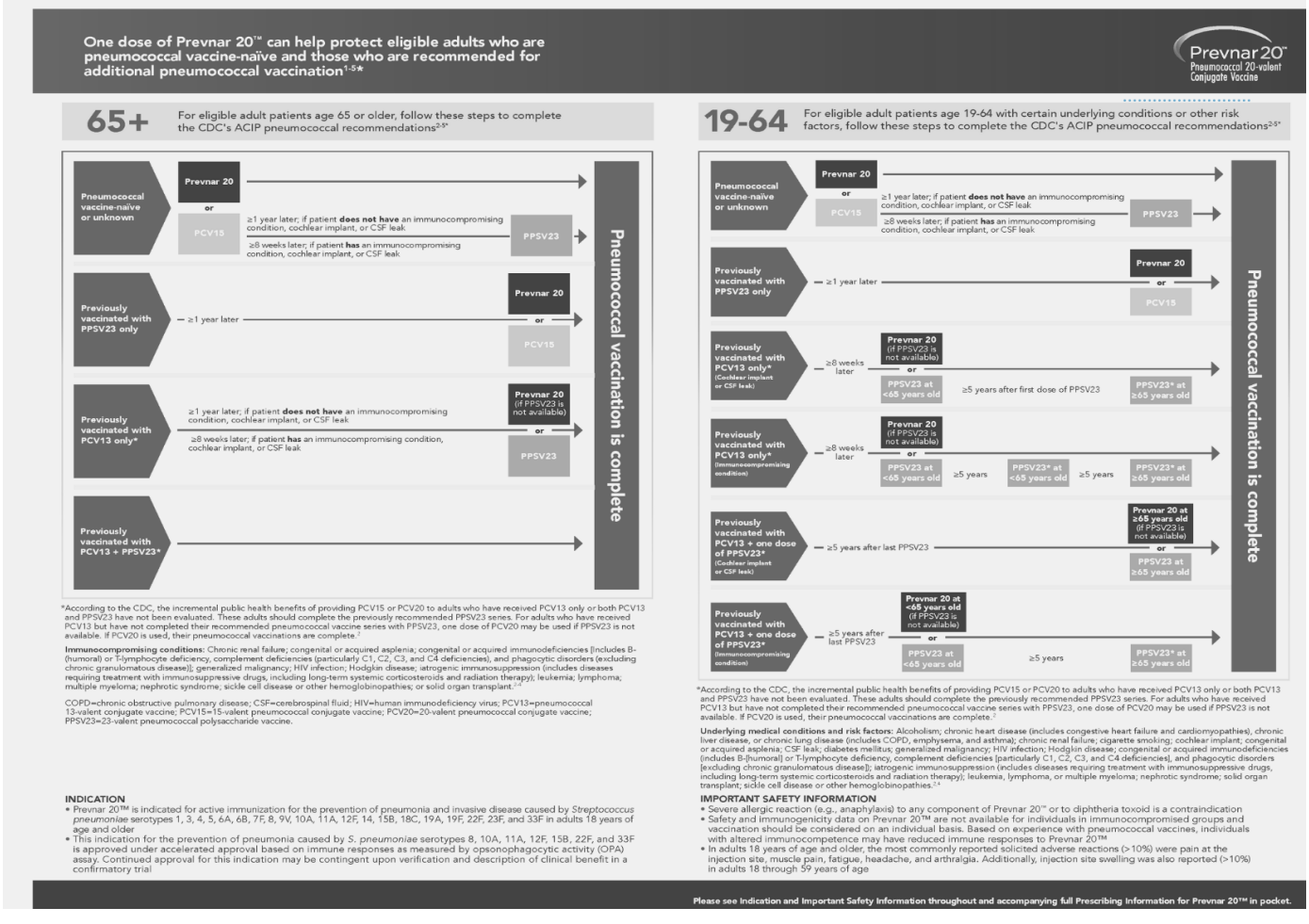
Immunization Information System (IIS) or "registry": Report the vaccination to the appropriate state/local IIS, if available.

7. Be Prepared to Manage Medical Emergencies

Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications. For Immunize.org's "Medical Management of Vaccine Reactions in Adults in a Community Setting," go to www.immunize.org/catg.d/p3082. pdf. To prevent syncope, vaccinate patients while they are seated or lying down and consider observing them for 15 minutes after receipt of the vaccine

8. Report All Adverse Events to VAERS

Report all adverse events following the administration of pneumococcal vaccine to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov. To submit a VAERS report online (preferred) or to download a writable PDF form, go to https://www.vaers.hhs.gov/reportevent.html. Further assistance is available at (800) 822-7967.



Standing Orders for Administering Rotavirus Vaccine to Infants

Purpose

- To reduce morbidity and mortality from rotavirus disease by vaccinating all infants who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy

- Where allowed by state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess the need for and vaccinate children and teens who meet any of the criteria below.

- **Review the package insert prior to administration and confirm storage and handling guidance.**

Procedure

- **Assess Infants in Need of Vaccination** against rotavirus disease based on the following criteria:
    - ***Routine rotavirus vaccination***
        - Age 2 months through 14 weeks, 6 days who have not initiated a series of rotavirus vaccine
        - Age 8 months, 0 days or younger who have not completed a series of rotavirus vaccine

Screen for contraindications and precautions

- **Contraindications**
    - Do not give rotavirus vaccine (Rotarix [RV1] by GSK or RotaTeq [RV5] by Merck) to a child who has experienced a serious reaction (e.g., anaphylaxis) to a prior dose of the vaccine or to any of its components. For information on vaccine components, refer to the manufacturers' package insert (www.immunize.org/fda) or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf. If child has allergy to latex, use RV5.
    - Do not give rotavirus vaccine to an infant who has had a diagnosis of severe combined immunodeficiency (SCID).
    - Do not give rotavirus vaccine to an infant who has a history of intussusception.
- **Precautions**
    - Moderate or severe acute illness. with or without fever
    - Altered immunocompetence other than SCID
    - Chronic gastrointestinal disease
    - For RV1 only, spina bifida or bladder exstrophy

Provide Vaccine Information Statements

- Provide all patients (or, in the case of minors, their parent, or legal representative) 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 www.immunize.org/vis. (For information about how to document that the VIS was given, see section 6 titled "Document Vaccination.")

Prepare to Administer Vaccine

- Both rotavirus vaccines (RV1 and RV5) are administered via the oral route. RV1 also needs to be

reconstituted with the supplied diluent no more than 24 hours before use. The schedule for administering each vaccine is as follows:

- Schedule for routine vaccination:

VACCINE PRODUCT	SCHEDULE
Rotarix (RV1)	Ages 2m[1], 4m[2,3]
RotaTeq (RV5)	Ages 2m[1], 4m[2], 6m[2,3]

1 May give dose #1 as early as age 6 weeks. If not given by age 2 months, vaccine may be initiated at an older age but not exceeding age 14 weeks, 6 days.
2 Intervals between doses may be as short as 4 weeks.
3 Give final dose no later than age 8 months, 0 days.
Note: If prior vaccination included use of a different or unknown brand(s), a total of 3 doses should be given.

Administer Rotavirus Vaccine (RV1 or RV5)

- To all healthy children via the oral route according to the guidance.

Document Vaccination

- Document each patient's vaccine administration information and follow-up in the following places:
    - ***Medical record:*** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and address and, if appropriate, the title of the person administering the vaccine. You must also document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Note that medical records/charts should be documented and retained in accordance with applicable state laws and regulations. If vaccine was not administered, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal). Discuss the need for vaccine with the patient (or, in the case of a minor, their parent or legal representative) at the next visit.
    - ***Personal immunization record card:*** Record the date of vaccination and the name/location of the administering clinic.
    - ***Immunization Information System (IIS) or "registry":*** Report the vaccination to the appropriate state or local IIS, if available.

Be Prepared to Manage Medical Emergencies

- Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications. For IAC's "Medical Management of Vaccine Reactions in Children and Teens," go to www.immunize.org/catg.d/p3082a.pdf. For "Medical Management of Vaccine Reactions in Adult Patients," go to www.immunize.org/catg.d/p3082.pdf.
- To prevent syncope, vaccinate patients while they are seated or lying down and consider observing them for 15 minutes after receipt of the vaccine.

Report Adverse Events to VAERS

- Report all adverse events following the administration of rotavirus vaccine to the federal Vaccine Adverse Event Reporting System (VAERS). To submit a VAERS report online (preferred) or to download a writable PDF form, go to https://www.vaers.hhs.gov/reportevent.html. Further assistance is available at (800) 822-7967.

STANDING ORDERS FOR
Administering Td/Tdap Vaccine to Adults

Purpose

To reduce morbidity and mortality from tetanus, diphtheria, and pertussis infection by vaccinating all adults who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Policy

Where allowed by state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess the need for vaccination and to vaccinate adults who meet any of the criteria below.

Procedure

1. **Assess Adults for Need of Vaccination** against tetanus, diphtheria, and pertussis based on the following criteria:
   - Lack of documentation of ever receiving a dose of tetanus and diphtheria toxoids and acellular pertussis vaccine (Tdap) as an adolescent or adult
   - Currently pregnant (preferably between 27 and 36 weeks gestation) and no documentation of Tdap given during current pregnancy
   - Lack of documentation of receiving at least 3 doses of tetanus- and diphtheria-containing toxoids
   - Completion of a 3-dose primary series of tetanus- and diphtheria-containing toxoids with no documentation of receiving a booster dose in the previous 10 years
   - Recent deep and dirty wound (e.g., contaminated with dirt, feces, saliva) and lack of evidence of having received tetanus toxoid-containing vaccine in the previous 5 years

2. **Screen for Contraindications and Precautions**

   Contraindications

   - Do not give Tdap or Td to a person who has experienced a serious systemic or anaphylactic reaction to a prior dose of either vaccine or to any of its components. For a list of vaccine components, refer to the manufacturer's package insert (www.immunize.org/fda) or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/ appendices/B/excipient-table-2.pdf.
   - Do not give Tdap to a person who has experienced encephalopathy within 7 days following DTP/DTaP/Tdap not attributable to another identifiable cause.

   Precautions

   - History of Guillain-Barré syndrome within 6 weeks of a previous dose of tetanus toxoid-containing vaccine
   - History of an Arthus-type hypersensitivity reaction after a previous dose of tetanus or diphtheria toxoid-containing vaccine; in such cases, defer vaccination until at least 10 years have elapsed since the last tetanus toxoid- containing vaccine
   - Moderate or severe acute illness with or without fever
   - For Tdap only: progressive or unstable neurologic disorder, uncontrolled seizures or progressive encephalopathy until the patient's treatment regimen has been established and the condition has stabilized

3. **Provide 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 www.immunize.org/vis. (For information about how to document that the VIS was given, see section 6 titled "Document Vaccination.")

4. Prepare to Administer Vaccine

Choose the needle gauge, needle length, and injection site according to the following chart:

GENDER AND WEIGHT OF PATIENT	NEEDLE GAUGE	NEEDLE LENGTH	INJECTION SITE
Female or male less than 130 lbs	22–25	5/8*–1"	Deltoid muscle of arm
Female or male 130–152 lbs	22–25	1"	Deltoid muscle of arm
Female 153–200 lbs	22–25	1–11/2"	Deltoid muscle of arm
Male 153–260 lbs	22–25	1–11/2"	Deltoid muscle of arm
Female 200+ lbs	22–25	11/2"	Deltoid muscle of arm
Male 260+ lbs	22–25	11/2"	Deltoid muscle of arm

* A 5/8" needle may be used in patients weighing less than 130 lbs (<60 kg) for IM injection in the deltoid muscle only if the skin is stretched tight, the subcutaneous tissue is not bunched, and the injection is made at a 90° angle to the skin.

5. Administer Td or Tdap Vaccine, 0.5 mL, via the intramuscular (IM) route, according to the following criteria and schedule:

The routine schedule for Td or Tdap vaccination in adults with no history of receiving any diphtheria-, tetanus-, and/or pertussis-containing vaccine as children or adults, is to administer a 3-dose series at 0, 1, and 6–12 month intervals, including one dose of Tdap, preferably as the first dose, followed by a either Td or Tdap booster every 10 years.

HISTORY OF PREVIOUS DTP, DTaP, Td, or Tdap VACCINATION	DOSE AND SCHEDULE FOR ADMINISTRATION OF Td and Tdap**
0 documented doses, or none known	Give Tdap as dose #1. Give dose #2 (Td or Tdap) at least 4 weeks later, and dose #3 (Td or Tdap) 6–12 months after dose #2.
1 previous dose (not Tdap)	Give Tdap as dose #2 at least 4 weeks after dose #1. Give dose #3 (Td or Tdap) 6–12 months after dose #2.
1 previous dose (as Tdap)	Give Td or Tdap as dose #2 at least 4 weeks after dose #1. Give dose #3 (Td or Tdap) 6–12 months after dose #2.
2 previous doses (none Tdap)	Give Tdap as dose #3 at least 6 months after dose #2.
2 previous doses (including 1 Tdap)	Give dose #3 (Td or Tdap) at least 6 months after dose #2.
3 or more previous doses (none Tdap)	Give Tdap as soon as possible. (You do not need to wait 10 years from previous dose.)
3 or more previous doses (including 1 dose of Tdap)	Give Td or Tdap booster every 10 years unless patient needs pro-phylaxis for wound management sooner.

**Either Td or Tdap may be given for catch-up and booster doses.

Tdap vaccination for pregnant women

Pregnant women should receive Tdap during **each** pregnancy, preferably early during the window of 27 through 36 weeks' gestation, regardless of number of years since prior Td or Tdap vaccination.

6. Document Vaccination

Document each patient's vaccine administration information and follow up in the following places:

Medical record: Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. You must also document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Note that medical records/charts should be documented and retained in accordance with applicable state laws and regulations. If vaccine was not administered, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal). Discuss the need for vaccination with the patient at the next visit.

Personal immunization record card: Record the date of vaccination and the name/location of the administering clinic.

Immunization Information System (IIS) or "registry": Report the vaccination to the appropriate state/local IIS, if available.

7. Be Prepared to Manage Medical Emergencies

Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications. For IAC's "Medical Management of Vaccine Reactions in Adults in a Community Setting," go to www.immunize.org/catg.d/p3082.pdf. To prevent syncope, vaccinate patients while they are seated or lying down and consider observing them for 15 minutes after receipt of the vaccine.

8. Report all Adverse Events to VAERS

Report all adverse events following the administration of tetanus-, diphtheria-, and pertussis-containing vaccine to the federal Vaccine Adverse Event Reporting System (VAERS). To submit a VAERS report online (preferred) or to download a writable PDF form, go to http://vaers.hhs.gov/reportevent.html. Further assistance is available at (800) 822-7967.

Standing Orders For
Administering Tdap To Pregnant Women

Purpose

- To reduce morbidity and mortality from tetanus, diphtheria, and pertussis by vaccinating all pregnant women who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Policy

- Where allowed by state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess the need for and vaccinate pregnant women who meet any of the criteria below.
- **Review the package insert prior to administration and confirm storage and handling guidance.**

Procedure

- **Assess pregnant women, including teens, for need of vaccination** against tetanus, diphtheria, and pertussis based on the following criteria:
    - Currently pregnant (preferably between 27- and 36-weeks gestation) and no documentation of receiving a dose of tetanus and diphtheria toxoids and acellular pertussis vaccine (Tdap) during current pregnancy
    - Lack of documentation of receiving at least 3 doses of tetanus- and diphtheria-containing toxoids (Tdap/Td)

Screen for contraindications and precautions

- **Contraindications**
    - Do not give Tdap vaccine to a pregnant woman or teen who has experienced a serious systemic or anaphylactic reaction to a prior dose of the vaccine or to any of its components. For information on vaccine components, refer to the manufacturer's package insert (www.immunize.org/fda) or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.
    - Do not give Tdap to a pregnant woman or teen who has experienced encephalopathy within 7 days following DTP/DTaP/Tdap not attributable to another identifiable cause.
- **Precautions**
    - Moderate or severe acute illness with or without fever
    - History of Guillain-Barré syndrome within 6 weeks of a previous dose of tetanus toxoid-containing vaccine
    - History of an Arthus-type hypersensitivity reaction after a previous dose of tetanus or diphtheria toxoid- containing vaccine; in such cases, defer vaccination until at least 10 years have elapsed since the last tetanus toxoid-containing vaccine
    - Coma, progressive or unstable neurologic disorder, uncontrolled seizures or progressive encephalopathy until the patient's treatment regimen has been established and the condition has stabilized

Provide Vaccine Information Statements

- Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS) available at www.immunize.org/vis. You must document in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. 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 www.immunize.org/vis. (For information about how to document that the VIS was given, see section 6 titled "Document Vaccination.")

Prepare to Administer Vaccine

Choose the needle gauge, needle length, and injection site according to the following chart:

Weight of Female Patient	Needle Gauge	Needle Length	Injection Site
Less Than 130 Lbs.	22–25	5/8"*–1"	Deltoid Muscle of Arm
130–152 Lbs.	22–25	1"	Deltoid Muscle of Arm
153–200 Lbs.	22–25	1–11/2"	Deltoid Muscle of Arm
200+ Lbs.	22–25	11/2"	Deltoid Muscle of Arm

* A 5/8" needle may be used in patients weighing less than 130 lbs (<60 kg) for IM injection in the deltoid muscle only if the skin is stretched tight, the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle to the skin.

Administer Tdap Vaccine, 0.5 mL, IM, according to the table below:

History of Previous Dtp, DTap, Td, or Tdap Vaccination	Dose and Schedule for Administration Of Tdap (During Current Pregnancy) And Subsequent Td Or Tdap
0 documented doses, or none known	Give Tdap† as dose #1. Give dose #2 (Td or Tdap) at least 4 weeks later, and dose #3 (Td or Tdap) 6–12 months after dose #2.
1 previous dose (not Tdap)	Give Tdap† as dose #2 at least 4 weeks after dose #1. Give dose #3 (Td or Tdap) 6–12 months after dose #2.
1 previous dose (as Tdap) given before current pregnancy	Give Tdap† as dose #2 and at least 4 weeks after dose #1. Give dose #3 (Td or Tdap) 6–12 months after dose #2.
2 previous doses (none Tdap)	Give Tdap† as dose #3.
2 previous doses (including 1 Tdap given before current pregnancy)	Give Tdap† as dose #3.
3 or more previous doses (none Tdap)	Give Tdap.†
3 or more previous doses (including 1 dose of Tdap given before current pregnancy)	Give Tdap.†

†Tdap should be administered early in the third trimes-ter of each preg-nancy, preferably in early part of gestational weeks 27–36.

Document Vaccination

- Document each patient's vaccine administration information and any needed follow-up in the following places:
    - *Medical record:* Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and address and, if appropriate, the title of the person administering the vaccine. Note that medical records/charts should be documented and retained in accordance with applicable state laws and regulations. If vaccine was not administered, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal). Discuss the need for vaccination with the patient at the next visit.
    - *Personal immunization record card:* Record the date of vaccination and the name/location of the administering clinic.
    - *Immunization Information System (IIS) or "registry":* Report the vaccination to the appropriate state/local IIS, if available.

Be Prepared to Manage Medical Emergencies

- Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications. For IAC's "Medical Management of Vaccine Reactions in Adults in a Community Setting," go to www.immunize.org/catg.d/p3082.pdf. For IAC's "Medical Management of Vaccine Reactions in Children and Teens in a Community Setting," go to www.immunize.org/catg.d/p3082a.pdf. To prevent syncope, vaccinate patients while they are seated or lying down and consider observing them for 15 minutes after receipt of the vaccine.

Report Adverse Events to VAERS

- Report all adverse events following the administration of Tdap vaccine to the federal Vaccine Adverse Event Reporting System (VAERS). To submit a VAERS report online (preferred) or to download a writable PDF form, go to https://vaers.hhs.gov/reportevent.html. Further assistance is available at (800) 822-7967.

STANDING ORDERS FOR
Administering Tdap/Td Vaccine to Children Age 7 Years and Older

Purpose

To reduce morbidity and mortality from tetanus, diphtheria, and pertussis by vaccinating all children and teens who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy

Where allowed by state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess the need for and vaccinate children and teens who meet any of the criteria below.

Procedure

1. **Assess Children in Need of Vaccination** against diphtheria, tetanus, and pertussis based on the following criteria:
   - Lack of documentation of at least 4 doses of diphtheria and tetanus toxoids and pertussis vaccine (DTaP), with at least one dose given after age 4 years and with the most recent dose given a minimum of 4 calendar months after the preceding dose
   - Lack of documentation of at least 3 doses of diphtheria and tetanus toxoid-containing vaccine (e.g., DT, Tdap, Td)
   - Lack of documentation of a pertussis-containing vaccine given at age 10 years or older
   - Currently pregnant (preferably between 27 and 36 weeks gestation) and no documentation of Tdap given during the current pregnancy, or
   - Completion of a 3-dose primary series of diphtheria and tetanus toxoid-containing vaccine (DTaP, DT, Tdap, Td) with receipt of the last dose being 10 years ago or longer

2. **Screen for contraindications and precautions** ***Contraindications***
   - Do not give Td or Tdap to a child or teen who has experienced a serious reaction (e.g., anaphylaxis) to a prior dose of the vaccine or to any of its components. For information on vaccine components, refer to the manufacturers' package insert (www.immunize.org/fda) or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.
   - Do not give any Tdap to a child or teen who has experienced encephalopathy not attributable to another identifiable cause within 7 days following a previous dose of DTP, DTaP or Tdap.

   Precautions
   - Moderate or severe acute illness with or without fever
   - History of an Arthus-type hypersensitivity reaction after a previous doses of tetanus or diphtheria toxoid- containing vaccine; in such cases, defer vaccination until at least 10 years have elapsed since the last tetanus toxoid-containing vaccine
   - History of Guillain-Barré syndrome within 6 weeks of previous dose of tetanus toxoid-containing vaccine
   - For Tdap only: progressive or unstable neurologic disorder (including infantile spasms), uncontrolled seizures, or progressive encephalopathy until a treatment regimen has been established and the condition has stabilized

3. **Provide Vaccine Information Statements**

   Provide all patients (or, in the case of minors, their parent, or legal representative) 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 www.immunize.org/vis. (For information about how to document that the VIS was given, see section 6 titled "Document Vaccination.")

4. Prepare to Administer Vaccine

Choose the needle gauge, needle length, and injection site according to the following chart

AGE OF CHILD/TEEN	NEEDLE GAUGE	NEEDLE LENGTH	INJECTION SITE
Children (7 through 10 years)	22–25	5/8*–1"	Deltoid muscle of arm**
		1–11/4"	Anterolateral thigh
Adolescents and Teens (11 through 18 years)	22–25	5/8*–1"	Deltoid muscle of arm**
		1–11/2"	Anterolateral thigh muscle

*A 5/8" needle may be used for children for IM injection in the deltoid muscle only if the skin is stretched tight, the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle to the skin.

**Preferred site

5. Administer Td/Tdap vaccine, 0.5 mL, via the intramuscular (IM) route, according to the following tables:

Schedule for routine vaccination

	MINIMUM AGE FOR ADOLESCENT DOSE	RECOMMENDED INTERVAL TO NEXT DOSE	MINIMUM INTERVAL TO NEXT DOSE
11–12 years[1,2,3] (Tdap)	10 years[3,4] (Tdap)	10 years[5] (Td or Tdap)	5 years[5] (Td or Tdap)

Schedule for catch-up vaccination

NUMBER OF PRIOR DOCUMENTED DOSES[5]	MINIMUM INTERVAL BETWEEN DOSES OF TD[5] AND/OR TDAP[5] STARTING FROM THE MOST RECENT DOSE GIVEN		
	DOSE 1 TO DOSE 2	DOSE 2 TO DOSE 3	DOSE 3 TO DOSE 4
Unknown	4 weeks	6 months	
0	4 weeks	6 months	
1	4 weeks	4 weeks, if dose #1 is given at younger than age 12 months; 6 months if dose #1 is given at age 12 months or older	6 months, if dose 1 given at younger than age 12 months
2		4 weeks, if dose #1 is given at younger than age 12 months; 6 months if dose #1 is given at age 12 months or older	6 months, if dose 1 given at younger than age 12 months
3			6 months, if dose 1 given at younger than age 12 months

NOTES

1. Tdap should be administered at 11–12 years. It should also be given to all pregnant teens during each pregnancy, preferably during the early part of gestational weeks 27–36.

2. Children who received Tdap at age 7 through 9 years should receive the routine Tdap dose

at age 11–12 years.
3. Children who received Tdap at age 10 years do not need to receive the routine Tdap dose at age 11–12 years.
4. The minimum age for Tdap in children with an incomplete history of DTaP is 7 years. It should be given as the first dose in the catch-up series.
5. Either Td or Tdap may be given for catch-up and booster doses

6. Document Vaccination

Document each patient's vaccine administration information and follow-up in the following places:

Medical record: Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. You must also document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Note that medical records/charts should be documented and retained in accordance with applicable state laws and regulations. If vaccine was not administered, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal). Discuss the need for vaccination with the patient (or, in the case of a minor, their parent or legal representative) at the next visit.

Personal immunization record card: Record the date of vaccination and the name/location of the administering clinic.

Immunization Information System (IIS) or "registry": Report the vaccination to the appropriate state/local IIS, if available.

7. Be Prepared to Manage Medical Emergencies

Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications. For IAC's "Medical Management of Vaccine Reactions in Children and Teens in a Community Setting," go to www.immunize.org/catg.d/p3082a.pdf. For "Medical Management of Vaccine Reactions in Adult Patients in a Community Setting," go to www.immunize.org/catg.d/p3082.pdf. To prevent syncope, vaccinate patients while they are seated or lying down and consider observing them for 15 minutes after receipt of the vaccine.

8. Report Adverse Events to VAERS

Report all adverse events following the administration of Td or Tdap vaccine to the federal Vaccine Adverse Event Reporting System (VAERS). To submit a VAERS report online (preferred) or to download a writable PDF form, go to https://www.vaers.hhs.gov/reportevent.html. Further assistance is available at (800) 822-7967.

STANDING ORDERS FOR
Administering Varicella Vaccine to Children and Teens

Purpose

To reduce morbidity and mortality from varicella disease by vaccinating all children and teens who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Policy

Where allowed by state law, standing orders enable eligible nurses and other health care professionals (e.g., pharmacists) to assess the need for vaccination and to vaccinate children and teens who meet any of the criteria below.

Procedure

1. **Assess Children and Teens for Need of Vaccination** against varicella who are age 12 months or older and who have not met any of the following criteria:
   - Documentation of at least two doses of vaccine, both given on or after age 12 months, separated by at least 12 weeks (separated by at least 4 weeks if given at age 13 years or older)
   - History of varicella disease based on diagnosis or verification of varicella by a healthcare provider
   - History of herpes zoster based on a diagnosis or verification of herpes zoster by a healthcare provider
   - Laboratory evidence of immunity or laboratory confirmation of disease
2. **Screen for Contraindications and**

   Precautions *Contraindications*

   - Do not give varicella vaccine to a child or teen who has experienced a serious systemic or anaphylactic reaction to a prior dose of vaccine or to any of its components. For a list of vaccine components, refer to the manufacturer's package insert (www.immunize.org/packageinserts) or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.
   - Do not give varicella vaccine to a child or teen who is pregnant or may become pregnant within 1 month (pregnant teens should be vaccinated upon completion or termination of pregnancy).
   - Do not give varicella vaccine to a child or teen having any malignant condition, including blood dyscrasias, leukemia, lymphomas of any type, or other malignant neoplasms affecting the bone marrow or lymphatic systems.
   - Do not give varicella vaccine to a child or teen receiving high-dose systemic immunosuppressive therapy (e.g., two weeks or more of daily receipt of 20 mg or more [or 2 mg/kg body weight or more] of prednisone or equivalent).
   - Do not give varicella vaccine to a child age 1 year or older with CD4+ T-lymphocytes percentages less that 15% or a child or teen age 6 years or older with CD4+ T-lymphocytes count less than 200 cells per microliter. *(Because HIV-infected children are at increased risk for morbidity from varicella and herpes zoster [shingles], single-antigen varicella should be considered for HIV-infected children with CD4+ T-lymphocyte percentages greater than or equal to 15% as well as for children age 9 years or older with CD4+ T-lymphocytes count greater than or equal to 200 cells per microliter.)*

- Do not give varicella vaccine to a child or teen with a family history of congenital or hereditary

immunodeficiency in first-degree relatives (e.g., parents, siblings) unless the immune competence of the potential vaccine recipient has been clinically substantiated or verified by a laboratory. Do not give combination measles-mumps-rubella and varicella vaccine (MMRV) to a child with primary or acquired immunodeficiency, including immunosuppression associated with AIDS or other clinical manifestations of HIV infections, cellular immunodeficiencies, hypogammaglobulinemia, and dysgammaglobulinemia.

Precautions

- History of recent (within the past 11 months) receipt of antibody-containing blood product (specific interval depends on product)
- History of receipt of specific antivirals (i.e., acyclovir, famciclovir, or valacyclovir) 24 hours before vaccination; avoid use of these antiviral drugs for 14 days after vaccination
- Moderate or severe acute illness with or without fever

3. Provide 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 www.immunize.org/vis. (For information about how to document that the VIS was given, see section 6 titled "Document Vaccination.")

4. Prepare to Administer Vaccine

Choose the needle gauge, needle length, and injection site according to the following chart:

NEEDLE LENGTH	INJECTION SITE
5/8"	Fatty tissue over triceps or fatty tissue over anterolateral thigh muscle.

Reconstitute the vaccine with the manufacturer-supplied diluent just prior to administration.

5. Administer Varicella Vaccine, 0.5 mL, via the subcutaneous (Subcut) route, according to the following criteria and schedule:

HISTORY OF PREVIOUS VARICELLA VACCINATION	AGE GROUP	SCHEDULE FOR ADMINISTRATION OF VARICELLA
0 documented doses, or none known	12 months to 12 years	Give dose #1. Give dose #2 at least 12 weeks later.
1 documented dose	12 months to 12 years	Give dose #2 at least 12 weeks after dose #1.
0 documented doses, or none known	13 years and older	Give dose #1. Give dose #2 at least 4 weeks later.
1 documented dose	13 years and older	Give dose #2 at least 4 weeks after dose #1.

6. Document Vaccination

Document each patient's vaccine administration information and follow up in the following places:

Medical record: Document the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. You must also document, in the patient's medical record or office log, the publication date of the VIS and the date it was

given to the patient. Note that medical records/charts should be documented and retained in accordance with applicable state laws and regulations. If vaccine was not administered, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal). Offer this vaccine at the next visit.

Personal immunization record card: Record the date of vaccination and the name/location of the administering clinic.

Immunization Information System (IIS) or "registry": Report the vaccination to the appropriate state/local IIS, if available.

7. Be Prepared to Manage Medical Emergencies

Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications. For IAC's "Medical Management of Vaccine Reactions in Children and Teens," go to www.immunize.org/catg.d/p3082a.pdf. For IAC's "Medical Management of Vaccine Reactions in Adult Patients," go to www.immunize.org/catg.d/ p3082.pdf. To prevent syncope, vaccinate patients while they are seated or lying down and consider observing them for 15 minutes after receipt of the vaccine.

8. Report All Adverse Events to VAERS

Report all adverse events following the administration of varicella vaccine to the federal Vaccine Adverse Event Reporting System (VAERS). To submit a VAERS report online (preferred) or to download a writable PDF form, go to https://www.vaers.hhs.gov/reportevent.html. Further assistance is available at (800) 822-7967.

Standing Orders for Administering Varicella Vaccine to Adults

Purpose

- To reduce morbidity and mortality from varicella disease by vaccinating all adults who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Policy

- Where allowed by state law, standing orders enable eligible nurses and other health care professionals (e.g., pharmacists) to assess the need for vaccination and to vaccinate adults who meet any of the criteria below.
- **Review the package insert prior to administration and confirm storage and handling guidance.**

Procedure

- **Assess Adults for Need of Vaccination** who (a) were born in the U.S. in 1980 or later or (b) are a healthcare worker or non-U.S.-born person and who do not meet evidence of immunity by having met any of the following criteria:
    - Documentation of receiving 2 doses of varicella vaccine, separated by at least 4 weeks
    - History of varicella disease based on diagnosis or verification of varicella by a healthcare provider
    - History of herpes zoster based on a diagnosis or verification of herpes zoster by a healthcare provider
    - Laboratory evidence of immunity or laboratory confirmation of disease

Screen for Contraindications and Precautions

- **Contraindications**
    - Do not give varicella vaccine to a person who has experienced a serious systemic or anaphylactic reaction to a prior dose of either vaccine or to any of its components. For a list of vaccine components, refer to the manufacturer's package insert (www.immunize.org/packageinserts) or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.
    - Do not give varicella vaccine to a woman who is pregnant or may become pregnant within 1 month (pregnant women should be vaccinated upon completion or termination of pregnancy)
    - Do not give varicella vaccine to a person having any malignant condition, including blood dyscrasias, leukemia, lymphomas of any type, or other malignant neoplasms affecting the bone marrow or lymphatic systems.
    - Do not give varicella vaccine to a person receiving high-dose systemic immunosuppressive therapy (e.g., two weeks or more of daily receipt of 20 mg or more [or 2 mg/kg body weight or more] of prednisone or equivalent)
    - Do not give varicella vaccine to an adult or adolescent with CD4+ T-lymphocytes count <200 cells/μL
    - Do not give varicella vaccine to a person with a family history of congenital or hereditary immunodeficiency in first-degree relatives (e.g., parents, siblings) unless the immune competence of the potential vaccine recipient has been clinically substantiated or verified by a laboratory.
- **Precautions**
    - History of recent (within the past 11 months) receipt of antibody-containing blood

product (specific interval depends on product)
- History of receipt of specific antivirals (i.e., acyclovir, famciclovir, or valacyclovir) 24 hours before vaccination; avoid use of these antiviral drugs for 14 days after vaccination
- Moderate or severe acute illness with or without fever

Provide 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 www.immunize.org/vis. (For information about how to document that the VIS was given, see section 6 titled "Document Vaccination.")

Prepare to Administer Vaccine

Choose the needle gauge, needle length, and injection site according to the following chart:

Needle Gauge	Needle Length	Injection Site
23–25	5/8"	Fatty tissue over triceps

- Reconstitute the vaccine with the manufacturer-supplied diluent just prior to administration.

Administer Varicella Vaccine

0.5 mL, via the subcutaneous (SubCut) route, according to the following criteria and schedule:

History Of Previous Varicella Vaccination	Dose And Schedule For Administration Of Varicella
0 documented doses, or none known	Give 0.5 mL VAR as dose #1. Give dose #2 at least 4 weeks later.
1 previous dose of VAR	Give 0.5 mL VAR as dose #2 at least 4 weeks after dose #1.

Document Vaccination

- Document each patient's vaccine administration information and follow up in the following places:
  - *Medical record:*
    - Document the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. You must also document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. If vaccine was not administered, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
  - *Personal immunization record card:*
    - Record the date of vaccination and the name/location of the administering clinic.
  - *Immunization Information System (IIS) or "registry":*
    - Report the vaccination to the appropriate state/local IIS, if available.

Be Prepared to Manage Medical Emergencies

- Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications. For IAC's "Medical Management of Vaccine Reactions in Adults," go to

www.immunize.org/catg.d/p3082.pdf. To prevent syncope, vaccinate patients while they are seated or lying down and consider observing them for 15 minutes after receipt of the vaccine.

Report All Adverse Events to VAERS

- Report all adverse events following the administration of varicella vaccine to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov. Forms are available on the website or by calling (800) 822-7967.

STANDING ORDERS FOR
Administering Vaxelis
(Diphtheria and Tetanus Toxoids and Acellular Pertussis, Inactivated Poliovirus, Haemophilus b Conjugate and Hepatitis B Vaccine) in Children 6weeks to 4 years of Age

Purpose

- To reduce morbidity and mortality from tetanus, diphtheria, and pertussis by vaccinating all infants and children who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy

- Where allowed by state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess the need for and vaccinate children and teens who meet any of the criteria below.
- **Review the package insert prior to administration and confirm storage and handling guidance**

Procedure

- **Assess Children in Need of Vaccination** against diphtheria, tetanus, and pertussis, poliomyelitis, hepatitis B, and invasive disease due to Haemophilus influenzae type b based on the following criteria:
    - The is a 3 dose immunization series administered at 2, 4 and 5 months of age

Screen for Contraindications and Precautions

- **Contraindications**
    - Severe allergic reaction (e.g., anaphylaxis) to a previous dose of VAXELIS, any ingredient of VAXELIS, or any other diphtheria toxoid, tetanus toxoid, pertussis-containing vaccine, inactivated poliovirus vaccine, hepatitis B vaccine, or Haemophilus influenzae type b vaccine.
    - Encephalopathy within 7 days of a previous pertussis-containing vaccine with no other identifiable cause.
    - Progressive neurologic disorder until a treatment regimen has been established and the condition has stabilized.
- **Precautions**
    - Carefully consider benefits and risks before administering VAXELIS to persons with a history of:
        - -hyporesponsive episode (HHE) or
        - persistent, inconsolable crying lasting hours within 48 hours after a previous pertussis-containing vaccine.
        - seizures within 3 days after a previous pertussis-containing vaccine.
        - If Guillain-Barré syndrome occurred within 6 weeks of receipt of a prior vaccine containing tetanus toxoid, the risk for Guillain-Barré syndrome may be increased following VAXELIS.

Apnea following intramuscular vaccination has been observed in some

infants born prematurely. The decision about when to administer an intramuscular vaccine, including VAXELIS, to an infant born prematurely should be based on consideration of the individual infant's medical status and the potential benefits and possible risks of vaccination.

- Urine antigen detection may not have definitive diagnostic value in suspected H. influenzae type b disease following vaccination with VAXELIS.

Provide Vaccine Information Statements

a. Provide all patients (or, in the case of minors, their parent, or legal representative) 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 www.immunize.org/vis. (For information about how to document that the VIS was given, see section 6 titled "Document Vaccination.")

Prepare to Administer Vaccine

- Choose the needle gauge, needle length, and injection site according to the chart below:

AGE OF INFANT	NEEDLE GAUGE	NEEDLE LENGTH	INJECTION SITE
Younger than 12 months	22–25	1"	Anterolateral thigh muscle

Administer Vaxelis

- Just before use, shake the vial or syringe until a uniform, white, cloudy suspension results
- Administer 0.5mL intermuscular

Vaccine Schedule

- VAXELIS is to be administered as a 3-dose series at 2, 4, and 6 months of age.
  - The first dose may be given as early as 6 weeks of age.
  - Three doses of VAXELIS constitute a primary immunization course against diphtheria, tetanus, H. influenzae type b invasive disease and poliomyelitis.
  - VAXELIS may be used to complete the hepatitis B immunization series.
  - A 3-dose series of VAXELIS **does not** constitute a primary immunization series against **pertussis**;
    - an additional dose of pertussis-containing vaccine is needed to complete the primary series.
  - Pertussis Vaccination following VAXELIS
    - Children who have received a 3-dose series of VAXELIS should complete the primary and pertussis vaccination series with Pentacel, Quadracel or DAPTACEL according to the respective prescribing information in the approved package inserts.
  - Administration of VAXELIS following previous doses of other DTaP-containing vaccine.
    - VAXELIS may be used to complete the first 3 doses of the 5-dose DTaP series in infants and children who have received 1 or 2 doses

of Pentacel or DAPTACEL and are also scheduled to receive the other antigens in VAXELIS.

- Administration of VAXELIS following previous doses of any Hepatitis B Vaccine
    - A 3-dose series of VAXELIS may be administered to infants born to HBsAg-negative mothers, and who have received a dose of any hepatitis B vaccine, prior to or at 1 month of age.
    - VAXELIS may be used to complete the hepatitis B vaccination series following 1 or 2 doses of other hepatitis B vaccines, in infants and children born of HBsAg-negative mothers and who are also scheduled to receive the other antigens in VAXELIS. However, data are not available on the safety and effectiveness of VAXELIS in such infants and children.
- Administration of VAXELIS following previous doses of Inactivated Polio Vaccine (IPV)
    - VAXELIS may be administered to infants and children who have received 1 or 2 doses of IPV and are also scheduled to receive the other antigens in VAXELIS. However, data are not available on the safety and effectiveness of VAXELIS in such infants and children.
- Administration of VAXELIS following previous doses of Haemophilus b Conjugate Vaccines
    - VAXELIS may be administered to infants and children who have received 1 or 2 doses of H. influenzae type b Conjugate Vaccine and are also scheduled to receive the other antigens in VAXELIS. However, data are not available on the safety and effectiveness of VAXELIS in such infants and children

Document Vaccination

- Document each patient's vaccine administration information and follow-up in the following places:
    - Medical record*:*
        - Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. You must also document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Note that medical records/charts should be documented and retained in accordance with applicable state laws and regulations. If vaccine was not administered, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal). Discuss the need for vaccine with the patient at the next visit.
    - Personal immunization record card:
        - Record the date of vaccination and the name/location of the administering clinic.
    - Immunization Information System (IIS) or "registry*":*
        - Report the vaccination to the appropriate state/local IIS, if available
        - .

Be Prepared to Manage Medical Emergencies

- Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications. For IAC's "Medical Management of Vaccine Reactions in Adult Patients in a Community Setting," go to

www.immunize.org/catg.d/p3082.pdf. For “Medical Management of Vaccine Reactions in Children and Teens in a Community Setting,” go to www.immunize.org/catg.d/p3082a.pdf.

- To prevent syncope, vaccinate patients while they are seated or lying down and consider observing them for 15 minutes after receipt of the vaccine.

Report Adverse Events to VAERS

- Report all adverse events following the administration of Hepatitis A vaccine to the federal Vaccine Adverse Event Reporting System (VAERS). To submit a VAERS report online (preferred) or to download a writable PDF form, go to https://vaers.hhs.gov/reportevent.html. Further assistance is available at (800) 822-7967.

Standing Order for
Administering Recombinant Zoster Vaccine to Adults

Purpose

- To reduce morbidity and mortality from herpes zoster (shingles) by vaccinating all adults who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy

- Where allowed by state law, standing orders enable eligible nurses, pharmacists, and other healthcare professionals to assess the need for vaccination and to vaccinate adults who meet any of the criteria below.

Procedure

- **Assess Adults for Need of Vaccination** against herpes zoster based on the following criteria:
  - Adults lacking documentation of ever receiving two doses of recombinant zoster vaccine (RZV; Shingrix, GlaxoSmithKline) and who are:
    - Age 50 years or older and immunocompetent
    - Age 19 years or older who are or will be immunodeficient or immunosuppressed due to disease or therapy. For patients in this category, consult medical director and consider consulting the provider primarily responsible for managing the patient's immunocompromising condition or therapy, as needed. Detailed clinical considerations for vaccination of people who are or will be immunocompromised are available at www.cdc.gov/shingles/vaccination/immunocompromised-adults.html.
  - ***Notes on history of varicella, herpes zoster, and vaccination:***
    - RZV is not indicated and has not been studied for the prevention of primary infection with varicella zoster virus (chickenpox). People who have been vaccinated against varicella are at lower risk of zoster but may benefit from zoster vaccination.
    - Screening for a history of chickenpox is not required for immunocompetent people born in the United States before 1980 because more than 99% have serologic evidence of infection. For immuno- compromised adults with no documented history of varicella, varicella vaccination, or herpes zoster, see www.cdc.gov/shingles/vaccination/immunocompromised-adults.html#special-populations.
    - A history of herpes zoster or of receiving zoster vaccine live (ZVL; Zostavax, Merck) does not change the recommendation to receive two doses of RZV.

Screen for Contraindications and Precautions

- **Contraindications**
  - Do not give RZV to a person who has experienced a serious systemic or anaphylactic reaction to a vaccine component. For a list of vaccine components, refer to the manufacturer's package insert (see www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states) or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.
- **Precautions**
  - Moderate or severe acute illness with or without fever.
  - If an individual is experiencing an episode of shingles, vaccination should be delayed until the acute stage of the illness is over, and symptoms abate. RZV is not a treatment for shingles or postherpetic neuralgia.
  - There is currently no ACIP recommendation for RZV use in pregnancy; consider delaying RZV until after pregnancy.
  - Breastfeeding is not a precaution to vaccination. Recombinant vaccines such as RZV pose no known risk to mothers who are breastfeeding or to their infants. Consider vaccination without regard to breastfeeding status if RZV is otherwise indicated.

Provide 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 preferred language, if one is available and desired; these can be found at www.immunize.org/vis. (For information about how to document that the VIS was given, see section 6 titled "Document Vaccination.")

Prepare to Administer Vaccine

- **For administration of RZV (Shingrix),** administer 0.5 mL intramuscularly according to the following chart:

GENDER AND WEIGHT OF PATIENT	NEEDLE GAUGE	NEEDLE LENGTH	INJECTION SITE
Female or male less than 130 lbs.	22–25	–1"	Deltoid muscle of arm
Female or male 130–152 lbs.	22–25	1"	Deltoid muscle of arm
Female 153–200 lbs.	22–25	1–1½"	Deltoid muscle of arm
Male 153–260 lbs.	22–25	1–1½"	Deltoid muscle of arm
Female 200+ lbs.	22–25	1½"	Deltoid muscle of arm
Male 260+ lbs.	22–25	1½"	Deltoid muscle of arm
Female or male, any weight	22–25	1"*–1½"	Anterolateral thigh muscle

Alternative needle lengths may be used for IM injections if the skin is stretched tight, the subcutaneous tissue is not bunched, and the injection is made at a 90° angle to the skin as follows: a) a 5/8" needle for patients weighing less than 130 lbs. (<60 kg) or b) a 1" needle for administration in the thigh muscle for adults of any weight.

Administer Recombinant Zoster Vaccine, according to the information in the package insert and the table below:

PRIOR DOCUMENTED DOSES OF RZV	SCHEDULE
0	Administer 2-dose series of RZV, separated by 2–6 months†
1 dose RZV	Administer dose #2 of RZV, 2–6 months† following dose #1

†For patients who are or will be immunodeficient or immunosuppressed and who would benefit from completing the series in a shorter time period, the second dose can be administered 1–2 months after the first.

Document Vaccination

- Document each patient's vaccine administration information and follow up in the following places:
    - ***Medical record:*** Document the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. You must also document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Note that medical records/charts should be documented and retained in accordance with applicable state laws and regulations. If vaccine was not administered, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal); discuss the need for vaccine with the patient at the next visit.
    - ***Personalimmunization record card:*** Record the date of vaccination and the name/location of the administering clinic.
    - ***Immunization Information System (IIS) or "registry":*** Report the vaccination to the appropriate state/local IIS, if available.

Be Prepared to Manage Medical Emergencies

- Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications. For Immunize.org's "Medical Management of Vaccine Reactions in Adult Patients in a Community Setting," go to www. immunize.org/catg.d/p3082.pdf .
- To prevent syncope, vaccinate patients while they are seated or lying down and consider observing them for 15 minutes after receipt of the vaccine.

Report All Adverse Events to VAERS

- Report all adverse events following the administration of zoster vaccine to the federal Vaccine Adverse Event Reporting System (VAERS). To submit a VAERS report online (preferred) or to download a writable pdf form, go to https://vaers.hhs.gov/reportevent.html. Further assistance is available at (800) 822-7967.

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.

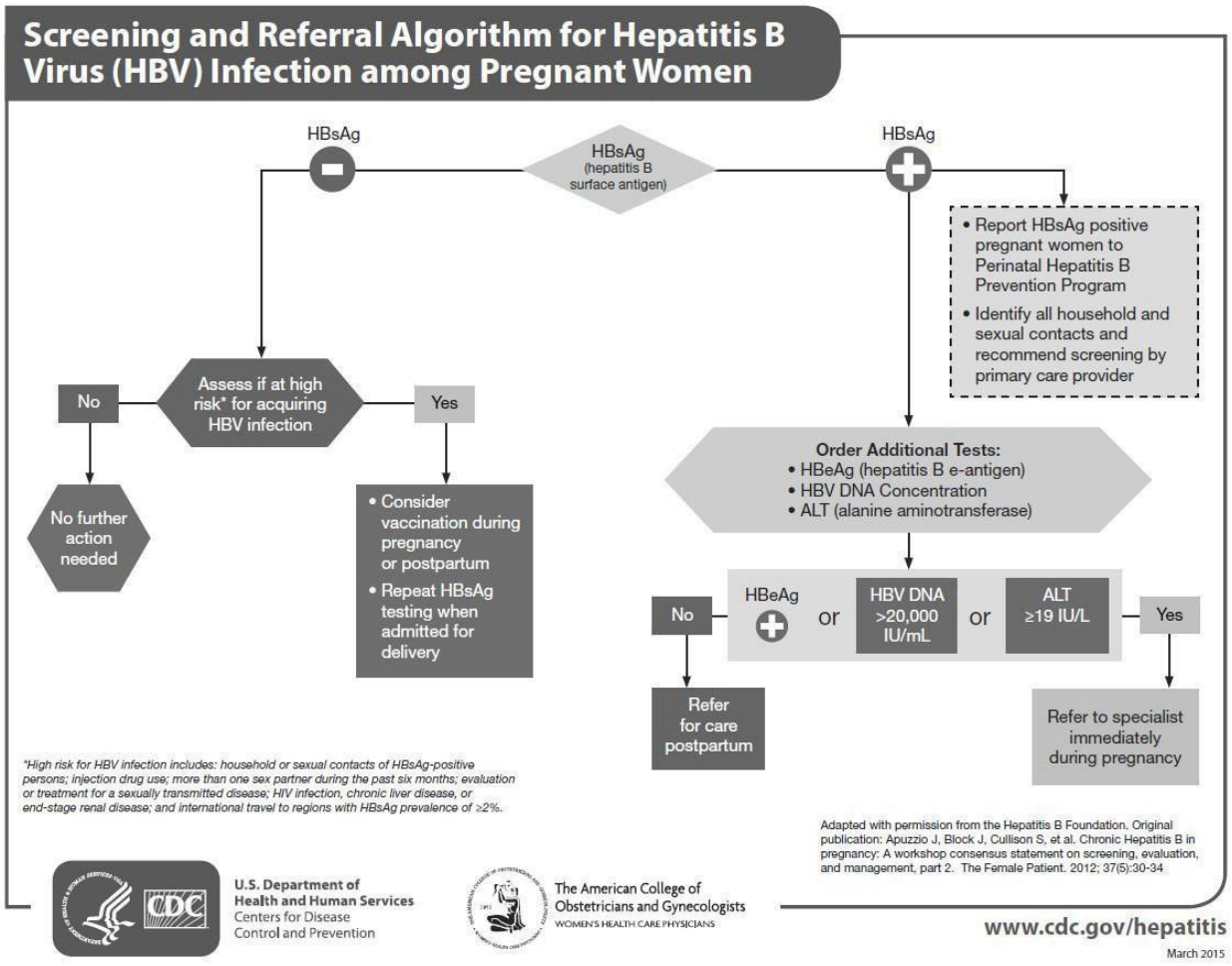
Screening and Reporting

- Kentucky Revised Statute 214.160, http://www.lrc.ky.gov/statutes/statute.aspx?id=8792, 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.
- 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).
- 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.

- 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:

    1) Mail the results to:
       Perinatal Hepatitis B Prevention Coordinator
       275 East Main Street, HS2E-B
       Frankfort, KY 40621

    2) Fax the results to 502-564-4760



https://www.cdc.gov/hepatitis/hbv/pdfs/prenatalhbsagtesting.pdf

Table 1: Interpretation of Hepatitis B Serologic Tests		
Test	**Results**	**Interpretation**
HBsAg Anti-HBc Anti-HBs	Negative Negative Negative	Susceptible to infection
HBsAg Anti-HBc Anti-HBs	Negative Negative Positive with ≥10 mIU/mL[+]	Immune due to vaccination
HBsAg Anti-HBc Anti-HBs	Negative Positive Positive	Immune and recovered from past hepatitis B virus (HBV) infection
HBsAg Anti-HBc IgM anti-HBc Anti-HBs	Positive Positive Positive Negative	Acutely infected
HBsAg Anti-HBc IgM anti-HBc Anti-HBs	Positive Positive Negative Negative	Chronically infected
HBsAg Anti-HBc Anti-HBs	Negative Positive Negative	Four interpretations are possible**

Table 1: Interpretation of Hepatitis B Serologic Tests

[+] For infants born to hepatitis B-infected mothers, post-vaccination 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.

Post-vaccination 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 detected 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*

Maternal HBsAg Status	Monovalent (Single-antigen) HepB vaccine		Monovalent (Single-antigen) HepB and Combination Vaccine	
	Dose	Age	Dose	Age
Positive	1†	Birth (12 hours or less)	1†	Birth (12 hours or less)
	HBIG§	Birth (12 hours or less)	HBIG§	Birth (12 hours or less)
	2	1 through 2 months	2	2 months
	3¶	6 months	3	4 months
			4¶	6 months (PEDIARIX®)
Unknown**	1†	Birth (12 hours or less)	1†	Birth (12 hours or less)
	2	1 through 2 months	2	2 months
	3¶	6 months	3	4 months
			4	6 months (PEDIARIX®)
Negative	1†,++	Birth (24 hours or less)	1†	Birth (24 hours or less)
	2	1 through 2 months	2	2 months
	3¶	6 through 18 months	3	4 months
			4¶	6 months (PEDIARIX®)

*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.

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": https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf, and ACIP VFC Resolution 10/16-1

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

Maternal HBsAgStatus	Recommendations
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	• Delayfirst 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).

Adapted from ***MMWR*** 2015, Vol 64, and (No. RR-39), ***Epidemiology and Prevention of Vaccine Preventable Diseases*** (Pink Book) 13th edition, and the Recommended Immunization Schedule for Children and Adolescents Aged 18 Years or Younger, UNITED STATES, 2017":
2015 CDC Update for PVST, and ACIP VFC Resolution 10/16-1

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.
    - 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.
    - Mail the updates and lab results to:
      Perinatal Hepatitis B Prevention Coordinator
      275 East Main Street, HS2E-B
      Frankfort, KY 40621
    - Fax the updates and lab results to 502-564-4760

HBsAg-positive women identified at or after delivery

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

Serology Test Results	Follow-up
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 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 CCSG 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 CCSG Forms Section, http://chfs.ky.gov/dph/CSG_Forms.htm, for the following forms:

EPID-399:	Perinatal Hepatitis B Prevention Form for Infants
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" http://www.cdc.gov/vaccines/programs/vfc/downloads/resolutions/2017-02-01-hepb.pdf

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

Last updated January 15, 2016; July 1, 2017; and September 5, 2017

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
2) Report by Fax: Download the VAERS form, http://vaers.hhs.gov/resources/vaers_form.pdf, and review the instructions for completing the VAERS paper form, http://vaers.hhs.gov/helpinstructions. Fax a completed VAERS form to 1-877-721-0366, or
3) Report by Mail: Download the VAERS form, http://vaers.hhs.gov/resources/vaers_form.pdf, and review the instructions for completing the VAERS paper form, http://vaers.hhs.gov/helpinstructions. Mail a completed VAERS form to:

   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.

- Additional Information

The Recommended Child and Adolescent Immunization Schedule, United States, 2020 is available at https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html. The full ACIP recommendations for each vaccine are also available at https://www.cdc.gov/vaccines/hcp/acip-recs/index.html. All vaccines identified in Tables 1, 2, and 3 (except DTaP, rotavirus, and poliovirus vaccines) also appear in the Recommended Adult Immunization Schedule for Ages 19 Years or Older, United States, 2020.¶ The notes for vaccines that appear in both the adult immunization schedule and the child and adolescent immunization schedule have been harmonized to the greatest extent possible.

Changes in the 2020 Adult Immunization Schedule

Changes in the 2020 adult immunization schedule for persons aged ≥19 years include new or revised recommendations for hepatitis A vaccine (HepA) (*2*); human papillomavirus vaccine (HPV) (*3*); influenza vaccine (*4*); serogroup B meningococcal vaccine (MenB); pneumococcal vaccine (*5*); and tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccine (Tdap) (*6*). Following are the changes to the cover page, Table 1, Table 2, and Notes.

Cover page

- Trademark symbols (®) were added to all vaccine trade names.
- PedvaxHIB was added to the table of trade names for *Haemophilus influenzae* type b vaccine.

- The footnote on the cover page has been edited and now reads "Do not restart or add doses to vaccine series if there are extended intervals between doses."

Table 1

- **Age ranges:** The columns for age groups 19–21 years and 22–26 years have been combined, thereby reducing the number of columns for age ranges from five to four. This change was made because of the change in recommendation for catch-up HPV vaccination for all adults aged ≤26 years.
- **Tetanus, diphtheria, pertussis row:** This row has been edited to state that tetanus and diphtheria toxoids (Td) or Tdap may be used for the decennial tetanus booster.
- **Human papillomavirus (HPV) row:** The rows for males and females have been combined, reflecting that catch-up vaccination is now recommended for all adults aged ≤26 years. In addition, a blue box has been added for persons aged 27–45 years to indicate that shared clinical decision-making regarding vaccination is now recommended for this group.
- **Pneumococcal conjugate (PCV13) row:** The box for persons aged ≥65 years who do not have an additional risk factor or another indication has been changed to blue to indicate that shared clinical decision-making regarding vaccination is now recommended for this group.
- **Meningococcal B (MenB) row:** A blue box has been added for persons aged 19–23 years who are not at increased risk for meningococcal disease, indicating that shared clinical decision-making regarding vaccination is now recommended for this group.
- **Legend:** A blue box has been added to indicate that shared clinical decision-making is recommended regarding vaccination. The text defining the gray box has been edited and now reads "No recommendation/not applicable."

Table 2

- **Tdap or Td row:** This row has been revised to read that Td or Tdap may be used for the decennial tetanus booster.
- **Human Papillomavirus (HPV) row:** This row has been combined into a single row including both males and females, reflecting that HPV vaccine is now recommended for all adults aged ≤26 years.
- **Hepatitis A (HepA) row:** The box for persons living with human immunodeficiency virus (HIV) infection (regardless of CD4 count) is now yellow, reflecting the new recommendation that previously unvaccinated persons in this group should be vaccinated.
- **Legend and bar text:** The gray box in the Legend has been edited and now reads "No recommendation/not applicable." The red box has been edited and now reads "Not recommended/contraindicated — vaccine should not be administered." The text appearing in the red bars has been changed from "Contraindicated" to "Not Recommended."

Notes

- Edits have been made throughout the Notes section to harmonize language between the child/adolescent immunization schedule and the adult immunization schedule, where possible.
- A new subsection entitled "Shared Clinical Decision-Making" was added for each vaccine that includes this new ACIP recommendation (e.g., for HPV, PCV13, and MenB).
- **Hepatitis A:** The note was revised to include minor changes to the chronic liver disease definition, minor changes for the pregnancy indication, addition of the recommendation for vaccination in settings of exposure, and removal of clotting factor disorders as an indication for vaccination.
- **Hepatitis B:** The note was revised to include minor changes to the chronic liver disease definition and minor changes for the pregnancy indication.
- **Human papillomavirus:** The note was revised to indicate that HPV vaccination is recommended for all persons aged ≤26 years. A shared clinical decision-making subsection was added for persons aged 27–45 years.
- **Influenza:** The note was updated to include a bulleted list indicating when live attenuated influenza vaccine (LAIV4) should not be used and minor edits to the guidance for persons with a history of Guillain-Barré syndrome.
- **Measles, mumps, and rubella:** The note was revised to clarify recommendations for health care personnel, with a separate bullet for personnel born in 1957 or later with no evidence of immunity and for health care personnel born before 1957 with no evidence of immunity.

- **Meningococcal:** The note was revised to include the use of the complement inhibitor ravulizumab as an indication for MenB administration in these patients. A shared clinical decision-making subsection was added that includes a bullet for adolescents and young adults aged 16–23 years who are not at increased risk for meningococcal disease. Under the "Special situations" section, the recommendation to administer a booster dose of MenB 1 year after the primary series and to revaccinate every 2–3 years if the risk remains was added.
- **Pneumococcal:** The note has been updated to reflect the updated recommendations for vaccination of immunocompetent (defined as adults without an immunocompromising condition, cerebrospinal fluid leak, or cochlear implants) adults aged ≥65 years. One dose of 23-valent pneumococcal polysaccharide vaccine (PPSV23) is still recommended. Shared clinical decision-making is recommended regarding administration of PCV13 to immunocompetent persons aged ≥65 years.
- **Tetanus, diphtheria, and pertussis:** The note has been updated to indicate that Td or Tdap may be used in situations where only Td vaccine was indicated for the decennial tetanus, diphtheria, and pertussis booster vaccination, tetanus prophylaxis for wound management, and catch-up vaccination.
- **Varicella:** The note has been updated to indicate that vaccination may be considered for persons with HIV infection without evidence of varicella immunity who have CD4 counts ≥200 cells/μL.

Additional Information

The Recommended Adult Immunization Schedule, United States, 2020 is available at https://www.cdc.gov/vaccines/schedules/hcp/adult.html and in the Annals of Internal Medicine (*7*). The full ACIP recommendations for each vaccine are also available at https://www.cdc.gov/vaccines/hcp/acip-recs/index.html. All vaccines identified in Tables 1 and 2 (except zoster vaccines) also appear in the Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger, United States, 2020.¶ The notes for vaccines that appear in both the adult immunization schedule and the child and adolescent immunization schedule have been harmonized to the greatest extent possible.

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Acknowledgments

Rosters of current and past members of the Advisory Committee on Immunization Practices (ACIP) are available at https://www.cdc.gov/vaccines/acip/committee/members-archive.html.

Last updated July 31, 2008 and August 1, 2012 and February 26, 2020

Laboratory Services

Table of Contents

CLINICAL PROTOCOLS

Overview

Laboratory tests may involve the testing of body fluids such as blood and urine, or other tissues, secretions, and substances. Laboratory tests provide the Local Health Departments (LHD), clinicians and health care 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 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), 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. Programs within the Kentucky Department for Public Health (KDPH), the state reference laboratory; Division of Laboratory Services (DLS), and this CSG helps to provide guidance to LHDs and health care providers in their efforts to improve the lives of the citizens and visitors of the Commonwealth through prevention of negative health outcomes, promotion of healthy lifestyles and by providing protection from diseases, injuries, and environmental health impacts.

DLS Resources and Services

The Division of Laboratory Services (DLS) website, Division of Laboratory Services - Cabinet for Health and Family Services (ky.gov), provides a wealth of information and resources for health departments and other public health and clinical partners. They include the following:

- Contact numbers - normal business hours of operations (M - F 8:00am – 4:30pm) and for after-hours emergencies
- Laboratory Submission Forms and Requisitions
- CLIA Certification & Questions - contact number for the Office of Inspector General
- LIS registration for “Outreach” - lab’s electronic information system for efficient submission of test orders and retrieval of results
- Ordering lab kits/supplies – fillable/pintable requisition Form (check periodically for updates).
- Reference list of tests (specimen sources, test and CPT codes, and reference ranges)
- Collection and Packaging Guides - instructions with colorful graphics & user-friendly instructions
- Newborn Screening reports KOG portal and cystic fibrosis 139 Variant Physician Insert

Timely resources, guidance, and healthcare provider and patient facts are posted to the DLS website as applicable in response to pandemics and other public health events, crisis, and emergencies.

LIS – Outreach

Become a certified user to access the laboratory's electronic information system, Outreach, to reduce turnaround time, decrease risks for clerical errors and to conveniently submit test orders and retrieve laboratory results. Sign up information is on the website. Contact the Customer Call Center at (502) 564-4446, ext. 1 or email e-mail@ky.gov for any questions or concerns.

DLS Certificates

The DLS has the following downloadable certificates:

- CAP
- CLIA
- KY Medical Licensure

Requisition for Laboratory Supplies

Fillable electronic forms that can be sent via email to DPHLabkits@ky.gov or printed and faxed to 502-564-7019 are on the website. Please check laboratory kit and supplies expiration dates and rotate them so the earliest in expiration gets used first. Periodically check the DLS website for updates to this form. For more information call 502-782-7703 or the main line at 502-564-4446.

Laboratory Submission Forms

The DLS website has links to the following forms: CTGC, HIV, Prenatal Profile, Serodiagnosis, Rabies, virology, Mycobacteriology (TB), Bacteriology, Food, Dental Fluoride, and Water. It is important to complete ALL order entry questions as thorough as possible and to include an email as requested such as for water bacteriology requests. Having a contact is necessary if the lab needs to contact the collector or a facility concerning questions and concerns about a submitted sample.

Collection and Packaging

Collection, specimen type, storage and shipment temperature, and packaging and shipping instructions with helpful colored graphics can be obtained from the DLS website to help LHDs and health care providers ensure the integrity and optimal conditions of specimens are preserved so they arrive to the DLS in an acceptable state. This helps to ensure laboratory results are accurate, reliable, and valid. Collection and packaging guidance include bulk collection and packaging of COVID-19, Multishippers, Sputum, Blood, Hepatitis, Viral swabs, Newborn Screening, Norovirus, Rabies, Enterics, Food, and Water. It is important to note that many specimens collected are time sensitive and it is essential that they arrive for testing in a timely manner.

DLS Reference List of Tests

The DLS reference list of tests is comprehensive and includes important information and instructions on the following:

- Specimen criteria
- Specimen and sample identification & labeling instructions
- Description of collection/submission kit components and supplies
- Collection and Packaging Instructions
- Special notes
- Outreach and CPT codes
- Tests and their method
- Reference Range of lab results

Refer to: https://chfs.ky.gov/agencies/dph/dls/Documents/ReferenceListofTests.pdf

List of Commonly Performed Lab Tests and Procedures (Not all-inclusive) at DLS:

HEPATITIS (Virology Section)

Test	OutreachTest Code	CPT Code	Reference Range
Hepatitis A	HAV	86709	Non-reactive
Hepatitis B surface antigen	HBSG	87340, 87341	Non-reactive
Hepatitis B surface antibody	HBSB	86706	Non-reactive
Hepatitis Bcore antibody	HBCB	86704	Non-reactive
Hepatitis C	HEPC	Antibody – 86803 Quantification - 87522	Non-reactive

HUMAN IMMUNODEFICIENCY VIRUS (HIV) (Virology Section)

Test	Outreach Test Code	CPT Code	Reference Range
HIV	HIV	HIV Combo- 87389 Geenius - 86701 & 86702	Non-Reactive: No P24 Antigen or Antibodies to HIV-1/HIV-2 Detected Not detected

PRENATAL PROFILE (Virology Section)

Test	Outreach Test Code	CPT Code	Reference Range
Prenatal Profile	PNP	Syphilis IgG – 86780 HBsAg – 87340 Rubella IgG - 86762	Non-Reactive Non-Reactive Consistent with Immunity, Immunity Reference Range- >1.1 Index

SYPHILIS, CHLAMYDIA, & GONORRHEA (Virology Section)

Test	OutreachTest Code	CPT Code	Reference Range
Syphilis	IGGE	Syphilis IgG 86780 VDRL 86593 TP-PA 86780	Non-Reactive Non-Reactive Non-Reactive
Chlamydia/ gonorrhea	CTGC	87491	Negative

VIRAL SEROLOGY TO DETECT ANTIBODY (Virology Section)

Test	Outreach Test Code	CPT Code	Reference Range
Varicella Zoster	VZE	86787	Consistent with Immunity – Immunity Reference Range >20.0 eu/mL
Mumps	MUEG	86735	Mumps IgG antibody detected. Indicative of current or past infection, or consistent with immunity. Reference range > 1.1 Index. IgM - Detected/Not Detected
Measles	MEAE	86765	Consistent with Immunity – Immunity Reference Range >20.0 eu/mL
German Measles	RUBG	86762	Consistent with Immunity, Immunity Reference Range ≥1.1 Index
SARS-CoV-2	COVAB	86769	Negative for the presence of Total Anti-SARS-CoV-2 Nucleocapsid Antibodies

VIRAL POLYMERASE CHAIN REACTION (PCR) (Virology Section)

Test	Outreach Test Code	CPT Code	Reference Range
Respiratory Panel	RESP	87633	Not Detected
Chickenpox	HSVP	87798	Varicella Zoster Virus DNA Not Detected
SARS-CoV-2	NCOV	CDC Panther GeneXpert - 87635-QW[2]	COVID-19 Not Detected SARS-COV-2 Not Detected SARS-COV-2 Negative
Herpes	HSVP	87529 x2	Herpes Virus Type 1 DNA Not Detected Herpes Virus Type 2 DNA Not Detected
Influenza	FPCR	87501	Negative Influenza A/B by PCR
Measles	MEPCR	87798	Not Detected
Mumps	MUPCR	87798	Not Detected
Norovirus	NORX	87798 x2	Negative for Norovirus by PCR

MYCOBACTERIOLOGY (TB) (Bacteriology Section)

Test	Outreach Test Code	CPT Code	Reference Range
Clinical Samples (Sputum, bronchial wash, bronchial alveolar lavage (BAL), fresh tissue, spinal fluid, pleural fluid, pus, urine, other body fluids. No stool	SCP	87015	No acid-fast bacilli
Clinical Isolates (identification and drug susceptibility studies)	TBCP	87116 87149- Nucleic Acid Probe	No acid-fast bacilli

RABIES DETECTION IN ANIMALS (Virology Section)

Test	Outreach Test Code	CPT Code	Reference Range
Rabies (Bats not live and small animal heads, brain with stem & cerebellum)	RABP	NA	No evidence of Rabies seen

WATER BACTERIOLOGY (Environmental Microbiology Section)

Test	Outreach Test Code	CPT Code	Reference Range
Water Bacteriology E. coli and Total Coliforms (Private drinking water; wells, cisterns, springs Public Swimming Beaches, Public Swimming Pools, Dairy Water)	WATERB	NA	Acceptable limits for drinking water: <1 per 100ml (none detected) Acceptable limits for recreation water • Total Coliform limit not established for beach water • E. coli content shall not exceed 130 colonies per 100ml as a geometric mean based on not less than 5 samples taken during a 30-day period. Acceptable limits for Dairy water: Presence of total coliforms is unacceptable in dairy or food manufacturing source/processing water.
Legionella (Private drinking water; wells, cisterns, springs Recreational water Commercial water)	WLEG	NA	<1 per 100ml (none detected)

NEWBORN SCREENING INDIVIDUAL TESTS			
DISORDER	METHODOLOGY	REFERENCE RANGE	INDIVIDUAL CPT CODE
ACYLCARNITINES Includes:	MS/MS	Within Profile Range	82016
	FATTY ACID DISORDERS: Carnitine uptake defect, Long-chain -3hydroxyacyl-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 (VLCAD), Carnitine acylcarnitine translocase deficiency, Carnitine palmitoyl transferase deficiency, Glutaric academia type II ORGANIC ACID DISORDERS: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, Isobutryl-CoA dehydrogenase deficiency, Malonic academia, Ethylmalonic encephalopathy, 2-Methylbutyryl-CoA dehydrogenase deficiency		
AMINO ACID DISORDERS Includes:	MS/MS	Within Profile Range	82139
	Argininosuccinate Acidemia, Citrullinemia, Homocystinuria, Maple Syrup Urine Disease, Phenylketonuria, Tyrosinemia, Argininemia, Hyperphenylalaninemia, Hypermethioninemia, Nonketotic Hyperglycinemia		
BIOTINIDASE DEFICIENCY	FIA	>45U/dL	82261
CONGENITAL ADRENAL HYPERPLASIA (CAH)	FIA	Weight Based	83498
CONGENITAL HYPOTHYROIDISM	FIA	TSH: <20 µU/mL T4: Age based	84437, 84443
CYSTIC FIBROSIS	FIA	<58.0 ng/mL	83516
GALACTOSEMIA	Beutler-Baluda (adaptation)	>2.5U/dL	82776
HEMOGLOBINOPATHIES	HPLC	F + A	83021
PEROXISOMAL STORAGE DISORDERS Includes:	FIA, MS/MS	Within Normal Limits	NA
	X-Linked adrenoleukodystrophy disorders (X-ALD))		
SEVERE COMBINED IMMUNODIFICIENCY (SCID)	PCR	Within Normal Limits	81479
SPINAL MUSCULAR ATROPHY (SMA)	PCR	Within Normal Limits	81400
VARIOUS LYSOSOMAL DISORDERS (POMPE, MPS-1, KRABBE)	MS/MS	Full Enzyme Activity	82542,83789

Dental Fluoride (Supplement Program) (Environmental Chemistry Section)

	OutreachTest Code	CPT Code	Reference Range
Dental Fluoride	FL	NA	0.8-1.4 PPM Kentucky's optimal fluoride concentration is: 0.90PPM

CLIA Certification

LHDs and sites that want to perform testing under a CLIA Certificate of Waiver or Provider-Performed Microscopy (PPM) must apply for a CLIA certificate by completing the CLIA application form, CMS-116, and paying the application fee. The application, instructions to complete the application, and guidelines for CLIA certification can be found at the following links below:

- How to Apply for a CLIA Certificate, Including International Laboratories | CMS
- https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/HowObtainCLIACertificate.pdf
- https://www.cms.gov/files/document/laboratory-quick-start-guide-cms-clia-certification.pdf

NOTE: Pay applicable certificate renewal fees biennially. Start renewal months in advance of the Certificate expiration to ensure no lapse in laboratory testing services. Call the Office of Inspector General (OIG) for changes, questions, and issues with certification.

CLIA Certificate of Waiver

CLIA waived tests are simple tests with a low risk for an incorrect result. They include:

- Certain tests listed as specified in the CLIA regulations
- Tests that are cleared by the FDA for home use
- Tests that the manufacturer applies to the FDA to obtain waived status by providing scientific data that verifies that the CLIA waiver criteria have been met

Sites that perform only waived testing must have a CLIA certificate and they must follow the manufacturer's instructions. Below are links to further information and resources for those sites that have a certificate of waiver.

- Waived Tests | CDC
- https://www.cdc.gov/labquality/docs/waived-tests/15_255581-test-or-not-test-booklet.pdf
- **https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5413a1.htm**

CLIA Certificate for PPM

A CLIA Certificate for Provider-Performed Microscopy (PPM) procedures allows physicians midlevel practitioners (nurse midwife, nurse practitioner, or physician assistant), and dentists to perform a limited list of moderate complexity microscopic tests. The limited set of microscopic evaluations listed in the CLIA regulations are performed on samples such as urine, Vaginal excretions, and skin scrapings.

PPM-certified sites and laboratories must meet the same CLIA quality standards as laboratories performing moderate complexity tests. The CLIA requirements for testing under a Certificate for PPM are in 42 CFR 493.19 found at Code of Federal Regulations (govinfo.gov).

Helpful Resources:

- https://www.cdc.gov/labquality/docs/PMP_Booklet_7252019.pdf.
- CLIA and Provider-Performed Microscopy (PPM) Procedures: An Introduction

Laboratory Director Responsibilities

Guidance for new laboratory directors can be found in the CLIA brochure entitled "What Are My Responsibilities as A Laboratory Director". Refer to brochure7.pdf (cms.gov)

Good Laboratory Testing Practices Resource

Use the following checklist to ensure no lapse in CLIA certification and to implement recommended practices for good testing practices and reliable, high quality test results.

self-assessment-checklist-good-testing-practices.pdf (cdc.gov)

Recommendations for Waived/PPM/Moderate Complexity Laboratories
Director/Site Coordinator Responsibilities

The Laboratory Director/Site Coordinator is a local health department staff member who is responsible for the overall operation and administration of the laboratory. They are responsible for ensuring that the laboratory provides accurate, reliable, and timely testing. They communicate effectively with accrediting, licensing, and regulatory bodies and serve as the point of contact person for the State Laboratory staff.

Director/Site Coordinator Responsibilities

Personnel

- Ensure personnel are qualified with the appropriate education and experience to perform the work and testing required of the laboratory.
- Ensure personnel receive appropriate general, safety, and technical training for the type and complexity of testing performed. Document and maintain training and continuing education files on each employee.
- Ensure required employee competency and proficiency assessments are documented and reviewed.

- Ensure test procedures are performed, recorded, and reported promptly, accurately, and proficiently by laboratory testing personnel for all phases of testing; preanalytical, analytical, and postanalytical.

Laboratory Procedures

- Establish an authorization and approval process for all tests.
- Maintain a readily accessible approved laboratory procedure manual.
- Review, sign, and date the laboratory procedure manual at least annually.
- Maintain a current copy of the CLIA certificate and applicable certification/licensures of reference labs. Review reference lab specimen referral criteria for specimen collection and results. Implement changes when necessary.
- Enroll “regulated” analytes in an approved Proficiency Testing (PT) Program. Develop a PT review, compliance, and evaluation program (ensure PT samples are tested in the same manner as patient samples and submitted on time).
- Perform related remedial action and documentation with a Corrective Action/Incident. Report (within 5 working days) for unsatisfactory or unacceptable PT results or performance.

Quality Assurance

- Ensure the laboratory has an effective Quality Control (QC) and Quality Assurance (QA) Program. Establish a QA committee.
- Develop systems to identify, document and monitor failures in quality as they occur and to promote quality improvement.
- Monitor and evaluate incidents, deficiencies, and non-compliance or conforming events. Provide effective and measurable corrective and remedial action and resolution as necessary to prevent reoccurrence.
- Review a sampling of patient records monthly to assure all relevant elements are documented and reports of results are accurate and include all required information. (CH-12 or Quality Assessment Record Search Form - PHLOK-5 Form may be used).

Safety

- Ensure a safe work environment in which employees are protected from physical, biological, and chemical hazards.
- Ensure compliance to all local, state, and federal safety regulations and practices.
- Maintain adequate supplies of personal protective equipment (PPE), safety, first aid, and spill kits, disinfectant and sanitizers, and biohazard waste containers.
- Promote safety and good laboratory practices Record Keeping July 2021 386
- Maintain and retain records consistent with CLIA, OSHA, site policy, and any other applicable accreditation, licensure, and regulatory standards
- Maintain personnel records on training, continuing education, competency assessments, proficiencies, HIPPA, confidentiality, and security agreements, health assessments required for employment and job duties, and applicable performance evaluations
- Maintain records and logs on equipment maintenance, quality control, temperatures, incident reports, OSHA, etc. Records should be readily accessible to inspectors as required
- See the CSG “Forms and Teaching Sheets” Lab Section and the tools and resources from the CDC; https://www.cdc.gov/labquality/ for further recommendations.

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

- Maintain, update, and renew CLIA certification (2 years)
- Inform the Office of Inspector General (OIG) office/LHD assigned Laboratory surveyor of any change in status of the lab (e.g., change in the medical director, practice name, address, etc.). Submit change and form per CLIA requirements.
- 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 instruction or procedural changes must be reflected in the procedure. Director/Site coordinator and staff must read and resign the revised procedure with changes and trained as applicable on major changes.
- 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.
- Never use outdated reagents. Check expiration dates on all kits, reagents, and Quality control (QC) materials
- Perform quality control and/or calibration as specified by the kit manufacturer – Maintain the QC documentation for two years.
- Store and handle all test kits according to the manufacturer's instructions.
- Maintain safety and laboratory equipment checks and maintenance logs. Perform on schedule per regulatory and manufacturer's requirements and recommendations
- Follow all OSHA regulations that pertain to laboratory testing (e.g., Bloodborne Pathogens regulations).
- Document all trainings 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.
- Perform monthly record search
- Complete Corrective Action/Incident reports- Reports used as a 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.
- 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.
- Maintain all proficiency testing records and remedial actions documentation for at least 2 years
- Director must review and sign the laboratory procedure manual at least annually and with any changes and revisions.

See the CSG "Forms and Teaching Sheets" Lab Section and the tools and resources from the CDC: https://www.cdc.gov/labquality/ for further recommendations.

Shipping Laboratory Specimens to Division of Laboratory Services (DLS)

• Packaging and Shipping information can be found in the Administrative Reference.

Lead

Kentucky Childhood Lead Poisoning Prevention Program (KYCLPPP)

Table of Contents

Lead Levels and Definitions

The amount of lead in blood is referred to as the blood lead level is measured in micrograms of lead per deciliter of blood No safe lead level in children has been identified. In 2021, the CDC revised the language and utilizes the term "blood lead reference value" (BLRV), which is used to identify children with higher levels of lead in their blood compared to most children. The BLRV is based on the 97.5th percentile of the blood lead values among U.S. children ages 1-5 years from 2015-2016 and 2017-2018 National Health and Nutrition Examination Survey (NHANES) cycles. The Federal Advisory Committee, called the Lead Exposure and Prevention Advisory Committee, unanimously voted in 2021 in favor of recommending that CDC update the ref N NES

An elevated blood lead level (EBLL) is defined at a blood lead level (BLL) greater or equal (≥) to 3.5 µg/dL.

Verbal Risk Assessment and Screening Guidelines

Any child or pregnant woman having a positive risk factor but not having an EBLL must be provided preventive lead education in an effort to prevent future exposures.

- **Medicaid Enrolled Children:** Children under 72 months of age who are enrolled in Medicaid are considered high risk for lead exposure and must be assessed for lead exposure. A blood lead test should be performed for any "Yes" or "I don't know" responses.
  - The Lead Poisoning Verbal Risk Assessment should be completed at 6 and 9 months.
  - The Lead Poisoning Verbal Risk Assessment should be completed at age 3 through 6 if the child was not previously screened or experienced a change in risk status.
  - All children enrolled in Medicaid, regardless of whether coverage is funded through title XIX or XXI, are **required** to receive blood lead screening tests at ages 12 months and 24 months.
  - In addition, any child between 24 and 72 months with no record of a previous blood lead screening test must receive one.
  - Completion of a risk assessment questionnaire does not meet the Medicaid requirement. The Medicaid requirement is met only when the two blood lead screening tests identified above (or a catch-up blood lead screening test) are conducted.

- **Non-Medicaid Enrolled Children:** Children under 72 months of age who are not enrolled in Medicaid must be assessed for lead exposure. A blood lead test should be performed for any "Yes" or "I don't know" responses.
  - The Lead Poisoning Verbal Risk Assessment should be completed at 6, 9, 12, and 18 months, and again at 2 years.
  - The Lead Poisoning Verbal Risk Assessment should be completed at ages 3 through 6 if the child was not previously screened or experienced a change in risk status.
- **Refugee Children:** The CDC recommends blood lead testing for all refugee children who are 6 months to 16 years of age upon entering the United States. Repeated blood lead level testing of all refugee children who are 6 months to 6 years of age at 3 to 6 months after they are placed in permanent residences should be considered a "medical necessity," regardless of initial test results. Resources are available in the resource section of this document.
- **Pregnant Women**: (See also the Prenatal Section for Lead Screening Guidelines/ Follow-Up). Use the verbal risk assessment to assess a pregnant woman's risk for lead exposure during their first prenatal visit. Any "Yes" or "I don't know" responses result in a blood lead test. 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.

Blood Lead Specimen Collection

All LHD staff obtaining blood lead specimens must click the link CDC Blood Lead Collection Guidelines to view the video and documents as indicated in the Training Requirements: Administrative Reference (AR)/Training Guidelines and Program Descriptions.

Tips for reducing contaminated capillary lead tests:

- Vigorous washing of the hand and nail must be completed to remove excess lead.
- Do not simply wipe the finger with an alcohol prep pad.
- Washing of the hand must be completed by the nurse, not the patient or patient's guardian.
- Use warm water when washing the hand to help blood flow and assure your specimen is adequate in volume.
- Avoid drying the hand with recycled paper towels as these can be processed with materials that contain lead.
- Do not allow the child to touch surfaces after the hand as been scrubbed.
- Discard the first drop of blood to rid the finger of any remaining lead.

For more information, watch the CDC's guidance on avoiding contaminated specimens found here: https://www.youtube.com/watch?v=g2p2qREch9g

Using a Commercial Lab

- 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.
- Blood lead tests that are analyzed through a commercial lab (such as MedTox, Mayo, LabCorp, Quest etc.) handle reporting these tests to the Cabinet for Health and Family Services. Health departments do not need to report these tests to the cabinet.

LeadCare Point-of-Care Devices

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 EBLL ≥
devices can only to be used as a screening tool and is not a diagnosis tool.
If your LHD uses a LeadCare device, please contact the program epidemiologist to set up reporting of these lead tests. Visit https://kog.chfs.ky.gov/home/ to create an account to report these tests to the Cabinet for Health and Family Services as mandated by KRS 211.902.

Initial Blood Lead Test

A capillary or venous sample may be used for an initial BLL screening. Refer to Table 1 and Table 2 for further guidance. If the BLL is ≥ to 3.5 read the section below on confirmatory blood lead tests.

Confirmatory Blood Lead Tests

A confirmatory test is used to assure an EBL result is indeed elevated and not the result of a contaminated specimen. If the capillary results are elevated (greater or equal ≥
confirmatory test must be completed through a venous sample per the CDC. If the initial screening test was a venous sample, the patient does not need another venous draw as venous blood lead tests are less likely to be contaminated. **DO NOT WAIT TO CONFIRM AN EBLL.** Delaying a confirmatory result only prolongs a child's potential lead exposure. Refer to Table 1 and Table 2 for further guidance.

Table 1: Initial Blood Lead Level			
Blood Lead Level	**Assessment**	**Intervention**	**Follow-Up**
1-3.4 µg/dL	• Not considered an elevated blood lead level. (***No amount of lead in the body is normal***. *Even low BLLs can cause adverse neurological effects such as loss of IQ points and learning disabilities. It is very important that education on ways to prevent lead poisoning begin at this 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.
≥ 3.5 µg/dL	• Confirm BLL through a venous sample if the initial test was capillary.	• Confirm BLL through a venous sample if the initial test was capillary. Venous is considered confirmed. • Confirmatory tests should immediately but not later than: o Level 3.5-9: within 3 months o Level 10-19: within 1 month o Level 20-44: within 2 weeks o Level ≥ 45: within 48 hours	• Ensure BLL is confirmed. • **DO NOT** wait to confirm. This only prolongs potential exposure.

Table 2: Confirmed Venous Blood Lead Level			
Blood Lead Level	**Assessment**	**Interventions**	**Follow-Up**
≤ 3.4 µg/dL	• Not considered an EBLL.	• Provide **Lead Poisoning Prevention Education** listed in Table 1.	• Continue to review risk assessment questions at each preventive health visit up to < 72 months of age. • During well-child visits, check development to make sure age-appropriate milestones are being met and discuss diet and nutrition with a focus on iron and calcium intake. • Conduct follow-up blood lead testing at recommended intervals based on the child's age.
3.5–19 µg/dL	• Considered an EBLL. • Complete case management forms*	• Complete the Home Visit: o A Visual Investigative Home Visit* *must* be made within **30 DAYS OR SOONER** of a confirmed EBLL in order to help families visually identify potential lead hazards. Refer to Table 4 below for the BLL and timeframe the Home Visit should be completed. o A review on how to minimize the child's lead hazard exposure must be completed during this home visit. • Provide **Lead Poisoning Prevention Education** listed in Table 1. • Discuss diet and nutrition with a focus on iron and calcium intake. • Check the child's development to ensure appropriate milestones are being met per the AAP guidelines. • Referrals: o Refer for WIC services o Refer for Medical Nutrition Therapy	• Complete the items listed above. • Follow-up tests must be repeated according to Table 3 below (or as ordered by physician if more frequent) until the BLL level is < 3.5 • Establish a tracking system that ensures retesting and follow-up intervention. • Environmental: Lead hazards have been addressed.
≥15 µg/dL	• Considered an EBLL. • Follow guidance listed above.	• Complete the items listed above. • 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.	• Complete the items listed above. • Establish a tracking system that ensures follow-up retesting and interventions.

	• A Certified Risk Assessment must be completed according to KRS 211.905		• The case manager must assure a certified risk assessment is completed once it has been referred. • Environmental: Lead hazards have been addressed.
20–44 µg/dL	• Considered an EBLL. • Follow guidance listed above.	• Complete the items listed above. • Refer to a primary care provider (PCP) for medical evaluation. • For BLLs >25 please provide PCP with information on lead specialist consult. • Contact a **Pediatric Environmental Health Specialty Unit (PEHSUs) or the Poison Control Center for guidance.	• Complete the items listed above. • The case manager must assure a complete history and physical was completed.
≥45 µg/dL	• Considered an EBLL. • Follow guidance listed above.	• Complete the items listed above. • Immediately refer to a healthcare provider who consults with or is a medical toxicologist or pediatrician with experience in treating lead poisoning.	
*Fax the Case Management and Home Visit forms to (502) 564-5766 Attn: KYCLPPP once these interventions have occurred. Please **do not** send a Home Visit form without the environmentalist's section. ** PEHSUs provide information on protecting children and reproductive-age adults from environmental hazards.			

Table 3: Schedule for Follow-Up Blood Lead Testing		
Venous BLLs (µg/dL)	**Early Follow-Up Testing *(2–4 tests after initial test above specific venous BLLs)***	**Subsequent Follow-Up Testing *(after BLL declining)***
–9	3 months*	6–9 months
10–19	1–3 months*	3–6 months
20–44	2 weeks–1 month	1–3 months
	As soon as possible	As soon as possible

**Some case managers or healthcare providers may choose to repeat blood lead tests on all new patients within a month. Repeated testing may ensure that the patient's BLL is not rising more quickly than expected.*

Lead Poisoning Prevention and Case Management

According to the Centers for Disease Control and Prevention (CDC), case management of children and pregnant women with EBLLs involves the coordination, provision and oversight of services required to reduce BLLs 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
- Linking of clients to needed services
- Service implementation and coordination
- Monitoring of service delivery
- Advocacy
- Evaluation

When a blood lead result is ≥ 3.5 ug/dL, education on what lead is and sources of lead and how to minimize exposure must be provided to the family. Follow-up interventions must be initiated for every child and pregnant woman having a confirmed EBLL. Children and pregnant women with EBLLs become "**health department patients**" when that level 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 reports of EBLLs. 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 Case Management form must be filled out for all children and pregnant women having a confirmed EBLL of ≥ The original report form is to be placed in the patient's chart and a copy must be faxed to KYCLPPP. Updates on EBLLs and interventions must be made in the notes section and a copy faxed to KYCLPPP. Staff need to write the current BLL and **date of specimen collection** clearly on the notes page.

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 exposures and help guide the family in taking corrective action
- Work to reduce patient's EBLL to < 3.5 by reducing/eliminating lead exposure
- Ensure that patients with EBLLs receive timely and appropriate care.

It is the responsibility of the case management nurse to request assistance from a certified risk assessor or environmentalist. A home visit can be performed solely by a nurse, but every effort should be made to include an environmentalist.

It is also the responsibility of the case management nurse to compile the required home visit form (including the section completed by an environmentalist) and fax these to KYCLPPP at (502) 564-5766 with Attn: KYCLPPP.

Certified Risk Assessments

According S sampling) of the property where a 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 patients with EBLL. Interventions during environmental investigations include:

- Informing the patient/parent/guardian/caregiver of child's EBLL, review level of understanding, and monitoring of BLLs.
- 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 the patient's physical status, behavior problems/changes, nutritional status, and specific habits such as placing fingers in mouth or eating dirt/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
E

Upon receipt of confirmed EBLL, LHD staff are responsible for collaboration and referrals to the environmentalist for the appropriate environmental intervention. Environmentalists will only be aware of EBLL if the case-managing nurse informs them and requests assistance.

For children identified as having BLLs of:

- >3.5 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.
- > In addition to the visual investigative home visit, a referral must be made to the environmentalist to ensure a lead hazard inspection/risk assessment with sampling is completed by a

certified risk assessor. **Requesting a risk assessment is the responsibility of the case managing nurse.**

Investigation of the Primary Address

Part I of the home visit form must be initiated by the LHD case-managing nurse. This equips the environmentalist with information in best identifying potential sources of current and past lead hazard exposure. Investigations must be conducted within the appropriate timeframes according to CDC's recommendations (See Table 4). 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 4: Time Frames for Environmental Investigation

Blood Lead Level	Time Frame for Assessment
3.5-14.9 ug/dL	30 days for confirmed BLL in this range
15-19.9	2 weeks; & refer for comprehensive lead risk assessment
20-44.9	1 weeks; & refer for comprehensive lead risk assessment
45-69.9	48 hours; & refer for comprehensive lead risk assessment
>70	24 hours; & refer for comprehensive lead risk assessment

Centers for Disease Control and Prevention.

A thorough visual investigation of the child's home helps families to identify possible sources of lead. The investigator must visually assess both the interior and exterior environment of the child with attention given to those areas that are **child-accessible,** painted surfaces, and areas with dust and soil accumulation. Other potential sources of lead must also be considered during the assessment (i.e., water, family occupation, hobbies, etc.). A lead exposure can frequently include multiple sources.

At the time of the 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 recommended to immediately keep the child from accessing potential lead hazard sources.

If the child's BLL should increase to a confirmed level of > 15ug/dL, certified risk assessment is required. The case should be referred to the environmentalist by the case managing nurse.

Helping a Family Reduce a Lead Exposure

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 a potentially 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.

If the BLL remains ≥ 3.5 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.

Additional and Follow-Up Home Visits

Additional or follow-up home visits ensure preventive measures for lead poisoning prevention are continuing. Conducting additional or follow-up home visits is at the discretion of the case- managing nurse and relevant LHD staff. Some reasons why an additional or follow-up home visit might be completed:

a. BLLs remain elevated or are increasing over a period of months.
b. The child moves to a new residence.
c. Custody of the child changes and the new guardians need assistance controlling a lead exposure.
d. A new lead source is discovered, and the family needs further assistance on controlling the exposure.

Case Closure

Case closure is determined according to the case's highest confirmed blood level and can be closed as follows:

- For BLLs of 3.5-14.9 – Case closure occurs when BLL is < 3.5 repeat at- risk blood testing as indicated.
- _____ – months, environmental hazards have been addressed; there are no new environmental hazards or as ordered by the physician.

For a pregnant woman with an EBLL, case closure of the pregnant woman occurs at the time of the delivery of the newborn. **If the pregnant woman'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 must be initiated for newborns with BLLs ≥

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.

Referring a family to Department for Community Based Services (DCBS) on the basis of non-compliance is at the discretion of the case-managing nurse and any specific health department guidance. Please see Administrative Reference (AR) Volume I, Abuse, Neglect and Violence section/ Department for Community Based Services. If the only deciding factor is non- compliance for lead follow-up care, special consideration must be given to the severity of the child's elevation.

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 the initial BLL and updated information. Please do not continue to use the old file and write "reopened".

KY CLPPP forms available at Clinical Service Guide Forms and Teaching Sheets - Cabinet for Health and Family Services (ky.gov). Fax completed forms to (502) 564-5766 with Attn: KYCLPPP

Manuals

1. *Screening Young Children for Lead Poisoning: Guidance for State and Local Public Health Officials*. (CDC, 1997)
2. *Managing Elevated Blood Lead Levels Among Young Children: Recommendations from the Advisory Committee on Childhood Lead Poisoning Prevention*. (CDC, 2002)
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/
  - CDC. Blood Lead Reference Value available at Blood Lead Reference Value | Lead | CDC. (2021).
  - CDC. Recommended Actions Based on Blood Lead Levels available at Recommended Actions Based on Blood Lead Levels. (2022).
  - CDC. Screening for Lead during the Domestic Medical Examination for Newly Arrived Refugees available at Lead Screening Guidelines: Domestic Guidelines | CDC. (2022).
  - CDC. Guidelines for the Identification and Management of Lead Exposure in Pregnant and Lactating Women available at https://www.cdc.gov/nceh/lead/publications/leadandpregnancy2010.pdf. (2010)
  - CDC. Preventing Lead Poisoning in Young Children available at https://www.cdc.gov/nceh/lead/publications/prevleadpoisoning.pdf . (2005)
- American Academy of Pediatrics (AAP)
  - Bright Future Medical Reference Screening Tables Including lead screening and testing are available for download at Medical Screening Reference Tables (aap.org)
- Environmental Protection Agency: www.epa.gov/lead
  - Lead Safety Documents and Outreach Materials (most in English and Spanish) are available at https://www.epa.gov/lead/lead-safety-documents-and-outreach-materials
  - EPA. Lead Poisoning and Your Children available at https://www.epa.gov/sites/default/files/documents/lpandyce.pdf. (2000)
  - EPA. Lead Poisoning Home Checklist available at https://www.epa.gov/sites/default/files/documents/parent_checklist3.pdf. (2014)
- Resources for Refugee Populations
  - Reducing Childhood Lead Poisoning in Immigrant Communities from Imported Makeup. Information and fact sheets in six languages (English, Dari, Pashto, Urdu, Hindi, Arabic, and Somali) available at https://wspehsu.ucsf.edu/projects/reducing-childhood-lead-poisoning-in-immigrant-communities-from-imported-makeup/
  - Kohl, Kajal, Al-Kahal, Surma, Tiro, Tozali, or Kwalli: By Any Name, Beware of Lead Poisoning. Provides information and alerts. Available at Kohl, Kajal, Al-Kahal, Surma, Tiro, Tozali, or Kwalli: By Any Name, Beware of Lead Poisoning | FDA

Newborn Metabolic Screening

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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 Dried Blood Spot test and Critical Congenital Heart Defect screening at the first well child visit.
    b. If those results have not been received, the LHD should contact the Division of Lab Services (DLS), Newborn Screening Division at
        - 502-782-7713 or
        - 502-782-7734 to obtain those results and put them in the infant's chart.
    c. LHDs should request access for obtaining NBS results electronically with the DLS NBS Division.
    d. Initial Screening should occur at the LHD when an infant has not received the dried blood spot newborn screening or critical congenital heart defect screening as a result of:
        - home delivery
        - early hospital discharge (release less than 24 hours); or
        - the parent has been notified that the dried blood spot newborn screen needs to be repeated.
    e. If a newborn screening dried blood spot specimen is obtained 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. Newborn Metabolic Screening Results:
    a. Unsatisfactory Specimen:
        - DLS will notify the LHD to obtain another dried blood spot specimen immediately.
        - The parent/guardian will be sent a letter from the MCH NBS program to contact their PCP for additional testing.
    b. Abnormal Specimen:
        - DLS and MCHNBS notify the PCP, and University Specialist for further evaluation and guidance for the parent/guardian to follow.
        - MCH NBS calls the university specialist and PCP with results and sends a packet of information that includes information about the abnormal result and educational handouts for the parent/guardian.
        - If the LHD is the PCP for the newborn, this information will be sent to the fax number supplied on the dried blood spot specimen.
        - IF the LHD is not the PCP – they should clearly note the correct name and contact number for the PCP on the dried blood spot specimen to prevent delay in care for the newborn.
    c. Repeat Labs required: Some NBS results require a variety of repeat labs be obtained for further evaluation/screening. In the event, these are required, the need is reflected in the notes at the bottom of the NBS lab report.
        - A letter requesting repeat test(s) from the MCH NBS program is sent to the infant's health caregiver/submitter (physician, hospital, primary care provider or LHD).
        - In some instances, the submitter is notified via telephone.
        - MCH NBS staff will send a letter to the infant's mother or guardian notifying of the continued need for repeat testing.
        - LHD should continue to monitor and/or obtain 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 for newborn screening specimens on patients over six (6) months of age *unless they fall under one or both categories*:
    - Prematurity
    - 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,
    - The parent/guardian must sign a refusal of treatment form
    - Fax the form to the MCH NBS program at (502) 564-1510.
    - If you have questions, call the MCH NBS program can be reached at (502) 564-2154.

Pediatrics

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CLINICAL PROTOCOLS

Pediatric Preventive Health Care: https://downloads.aap.org/AAP/PDF/periodicity_schedule.pdf

PEDIATRIC PREVENTIVE HEALTH CARE

Pediatric exams for preventive care should follow and meet the standards as established by the American Academy of Pediatrics (AAP) and referenced through the Bright Futures Guidelines for Health Supervision of Infants, Children and Adolescents. Each LHD is responsible for ensuring practice standards/clinical practice is in alignment with the most recent information from the AAP. The clinical practice, preventive services, periodicity schedule and anticipatory guidance can be found at the following links. These are updated periodically by the AAP and LHDs must develop a process for ensuring they are reviewing the latest updates available.

The following are direct links to Bright Futures: Guidelines for Health Supervision of Infants, Children and Adolescents, 4th Edition. Each link has tables that provide reference information for each well-child visit to include relevant history, risk assessment, and action for abnormal findings.

- **Infancy Medical Screening Reference (MSR) Tables (0 - 9 Months)**
- **Early Childhood Medical Screening Reference (MSR) Tables (12 Months - 4 Years)**
- **Middle Childhood Medical Screening Reference (MSR) Tables (5 - 10 Years)**
- **Adolescence Medical Screening Reference (MSR) Tables (11 - 21 Years)**

A preventive pediatric exam should include all components as defined by the American Academy of Pediatrics, *Bright Futures Guidelines for Health Supervision of Infants, Children, and Adolescent.* Abnormal findings may require additional exams by the primary health care provider, or a health care specialist.

Comprehensive health and developmental history, including assessment of physical and mental health development

Physical examination - A comprehensive unclothed physical exam as per at brightfutures.aap.org.

Nutritional assessment - Assessment is based on the child's health history, physical exam including oral exam, growth pattern, and appropriate blood work as identified on periodicity schedule (usually, this includes hemoglobin and lead screening). It is also recommended that providers plot body mass index (BMI) beginning at age 2.

Developmental surveillance or screening: (the process of recognizing children who may be at risk of developmental delays) should be incorporated into every visit, except for the 9-month, 18-month, and 30-month visits.

Structured developmental screening (the use of standardized tools to identify and refine the risk of developmental delays) should be administered regularly during the 9-month, 18-month, and 30-month visits. Psychosocial/behavioral assessment

Psychosocial/behavioral assessment. This assessment should be family centered and may include an assessment of child's social-emotional health, caregiver depression, and social determinants of health.

Vision assessment or screening: Direct referral to an optometrist or ophthalmologist is required when objective screening methods indicate a referral is warranted.

Hearing assessment or screening: Required at 4 to 5 years old should be administered in the primary care providers, or the patient should be referred to a hearing specialist.
Oral Health: The risk assessment, as well as referrals to a home dentist, should also be provided at when indicated.

Administration of or referral to any laboratory tests, procedures, or immunizations appropriate for age and risk factors as identified during the clinical exam, or as per Advisory Committee on Immunization Practice (ACIP) and as by 902 KAR 2:060.

Health education: Patient health education is a required component and should include documented and appropriate anticipatory guidance to promote understanding of what to expect in terms of the child's development, healthy lifestyle choices, and accident and disease prevention.

Diagnostic Services and Follow-Up Treatment

Providers must assist in setting appointments to establish a medical home for the infant or child. Abnormalities identified should be referred to the appropriate provider for ongoing evaluation and care.

Prenatal

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Prenatal Service Guidelines

X= Required service; Services to be performed according to ACOG guidelines

Component	Initial Workup	Initial Exam	Return Visits	15-20 Weeks	20-24 Weeks	28 Weeks	32 Weeks	35-37 Weeks	Post-Partum Visit
History									
Comprehensive History (see ACOG antepartum/post-partum forms)		X	Review						X
Assess Immunization Status									
Lead Risk Assessment	X								X
Assess Domestic Violence/ IPV	X			X – second	trimester	X - third	trimester		X
Assess Depression/Post-Partum Depression	X	X	X					X	X
Assess for Minor Discomforts	X	X	X						
EXAMINATION									
Determine Estimated Date of Confinement	X	X							
Blood Pressure/Weight/BMI	X	X	X						X
Height	X								
Oral Health Screen	Within first	trimester							
Complete Physical Exam		X							X
Pelvic Exam (See cancer screening section re. Pap exams)		X							
ACOG Antepartum/Post-partum Forms		X	X						X
Document Fetal Movement	X	X	X						
Lab Tests/Procedures									
Hgb/Hct	X				If indicated	If indicated	X	X	
Blood Type/Rh Factor	X								
Rh Antibody Titer	X					If negative			
Prenatal RhoGam						If negative			
Hepatitis B surface Antigen (HBsAG) See guidelines	X							At risk	
Syphilis IGG (with reflex testing if positive)	X						At risk	At risk	
Hepatitis C	X						At risk	At risk	
HIV (see guidelines)	X					At risk	At risk	At risk	
Rubella Titer	X								
Blood Lead Levels (see guidelines)	If positive screen								
Blood Glucose	X			At risk		At 24-28 weeks			If had GDM
Glucose Challenge Test (see guidelines)					If indicated	If indicated			
Triple Screen or Quad Screen (see guidelines)				X					
Ultrasound				X				At risk	
TB Skin Test	At risk								
Dipstick Urinalysis	X		X						
Urine Culture (clean catch midstream)	X								
Pap Test	If indicated		See	Cancer	Screening	Section			
Gonorrhea/Chlamydia/BV cultures		At risk					At risk	At risk	
Cystic Fibrosis (see guidelines)	Offer to all								
GBS Vaginal Culture (see guidelines)							X	X	
Counseling									
Nutrition/Weight Gain/Vitamins/Folic Acid & WIC Referral	X		X						
Breastfeeding Benefits	X							X	
Exercise	X (PN-3)								
Dental Care	X	X	At risk						
Smoking/Alcohol/Drug/SHS Exposure	X	X	X						
Paternity	If indicated								
Post-partum Depression/Depression								X	X
Preterm Risk Status/Prevention/Referral	X		X						
Intimate Partner Violence (per trimester)	X			X- second	trimester	X- third	trimester	X third trimester	X
HIV/AIDS & Other Prenatal Tests	X								
Environmental/Work Hazards/Toxoplasmosis	X								
Medication Use (OTC & Rx)	X		X						
Referral to HANDS	If indicated								
Enroll with PE/Medicaid/Emergency Medicaid	X		If applicable						X
Provide Client with Education Forms	MCH/PN-3, 8, 11; PAM-ACH 263; PN-2, PN-T1			PN-T2		PN-T3			PN-T4
Anticipatory Guidance by gestational age/ interests/risk factors/common discomforts	X	X	X						

- 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.
- 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 stage of pregnancy. According to ACOG guidelines, pregnant women

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.

- 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, alcohol and substance use, depression, safety, intimate partner violence (IPV) and stress. These factors can contribute to risk of preterm birth, which should also be assessed.
- 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
- 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.
- Folic Acid: Before pregnancy and during pregnancy, women need 400 micrograms (mcg.) 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.
- Prenatal Vitamins: Vitamin supplementation should be prescribed/encouraged during pregnancy, the post-partum 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.)
- Medication Use: Prenatal clients should be advised to consult with their health care provider before using non-prescription 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.
- 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, including recreational use of prescriptions and over-the-counter medications. This should be documented in the medical record and clients should be educated and referred appropriately. The *Pregnancy Health Risk Screen* (PN-2) 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.

References:

1. ACOG.org. (2019). ACOG statement on 17p hydroxyprogesterone caproate. Find at: acog.org/new-release/2019/10/acog-statement-17p-hydroxyprogesterone-caproate.
2. ACOG.org (2020). Committee opinion #718 [replaces #566 (2017)]. Update on immunization and pregnancy: tetanus, diphtheria and pertussis vaccination. Find at: acog.org/clinical-guidance/committee-opinion/articles/2017/09/update-on immunization-and-pregnancy-tetanut-diphtheria-and-pertusis-vaccination.
3. ACOG (2021). *Your pregnancy and childbirth month to month. Chapter 1: getting ready for pregnancy.* American College of Obstetricians and Gynecologists, Washington, DC.
4. Centers for Disease Control and Prevention (2021). *Vaccines and immunization.* CDC, Atlanta, Georgia. Available at: https://www.cdc.gov/vaccines/index.html.

Guidelines for Prenatal Vitamins

	1997-2011 Dietary Reference Intakes (DRI)	Minimal Level	Maximum Level
Vitamin A	Age ≤ 18 750 mcg. RAE (3750 IU) Age 19-50 770 mcg. RAE (3850 IU)	Age ≤ 18 750 mcg. RAE (3750 IU) Age 19-50 770 mcg. RAE (3850 IU)	Age ≤18 2800 mcg. RAE (14,000 IU) Age 19-50 3000 mcg. RAE (15,000 IU)
Vitamin D	5 mcg. (200 IU)	5 mcg. (200 IU)	100 mcg. (4000 IU)
Vitamin E	15 mg. (10 IU)	10 mg. (7 IU)	Age ≤18 800 mg. (536 IU) Age 19-50 1000 mg (670 IU)
Vitamin C (Ascorbic Acid)	Age ≤ 18 80 mg. Age 19-50 85 mg.	70 mg.	Age ≤18 1800 mg. Age 19-50 2000 mg.
Vitamin K	Age ≤ 18 75 mg. Age 19-50 90 mg.		NA
Thiamin	1.4 mg	1.4 mg.	NA
Riboflavin	1.4 mg.	1.4 mg.	NA
Niacin	18 mg.	17 mg.	Age ≤ 18 30 mg. Age 19-50 35 mg.
Vitamin B_6	1.9 mg.	2.0 mg.	Age ≤18 80 mg. Age 19-50 100 mg.
Folic Acid *	600 mcg.	400 mcg.	Age ≤ 18 800 mcg. Age 19-50 1000 mcg.
Vitamin B_{12}	2.6 mcg.	2.2 mcg.	NA
Biotin	30 mcg.	AI of 30 mcg.	NA
Pantothenic Acid	6.0 mg.	6.0 mg.	NA
Calcium	Age 14-18 1300 mg. Age 19-50 1000 mg.	250 mg.	Age ≤ 18 3000 mg. Age > 18 2500 mg.
Choline	Age ≤ 18 4.5 gm. Age 19-50 4.5 gm.		Age ≤ 18 3.0 gm. Age 19-50 3.5 gm.
Copper	1000 mcg.	1000 mcg.	8000 mcg.
Iodine	220 mcg.	220 mcg.	Age ≤ 18 900 mcg. Age 19-50 1100 mcg.
Iron	27 mg.	27 mg.	45 mg.
Magnesium	Age 14-18 400 mg. Age 19-30 350 mg. Age 31-50 360 mg.	100 mg.	350 mg.
Molybdenum	50 mcg.	50 mcg.	Age ≤ 18 1700 mcg. Age 19-50 2000 mcg.
Phosphorus	Age ≤ 18 1250 mg. Age 19-50 700 mg.	Age ≤ 18 1250 mg. Age 19-50 700 mg.	3500 mg.
Selenium	60 mcg.	60 mcg.	400 mcg.
Zinc	Age ≤ 18 12 mg. Age 19-50 11 mg.	9 mg.	Age ≤ 18 34 mg. Age > 18 40 mg.

NA = Not available.

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 (2^{nd}) trimester the prenatal supplement should contain at least the following: Iron 30 mg; Zinc 15 mg.; Copper 2 mg.; Calcium 250 mg.; Vitamin B_6 2 mg.; Folic Acid 300 mcg.; Vitamin C 50 mg. and Vitamin D 5 mcg.
- LHDs should have a protocol for documenting the distribution of any medication, including vitamins.

References:

1. Brown, J.E. (2005). *Nutrition Now, 4th Edition.* University of Minnesota. Belmont, CA; Wadsworth Publishing Company.
2. Brown, J.E. (2005). *Nutrition through the life cycle, 2nd Edition.* University of Minnesota. Belmont, CA; Wadsworth Publishing Company.
3. ACOG.org. (2022). ACOG FAQ Nutrition During Pregnancy. Find at: https://www/acog.org/Patients/FAQs/Nutrition-During-Pregnancy.
4. Institute of Medicine. (2006). *Dietary reference intakes: the essential guide to nutrient requirements. Washington, DC; The National Academies Press.*
5. *ACOG. (2021). Your pregnancy and childbirth month to month. Chapter 1: getting ready for pregnancy.* Washington, DC. The American College of Obstetricians and Gynecologists.

Recommendations for Weight Gain During Pregnancy

Pre-Pregnancy BMI	BMI (kg/m^2)	Total Weight Gain (lbs.)	Rate of Weight Gain 2nd & (3rd Trimester)
Underweight *	<18.5	28-40	1 (1-1.3)
Normal Weight	18.5-24.9	25-35	1 (0.8-1)
Overweight *	25.0-29.9	15-25	0.6 (0.5-0.7)
Obese * (Includes all Classes)	≥30	11-20	0.5 (0.4-0.6)
Twins[2]		Normal weight status: 37-54 Overweight status: 31-50 Obese status: 25-43	

- 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 (especially after 24 weeks gestation).
- Determining appropriate weight gain is professional judgment that must be based upon the individual client'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, food insecurity and weight loss during pregnancy.

*Excessive weight gain = greater than eight pounds/month

*Inadequate weight gain = less that two pounds/month after 1st trimester

References:

1. Institute of Medicine (2009). *Weight gain during pregnancy: reexamining the guidelines.* Washington, DC. National Academy Press.
2. ACOG (2013, reaffirmed 2020). *Committee opinion #548: Weight gain during pregnancy.* Washington, DC. The American College of Obstetricians and Gynecologists.

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.

BMI	19	19.8	20	21	22	23	24	25	26	26.1	27	28	29	29.1	30	32	34	36	38	40
4'10" (58")	91	95	96	100	105	110	115	119	124	125	129	134	138	>138	143	153	162	172	181	191
4'11" (59")	94	98	99	104	109	114	119	124	128	129	133	138	143	>143	148	158	168	178	188	198
5'0" (60")	97	102	102	107	112	118	123	128	133	134	138	143	148	>148	153	163	174	184	194	204
5'1" (61")	100	105	106	111	116	122	127	132	137	138	143	148	153	>153	158	169	180	190	201	211
5'2" (62")	104	108	109	115	120	126	131	136	142	143	147	153	158	>158	164	175	186	196	207	218
5'3" (63")	107	112	113	118	124	130	135	141	147	147	152	158	163	>163	169	180	191	203	214	225
5'4" (64")	110	116	116	122	128	134	140	145	151	152	157	163	169	>169	174	186	197	209	221	232
5'5" (65")	114	119	120	126	132	138	144	150	156	157	162	168	174	>174	180	192	204	216	228	240
5'6" (66")	118	123	124	130	136	142	148	155	161	162	167	173	179	>179	186	198	210	223	235	247
5'7" (67")	121	127	127	134	140	146	153	159	166	167	172	178	185	>185	191	204	217	230	242	255
5'8" (68")	125	130	131	138	144	151	158	164	171	172	177	184	190	>190	197	210	223	236	249	262
5'9" (69")	128	134	135	142	149	155	162	169	176	177	182	189	196	>196	203	216	230	243	257	270
5'10" (70")	132	138	139	146	153	160	167	174	181	182	188	195	202	>202	209	222	236	250	264	278
5'11" (71")	136	142	143	150	157	165	172	179	186	187	193	200	208	>208	215	229	243	257	272	286
6'0" (72")	140	146	147	154	162	169	177	184	191	192	199	206	213	>213	221	235	250	265	279	294
6'1" (73")	144	150	151	159	166	174	182	189	197	198	204	212	219	>219	227	242	257	272	288	302
6'2" (74")	148	154	155	163	171	179	186	194	202	203	210	218	225	>225	233	249	264	280	295	311
6'3" (75")	152	158	160	168	176	184	192	200	208	208	216	224	232	>232	240	256	271	287	303	319
6'4" (76")	156	162	164	172	180	189	197	205	213	214	221	230	238	>238	246	262	279	295	312	328
6'5" (77")	160	166	168	176	185	193	202	210	218	219	227	235	244	>244	252	269	286	303	319	336
6'6" (78")	164	170	172	181	190	198	207	216	224	225	233	241	250	>250	259	276	293	310	328	345

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

- Risk 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 mcg/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.

- 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.

- 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.

- Results of screening test:

Level 5-14.9 mcg/dl	Level $\geq$ 15 mcg/dl
Lead exposure	Lead poisoning
Home visit and counseling to reduce of eliminate know risk factors. *	Home visit and counseling to reduce or eliminate known risk factors. *
Notify delivering physician of test results and repeat blood specimen in 8 weeks.	Notify delivering physician of test results and repeat blood specimen in 8 weeks.
At-risk prenatal patients should be followed up by case management. *	At-risk prenatal patients should be followed up by case management. *
	Refer women for an environmental risk assessment. *

*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 limited and critical in preventing poor pregnancy outcomes. Pregnant women with lead levels above 5mcg/dl should be advised that any children in the household (6 months-6 years) should be referred to the LDH's Well-Child/EPSDT program or 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 (HBsAB) 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 third trimester.

- Negative test and vaccination in pregnancy
  Any pregnant woman with a negative Hepatitis B HBsAG who is at risk for acquiring Hepatitis B infection should receive the vaccine as soon as possible. The vaccine is purified surface antigen and poses no risk to the fetus. SEE: Immunization protocols for specific information on vaccine administration.

- Positive test
  Refer to the Immunization/Perinatal Hepatitis B Prevention program and Case Management Protocol section of the CSG for reporting, management and required tracking of mother and infant.

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 sub-specialist 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 testing after birth. The prenatal provider shall verbally inform the pregnant woman or the legal guardian of the child/children affected during the pregnancy and document that in the medical record; and that KRS 214.160 recommends that all children born to HCV-positive women receive serologic testing for the presence of Hepatitis C virus antibodies and confirmatory 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 section delivery will not decrease the transmission of HCV infection to her baby. Women who are positive for HCV infection can still breastfeed but should consider abstaining if their nipples are cracked or bleeding.

References:

1. ACOG, (2016). *Protecting Yourself Against Hepatitis B and Hepatitis C.* Available at: https://www.acog.org/Patients/FAQs/Protecting-Yourself-Against-Hepatitis-B-and-Hepatitis-C
2. Hughes, B.L., Page, C.M. & Kuller, J.A. (2017). Hepatitis C in pregnancy: screening, treatment, and management. *American Journal of Obstetrics and Gynecology, 217(5).*
3. Centers for Disease Control and Prevention, (2015). Sexually transmitted diseases treatment guidelines. *MMWR Recomm Rep, 2015; 64(3):19.*
4. ACOG (2021; reaffirmed in 2022). ACOG Practice Advisory: Routine hepatitis c virus screening in pregnant individuals. Available at: acog.org/clinical/clinical-guidance/practice-advisory/articles/2021/05/routine-hepatitis-c-virus-screening-in-pregnant-individuals.

Preventing Perinatal HIV/AIDS Transmission

All pregnant women should be counseled on HIV, including identification of risk factors and effective ways to reduce risk. Because of recent advances in both antiretroviral and obstetrical interventions, the use of antiretroviral medications during pregnancy and delivery, and with the newborn in the first few weeks of life, the rate of vertical transmission can be reduced 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 to the patient on the initial prenatal visit and documented in the medical record.
- Repeat HIV testing in the third trimester, preferably before 36 weeks gestation, is recommended for women in areas with a high incidence or prevalence of HIV and for women who are known to be or report 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 can promote health education and trust building and allow some women to accept testing later.
- Documentation of informed consent shall use language the client understands.
- Pregnant women should be provided with verbal and/or written information about HIV, including interventions to reduce the risk of transmission from mother to infant. No additional written documentation of informed consent beyond that which is required for routine prenatal testing is recommended. Refusal of the HIV test at the initial visit or at the recommended retesting time frame should be documented in the medical record.
- Women who have an established diagnosis of HIV/AIDS should be linked to specialists in HIV care for ongoing care and co-management.

See HIV/AIDS section for further information and protocols.

References:

1. ACOG, (2018). ACOG Committee Opinion # 752, *Prenatal and perinatal human immunodeficiency virus testing.* Available at: acog.org/clinical/clinical-guidance/committee-opinion/articles/2018/09/prenatal-and-perinatal-human-immunodeficiency-virus-testing
2. Patient fact sheet available at: https://www.acog.org/patient-resources/faqs/pregnancy/hiv-and-pregnancy.

Multiple Marker Test (Triple or Quad Screen)

Maternal serum screening has become an important, non-invasive diagnostic tool for several congenital and chromosomal abnormalities in the fetus. 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. Patient counseling must emphasize this is a screening test that will identify a high-risk pregnancy. If the patient declines testing this should be documented in the medical record.
- The multiple marker specimen must be submitted to a clinical laboratory that has normative data specific to each week of gestation and is able to provide interpretation that considers maternal age, weight, race and relevant history such as diabetes and neural tube defects. Imprecise information could 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 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 client 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 test, the client should be referred to an obstetrician for possible amniocentesis.

References:

1. ACOG, (2020). *FAQs: Prenatal genetic screening tests.* Available at: acog.org/womens-health/faqs/prenatal-genetic-screening-tests.

Cystic Fibrosis 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, and each pregnancy has a 25% change of developing CF. Most clients are unfamiliar with CF and will need education. Written educational materials 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. In some circumstances a referral to a medical geneticist may be helpful.

- CF screening should be offered to all prenatal clients, 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 the client has previously been screened for CF the results should be documented by 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 client's screening test shows that she is a carrier, the father of the baby should be offered testing. This test may be performed by the LHD or referral can be made to a provider for testing. The LHD, however, does not have to pay for this test and it should not be coded to cost center 803. If testing is provided at the LHD, the father should sign a consent form. Any education and interventions should be documented.
- The provider may offer the client additional testing during pregnancy, such as chorionic villus sampling (generally done around 11th week of gestation) and amniocentesis (generally done around 16th week of gestation) to further determine if the fetus has CF.
- Cystic Fibrosis is not a curable disease and there are no treatments available before the baby is born. There are treatments available after birth. Families can use the time prior to birth to educate themselves on CF, current treatment options and the experiences of families with CF children as well as talking to care providers.
- Documentation of the consent process is important. A sample consent for is available in English and Spanish in the Forms Section.

References:

1. ACOG, (2017, reaffirmed 2020). Committee Opinion #691: *Carrier screening for genetic condition.* Available at acog.org
2. ACOG faq guide available at: acog.org/womens-health/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 should be screened for GBS between 35-37 weeks gestation. Clinicians should follow the most recent CDC/ACOG algorithms for management.

Screening Procedure

- Swab the lower vagina (vaginal introitus), followed by the rectum (through the anal sphincter) using the same or two different swabs.
  Cervical, peri-anal, peri-rectal or perineal specimens are not acceptable. A speculum should not be used for culture collection.
- Place the swab(s) into a non-nutritive transport medium. Group B streptococci isolates can remain viable in transport media at room temperature for 1 day with out risk of false-negative results. Specimen requisitions should clearly indicate the specimens are for group B streptococci culture.
- Laboratories performing these cultures should ensure clinicians have continuous access to results 24 hours per day/7 days a week.
- If group B streptococcal bacteria is detected any time during pregnancy, it should be treated.

Reference:

1. ACOG, (2020). ACOG Committee Opinion #797: *Prevention of Group B Streptococcal Early-Onset Disease in Newborns.* Available at: https://www.acog.org/search#q=preventingGroupBstreptococcaldiseaseinthenewborn&sort=relevancy

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:

1. ACOG, (2019). *FAQ054 Genital Herpes*. Available at: 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 increased risk of macrosomia, neonatal hypoglycemia, hyperbilirubinemia, shoulder dystocia and cesarean delivery.

Screening
According to ACOG guidelines, all pregnant women should be screened for GDM, either by 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 for women with risk factors.

Early screening of undiagnosed type 2 diabetes is also suggested in women with the following risk factors:

- A previous medical history of GDM
- A known impaired glucose metabolism
- Obesity (BMI≥30)

If GDM is not diagnosed, blood glucose testing should be repeated at the 24-28 week prenatal visit.

Diagnostic Testing Procedures

- The Glucose Challenge Test (GCT) entails the consumption 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 client does not need to be fasting for this test.
    - If the one-hour test is abnormal (>140-179mg/dl), a 100-gram diagnostic Oral Glucose Tolerance Test (OGTT) is performed. (If the 1 hour 50-gram load venous blood glucose is ≥180, do not proceed to the 3-hour OGTT – refer to physician).
    - Schedule 3-hour OGTT within 7 days.

- 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 grams carbohydrate/day) and unrestricted activity (unless contraindicated) need to precede the test.
    - Women taking prescription medications should check with their health provider for specific instructions.
    - Women need to remain seated and not smoke during the test.
    - A finger stick (capillary) blood sample along with a fasting venous (plasma) blood sugar should be obtained prior to the administration of the commercially prepared glucose solution.
    - If the fasting capillary sample glucose level is >126mg/dl, do not administer oral glucose without consulting the client's provider. The provider should determine whether to proceed with the 3-hour OGTT.
    - If the fasting capillary sample glucose level is below 126mg/dl proceed with the test. Venous blood samples are then collected at 1, 2, and 3-hour intervals.

Diagnosis

- According to ACOG guidelines, diagnosis of GDM can be determined by the result of a 100-gram, 3-hour OGTT.
- Either plasma or serum glucose level established by Carpenter & Coustan or the plasma level designated by the National Diabetes Data Group is appropriate for use.
- A definitive diagnosis of GDM requires that 2 or more thresholds be met or exceeded.

Table 1. Diagnostic Criteria for the 100-gram, 3-hour Oral Glucose Tolerance Test (OGTT) for GDM

Status	Carpenter & Coustan Conversion Plasma or Serum Glucose Level (mg/dl)	National Diabetes Data Group Conversion Plasma Level (mg/dl)
Fasting	95	105
1 Hour	180	190
2 Hours	155	165
3 Hours	140	145

- A positive diagnosis requires that 2 or more thresholds are met or exceeded.
- To make this test reliable, the client 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 post-partum follow-up.
- Counsel re. self-monitoring of blood glucose and daily fetal kick counts (starting between 26-32 weeks gestation).

Home Blood Glucose Monitoring and Follow-Up

Controlled	Uncontrolled
Fasting whole blood ≤95 Fasting plasma ≤105	Fasting whole blood >95 Fasting plasma >105
1 hour pp. whole blood ≤140 1 hour pp. plasma ≤155	1 hour pp. whole blood >140 1 hour pp. plasma >155
2 hour pp. whole blood ≤120 2 hour pp. plasma ≤130	2 hour pp. whole blood >120 2 hour pp. plasma >130
Continue current therapy	Refer to physician

Note: Many blood glucose monitors now calibrate to plasma glucose. Values depend on the meter.

GDM ASSESSMENT	APPROPRIATE SCREENING	RESULTS	MANAGEMENT
Abnormal BG at initial prenatal visit: ○ Fasting BG ≥126mg/dl ○ Random BG ≥200mg/dl Note: If a capillary specimen is performed, the blood glucose meter must yield a plasma equivalent value.	Refer immediately for subsequent testing – do no further testing.	A fasting plasma glucose level ≥126mg/dl or a random plasma glucose ≥200mg/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 50gm load prior to 20 weeks gestation.	≤139mg/dl 140-179mg/dl ≥180mg/dl	Repeat at 24-28 weeks gestation. Schedule 3-hour OGTT within 7 days Refer to a physician
Repeat screening at 24-28 weeks gestation	Perform 1-hour plasma glucose following a 50-gram load. (See procedure).	≤139mg/dl 140-179mg/dl ≥180mg.dl	Further testing not needed. Schedule for 3-hour OGTT within 7 days. (See procedure) Refer to a physician
Post-partum screening for all women diagnosed with GDM.	Either a fasting plasma glucose or a 2-hour OGTT performed 6-12 weeks post-partum.	Negative: <100mg/dl Positive: ≥100mg/dl	Repeat every 3 years or more often depending on risk factors or if symptoms develop. Provide counseling and referral to physician and nutritionist.

References:

1. ACOG, (2020). *Gestational Diabetes FAQ177.* Available at: acog.org/womens-health/faqs/gestational-diabetes.
2. ACOG, (2018). *Gestational Diabetes Mellitus Practice Bulletin #190.* Available at: https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2018/02/gestational-diabetes-mellitus.

COUNSELING & REFERRAL FOR COMMON DISCOMFORTS IN PREGNANCY

DISCOMFORT	POSSIBLE CAUSE	NURSE ACTION
Backaches/Low Back Pain	• Possible sign of preterm labor • Possible symptom of a UTI • Normal lordosis of pregnancy caused by the enlarging uterus • Normal relaxation of pelvic joints	• Assess for symptoms of preterm labor or UTI • **Consult/refer to medical provider if preterm labor/UTI suspected** • Education: symptoms of preterm labor; proper body mechanics; prenatal exercises (pelvic tilt); avoid high 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 increased estrogen, progestins, vascularity and glandular components of the breasts. Usually decreases or subsides after 1st 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 gastrointestinal tract because 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 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 2nd or 3rd 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 lower extremities/ increase rest (preferably 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, increasing 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)	• Increased hormones cause increase vascularity • Increased dilation of capillaries in the skin and mucous membranes • Most common in the 2nd trimester, returns to normal following pregnancy	• **Refer to medical provider if heavy nosebleeds or infection: check BP** • Education: avoid trauma such as hard blowing of nose; avoid nasal sprays and decongestants; may apply gentle external nasal pressure to stop the bleeding
Headaches	• May be a sign of preeclampsia in late 2nd or 3rd trimesters • Other causes include hypoglycemia, migraines, dehydration and illness • Emotional tension/stress • Nasal congestion from estrogen levels • Increase in circulating blood volume • Common in the 1st trimester due to increased hormone levels	• Assess for signs of preeclampsia if 2nd or 3rd trimester • Refer to medical provider if symptomatic • Education: importance of adequate rest/sleep; adequate diet/fluid intake; avoid aspirin and ibuprofen products in pregnancy

DISCOMFORT	POSSIBLE CAUSE	NURSE ACTION
Heartburn and Indigestion	• Causes include vomiting, ulcers, hiatal hernia, gastro-esophageal reflux disease (GERD) • Fatty food intolerance • Stomach displacement and compression due to enlarging uterus • Increased gastric reflux due to progesterone levels • Decrease pepsin secretion due to estrogen elevations • Emotional tension/stress	• **Refer to medical provider if underlying disease or persistent symptoms** • Education: eat small, frequent meals; eat slowly; avoid lying down after meals; avoid gas producing foods; sip on milk or herbal tea; avoid baking soda; eliminate greasy, spicy, fried foods from the diet and clarify use of over-the-counter antacids (low sodium, high calcium)
Insomnia	• Contributing causes may include fetal movement*, heartburn, leg cramps, shortness of breath, nocturia, caffeine intake, stress and apprehension • Difficult positioning due to enlarged uterus • Inability to sleep usually occurs in the 3rd trimester	• **Consult/refer to provider immediately if patient reports decreased or no fetal movement** • Education: Fetal kick counts; use pillows for support of back and between legs; avoid caffeine; increase activity; take warm bath or shower; massage of back and neck and avoid long daytime napping.
Leg Cramps/Pain	• Thrombophlebitis and varicosities • Calcium/phosphorus imbalance • Muscle strain/fatigue/lack of exercise • Blood vessel compression in legs • Nerve compression in legs from the enlarging uterus	• Assess for redness, warmth, edema, positive Homan's sign or severe pain • Refer to medical provider if symptomatic • Education: avoid sodas and processed foods (very high in phosphorus); increase dietary calcium if needed; apply local heat; exercise such as walking (unless contraindicated) and avoid leg massage (may dislodge a clot if present)
Skin Changes	• Striae (stretch marks), spider angiomas, chloasma (mask of pregnancy), linea nigra, darkening of areola, increased hair and fingernail growth, redness of the palms of hands and soles of feet • Caused by increased production of estrogen and increase in circulation	• Refer to medical provider for rashes, allergic reactions, changes in moles, increased excoriation as indicated by client's history • Education: eliminate direct sunlight exposure and use sunscreen on exposed body parts
Vaginal Discharge	• **An increase in vaginal discharge over a short period of time may be a sign of impending 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 mucous production • Increase in odorless, thin-mucoid, 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 gestation • Metabolic changes (possible reduction in Vitamin B_6 metabolism) • Changes in hormonal balance, increase in estrogen primarily • Decreased gastric motility • Gastro-esophageal 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 medical provider if intractable vomiting, signs of dehydration, fever or significant weight loss.** • Refer for MNT if applicable • Education: Avoid overeating, fried, greasy or spicy foods, cooking odors, smoking and medications unless prescribed by the medical provider; eat small frequent high protein meals (6-8 peer day) and drink fluids between meals instead of with meals; may also try dry toast, crackers, ginger ale, peppermints and fresh fruit

DISCOMFORT	POSSIBLE CAUSE	NURSE ACTION
Palpitations	• Increase in blood volume, cardiac output and heart rate • Awareness of 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
Pelvic Pressure	• Possible sign of impending preterm labor or UTI • Pressure of the enlarging uterus pulls 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/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 client is anemic, obese or has a multiple gestation • Expansion of the 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/cardiac disease** • Education: importance of smoking cessation and avoiding secondhand smoke; avoid overeating, exertion and fatigue; utilize an extra pillow or elevate 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 • Hereditary 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 well-fitting girdle; support/elevate legs for varicosities and elevate 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

Rabies
Table of Contents

CLINICAL PROTOCOLS

Rabies preexposure prophylaxis recommendations-United States, 2022

http://dx.doi.org/10.15585/mmwr.mm7118a2

Risk category	Nature of exposure	Typical Population	Disease Biogeography	Primary Immunogenicity PrEP	Long-term immunogenicity
1. Elevated risk for unrecognized** and recognized†† exposures including unusual or high-risk exposures	Exposure, often in high concentrations, might be recognized or unrecognized, might be unusual (e.g., aerosolized virus)	Persons working with live rabies virus in research or vaccine production facilities or performing testing for rabies in diagnostic laboratories	Laboratory	IM rabies vaccine on days 0 and 7	Check titers every 6 months; booster if titer <0.5 IU/mL§§
2. Elevated risk for unrecognized** and recognized†† exposures	Exposure typically recognized but could be unrecognized; unusual exposures unlikely	Persons who frequently 1) handle bats, 2) have contact with bats, 3) enter high-density bat environments, or 4) perform animal necropsies (e.g., biologists who frequently enter bat roosts or who collect suspected rabies samples)	All geographic regions where any rabies reservoir is present, both domestic and international	IM rabies vaccine on days 0 and 7	Check titers every 2 years; booster if titer <0.5 IU/mL§§
3. Elevated risk forrecognized†† exposures, sustained risk	Exposure nearly always recognized; risk for recognized exposures higher than that for the general population and duration exceeds 3 years after the primary vaccination	Persons who interact with animals that could be rabid***; occupational or recreational activities that typically involve contact with animals include 1) veterinarians, technicians, animal control officers, and their students or trainees; 2) persons who handle wildlife reservoir species (e.g., wildlife biologists, rehabilitators, and trappers); and 3) spelunkers	Alldomestic and international geographic regions where any rabies reservoir is present	IM rabies vaccine on days 0 and 7	1) One-time titer check during years 1–3 after 2-dose primary series; booster if titer <0.5 IU/mL,§§ or 2) booster no sooner than day 21 and no later than year 3 after 2-dose primary series†††
		Selected travelers. PrEP considerations include whether the travelers 1) will be performing occupational or recreational activities that increase risk for exposure to potentially rabid animals (particularly dogs) and 2) might have difficulty getting prompt access to safe PEP (e.g., rural part of a country or far from closest PEP clinic)	International geographic regions with rabies virus reservoirs, particularly where rabies virus is endemic in dog populations		
4. Elevated risk for recognized†† exposures, risk not sustained	Exposure nearly always recognized; risk for exposure higher than for general population but expected to be time-limited years from the 2-dose primary PrEP vaccination series)	Same as for risk category 3 (above), but risk duration years (e.g., short-term volunteer providing hands-on animal care or infrequent traveler with no expected high-risk travel >3 years after PrEP administration)	Same as for risk category 3 (above)	IM rabies vaccine on days 0 and 7	None
5. Low risk for exposure	Exposure uncommon	Typical person living in the United States	Not applicable	None	None

Primary Course for Pre-exposure Rabies Vaccination

Two rabies vaccines are currently available in the United States, i.e., human diploid cell vaccine (HDCV, Imovax/Sanofi Pasteur)) and purified chick embryo cell vaccine (PCECV, RabAvert/Bavarian Nordic)). For immune-competent persons, a primary course is a series of two 1-mL doses of HDCV or PCECV, given intramuscularly (IM). The initial dose is given on designated day 0. An additional dose of HDCV or PCECV is given on day 7. 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)

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, or they fit one of the risk categories that recommend post-exposure titers.

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 should be collected after pre-exposure prophylaxis according to Table 1. An adequate title is considered to be >0.5 IU/ml, a titer less than that, a booster vaccination should be provided.

Pre-Exposure Booster Doses of Vaccine (Table 1)

Persons who work with rabies virus in research laboratories or vaccine production facilities or performing testing for rabies in diagnostic laboratories (elevated risk for unrecognized and recognized exposures including unusual or high-risk exposures, 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 of vaccine should be administered if the serum titer < 0.5 IU/ml.

Category 2: Elevated risk for unrecognized and recognized exposures, includes, persons who frequently handle bats, have contact with bats, enter high-density bat environments perform animal necropsies. This 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 this category should have a serum sample tested for rabies virus neutralizing antibody every 2 years. If the titer is less than <0.5 IU/ml, the person also should receive a single booster dose of vaccine.

Risk category 3 includes persons who interact with animals that could be rabid, occupational, or recreational activities that typically involve contact with animals to include: veterinarians, veterinary students, and terrestrial animal-control and wildlife officers working in areas where rabies is uncommon to rare (infrequent exposure group), persons who handle wildlife reservoir species (wildlife biologists, rehabilitators and trappers) and spelunkers. and certain at-risk international travelers performing occupational or recreational activities that increase risk for exposure to potentially rabid animals (especially canines) or who might have difficulty getting prompt access to safe PEP. They should complete the 2 dose (days 1 and 7) 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).

Risk category 4 includes the same persons as risk category 3, but for a short term of exposure, such as a volunteer providing hands-on animal care or infrequent traveler with risk anticipated to be 3 years or less. No titers or boosters are recommended.

Risk category 5 is for the typical person living in the United States. No risk to rabies is anticipated and no pre-exposure vaccines or titers are recommended.

References:

Centers for Disease Control and Prevention. Human Rabies Prevention – United States, 2008: Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2008; 57(no. RR-3)

Centers for Disease Control and Prevention. Use of a Modified Preexposure Prophylaxis Vaccination Schedule to Prevent Human Rabies: Recommendations of the Advisory Committee on Immunization Practices-United States, 2022. MMWR 2022; Vol. 71; No. 18

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 non-bite), 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 (HRIG) 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 HRIG and vaccine is recommended for both bite and non-bite 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 auto- immune disorder, HIV positive individuals should receive five postexposure doses on day 0, day 3, day 7, day 14 and day 21 or day 28. If rabies exposure occurred outside of the United States and in an area of endemic canine rabies, a 5th rabies vaccine on day 21 or 28 is recommended.

PreviouslyVaccinated 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 be <0.5 IU/ml.

Rabies Postexposure Prophylaxis Schedule, KentuckyHealth Departments

Patient status	Treatment	Regimen[1]
Not previously vaccinated and Immunocompetent	Local wound cleansing	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.
	HRIG	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.
	Vaccine	PCECV or HDCV 1-mL, IM (deltoid area[2]), on days 0, 3, 7 and 14.
Previously vaccinated[3] and Immunocompetent	Local wound cleansing	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.
	HRIG	HRIG should not be administered.
	Vaccine	PCECV or HDCV 1- mL, IM (deltoid area[2]), on days 0 and 3
	Local wound cleansing	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

Immunosuppressed regardless of vaccinationstatus	HRIG	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.
	Vaccine	PCECV or HDCV 1.0 mL, IM (deltoid area[2]), on days 0, 3, 7, 14 - 21, and 28.

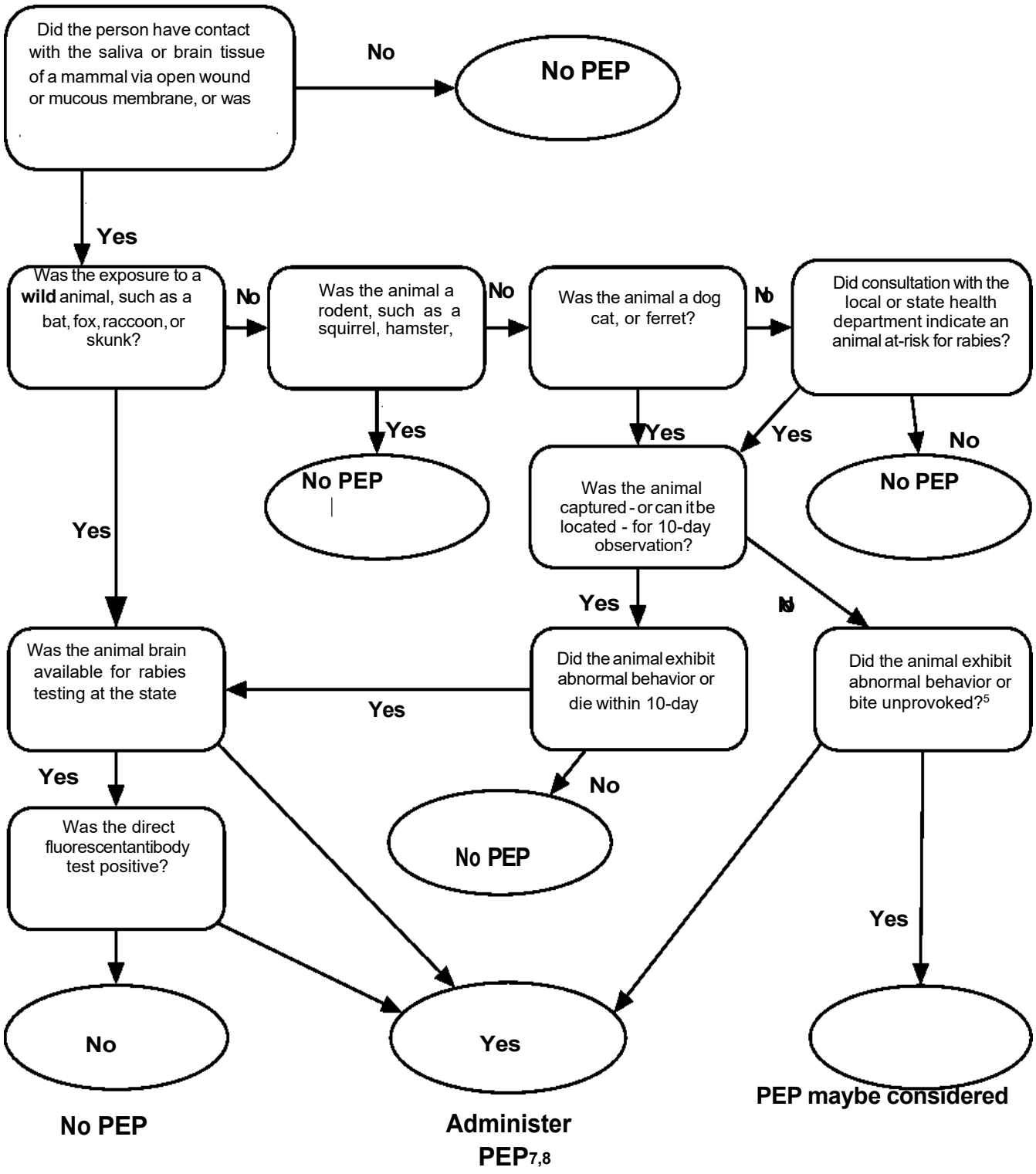
[1]Theseregimens areapplicable forall agegroups, including childrenandpregnant women.

[2]The deltoid area is the only acceptablesite 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.

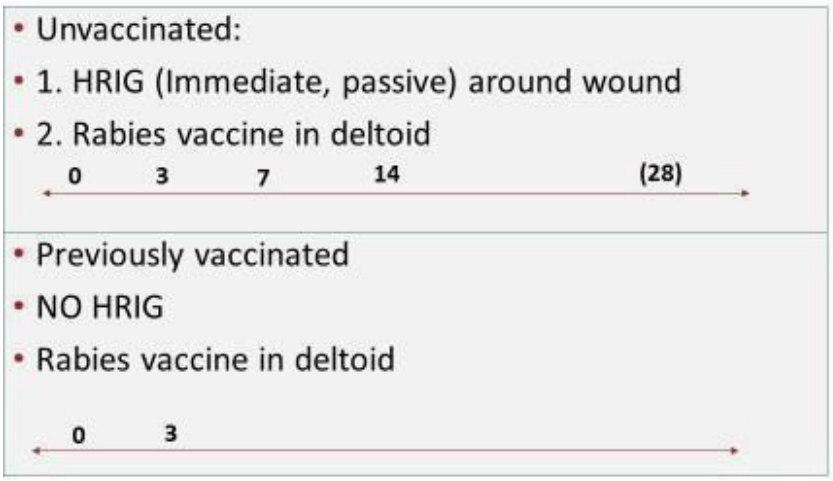
[3]Any person with a history of preexposure vaccination with HDCV, PCECV, or rabies vaccine adsorbed (RVA); prior PEP with HDCV, PCECV or RVA, or previous vaccination with any other type of rabies vaccine and a documented history of antibody response to prior vaccination.

Forquestions about PEP, calltheDivisionof Epidemiology andHealth Planning (502)564-3418.

Rabies Post-Exposure Prophylaxis (PEP)Protocol forPeople Exposed to Animals



Rabies PEP



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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.

   Modified from: The Vaccine Handbook: A Practical Guide for Clinicians, 5th Ed.

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 balancinga numberofcriteria:the species ofanimal and theendemicity of rabies for that species in Kentucky, the observed health and behavior of the animal, and thecircumstances of the bite.
2. This algorithm onlyaddresses rabiespost-exposure prophylaxis.Othertreatment such as wound care, antibiotics, and tetanus immunization may be indicated.
3. In addition to obvious s 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 thesame room, an adultwitnesses 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 or 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 ispredominantly adiseaseofcarnivorous animals (animalsthateatother animals)whilecarrion eaters like the opossum who eat dead or decaying flesh are seldom affected. Consultation with the state health departmentis strongly recommendedfor 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 neutralspace and attack. The physicianshould attempt to get the patient to describethe scenarioin orderto establishthe true natureorthecircumstancessurrounding the biting incident – DO NOT simply ask if the bite was provoked or unprovoked.
6. The severity andlocation of a wound (severe wounds or obvious wounds near the headand 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. Apreviously vaccinated person needs an abbreviatedPEP schedule, specifically day 0 and day 3. Immunocompromised individuals should receive the 5 seriesof 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. Ifthe biting animal is captured and tests negative forrabies after PEP has begun, PEP may be discontinued.

Modified from: KentCountyHealth Department. Determining the need forrabies post-exposure prophylaxis (PEP)with human rabies immuneglobulin (RIG)and rabies vaccine; Ohio Department of Health. Rabies Post-Exposure Treatment (PET)Algorithm, December2000.
Reference: Centers forDisease Control andPrevention. Human Rabies Prevention– UnitedStates,1999: Recommendations of theAdvisory Committee on Immunization Practices (ACIP). MMWR 1999;48(No. RR-1).
Reference:Centers for Disease Control and Prevention. Useof a Reduced(4-Dose) Vaccine Schedule for Postexposure Prophylaxis toPrevent HumanRabies,2010: Recommendations of the Advisory Committee on Immunization Practices *(ACIP). MMWR2010; 59(No. RR-2)*

Reportable Diseases

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<table>
<tr><th>Notification of the following diseases shall be considered urgent and shall be made within twenty-four (24) hours:</th><th colspan="2">Notification of the following diseases or conditions shall be considered priority and shall be made within one (1) business day:</th><th>Notification of the following diseases shall be considered routine and shall be made within five (5) business days:</th></tr>
<tr><td rowspan="3">Anthrax;
Botulism;
Brucellosis (multiple cases, temporally or spatially clustered);
Diphtheria;
Hepatitis A,acute;
Measles;
Meningococcal infections;
Middle East Respiratory Syndrome-associated Coronavirus (MERS-CoV) disease;
Multi-system Inflammatory Syndrome in Children (MIS-C);
Novel influenza A virus infections;
Plague;
Poliomyelitis;
Rabies,animal;
Rabies,human;
Rubella;
Severe Acute Respiratory Syndrome-Associated Coronavirus (SARS-CoV);
Severe Acute Respiratory Syndrome-Associated Coronavirus 2 (SARS-CoV-2) (The virus that causes COVID-19);
Smallpox;
Tularemia;
Varicella;
Viral hemorrhagic fevers due to:
1. Crimean-Congo Hemorrhagic Fever virus;
2. Ebola virus;
3. Lassa virus;
4. Lujo virus;
5. Marburg virus; or
6. New world arenaviruses including:
a. Guanarito virus;
b. Junin virus;
c. Machupo virus;
d. Sabia
virus. Yellow fever;</td><td>Arboviral diseases, neuroinvasive and non-neuroinvasive, including:
1. California serogroup virus diseases, including diseases caused by:
a. California encephalitis virus;
b. Jamestown Canyon virus;
c. Keystone virus;
d. La Crosse virus;
e. Snowshoe hare virus;
f. Trivittatus viruses;
2. Chikungunya virus disease;
3. Eastern equine encephalitis virus disease;
4. Powassan virus disease;
5. St. Louis encephalitis virus disease;
6. Venezuelan equine encephalitis disease;
7. West Nile virus disease;
8. Western equine encephalitis virus disease; and
9. Zika virus disease or infection or the birth of a child to a mother who was Zika-positive or Zika-inconclusive during any stage of pregnancy or during the periconceptional period;
Brucellosis (cases not temporally or spatially clustered);
Campylobacteriosis;
Carbon monoxide poisoning Cholera;
Cryptosporidiosis;
Cyclosporiasis;
Dengue virus infections;
Escherichia coli O157:H7;
Foodborne disease outbreak;
Giardiasis;
Haemophilus influenzae invasive disease;</td><td>Hansen’s disease (leprosy);
Hantavirus infection, non-Hantavirus pulmonary syndrome;
Hantavirus pulmonary syndrome (HPS);
Hemolytic uremic syndrome (HUS), post-diarrheal;
Hepatitis B, acute;
Hepatitis B infection in a pregnant woman;
Hepatitis B infection in an infant or a child aged five (5) years or less;
Newborns born to Hepatitis B positive mothers at the time of delivery;
Influenza-associatedmortality;
Legionellosis;
Leptospirosis;
Listeriosis;
Mumps;
Norovirusoutbreak;
Pertussis;
Pesticide-relatedillness, acute; Psittacosis;
Q fever;
Rubella, congenital syndrome;
Salmonellosis;
Shiga toxin-producing E. coli (STEC);
Shigellosis;
Streptococcal toxic-shock syndrome;
Streptococcus pneumoniae, invasivedisease;
Tetanus;
Toxic-shock syndrome (other than Streptococcal);
Tuberculosis;
Typhoidfever;
Varicella;
Vibriosis;
Waterborne disease outbreak;</td><td>Acute Flaccid Myelitis;
Anaplasmosis;
Babesiosis;
Coccidioidomycosis;
Creutzfeldt-Jakobdisease;
Ehrlichiosis;
Hepatitis C, acute;
Hepatitis C infection in a pregnant woman;
Hepatitis C infection in an infant or a child aged five (5) years or less;
Newborns born to Hepatitis C positive mothers at the time of delivery;
Histoplasmosis;
Lead poisoning;
Lyme Disease;
Malaria;
Spotted Fever Rickettsiosis (Rocky Mountain Spotted Fever);
Toxoplasmosis; and
Trichinellosis (Trichinosis).</td></tr>
<tr><td colspan="2">HIV infection or AIDS diagnosis;</td></tr>
<tr><td colspan="2">Congenital syphilis;</td><td>Syphilis - primary, secondary, or early latent;</td><td rowspan="2">Chancroid;
Chlamydia trachomatis infection;
Gonorrhea;
Granuloma inguinale;
Lymphogranuloma venereum; or
Syphilis, other than primary, secondary, early latent, or congenital.</td></tr>
</table>

Submission of Clinical Isolates, or if Not Available, the Direct Specimen for the Following Diseases	Routine Notification within One (1) Business Day, by Electronic Laboratory Reporting and EPID 250:	Routine Notification within Five (5) Business Days, by Electronic Laboratory Reporting:	Report Immediately by Telephone:
Botulism; Brucellosis; Campylobacterosis; Candida auris; Carbapenem-resistant Acinetobacter; Carbapenem-resistant Enterobacteriaceae; Carbapenem-resistant Pseudomonos; Cholera and diseases caused by other *Vibrio* species; Diphtheria; *Escherichia coli* O157:H7; Hemolytic Uremic Syndrome (HUS) –Post Diarrheal; Listerosis; Measles; Meningococcal infections; Rabies, animal; Rubella; Salmonellosis; Shiga toxin-producing *E. coli* (STEC); Shigellosis; Tuberculosis; Tularemia; Typhoid fever; Vancomycin-intermediate Staphylococcus aureus; Vancomycin-resistant Staphylococcus aureus; and Zika.	Candida auris; Carbapenem-resistant – Acinetobacter; Carbapenem-resistant – Enterobacteriaceae (CRE); Carbapenem-resistant – Pseudomonas; Vancomycin-intermediate Staphylococcus aureus (VISA); and Vancomycin-resistant Staphylococcus aureus (VRSA). **(Refer to 902 KAR 2:020 for details.)** **Notification of the following diseases or conditions shall be made within three (3) months of diagnosis:** Asbestosis; Coal worker's pneumoconiosis; or Silicosis.	1. Hepatitis B **&** Hepatitis C laboratory test results whether reported as positive or negative; a. Include the serum bilirubin levels taken within ten (10) days of the test of a patient who has tested positive; or b. Include the serum alanine aminotransferase levels taken within ten (10) days of the test of a patient who tested positive; and 2. Varicella laboratory test results reported as positive for: a. Isolation of varicella virus from a clinical specimen; b. Varicella antigen detected by direct fluorescent antibody test; or c. Varicella-specific nucleic acid detected by polymerase chain reaction (PCR); 3. Multi-drug Resistant Organisms: a. Clostridioides (Formerly *Clostridium*) *difficile (C. difficile)* b. Enterobacteriaceae species resistant to ceftazidime, ceftriaxone, or cefotaxime; c. Methicillin-resistant Staphylococcus aureus (MRSA); and d. Vancomycin resistant Enterococcus species (VRE). **(Refer to 902 KAR 2:020 for details.)**	1. A suspected incidence of bioterrorism caused by a biological agent; 2. Submission of a specimen to the Kentucky Division of Laboratory Services for select agent identification or select agent confirmation testing; or 3. An outbreak of a disease or condition that resulted in multiple hospitalizations or death. 4. An unexpected pattern of cases, suspected cases, or deaths which may indicate the following shall be reported immediately by telephone to the local health department in the county where the health professional is practicing or where the facility is located: a. A newly-recognized infectious agent; b. An outbreak; c. An emerging pathogen which may pose a danger to the health of the public; d. An epidemic; or e. A non-infectious chemical, biological, or radiological agent.

STD
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STD MATRIX

<table>
<tr><th></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
Males and Females</th></tr>
<tr><td>REASONFOR VISIT</td><td>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 <u>does not require an STD physical exam</u> unless STD symptoms are reported.</td><td>• Positive Test
• Symptoms – (list symptom and duration)
• Results
• Follow-up appointment
• Other</td></tr>
<tr><td>MEDICAL HISTORY</td><td>• 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)</td><td>• Identify any changes to the medical history obtained during the prior visit including allergies, prescriptions and/or antibiotics</td></tr>
<tr><td>SEXUAL & REPRODUCTIVE HISTORY</td><td>• 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><tr><th>Exposed Sites</th><th>≤ 60 days</th><th>≤ 12 months</th></tr><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></table>
• Frequency of condom usage
• FEMALES: Last menstrual period, obstetrical history, and gynecological conditions, and current contraceptiveuse.</td><td>• Sexual exposure since last visit
• Identify any changes to the sexual & reproductive history obtained during the prior visit.</td></tr>
</table>

	STD VISIT (Primary reason for visit is due to symptoms, exposure, partner problem, positive test and/or high-risk behavior)	STD RE-VISIT Requirements of an STD Visit Males and Females
RISK ASSESSMENT	Suggested Questions to Ask During the Sexual History • When was the last time you had sex? • How many partners have you had sex with in the last 12 months? • How many new partners have you had sex with in the last 2 months? • When is the last time you had sex with a man? Woman? Both? • At what age did you become sexually active? • What are you doing to prevent pregnancy? • Did you use a barrier the last time you had sex? • How often do you use a barrier when you have sex? • When is the last time you engaged in oral, anal, or vaginal intercourse? • Are you the insertive partner, the receptive partner, or both? • Was the sexual encounter consensual or nonconsensual? • Have you ever been paid for sex (exchanged sex for drugs or exchanged sex for money)? • Have you ever been a resident in a prison? • Do you have a history of sexually transmitted diseases? • Has your judgment ever been impaired using alcohol or drugs? • STD/HIV exposure • Substance abuse including IV drug use and alcohol • Multiple partners • Anonymous partners • Sex for money or drugs • Abuse or domestic violence	• Identify any changes since last visit

	STD VISIT (Primary reason for visit is due to symptoms, exposure, partner problem, positive test and/or high-risk behavior)	STD RE-VISIT Requirements of an STD Visit Males and Females
PHYSICAL EXAM	**ALL:** • Oral examination. • Skin inspection over entire body, especially the lower abdomen, inguinal areas, thighs, hands, palms, and forearms. • Inspection of the pubic hair for lice and nits. • Inspect external genitalia, perineum, and anus. • Palpate for lymphadenopathy, especially the inguinal and femoral regions. **FEMALES:** The examination for STDs should not be deferred for menses unless bleeding is extremely heavy. Urine specimen can be collected for CT/GC testing. A pregnant patient should be examined and tested in the same manner as the non-pregnant patient except for the bimanual pelvic exam. If a pregnant patient is experiencing vaginal bleeding, she should be immediately referred to her obstetrician or certified nurse midwife. • Examine the vagina and the cervix, using the appropriate speculum. Obtain an endocervical specimen for gonorrhea and Chlamydia utilizing an APTIMA test kit. A urine specimen should be obtained from females without a cervix.	Repeat physical exam per medical/sexual history and risk assessment.

	STD VISIT (Primary reason for visit is due to symptoms, exposure, partner problem, positive test and/or high-risk behavior)	STD RE-VISIT Requirements of an STD Visit Males and Females
PHYSICAL EXAM	• Obtain specimens for gonorrhea from other exposure sites as indicated i.e., throat, rectum • Perform a Bimanual pelvic examination. A bimanual exam is to be performed on all females presenting for STD evaluation except for pregnancy and hysterectomy. • Recommend women complaining of rectal symptoms to have an anoscopic exam at their primary care provider or an appropriate specialist. **MALES:** • Inspect scrotum and palpate scrotal contents; inspect rectal area (perineum & anus) if patient has had male-male sex. • 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. • Obtain specimens for gonorrhea from other exposure sites as indicated, i.e., throat, rectum. Recommend men complaining of rectal symptoms to have an anoscopic exam at their primary care provider or an appropriate specialist.	

	STD VISIT (Primary reason for visit is due to symptoms, exposure, partner problem, positive test and/or high-risk behavior)	STD RE-VISIT Requirements of an STD Visit Males and Females
LABORATORY	Note: Routine 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. Obtain blood specimens from all patients for Syphilis IGG (if using the Kentucky Division of Laboratory Services) and VDRL (Venereal Disease Research Laboratory) 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, TPPA and FTA. • Obtain specimen for Chlamydia and gonorrhea (CT/GC APTIMA Test). Except in pregnant women, a test of cure for chlamydia 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. Test of cure is also 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, preferably by culture; positive isolates should undergo antimicrobial susceptibility testing. • 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.	Repeat labs per medical/sexual history and risk assessment. (Note: 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)

	STD VISIT (Primary reason for visit is due to symptoms, exposure, partner problem, positive test and/or high-risk behavior)	STD RE-VISIT Requirements of an STD Visit Males and Females
	• 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. <u>Stat Testing (Dependent upon availability at the LHD)</u> 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 IGG (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 VISIT (Primary reason for visit is due to symptoms, exposure, partner problem, positive test and/or high-risk behavior)	STD RE-VISIT Requirements of an STD Visit Males and Females
PROVIDE	• Treatment as indicated in this guide or CDC Treatment Guidelines. • Recommendation/Referral for other health care needs or to a higher-level provider if needed. • Recommendation/Referral for social services (as needed) • Linkage for partner services (contact STD regional area to initiate partner services if patient is diagnosed with syphilis and/or HIV. • Follow up appointment (as needed) • Condoms Priority consideration regarding 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.	• As assessed for individual patient needs.
COUNSELING	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	• As assessed for individual patient needs.

REQUIREMENTS FOR STD

- 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 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.
- 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 occurs.
    - 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 partner 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 partner for CT)

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 800 mg

Chlamydia: Non-pregnant partners - Doxycycline 100 mg orally 2 times a day for 7 days
Pregnant partners - Azithromycin 1 gm

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

Guidance for Delivering Expedited Partner Therapy

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, to reduce the risk of recurrent infection.
- Index patients 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 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
- Whether the partner(s) are pregnant
- Or known to be allergic to antibiotics.

A log is kept documenting 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						
CONDITION	**SYMPTOMS**	**TESTS**	**RECOMMENDED TREATMENT**	**ALTERNATIVES**	**PARTNER SERVICES**	**REPORTING**
SYPHILIS	**(See 2021 CDC guidelines for follow-up recommendations and management of congenital syphilis)**					
PRIMARY (1º), SECONDARY(2º) OR EARLYLATENT (<1 YEAR) Adults	PRIMARY (1º) Induratedchancre usually painless SECONDARY(2º) Rash-bilateral macular, papular, follicular, papulosquamous pustular lesions. alopecia, condylomata lata, mucous patches EARLYLATENT • NoSymptoms (SX) at Exam PLUS, one of the following: • History of SX within last 12 months • Documented Negativetest w/in last 12 months • Epidemiological link to another infected individual	Specimens submitted to the Kentucky Division of Laboratory Services: Syphilis IGGE with reflex to VDRL/TPPA Specimens submitted to labs not usingreverse syphilis testing: VDRL/RPR plus, confirmatory test such as: TPPA, FTA, TP Abor MHA StatRPR is desired if primary or secondary SX are present.	BENZATHINE PENICILLIN G 2.4 million units IM Symptomatic men & women shall be treated empirically on their initial visit.	For penicillin allergic non-pregnant adult patients: DOXYCYCLINE 100 mg orally 2 times a day for 14 days OR CEFTRIAXONE[1] 1 g daily IV or IM for 10-14 days. (Please see footnote below. Ceftriaxone recommendation is based on limited studies. Therefore, the optimal dose and duration of ceftriaxone therapy have not been defined.)	Contact STD Supervisor within your regional area within 24 hours to initiate partner services for index patient. 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.	Complete EPID 200 and fax to State STD Program within 24 hours.

PROTOCOLS FOR TREATMENT OF COMMON SEXUALLY TRANSMITTED DISEASES						
CONDITION	**SYMPTOMS**	**TESTS**	**RECOMMENDED TREATMENT**	**ALTERNATIVES**	**PARTNER SERVICES**	**REPORTING**
SYPHILIS	**(See 2021 CDC guidelines for follow-up recommendations and management of congenital syphilis)**					
LATE LATENT OR LATENT OF UNKNOWN DURATION (>1 YEAR) Adults	None	See Above Plus See CDC Treatment Guidelines to determine if CSF exam is needed	Benzathine penicillin G 2.4 million units IM for 3 doses, 1 week apart (total: 7.2 million units)	For penicillin allergic non-pregnant adult patients: DOXYCYCLINE 100 mg orally 2 times a day for 28days (for adults only	Contact STD Supervisor within your regional area.	Complete EPID 200 and fax to State STD Program.
Children (aged > 1 month) Primary, Secondary or Early Latent See CDC Treatment Guidelines for the management of congenital syphilis.	Same as Adult	Same as Adult Plus	Benzathine penicillin G 50,000 units/kg IM, up to the adult dose of 2.4 MU Generally, RX for STDs found in a pre-pubertal child should be managed by the child's physician. LHDs shall assure adequate RX.	Infants and children who are allergic to penicillin should be desensitized	Contact STD Supervisor within your regional area ≥ 12 years of age.	Same as Adult Plus Report suspected cases
Children (aged > 1 month) Late Latent or Latent of Unknown Duration See CDC Treatment Guidelines for the	Same as Adult	Same as Adult Plus CSF Examination	Benzathine penicillin G 50,000 units/kg IM up to the adult dose of 2.4 million units, administered for three doses at 1-week intervals (Total 150,000 units/kg up to the	Infants and children who are allergic to penicillin should be desensitized. and then treated with penicillin.	Contact STD Supervisor within your regional area ≥ 12 years of age.	Same as Adult Plus Report suspected cases of sexual abuse to the Dept of Community Based Services.

PROTOCOLS FOR TREATMENT OF COMMON SEXUALLY TRANSMITTED DISEASES						
CONDITION	**SYMPTOMS**	**TESTS**	**RECOMMENDED TREATMENT**	**ALTERNATIVES**	**PARTNER SERVICES**	**REPORTING**
SYPHILIS	**(See 2021 CDC guidelines for follow-up recommendations and management of congenital syphilis)**					
management of congenital syphilis. Generally, RX for STDs found in a pre-pubertal child should be managed by the child's physician. LHDs shall assure adequate RX.			adult total dose of 7.2 million units)			
NEUROSYPHILIS, OCULAR SYPHILIS, and OTOSYPHILIS	Neurologic, ophthalmic,or otologic abnormalities	Refer for further evaluation including CSF Examination	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	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	Contact STD Supervisor within your regional area.	Complete EPID 200 and fax to State STDProgram.
SYPHILIS WITH A CO-INFECTION OF HIV	See Appropriate Section Above	See Appropriate Section Above	For 1º, 2º, and early latent syphilis: Treat as indicated above. Additional doses of Benzathine penicillin G in early syphilis do not enhance efficacy, regardless of HIV status.	The use of any alternative therapy in HIV infected persons has not been well studied, therefore the use of doxycycline and ceftriaxone must be undertaken with caution	Contact STD Supervisor within your regional area if index patient is co-infected w/HIV to initiate partner services.	Complete EPID 200 for the syphilis. Fax to State STD Program. Notify HIV/AIDS surveillance if newly diagnosed HIV case.

PROTOCOLS FOR TREATMENT OF COMMON SEXUALLY TRANSMITTED DISEASES						
CONDITION	**SYMPTOMS**	**TESTS**	**RECOMMENDED TREATMENT**	**ALTERNATIVES**	**PARTNER SERVICES**	**REPORTING**
SYPHILIS	**(See 2021 CDC guidelines for follow-up recommendations and management of congenital syphilis)**					
SYPHILISAND PREGNANCY	See Appropriate Section Above	See Appropriate Section Above	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]	None	Contact STD Supervisor within your regional area within 24 hours of laboratory receipt.	Complete EPID 200 and fax to State STD Program within 24 hours. Indicate pregnancy status on EPID 200.

Centers for Disease Control and Prevention. MMWR 2021; Vol. 70/No.4: Syphilis (Pages 39-59)

PROTOCOLS FOR TREATMENT OF COMMON SEXUALLY TRANSMITTED DISEASES (continued)						
CONDITION	**SYMPTOMS**	**TESTS**	**RECOMMENDED TREATMENT**	**ALTERNATIVES**	**PARTNER SERVICES**	**REPORTING**
GONOCOCCAL INFECTIONS						
GC - ADULTS Cervix, Urethra, Rectum	Females- Often asymptomatic. Cervical: Cervical discharge. Also-Increased vaginal discharge, bleeding between periods and dysuria. Males- May be asymptomatic. Males & Females- Urethra: Discharge (white, yellow, or green), Dysuria. Rectal: Pain, itching discharge, bleeding; may be asymptomatic.	MALE & FEMALE: APTIMACT/GC COMBO 2 (NAAT) TEST DLS offers this molecular test for rectal and pharyngeal specimens. Male: Gram stain of urethral discharge (if test is available at LHD). Men and women who have been treated for gonorrhea should be retested 3 months after treatment or whenever they next present for medical care within 12 months of initial treatment.	Ceftriaxone[1] 500 mg IM in a single dose (For persons >/= 300 lb., 1 gm should be given) PLUS If chlamydia infection has not been excluded, doxycycline 100 mg orally BID for 7 days Symptomatic men & women presenting for an STD visit shall be treated empirically for both GC and CT on their initial visit. ***Empirical treatment for chlamydia is doxycycline 100 mg orally 2 times a day for 7 days.***	Cefixime[1] 800 mg orally in a single dose PLUS If chlamydia infection has not been excluded, doxycycline 100 mg orally BID for 7 days **Special Considerations** Cephalosporin or IgE-mediated penicillin allergy: Consult an infectious disease specialist. Potential options: Gentamicin 240 mg IM PLUS Azithromycin 2 gm orally in a single dose.	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 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% of patients diagnosed w/GC should be treated within 14 days from the date of lab collection and 90% within 30 days from the date of lab collection.

PROTOCOLS FOR TREATMENT OF COMMON SEXUALLY TRANSMITTED DISEASES (continued)						
CONDITION	**SYMPTOMS**	**TESTS**	**RECOMMENDED TREATMENT**	**ALTERNATIVES**	**PARTNER SERVICES**	**REPORTING**
GONOCOCCAL INFECTIONS						
GC – PHARYNX	Sore throat, pharyngeal exudate, enlarged cervical lymph nodes; often asymptomatic.	APTIMACT/GC COMBO 2 (NAAT) TEST DLS offers this molecular test for rectal and pharyngeal specimens. DLS does not perform GC cultures Test of cure is recommended for those with pharyngeal gonorrhea 7-14 days after initial treatment.	Ceftriaxone[1] 500 mg IM in a single dose (For persons >/= 300 lbs., 1 gm should be given.) PLUS If chlamydia infection has not been excluded, doxycycline 100 mg orally BID for 7 days	No Reliable Alternative Treatment Cephalosporin or IgE-mediated penicillin allergy: Consult an infectious disease specialist.	SEE ABOVE	SEE ABOVE
GC in CHILDREN (<45KG or <100 lbs.) Uncomplicated Vulvovaginitis, Cervicitis, Urethritis, Pharyngitis, or Proctitis Generally, RX for STDs found in a prepubertal	SEEGC SX IN ADULTS	DLS lab does not perform GC cultures. Because of the legal implications of a diagnosis of N. gonorrhea infection in a child, culture is the preferred method. NAATs, however, can be used to test for *N.*	Ceftriaxone[1] 25-50 mg/kg IV or IM in a single dose, not to exceed 250 mg IM	N/A	SEE ABOVE if > 12 years of age.	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

PROTOCOLS FOR TREATMENT OF COMMON SEXUALLY TRANSMITTED DISEASES (continued)						
CONDITION	**SYMPTOMS**	**TESTS**	**RECOMMENDED TREATMENT**	**ALTERNATIVES**	**PARTNER SERVICES**	**REPORTING**
GONOCOCCAL INFECTIONS						
childshould be managed by the child's physician. LHDs shall assure adequate RX.		*Gonorrhea* from vaginal and urine specimens from girls and urine for boys.				
GC in CHILDREN (>45KG) Generally, RX for STDs found in a prepubertal child should be managed by the child's physician. LHDs shall assure adequate RX.	SEEGC SX IN ADULTS	DLS lab does not perform GC cultures. Because of the legalimplications of a diagnosis of N. gonorrhoeae infection in a child, culture is the preferred method. NAATs, however, can be used for *N. gonorrhoeae* from vaginal and urine specimens from girls and urine for boys.	Same regimen as recommended for adults	Same regimen as recommended for adults	SEE ABOVE if > 12 years of age.	Complete EPID 200 and fax or mail to State STD Programwithin 14 days. Report suspected cases of sexual abuse to the Dept of Community Based Services
GC - PREGNANCY	SEEGC SX IN ADULTS	SEEGC TESTS IN ADULTS	Ceftriaxone[1] 500 mg IM once	When cephalosporin allergy or other	Sex partners exposed during the previous	Complete EPID 200 and fax or mail to State STD

PROTOCOLS FOR TREATMENT OF COMMON SEXUALLY TRANSMITTED DISEASES (continued)						
CONDITION	**SYMPTOMS**	**TESTS**	**RECOMMENDED TREATMENT**	**ALTERNATIVES**	**PARTNER SERVICES**	**REPORTING**
GONOCOCCAL INFECTIONS						
			(For persons >/= 300 lb., 1 gm should be given) PLUS If chlamydia infection has not been excluded, Azithromycin 1 g orally in a single dose	considerations preclude treatment with the recommended regimen, consultation with an infectious-disease specialist.	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.	Programwithin 14 days. Indicate pregnancy status on EPID 200 form.

Centers for Disease Control and Prevention. MMWR 2021; Vol. 70/No. 4: Gonococcal Infections (Pages 71-80)

PROTOCOLS FOR TREATMENT OF COMMON SEXUALLY TRANSMITTED DISEASES (continued)						
CONDITION	**SYMPTOMS**	**TESTS**	**RECOMMENDED TREATMENT**	**ALTERNATIVES**	**PARTNER SERVICES**	**REPORTING**
CHLAMYDIAL INFECTIONS						
CT - ADULT	Men – Urethral discharge or dysuria; often asymptomatic Women – Vaginal or cervical discharge, dysuria; often asymptomatic.	MALE & FEMALE APTIMA CT/GC COMBO 2 (NAAT) TEST 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.	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. ***Empirical treatment for chlamydia is doxycycline 100 mg orally 2 times a day for 7 days.***	Azithromycin 1 gm orally in a single dose OR Levofloxacin [3] 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 Programwithin 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.

PROTOCOLS FOR TREATMENT OF COMMON SEXUALLY TRANSMITTED DISEASES (continued)						
CONDITION	**SYMPTOMS**	**TESTS**	**RECOMMENDED TREATMENT**	**ALTERNATIVES**	**PARTNER SERVICES**	**REPORTING**
CHLAMYDIAL INFECTIONS						
CT in CHILDREN (<45 KG or <100 lbs.) Generally, RX for STDs found in a pre-pubertal child should be managed by the child's physician. LHDs shall assure adequate RX	SEE CT SX IN ADULTS ABOVE	MALE & FEMALE APTIMA CT/GC COMBO 2 (NAAT) TEST Non-culture, non-amplified probe tests for CT should not be used because of the possibility of false-positive test results. (DLS lab does not perform CT culture)	Erythromycin base or ethylsuccinate 50 mg/kg/day orally divided into four doses daily for 14 days [4]	N/A	N/A	Complete EPID 200 and fax or mail to State STD Program within 14 days. PLUS Report suspected cases of sexual abuse to the Dept of Community Based Services.
CT in CHILDREN (>45 KG and <8 years of age) Generally, RX for STDs found in a pre-pubertal child should be managed by the child's physician. LHDs shall assure adequate RX.	SEE CT SX IN ADULTS ABOVE	SEE CT IN CHILDREN "TESTS" ABOVE	Azithromycin 1 g orally single dose	N/A	N/A	See Above

PROTOCOLS FOR TREATMENT OF COMMON SEXUALLY TRANSMITTED DISEASES (continued)						
CONDITION	**SYMPTOMS**	**TESTS**	**RECOMMENDED TREATMENT**	**ALTERNATIVES**	**PARTNER SERVICES**	**REPORTING**
CHLAMYDIAL INFECTIONS						
CT in CHILDREN (> 8 years)	SEE CT SX IN ADULTS ABOVE	SEE CT IN CHILDREN "TESTS" ABOVE	Azithromycin 1 g orally single dose OR Doxycycline 100 mg orally 2 times a day for 7 days	N/A	SEE ABOVE if >12 years of age.	See Above
CT IN PREGNANCY	SEE ABOVE	SEE ABOVE Repeat testing (preferably by NAAT) 4 weeks after completion of therapy is recommended for all pregnant women to ensure therapeutic cure.	Azithromycin 1 g orally in a single dose	Amoxicillin 500 mg orally 3 times 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. Please indicate pregnancy status on EPID 200 form.

Centers for Disease Control and Prevention. MMWR2021; Vol. 70/No. 4: Chlamydial Infections (Pages 65-71)

PROTOCOLS FOR TREATMENT OF COMMON SEXUALLY TRANSMITTED DISEASES (continued)						
CONDITION	**SYMPTOMS**	**TESTS**	**RECOMMENDED TREATMENT**	**ALTERNATIVES**	**PARTNER SERVICES**	**REPORTING**
MPC Mucopurulent Cervicitis						
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	Doxycycline 100 mg orally 2 times a day for 7 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.	Azithromycin 1 gm orally in a single dose* *Consider concurrent treatment for gonococcal infection if prevalence of gonorrhea is high in the patient population under assessment.	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. Asymptomatic sex partners should be preventively treated on their initial visit if the original patient's lab result is pending or positive. Symptomatic sex partners should be empirically treated on their initial visit.	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

PROTOCOLS FOR TREATMENT OF COMMON SEXUALLY TRANSMITTED DISEASES (continued)						
CONDITION	**SYMPTOMS**	**TESTS**	**RECOMMENDED TREATMENT**	**ALTERNATIVES**	**PARTNER SERVICES**	**REPORTING**
MPC Mucopurulent Cervicitis						
MPC in PREGNANCY	SEE ABOVE	SEE ABOVE	Azithromycin 1 g orally single dose* *Consider concurrent treatment for gonococcal infection if prevalence of gonorrhea is high in the patient population under assessment.	Azithromycin 1 gm orally in a single dose* *Consider concurrent treatment for gonococcal infection if prevalence of gonorrhea is high in the patient population under assessment.	SEE ABOVE	SEE ABOVE

Centers for Disease Control and Prevention. MMWR 2021; Vol. 70/No. 4: Cervicitis (Pages 63-65)

PROTOCOLS FOR TREATMENT OF COMMON SEXUALLY TRANSMITTED DISEASES (continued)

CONDITION	SYMPTOMS	TESTS	RECOMMENDED TREATMENT	ALTERNATIVES	PARTNER SERVICES	REPORTING
NGU Nongonococcal Urethritis						
NON-GONOCOCCAL URETHRITIS (NGU) Men Inflammation of the urethra not caused by gonorrhea. Chlamydia trachomatis has been implicated as the cause of NGU in up to 50% of cases; M. genitalium is estimated to account for 10%–25% and T. vaginalis for 1%–8% of cases.	Urethral discharge (Often early a.m.), dysuria, irritation, or meatal pruritus. 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 immersionfield with no evidence of gonorrhea. Submit APTIMACT/GC COMBO (NAATS) test	Doxycycline 100 mg orally 2 times a day for 7 days *PLUS* Adequate treatment for gonorrhea if gram stain is not available. Symptomatic men shall receive empirical treatment for both CT and GC during their initial visit.	Azithromycin 1 g orally single dose OR Azithromycin 500 mg orally in a single dose; then 250 mg orally daily for 4 days *PLUS* Adequate treatment for gonorrhea if gram stain is not available.	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. 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 NAATStesting in the original patient.	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.

Centers for Disease Control and Prevention. MMWR 2021; Vol. 70/No. 4: Nongonococcal Urethritis (Pages 62-63).

PROTOCOLS FOR TREATMENT OF COMMON SEXUALLY TRANSMITTED DISEASES (continued)						
CONDITION	**SYMPTOMS**	**TESTS**	**RECOMMENDED TREATMENT**	**ALTERNATIVES**	**PARTNER SERVICES**	**REPORTING**
EPIDIDYMITIS						
Epididymitis	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] 500 mg IM in a single dose (For persons >/= 300 lb., 1 gm should be given) 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.	Alternative for acute epididymitis most likely caused by chlamydia, gonorrhea, or enteric organisms (men who practice insertive anal sex) Ceftriaxone[1] 500 mg IM in a single dose (For persons >/= 300 lb., 1 gm should be given) PLUS Levofloxacin [3] 500 mg orally once a day for 10 days	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 2021; Vol. 70/No. 4: Epididymitis (Pages 98-100).

PROTOCOLS FOR TREATMENT OF COMMON SEXUALLY TRANSMITTED DISEASES (continued)						
CONDITION	**SYMPTOMS**	**TESTS**	**RECOMMENDED TREATMENT**	**ALTERNATIVES**	**PARTNER SERVICES**	**REPORTING**
PELVIC INFLAMMATORY DISEASE (PID)						
PELVIC INFLAMMATORY DISEASE (PID) (Outpatient management)	1. Low abdominal pain or painful intercourse by patient's history. 2. Low abdominal tenderness on bimanual exam. 3. Adnexal tenderness or adnexal mass. 4. Cervical motion tenderness or pain. 5. Fever and chills 6. Nausea and vomiting.	Submit CT/GC APTIMA test. Perform stat pregnancy test (Pregnant women suspected of having PID are at high risk and should be directed for admission to a hospital and treated with IV antimicrobials)	Ceftriaxone 500 mg IM once kg, 1 g of ceftriaxone should be administered) PLUS Doxycycline 100 mg orally 2 times a day for 14 days PLUS Metronidazole 500 mg orally 2 times a day for 14 days Assessment is made by identifying symptoms No. 3 or No. 4 or both. If symptoms No. 3, 4, 5, 6 and/or abdominal rebound tenderness is identified, treat, and refer to E.R. 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.	Cefoxitin 2 g IM once plus probenecid 1 g orally once PLUS Doxycycline 100 mg orally 2 times a day for 14 days with metronidazole 500 mg orally 2 times a day for 14 days	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.	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.

Centers for Disease Control and Prevention. MMWR 2021; Vol. 70/No. 4: Pelvic Inflammatory Disease (Pages 94-98).

PROTOCOLS FOR TREATMENT OF COMMON SEXUALLY TRANSMITTED DISEASES (continued)						
CONDITION	**SYMPTOMS**	**TESTS**	**RECOMMENDED TREATMENT**	**ALTERNATIVES**	**PARTNER SERVICES**	**REPORTING**
BV Bacterial Vaginosis						
BACTERIAL VAGINOSIS (BV)	1. Mild to moderate amount of homogeneous chalky white or grey-green discharge; patient may complain of odor. 2. Positive whiff test: fishy amine odor from vaginal fluids enhanced by mixing with 10% KOH. 3. pH of vaginal secretion > 4.5. 4. Clue cells on saline wet mount of vaginal discharge	1. 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 to discharge 6. Perform amine or whiff test after application of 10% KOH to discharge	Metronidazole 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 [5] 2% intravaginally at bedtime for 7 days Assessment is made by identifying 3 out of the 4 symptoms listed.	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 [6] 100 mg intravaginally at bedtime for 3 days	N/A	N/A

PROTOCOLS FOR TREATMENT OF COMMON SEXUALLY TRANSMITTED DISEASES (continued)						
CONDITION	**SYMPTOMS**	**TESTS**	**RECOMMENDED TREATMENT**	**ALTERNATIVES**	**PARTNER SERVICES**	**REPORTING**
BV Bacterial Vaginosis						
BV AND PREGNANCY	SEE ABOVE	SEE ABOVE	Metronidazole 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.	Metronidazole 250 mg orally 3 times a day for 7 days OR Clindamycin 300 mg orally 2 times a day for 7 days	N/A	N/A

Centers for Disease Control and Prevention. MMWR 2021; Vol. 70/No.4: Bacterial Vaginosis (Pages 83-87).

PROTOCOLS FOR TREATMENT OF COMMON SEXUALLY TRANSMITTED DISEASES (continued)						
CONDITION	**SYMPTOMS**	**TESTS**	**RECOMMENDED TREATMENT**	**ALTERNATIVES**	**PARTNER SERVICES**	**REPORTING**
Trichomoniasis						
Trichomoniasis Females	1. Frothy grey or yellow-green vaginal discharge 2. Pruritus/Itching Cervical 3. Petechiae ("strawberry-cervix")	Traditional mode of assessment has been made by observation of motile trichomonas in saline wet mount. If available, NAAT testing is a diagnostic option. (DLS, however, does not offer NAAT testing for trichomoniasis)	Metronidazole 500 mg orally 2 times a day for 7 days Consult and/or direct patient to an upper-level provider if Trichomoniasis is suspected.	Tinidazole[7] 2 g orally in a single dose (not recommended in pregnancy)	Advise females to have partners treated. Male partners shall be screened for CT, GC, syphilis, and HIV. Men exposed to Trichomoniasis should be treated on their initial visit: Metronidazole 2 g orally in a single dose OR Tinidazole[7] 2 g orally single dose	N/A

Centers for Disease Control and Prevention. MMWR 2021; Vol. 70/No. 4: Trichomoniasis (Pages 87-91).

PROTOCOLS FOR TREATMENT OF COMMON SEXUALLY TRANSMITTED DISEASES (continued)						
CONDITION	**SYMPTOMS**	**TESTS**	**RECOMMENDED TREATMENT**	**ALTERNATIVES**	**PARTNER SERVICES**	**REPORTING**
Candidiasis						
Candida (Yeast)	1. Thick white discharge of a cottage cheese consistency 2. Itching and burning of the labia and vulva 3. Painful intercourse 4. Burning during urination 5. Pelvic exam reveals cheese discharge in labialfolds and at vaginal opening with patches adhering to vaginal wall and cervix.	SEE ABOVE	Clotrimazole vaginal cream 1% (over the counter) – 5 g intravaginally for 7-14 days OR Clotrimazole vaginal cream 2% (over the counter) – 5 g intravaginally for 3 days OR Terconazole 0.4% vaginal cream, 5 g intravaginally daily for 7 days Assessment is made by observing budding yeast cells or pseudo hyphae on 10% KOH exam, wet mount, or Gram stain OR Clinical presentation and symptoms Consult and/or direct patient to a higher-level provider if candida is suspected (If pH is abnormally high (>4.5) consider concurrent BV or Trichomoniasis)	Butoconazole cream 2% (single dose bio adhesive product), 5 g intravaginally in a single application OR Fluconazole 150 mg PO for 1 dose (contraindicated in pregnancy) Pleasesee 2021 CDC STI Treatment Guidelines for additional regimens.	N/A	N/A

Centers for Disease Control and Prevention. MMWR 2021; Vol. 70/No. 4: Vulvovaginal Candidiasis (Pages 91-94)

PROTOCOLS FOR TREATMENT OF COMMON SEXUALLY TRANSMITTED DISEASES (continued)

CONDITION	SYMPTOMS	TESTS	RECOMMENDED TREATMENT	ALTERNATIVES	PARTNER SERVICES	REPORTING
HPV HUMAN PAPILLOMAVIRUS (Genital Warts)						
HPV(Genital Warts)	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	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,	EXTERNAL ANOGENITAL WARTS 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	EXTERNALANOGENITAL WARTS PATIENT- APPLIED (Available w/script) Podofilox 0.5% solution or gel. 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^2 and total volume applied daily not to exceed 0.5 mL. (Contraindicated in pregnancy). OR Imiquimod 5% cream. 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 Sinecatechins 15% ointment (Not for use in pregnancy)	N/A	N/A

		indurated, bleeding, etc.)				
HPV (Genital Warts) and Pregnancy	SEE ABOVE Genitalwarts can proliferate and become friable during pregnancy. Althoughremoval of warts during	SEE ABOVE	EXTERNAL ANOGENITAL WARTS PROVIDER – APPLIED Cryotherapy with liquid nitrogen or cryoprobe. Repeat application every	EXTERNALANOGENITAL WARTS N/A (Imiquimod, podophyllin, Sinecatechins and Podofilox should not be used during pregnancy.)	N/A	N/A

	pregnancy can be considered, resolution might be incomplete or poor until pregnancy is complete. HPV types 6 and 11 rarely can causerespiratory papillomatosis in infants and children.		1-2weeks. OR Trichloroacetic acid (TCA) or bichloroacetic acid (BCA) 80% -90%. Apply small amount only to warts. Allow to dry. Consult and or direct patient to a higher-level provider for evaluation and treatment of suspected HPV lesions (Imiquimod, podophyllin, Sinecatechins and Podofilox should not be used during pregnancy.)			

Centers for Disease Control and Prevention. MMWR 2021; Vol. 70/No. 4: Human Papillomavirus Infections (Pages 100-106).

PROTOCOLS FOR TREATMENT OF COMMON SEXUALLY TRANSMITTED DISEASES (continued)

[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. [2] 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. [3] 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. [4] Because erythromycin effectiveness in treating pneumonia caused by C. trachomatis is approximately 80%, a second course of therapy might be required. An association between oral erythromycin and azithromycin and infantile hypertrophic pyloric stenosis (IHPS) has been reported among infants aged <6 weeks. Infants treated with either of these antimicrobials should be followed for IHPS signs

and symptoms. [5] Clindamycin cream is oil-based and may weaken latex condoms and diaphragms for 5 days after use. [6] Clindamycin ovules use an oleaginous base that might weaken latex or rubber products (e.g., condoms and diaphragms). Use of such products within 72 hours after treatment with clindamycin ovules is not recommended. [7] Tinidazole should be avoided during pregnancy.

A. Table I **STD Drugs in Pregnancy**

DRUG	Use in Pregnancy	References
Acyclovir	OK	Centers for Disease Control and Prevention. MMWR 2010; Vol. 59/No. RR-12: Genital HSV (Page 24).
Amoxicillin	OK	Centers for Disease Control and Prevention. MMWR 2010; Vol. 59/No. RR-12: Chlamydial Infections-Pregnancy (Page 47).
Azithromycin	OK	Centers for Disease Control and Prevention. MMWR 2010; Vol. 59/No. RR-12: Chlamydial Infections-Pregnancy (Page 47).
Cefixime	OK	Centers for Disease Control and Prevention. MMWR 2010; Vol. 59/No. RR-12: Uncomplicated Gonococcal Infections-Pregnancy (Page 51-52).
Cefoxitin	OK	Centers for Disease Control and Prevention. MMWR 2010; Vol. 59/No. RR-12: Uncomplicated Gonococcal Infections-Pregnancy (Page 51-52).
Ceftriaxone	OK	Centers for Disease Control and Prevention. MMWR 2010; Vol. 59/No. RR-12: Uncomplicated Gonococcal Infections-Pregnancy (Page 51-52).
Clindamycin	OK; do not use cream in pregnancy	Centers for Disease Control and Prevention. MMWR 2010; Vol. 59/No. RR-12: Bacterial Vaginosis (Page 58).
Clotrimazole*	OK	Centers for Disease Control and Prevention. MMWR 2010; Vol. 59/No. RR-12: Vulvovaginal Candidiasis (Page 61).
Doxycycline	Contraindicated	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).
Erythromycin+	OK	Centers for Disease Control and Prevention. MMWR 2010; Vol. 59/No. RR-12: Chlamydial Infections-Pregnancy (Page 47).
Famciclovir	No data; avoid	Centers for Disease Control and Prevention. MMWR 2010; Vol. 59/No. RR-12: Genital HSV (Page 24).
Fluconazole	Avoid	Centers for Disease Control and Prevention. MMWR 2010; Vol. 59/No. RR-12: Vulvovaginal Candidiasis-Pregnancy (Page 63).

A. Table I **STD Drugs in Pregnancy**

DRUG	Use in Pregnancy	References
Imiquimod	Contraindicated	Centers for Disease Control and Prevention. MMWR 2010; Vol. 59/No. RR-12: Genital Warts-Pregnancy (Page 74).
Lindane	Contraindicated	Centers for Disease Control and Prevention. MMWR 2010; Vol. 59/No. RR-12: Pediculosis Pubis-Pregnancy (Page 89).

* 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)

Azithromycin (500 mg tablets)

Ceftriaxone (Rocephin) 500 mg

Benzathine Penicillin G (Bicillin LA)

Doxycycline Hyclate (100 mg tablets)

Cefixime (400 mg tablets)

STD Offices by Area Developmental Districts (ADD)

ADD	STD Office	Telephone
1, 2 & 4	Western Kentucky, Bowling Green, KY	(270) 781-2490, 218
3	Western Kentucky, Green River Health District	502-545-7784
5, 6, 13, 14, and 15 (excluding Fayette Co)	Specialty Clinic, Louisville, KY	(502) 574-6697
7	Northern Kentucky Independent District Health Dept., Florence, KY	(859) 363-2075
Only Fayette County	Fayette County Health Dept., Lexington, KY	(859) 288-2461
State Office	Kentucky Public Health Department – STD Program	(502) 564-4804, ext. 4300 or ext. 4301

Downloads & Resources:

2021 STDTreatment Guidelines

2021 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.

2020 Update to CDC's Treatment for Gonococcal Infections

Tuberculosis (TB)
Table of Contents

TUBERCULOSIS MATRIX

Condition	Assessment		Education	Follow-up
Classification 0 No TB Exposure Not Infected	Patient TB Risk Assessment (TB-4) with targeting testing of persons in at-risk groups. **Persons at Increased Risk for *Mycobacterium tuberculosis* infection:** • Close contacts of a person known or suspected to have active TB disease • Foreign-born persons, including children who have immigrated within the last 5 years from areas where TB is prevalent** • Persons who visit areas with a high TB prevalence, especially if visits are frequent or prolonged • Residents and employees of high-risk congregate settings • Healthcare workers (HCW) who serve high-risk clients • Medically underserved, low-income populations, homeless • High-risk racial or ethnic minority populations • Persons who abuse drugs or alcohol • Infants, children, and adolescents exposed to adults at high-risk for latent TB infection or active TB disease	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 5 years. 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 licensed medical professional per 902 KAR 20:205 A two-step TST is usually recommended initially for anyone required to have regular TB testing, regardless of age. 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 the person infected. • If second step TST is negative, consider the person uninfected. See TST recommendations for infants, children, and adolescents See procedure for TST in this reference. Review CDC TST video, 2006. BAMTs are one-step in-vitro tests that assess for the presence of infection with *M. tuberculosis*. • BAMT reported as positive, consider the person infected.	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.	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). All testing activities should be accompanied by a plan for follow-up care. Patients should return in 48-72 hours for TST readings, interpretation, and recording by a licensed medical professional. **Anergy Suspects**: Do not rule out TB diagnosis based on a negative skin test result. Consider anergy if the person is immunosuppressed. Also, see other diseases/conditions that can cause suppression of delayed-type hypersensitivity (DTH) response. **Delayed-type hypersensitivity DTH antigen tests are not recommended to be administered at local health departments.**

TUBERCULOSIS MATRIX

Condition	Assessment		Education	Follow-up
Classification 0 (Continued) No TB Exposure Not Infected *Targeted testing for low-risk individuals is no longer recommended (2016 LTBI Guidelines, pg.e4)	Groups that should be TB tested Persons at higher risk for developing active TB disease once infected • Persons with HIV infection • Infants and children less than 5 years old • Persons recently infected with *Mycobacterium tuberculosis* (within the past 2 years) • Cigarette smokers and abuse alcohol and drugs • Persons with a history of inadequately treated TB • Persons with certain medical conditions i) Persons with HIV ii) Persons who are receiving immunosuppressive therapy, such as tumor necrosis factor—alpha (TNF-a) antagonists, of prednisone per day, or immune suppressive drug therapy following organ transplantation. iii) Silicosis iv) Diabetes mellitus v) Chronic renal disease vi) Certain hematologic disorders (leukemia and lymphomas) vii) Cancer of the head, neck or lung viii) Gastrectomy or jejunoileal bypass ix) People receiving immunosuppressive therapy for rheumatoid arthritis or Crohn's disease x) Low body weight (BMI 19)	Develop a policy that the local health department will repeat TSTs given by other health care providers not licensed or trained by the local health department UNLESS their skills are known and trusted by the local health department. Local health department's do not need a similar policy for repeating BAMTs. TSTs administered by the local health departments can be read by staff in other local health departments and do not usually need to be repeated.		

*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 as outlined in the LHD Administrative Reference and 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.*

TUBERCULOSIS MATRIX

CONDITION	ASSESSMENT	TREATMENT	EDUCATION	FOLLOW-UP
Classification 1 TB Exposure (contact) No evidence of infection	Identify contacts within **3 working days** of suspect/case report, using prioritization and the Concentric Circle Approach (p.41) Administer TST or draw blood for BAMT and Examine high-risk contacts within **7 working days** of identification (See p. 37 and 46) Give TST or draw blood for BAMT for medium and low-risk contacts based on findings from the Concentric Circle Approach (See p. 41 and 46) Do the following: • Patient TB Risk Assessment (TB-4) • Medical History (TB H&P 13 or TB 20 follow-up form) • TST or BAMT (unless there is previously documented positive reaction) • Chest x-ray, at the same time as those who: Have TB symptoms; are HIV infected or have other immunosuppressed conditions or 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.	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. If repeat TST or BAMT is positive, continue medicines by DOPT (see classification 2). If repeat TST or BAMT is negative, stop medicines unless contact with infectious case has not or can not be broken. Contacts with immunocompromising conditions (i.e., HIV) 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. See medications to treat LTBI in this reference.	Discuss the following: • How TB is transmitted • LTBI vs 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 Steps for patient producing a sputum specimen at home: 1) Clean & thoroughly rinse mouth with water 2) Breathe deeply 3 times (a tickling sensation at the end of breath) 3) After 3rd breath, cough hard & try to bring up sputum from deep in the lungs 4) Expectorate sputum into a sterile container, collecting at least one teaspoonful 5) Perform this in a properly ventilated room, booth, or outdoors. Provide patient information for an informed consent.	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.

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.

TUBERCULOSIS MATRIX

CONDITION	ASSESSMENT	TREATMENT	EDUCATION	FOLLOW-UP
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 is abnormal, obtain sputum and consider as a suspect case. • Determine history of prior treatment of 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 who initial evaluation suggest liver disorder or regular use of alcohol • Patients 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 high-risk individuals when it comes to being adherent to taking 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 • Notifications of persons assigned a B Classification in the Electronic Disease Notification (EDN) System • 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.	Establish rapport with patient and emphasize the following: • Benefits of treatment • Importance of adherence to treatment regimen • Possible adverse side effects of medicines • 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 pgs 50-53 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.

TUBERCULOSIS MATRIX

CONDITION	ASSESSMENT	TREATMENT	EDUCATION	FOLLOW UP
Classification 3 TB Disease, Clinically Active **Tuberculosis Case Definition:** Documentation of a Positive Lab Test for *Mycobacterium tuberculosis* culture or *Mycobacterium tuberculosis* complex demonstrated in Nucleic Acid Amplification (NAA) test or PCR test, OR **Clinical Case** • Positive TST or positive BAMT • Abnormal Chest X-Ray or clinical evidence of disease • Placed on 2 or more antitubercular antibiotic drugs • Completed diagnostic evaluation to include a patient TB Risk Assessment (TB-4.)	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 HIV, 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. 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 (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, 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 regimen 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 53) 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 physician.	• Monitor for Adverse Reactions • See Recommendations for Sputum Collection • Chest x-rays initially, at 2 months after starting therapy, and at 0-60 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 http://www.lrc.ky.gov/kar/902/002/020.htm

Centers for Disease Control and Prevention, Core Curriculum on Tuberculosis (2013)

TUBERCULOSIS MATRIX

CONDITION	ASSESSMENT	TREATMENT	EDUCATION	FOLLOW UP
Classification 4	TB no longer clinically active		Teach patient signs and symptoms of possible recurrence of active TB disease	
Classification 5	TB suspected. Diagnosis pending. Should not have this classification more than 3 months. 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).	If NAA test on sputum is positive, treatment should begin with a 4-drug regimen until TB is ruled out.	Teach patient signs and symptoms of possible recurrence of active TB disease.	As indicated.

Centers for Disease Control and Prevention, Core Curriculum on Tuberculosis (2013)

SECTION I.

NURSING

CASE

MANAGEMENT

TB Nurse Case Management (NCM) required training and duties:

See the Administrative Regulation/Tuberculosis Section for summary of required trainings, duties and annual reports: https://chfs.ky.gov/agencies/dph/dafm/Pages/lhddocuments.aspx

I. **Initial Steps For Non-hospitalized Patients:** Upon notification of a suspected or confirmed active case, the TB Nurse Case Manager (NCM) should initiate the following steps:

1.) Assure or obtain medical standing orders for the following:

a. **Isolate patient** to prevent transmission
b. **Collect** 3 sputum (8-24 hours apart, with at least one early morning specimen) to assess infectiousness of patient
c. **Submit** sputum to the KY Division of Laboratory Services (DLS) with orders to perform PCR/GeneXpert rapid testing to rule out drug resistance

2.) Reporting

- **Notify the state TB Program** via phone call or secure email with the following information:
    1. Patient's name and DOB
    2. Any clinical evidence of suspected or known case
    3. Method of specimen shipment and estimated date of arrival to DLS
- Request state TB Program approval for PCR/GeneXpert testing
    - The state TB Program will notify DLS of approval

3.) Initiate patient interview

- Call patient to introduce yourself and explain the LHD role. (If patient is not alert or difficulty with providing a history, then you will need their emergency contact info to interview.)
- Schedule a home visit to initiate the Patient History and Physical form (TB-13)
- Assure use of appropriate PPE (i.e. N95 for nurse and medical mask for patient)

4.) Prepare for Plan of Care

- Assure your contracted LHD TB provider has provided you with clinical orders for:
    1. Ongoing isolation (if needed)
    2. Schedule a clinical examination (Performed by a contracted APRN or MD)
    3. Medication orders (RIPE therapy)
    4. Additional lab work (HIV, AST, ALT, BR, CREAT, and PLT)
    5. Additonal radiology ((Chest xray or CT)
    6. Initial vision acuity exam, with color assessment (if RIF prescribed) and/or hearing exam (If steroids prescribed)
    7. Referrals for additional healthcare and/or basic needs

5.) Documentation

- Initiate all required consent forms and NCM forms (See below Forms table)
- Use of the "TB Nurse Case Management Clinical Pathway Checklist (TB16-16b) will assist with assuring weekly case management milestones have been met

6.) Initiate Contact Investigation (CI)

- Explain that you follow the CDC systematic process for CI. You will need to test close contacts first to determine if need for CI expansion. Then based upon results, determine need to contact any additional healthcare facilities to alert if contact investigation would warrant testing any hospital staff, work, extended family or friends, or any social groups.
- See CI section for "Initiating a Contact Investigation"
- Contact the state TB Program for guidance and assistance

7.) NEDSS Reporting (See NEDSS Reporting Section IV)

II. **<u>Initial Steps For Hospitalized Patients:</u>** Upon notification of a suspected or confirmed hospitalized patient, The TB Nurse Case Manager (NCM) should immediately contact the facility Infection Control Preventionist (ICP). This individual should be your primary contact to assure continuity of care.
During this call, the NCM should initiate the following:

1.) Assure isolation

- If patient is not in Airborne Infection Isolation (AII), then it alert the ICP that this must be initiated immediately. If patient is in isolation, then confirm date patient was placed in AII.

2.) Assess infectiousness

- Assure sputum collection has been initiated and inquire is patient has any signs or symptoms
- Ask for results of sputum smear(s), PCR (GeneXpert), and/or culture(s)

3.) Rule out drug resistance

- Ask, if there is there is remaining sputum that can be sent to the state Division of Laboratory Services (DLS)

4.) If PCR or GeneXpert not performed, the facility will need to collect more sputum to send to DLS for GeneXpert (Send first one immediately upon collection, then collect two more to send)**Assess for initiation of standard conventional anti-TB medication regimen**

- Inquire about the name of the attending physician
- Ask if meds have been started. If so, confirm date initiated and dosages.
- If not, then recommend waiting to initiate until more sputum has been collected. *(Medication can be started after collection of first sputum)*

5.) Reporting

- Notify the state TB Program to relay all above information
    - Request approval for PCR/GeneXpert at DLS
        - The state TB Program will notify DLS of PCR approval
- Notify the contracted TB provider to relay all above information and provide name/contact info of attending physician to coordinate care and future discharge planning

6.) Assure continuity of care and collaboration of partnership

- Hospital must collaborate with the LHD to assure continuity of care and prevent community transmission of an infectious disease
- Request facility to share with the NCM weekly MAR, labs, radiology and patient disposition

7.) Assess for additional high risk for progression of disease

- Assess if the patient has any additional co-morbidities
- Initiate TB Risk Assessment <u>(TB-4)</u>
- Assess and/or recommend additional laboratory testing (HIV, AST, ALT, BR, CREAT, and PLT)

8.) Initiate patient interview

- Ask Infection Control if patient is alert and can be interviewed. Explain that you will need to inquire if and onset of any s/s to determine date of infectious period.

- If patient is not alert, then you will need their emergency contact info to interview.
- Initiate the Patient History and Physical form (TB-13)
- Assure use of appropriate PPE (i.e. nurse and patient)

9.) Documentation

- Initiate all required consent forms and NCM forms (See below Forms table)
- The "TB Nurse Case Management Clinical Pathway Checklist (TB16-16b) will assist with assuring weekly case management milestones have been met

10.) Prepare for Discharge Plan of Care

- Assure your contracted LHD TB Provider has provided you with clinical orders for care after discharge
    1. Ongoing isolation if needed
    2. Medication orders (RIPE therapy)
    3. Schedule a clinical examination (Performed by a contracted APRN or MD)
    4. Medication orders (RIPE therapy) Additional lab work and/or radiology
    5. Initial vision acuity exam (if RIF prescribed) and/or hearing exam (If steroids prescribed) Referrals for additional healthcare and/or basic needs
    6. Initiate all required consent forms and NCM forms listed in the below table

11.) Initiate Contact Investigation (CI)

- Explain that you follow the CDC systematic process for CI and that you are the lead investigator. You need to test close contacts first, then will let ICP know if contact investigation would warrant testing any hospital staff. Stress that hospital does not need to begin contact investigation until you confirm the infectiousness of patient:
    - Smear status
    - Close contact testing results
- See CI section for "Initiating a Contact Investigation"
- Contact the state TB Program for guidance and assistance

III. Forms:

The table below provides an overview of all current TB disease and infection (LTBI) forms. Please see the online Clinical Service Guide (CSG)/Forms and Teaching Sheets for access to all TB and LTBI NCM forms.

https://chfs.ky.gov/agencies/dph/dafm/Pages/lhddocuments.aspx

Form	Suspected or Active TB Disease	Latent TB Infection (LTBI)	Comments
TB-1 Infection Reporting Form		✓	Submit twice to the state TB program upon a.) Initiation and b.) Completion of therapy
TB-2 Contact Investigation	✓		TB-2a is Contact Roster instructions TB-2b is Contact Investigation Summary
TB-3 Report of TB Screening	✓		Patient may submit form to work or school
TB-4 TB Risk Assessment Form	✓	✓	TB-4b additional instructions
TB-5 Candidates for LTBI Treatment		✓	For clinical reference only
TB-14 KY Vdot packet	✓		Guidelines and consent forms
TB-16 Case Management	✓		TB-16a Guidelines for NCM TB-16b Clinical Pathway Checklist
TB-17 DOT Record Initial, Continuation	✓		TB-17a DOT record initial TB-17b DOT record continuation TB-17c DOT Tracking (missed doses)
TB-17d Clinic DOPT Record Continuation		✓	

TB-18 Bacteriology Report	✓		Tracking record
TB-19 Surveillance Report	✓		Case Management only. Do not place in patient chart
TB-20 Clinic Follow up Visit	✓		Optional form if LHD Clinical Forms not used
TB-21 Clinic Referral Form	✓	✓	Optional form if LHD Clinical Forms not used
TB-22 Physician/APRN orders	✓	✓	Optional form if LHD Clinical Forms not used
TB-23 Chronic Medication List	✓	✓	Optional form if LHD Clinical Forms not used
TB-24 Clinic Progress Note	✓	✓	Optional form if LHD Clinical Forms not used
TB-25 Education, Counseling Record	✓	✓	TB-25a Electronic references
TB-26 Social Service Assessment	✓	✓	TB-26a Progress notes TB-26b Care plan
TB-27 Activities for Providing DOT for Outreach Workers	✓		Instructions for Providing DOT
TB-28 Prioritization of Contacts	✓		Contact Investigation tool
TB-29 Disease Treatment Cards	✓		Provide to patient at end of treatment
TB-30 LTBI Treatment Cards		✓	Provide to patient at end of treatment
TB-31 Incentive, Enabler Request	✓	✓	
TB-32 LHD TB Monthly Report	✓	✓	Records all outreach activities

IV. **<u>NEDSS Reporting:</u>** Contact the state TB Program to request TB-NEDSS access, training, and guidelines at: 502-564-4276

TUBERCULOSIS CASE DEFINITIONS

TB SUSPECT DEFINITION: A tuberculosis (TB) suspect is a person for whom there is a high index of suspicion for active TB who is currently under evaluation for TB disease. The TB suspect definition is not a part of the official TB Case definition.

CASE DEFINITION: Tuberculosis (TB) (*Mycobacterium tuberculosis)*

2009 Case Definition, CSTE Position Statement: 09-ID-65

The official case definition for TB only contains confirmed case criteria. For surveillance purposes, in order to be classified as a confirmed case of TB, you must meet one of the following four (4) criteria:

1. **Positive Culture for *M. tuberculosis***
    - Isolation of *M. tuberculosis* from a clinical specimen culture result.
        - *This will most commonly be a pulmonary-sources specimen (i.e. sputum, bronchial lavage/washing, lung tissue biopsy), but can be a specimen from anywhere in the body.*
2. **Positive Nucleic Acid Amplification for M. tuberculosis Complex**
    - Demonstration of M. tuberculosis Complex from a clinical specimen by nucleic acid amplification test.
        - *A nucleic acid amplification test is also often referred to as a PCR test.*
        - *For M. tuberculosis Complex, this is most often conducted using a GeneXpert.*
3. **Clinical Case Criteria for TB**
    - If the patient does not meet bacteriologic criteria to meet the case definition (i.e. negative culture, and negative nucleic acid amplification result), they can been considered a confirmed clinical case if they meet **all** of the following criteria:
        - Positive TB skin test and/or Interferon Gamma Release Assay (IGRA) (i.e. Quantiferon or TSPOT)
        - Signs and symptoms compatible with active TB (i.e. abnormal chest radiograph, cough/hemoptysis, cheat pain, shortness of breath, night sweats, fatigue, etc.)
        - Treatment with at least two or more TB drugs (i.e. RIPE therapy)
        - A complete diagnostic evaluation.
4. **Verified by Provider Diagnosis**
    - If the patient does not meet bacteriologic criteria or the clinical case criteria, they can still quality as a confirmed case of TB by provider diagnosis.
    - The state TB Epidemiologist will have to manually override the patient's TB investigation in NEDSS to become "Verified by Provider Diagnosis" and officially counted as a confirmed case of TB.
        - *This is essentially the same process that a clinical case would go through to be counted as confirmed case, but they just do not meet at least one of the aforementioned criteria.*

Risk Factors for Developing *Mycobacterium tuberculosis (Mtb)* Disease

The below information may assist with explaining to your patient how or why they are being assessed for active TB disease:

Some people develop TB disease soon after becoming infected (within weeks) before their immune system can fight the TB bacteria. Other people may get sick years later when their immune system becomes weak for another reason.

Overall, about 5 to 10% of infected persons who do not receive treatment for latent TB infection will develop TB disease at some time in their lives. For persons whose immune systems are weak, especially those with HIV infection, the risk of developing TB disease is much higher than for persons with normal immune systems.

Generally, persons at high risk for developing TB disease fall into two categories:

- Persons who have been recently infected with TB bacteria
- Persons with medical conditions that weaken the immune system

Persons who have been Recently Infected with TB Bacteria

This includes:

- Close contacts of a person with infectious TB disease
- Persons who have immigrated from areas of the world with high rates of TB
- Children less than 5 years of age who have a positive TB test
- Groups with high rates of TB transmission, such as homeless persons, injection drug users, and persons with HIV infection
- Persons who work or reside with people who are at high risk for TB in facilities or institutions such as hospitals, homeless shelters, correctional facilities, nursing homes, and residential homes for those with HIV

Persons with Medical Conditions that Weaken the Immune System

Babies and young children often have weak immune systems. Other people can have weak immune systems, too, especially people with any of these conditions:

- HIV infection (the virus that causes AIDS)
- Substance abuse
- Silicosis
- Diabetes mellitus
- Severe kidney disease
- Low body weight
- Organ transplants
- Head and neck cancer
- Medical treatments such as corticosteroids or organ transplant
- Specialized treatment for rheumatoid arthritis or Crohn's disease

Source: TB Risk Factors | Basic TB Facts | TB | CDC

Recommendations for Sputum Collection

Purpose	Frequency	Number of Specimens
Baseline for TB suspects	Initial	3 samples that are collected 8 – 24 hours apart. Recommend at least one sample collection be observed by health care worker. **Obtain sputum samples BEFORE initiating tuberculosis therapy.**
NAA testing should be performed on at least one respiratory specimen from each patient with signs and symptoms of pulmonary TB for whom a diagnosis of TB is being considered but has not yet been established, and for whom the test result would alter case management or TB control activities.*		
Monitoring for **smear** and culture conversion (AFB Smear positive Culture positive) Initially positive	**Every 2 weeks** after 2 weeks of therapy have been completed, until 3 consecutive AFB smears are negative. After 2 months of uninterrupted therapy. ***Note:*** *3 negative smears are required per 902 KAR 20:200 and 902 KAR 20:016*	1 sample – Recommend collection be observed by health care worker 3 samples on consecutive days. Recommend collection be observed by health care worker If still positive, treatment regimen must be re-evaluated
Monitoring during treatment for **culture** conversion (AFB Smear negative Culture positive)	**Every 2 weeks** until 2 consecutive specimens are negative on culture.	3 samples on consecutive days. Recommend at least one be observed by health care worker • Patients who have positive cultures after 4 months of treatment should be treated as treatment failures (MMWR, June 20, 2003)
Monitoring after culture conversion to negative (or a clinical case)	**Monthly** until treatment is completed. Patient may not be able to produce sputum at this point	1 sample. Recommend collection be observed by health care worker 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 Send specimens to the state lab and instruct private hospitals and physicians to use the state lab
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.

GeneXpert MTB/RIF Assay TESTING PROTOCOL

- 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. canettii*, *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% E
(>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.

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6241a1.htm?s_cid=mm6241a1_e

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, "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). All direct specimens or clinical isolates from enteric disease shall be submitted within seventy-two (72) hours from collection.
- 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.
  Source: 902 KAR 2:020, *Reportable disease surveillance.* Kentucky Legislative Research Commission,

GUIDELINES FOR PATIENT FOLLOW-UP NOTIFICATION

For active TB cases, suspects, contacts to cases, and individuals receiving directly observed preventive therapy DOPT, 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.

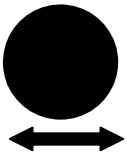
2. The second contact should be a regular mailed letter with directions for the patient to contact the LHD for follow-up.

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

 5 or More Millimeters	 10 or More Millimeters	 15 or More Millimeters
5 mm is classified as positive in: • HIV-positive persons • Recent contacts of a case with active TB disease • People who have previously had active TB disease • Persons with fibrotic changes on chest radiograph consistent with old healed TB • 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)	10 mm is classified as positive in: • People who have come to the U.S. within the last 5 years from areas of the world where TB is common * • Injection drug users • People who live or work in high-risk congregate settings • Mycobacteriology laboratory personnel • Children younger than 4 years • Infants, children, and adolescents exposed to adults in high-risk categories** • 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)	15 mm is classified as positive in: • Persons with no known risk factors for TB • Targeted skin testing programs should only be conducted among high-risk groups

A TST shall be performed by: 1. A Physician; 2. An advanced practice registered nurse; 3. A physician assistant; 4. A registered nurse; or 5. A pharmacist. (b) A licensed practical nurse under the supervision of a registered nurse may perform a TST. 902 KAR 20:205 TB Testing for Healthcare Workers.

A tuberculin skin test conversion is defined as an increase of 10 mm of induration within a 2-year period, regardless of age.

ATS Diagnostic Standards and Classification of Tuberculosis in Adults and Children. Am. J. Respir. Care Med., 4/00

Core Curriculum on Tuberculosis; What the Clinician Should Know (2013).

*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[1]

Children for whom immediate TST or IGRA is indicated[2]:

- 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[3]

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)

Situation	Recommended testing
No previous TST result	Two-step baseline TSTs
Previous negative TST result (documented or not) >12 months before new employment	Two-step baseline TSTs
Previous documented negative TST result ≤12 months before new employment	Single TST needed for baseline testing; this test will be the second-step
≥2 previous documented negative TSTs but most recent TST >12 months before new employment	Single TST; two-step testing is not necessary (result would have already boosted)
Previous documented positive TST result	No TST
Previous undocumented positive TST result*	Two-step baseline TST(s)
Previous BCG† vaccination	Two-step baseline TST(s)
Programs that use serial BAMT,§ including QFT¶ (or the previous version QFT)	See Supplement, Use of QFT-G** for Diagnosing *M. tuberculosis* Infections in Health-Care Workers (HCWs)

* For newly hired health-care workers and other persons 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:E12–3.
† 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.

https://www.cdc.gov/mmwr/pdf/rr/rr5417.pdf

II.

MANAGEMENT

OF

ACTIVE TB DISEASE

DEFINITIONS OF MYCOBACTERIUM COMPLEX:

Mycobacterium can cause a variety of diseases.

- *Mycobacterium tuberculosis* is the organism that causes TB in humans.
- *Mycobacterium africanum* is closely related to *Mycobacterium tuberculosis*, but is very rare in the United States.
- *Mycobacterium avium* complex is a common type of non-tuberculosis mycobacterium that can cause disease in humans.
- *Mycobacterium bovis* can cause disease similar to TB and usually occurs in cows. Before pasteurization of milk was common, these mycobacteria were often spread to humans through contaminated milk. It rarely affects humans in the United States today.
- *Mycobacterium canetti* can cause disease in humans.
- *Mycobacterium microti* can cause generalized tuberculosis.

CONVENTIONAL FOUR-DRUG ANTI-TUBERCULOSIS THERAPY: R.I.P.E.

Rifampin (RIF): a drug used to treat TB disease and latent tuberculosis infection; possible side effects include hepatitis, turning body fluids orange.

Isoniazid (INH): a drug used to treat TB disease and latent tuberculosis infection; relatively safe but may cause hepatitis and other adverse reactions in some patients.

Pyrazinamide (PZA): a drug used to treat TB disease; used along with other listed drugs to treat TB; may cause hepatitis and other adverse reactions in some patients.

Ethambutol (EMB): a drug used to treat TB disease; may cause vision problems; use with caution in children too young to be monitored for vision changes.

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-
  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 jejunoileal by-pass;
- 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

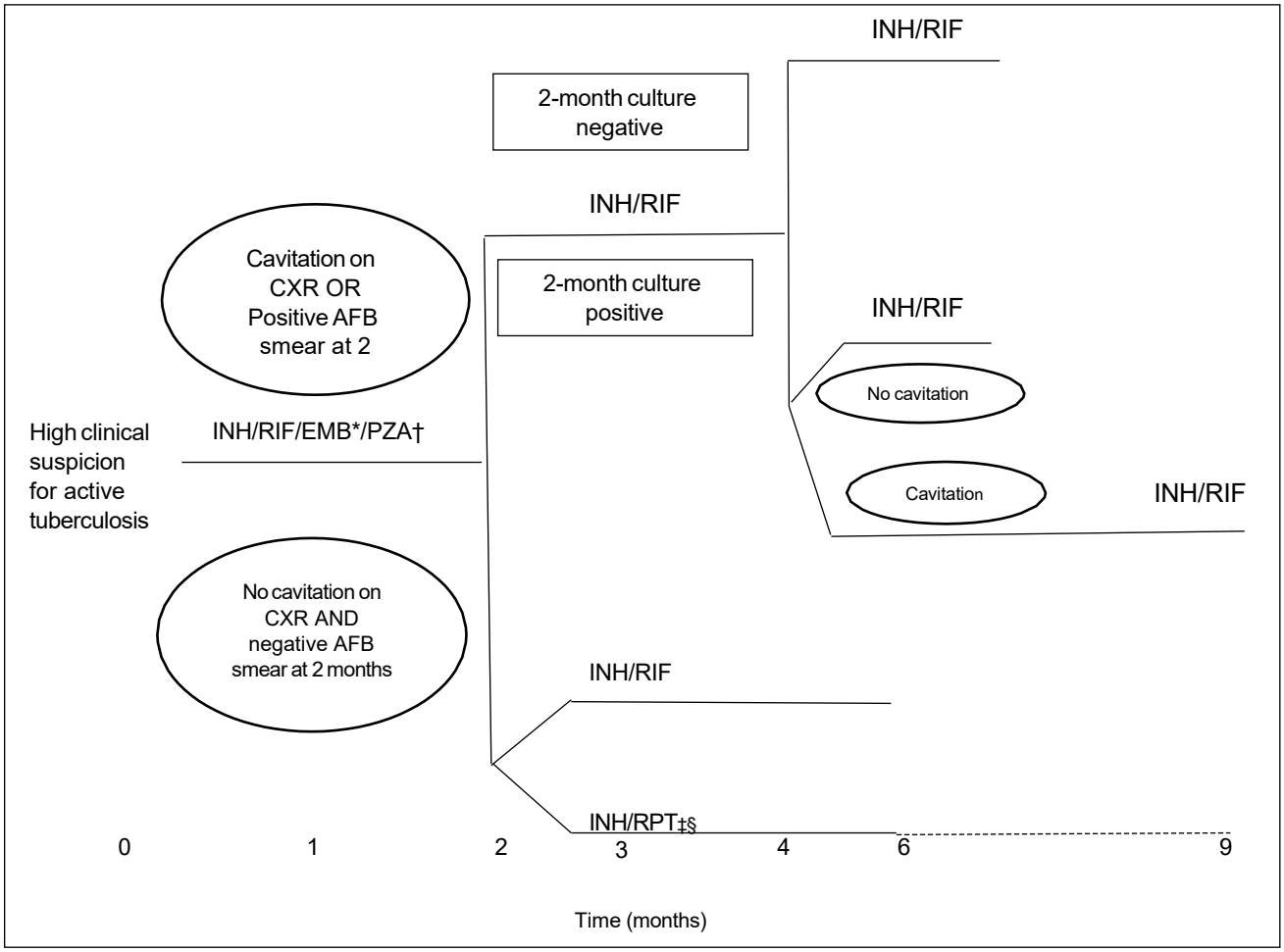
https://academic.oup.com/cid/article/64/2/e1/2629583

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



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 as 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 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.**

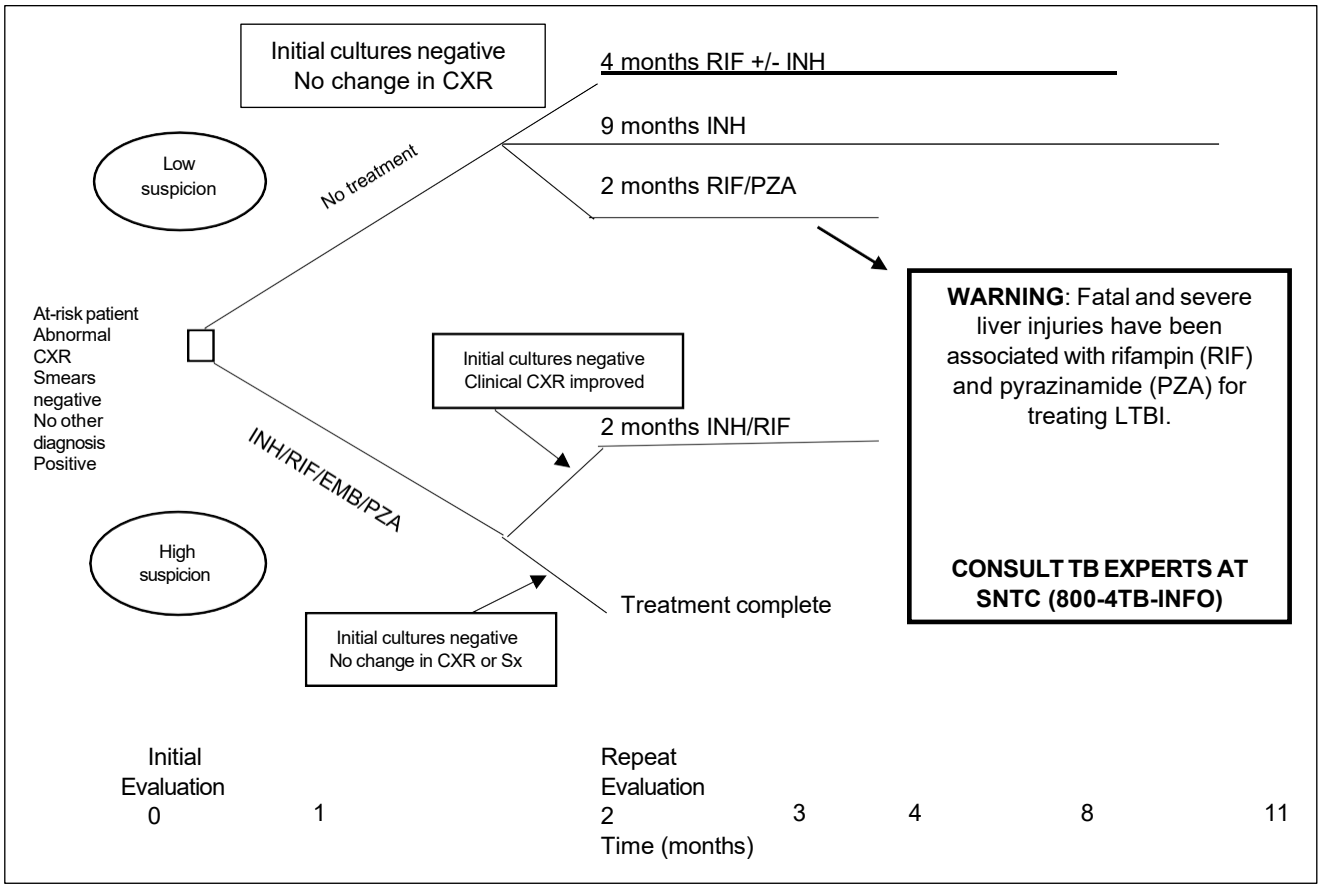
†PZA may be discontinued after it has been taken for 2 months (56 doses).

‡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

Centers for Disease Control and Prevention. Treatment of Tuberculosis, American Thoracic Society, CDC, and Infectious Diseases Society of America. MMWR 2003; 52(No. RR-11); 6.

Treatment Algorithm for Active, Culture-negative Pulmonary Tuberculosis and Inactive Tuberculosis



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 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.)

Centers for Disease Control and Prevention. Treatment of Tuberculosis, American Thoracic Society, CDC, and Infectious Diseases Society of America. MMWR 2003; 52(No. RR-11): 7.

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-rayand / or clinical improvement on anti-TB 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. Furthermore, staff providing additional daily healthcare services, such as dialysis or home health, can assist the LHD personnel with DOT therapy.

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 timethat 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.

All patients participating in Video DOT must have a face-to-face clinic visit at least one time per month during their treatment period.

See TB Program teaching sheet **TB-14a for Video DOT protocols and consent form **TB-14b**.*

Exclusion Criteria for Video DOT

- Patient in isolation to rule out infectiousness
- 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.
- Patient has received one (1) or more Health Orders due to noncompliance.
- 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

Table 2. Drug Regimens for Microbiologically Confirmed Pulmonary Tuberculosis Caused by Drug-Susceptible Organisms

	Intensive Phase		Continuation Phase				
Regimen	Drug[a]	Interval and Dose[b] (Minimum Duration)	Drugs	Interval and Dose[b,c] (Minimum Duration)	Range of Total Doses	Comments[c,d]	Regimen Effectiveness
1	INH RIF PZA EMB	7 d/wk for 56 doses (8 wk), or 5 d/wk for 40 doses (8 wk)	INH RIF	7 d/wk for 126 doses (18 wk), or 5 d/wk for 90 doses (18 wk)	182–130	This is the preferred regimen for patients with newly diagnosed pulmonary tuberculosis.	Greater
2	INH RIF PZA EMB	7 d/wk for 56 doses (8 wk), or 5 d/wk for 40 doses (8 wk)	INH RIF	3 times weekly for 54 doses (18 wk)	110–94	Preferred alternative regimen in situations in which more frequent DOT during continuation phase is difficult to achieve.	
3	INH RIF PZA EMB	3 times weekly for 24 doses (8 wk)	INH RIF	3 times weekly for 54 doses (18 wk)	78	Use regimen with caution in patients with HIV and/or cavitary disease. Missed doses can lead to treatment failure, relapse, and acquired drug resistance.	
4	INH RIF PZA EMB	7 d/wk for 14 doses then twice weekly for 12 doses[e]	INH RIF	Twice weekly for 36 doses (18 wk)	62	Do not use twice-weekly regimens in HIV-infected patients or patients with smear-positive and/or cavitary disease. If doses are missed, then therapy is equivalent to once weekly, which is inferior.	Lesser

Abbreviations: DOT, directly observed therapy; EMB, ethambutol; HIV, human immunodeficiency virus; INH, isoniazid; PZA, pyrazinamide; RIF, rifampin.

[a] Other combinations may be appropriate in certain circumstances; additional details are provided in the section "Recommended Treatment Regimens."

[b] 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.

[c] Based on expert opinion, patients with cavitation on initial chest radiograph and positive cultures at completion of 2 months of therapy should receive a 7-month (31-week) continuation phase.

[d] 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.

[e] See [426]. Alternatively, some US tuberculosis control programs have administered intensive-phase regimens 5 days per week for 15 doses (3 weeks), then twice weekly for 12 doses.

CID/IDSA Guideline…Clinical Practice Guidelines: Treatment of Drug-Susceptible Tuberculosis; CID 2016:63 (1 October), pg 4.

DRUG REGIMENS FOR

MICROBIOLOGICALLY CONFIRMED

PULMONARY TUBERCULOSIS CAUSED BY DRUG-SUSCEPTIBLE ORGANISMS

(Cont.)

TABLE 2. Drug regimens for culture-positive pulmonary tuberculosis caused by drug-susceptible organisms

Initial phase			Continuation phase			Range of total doses (minimal duration)	Rating* (evidence)†	
Regimen	Drugs	Interval and doses‡ (minimal duration)	Regimen	Drugs	Interval and doses‡§ (minimal duration)		HIV⁻	HIV⁺
1	INH RIF PZA EMB	Seven days per week for 56 doses (8 wk) or 5 d/wk for 40 doses (8 wk)¶	1a	INH/RIF	Seven days per week for 126 doses (18 wk) or 5 d/wk for 90 doses (18 wk)¶	182–130 (26 wk)	A (I)	A (II)
			1b	INH/RIF	Twice weekly for 36 doses (18 wk)	92–76 (26 wk)	A (I)	A (II)#
			1c**	INH/RPT	Once weekly for 18 doses (18 wk)	74–58 (26 wk)	B (I)	E (I)
2	INH RIF PZA EMB	Seven days per week for 14 doses (2 wk), then twice weekly for 12 doses (6 wk) or 5 d/wk for 10 doses (2 wk),¶ then twice weekly for 12 doses (6 wk)	2a	INH/RIF	Twice weekly for 36 doses (18 wk)	62–58 (26 wk)	A (II)	B (II)#
			2b**	INH/RPT	Once weekly for 18 doses (18 wk)	44–40 (26 wk)	B (I)	E (I)
3	INH RIF PZA EMB	Three times weekly for 24 doses (8 wk)	3a	INH/RIF	Three times weekly for 54 doses (18 wk)	78 (26 wk)	B (I)	B (II)
4	INH RIF EMB	Seven days per week for 56 doses (8 wk) or 5 d/wk for 40 doses (8 wk)¶	4a	INH/RIF	Seven days per week for 217 doses (31 wk) or 5 d/wk for 155 doses (31 wk)¶	273–195 (39 wk)	C (I)	C (II)
			4b	INH/RIF	Twice weekly for 62 doses (31 wk)	118–102 (39 wk)	C (I)	C (II)

Definition of abbreviations: EMB = Ethambutol; INH = isoniazid; PZA = pyrazinamide; RIF = rifampin; RPT = rifapentine.

* Definitions of evidence ratings: A = preferred; B = acceptable alternative; C = offer when A and B cannot be given; E = should never be given.

† Definition of evidence ratings: I = randomized clinical trial; II = data from clinical trials that were not randomized or were conducted in other populations; III = expert opinion.

‡ When DOT is used, drugs may be given 5 days/week and the necessary number of doses adjusted accordingly. Although there are no studies that compare five with seven daily doses, extensive experience indicates this would be an effective practice.

§ Patients with cavitation on initial chest radiograph and positive cultures at completion of 2 months of therapy should receive a 7-month (31 week; either 217 doses [daily] or 62 doses [twice weekly]) continuation phase.

¶ Five-day-a-week administration is always given by DOT. Rating for 5 day/week regimens is AIII.

Not recommended for HIV-infected patients with CD4⁺ cell counts <100 cells/µl.

** Options 1c and 2b should be used only in HIV-negative patients who have negative sputum smears at the time of completion of 2 months of therapy and who do not have cavitation on initial chest radiograph (see text). For patients started on this regimen and found to have a positive culture from the 2-month specimen, treatment should be extended an extra 3 months.

Centers for Disease Control and Prevention. Treatment of Tuberculosis, American Thoracic Society, CDC, and Infectious Diseases Society of America., MMWR June 20, 2003, Vol. 52, No. RR-11, pg 3 https://www.thoracic.org/statements/resources/mtpi/rr5211.pdf

DOSES[a] OF ANTITUBERCULOSIS DRUGS FOR ADULTS AND CHILDREN[b]

Drug	Preparation	Population	Daily	Once-Weekly	Twice-Weekly	Thrice-Weekly
First-line drugs						
Isoniazid	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.	Adults	5 mg/kg (typically 300 mg)	15 mg/kg (typically 900 mg)	15 mg/kg (typically 900 mg)	15 mg/kg (typically 900 mg)
		Children	10–15 mg/kg	. . .	20–30 mg/kg	. . .[b]
Rifampin	Capsule (150 mg, 300 mg). Powder may be suspended for oral administration. Aqueous solution for intravenous injection.	Adults[c]	10 mg/kg (typically 600 mg)	. . .	10 mg/kg (typically 600 mg)	10 mg/kg (typically 600 mg)
		Children	10–20 mg/kg	. . .	10–20 mg/kg	. . .[b]
Rifabutin	Capsule (150 mg)	Adults[d]	5 mg/kg (typically 300 mg)	. . .	Not recommended	Not recommended
		Children	Appropriate dosing for children is unknown. Estimated at 5 mg/kg.			
Rifapentine	Tablet (150 mg film coated)	Adults		10–20 mg/kg[e]	. . .	. . .
		Children	Active tuberculosis: for children ≥12 y of age, same dosing as for adults, administered once weekly. Rifapentine is not FDA-approved for treatment of active tuberculosis in children <12 y of age.			
Pyrazinamide	Tablet (500 mg scored)	Adults	See Table 10	. . .	See Table 10	See Table 10
		Children	35 (30–40) mg/kg	. . .	50 mg/kg	. . .[b]
Ethambutol	Tablet (100 mg; 400 mg)	Adults	See Table 11	. . .	See Table 11	See Table 11
		Children[f]	20 (15–25) mg/kg	. . .	50 mg/kg	. . .[b]

DOSES[a] OF ANTITUBERCULOSIS DRUGS FOR ADULTS AND CHILDREN[b]

Second-line drugs				
Cycloserine	Capsule (250 mg)	Adults[g]	10–15 mg/kg total (usually 250–500 mg once or twice daily)	There are inadequate data to support intermittent administration.
		Children	15–20 mg/kg total (divided 1–2 times daily)	
Ethionamide	Tablet (250 mg)	Adults[h]	15–20 mg/kg total (usually 250–500 mg once or twice daily)	There are inadequate data to support intermittent administration.
		Children	15–20 mg/kg total (divided 1–2 times daily)	
Streptomycin	Aqueous solution (1 g vials) for IM or IV administration.	Adults	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 give only 3 times weekly to allow for drug clearance.	
		Children	15–20 mg/kg [427] . . .	25–30 mg/kg[i] . . .
Amikacin/ kanamycin	Aqueous solution (500 mg and 1 g vials) for IM or IV administration.	Adults	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.	
		Children	15–20 mg/kg [427] . . .	25–30 mg/kg[i] . . .
Capreomycin	Aqueous solution (1 g vials) for IM or IV administration.	Adults	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.	
		Children	15–20 mg/kg [427] . . .	25–30 mg/kg[i] . . .
Para-amino salicylic acid	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.	Adults	8–12 g total (usually 4000 mg 2–3 times daily)	There are inadequate data to support intermittent administration.
		Children	200–300 mg/kg total (usually divided 100 mg/kg given 2 to 3 times daily)	
Levofloxacin	Tablets (250 mg, 500 mg, 750 mg); aqueous solution (500 mg vials) for IV injection.	Adults	500–1000 mg daily	There are inadequate data to support intermittent administration.
		Children	The optimal dose is not known, but clinical data suggest 15–20 mg/kg [427]	
Moxifloxacin	Tablets (400 mg); aqueous solution (400 mg/ 250 mL) for IV injection	Adults	400 mg daily	There are inadequate data to support intermittent administration.[j]
		Children	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 μL/mL 2 h postdose is proposed by experts as a reasonable target.	

 When using 2016 Treatment Guidelines, any resistance to first or second-line drugs, contact SNTC.

Doses of Antituberculosis Drugs for Adults and Children (cont)

*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. American Academy of Pediatrics, 2018 Red Book, 31st edition: In: Kimberlin, DW, Brady MT, Jackson, MA, Long, SS, eds. *Red Book: 2018 Report of the Committee of Infectious Diseases.* 31st ed. Itasca, IL: American Academy of Pediatrics: 2018:[ch.3p839] Official American Thoracic Society (ATS)/Centers for Disease Control and Prevention (CDC)/Infectious Diseases Society of America (IDSA) Clinical Practice Guidelines: Treatment of Drug-Susceptible Tuberculosis. Clin Infect Dis. 2016; 3:853-67,

Abbreviations: FDA, US Food and Drug Administration; HIV, human immunodeficiency virus; IM, intramuscular; INH, isoniazid; IV, intravenous.

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 + [0.40x [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.

For purposes of this document, adult dosing begins at age 15 years or at a weight of >40kg 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.

Higher doses of rifampin, currently as high as 35mg/kg, are being studied in clinical trials.

Rifabuten dose may need to be adjusted when there is concomitant use of protease inhibitors or nonnucleoside reverse transcriptase inhibitors.

TBTC Study 22 used rifapentine (RPT) dosage of 10mg/kg in the continuation phase of treatment for active disease [9]. However, RIFAQUIN and PREVENT TB safely used higher dosages of RPT, administered once weekly [164, 210]. Daily doses of 1200mg RPT are being studied in clinical trials for active tuberculosis disease.

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, have no prior tuberculosis treatment history, 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.

Clinicians experienced with using cycloserine suggest starting with 250mg once daily and gradually increasing as tolerated. Serum concentrations often are useful in determining the appropriate dose for a given patient. Few patients tolerate 500mg twice daily.

[h]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 250mg once daily and gradually increasing as tolerated. Serum concentrations may be useful in determining the appropriate dose for a given patient. Few patients tolerate 500mg twice daily.

[i]Modified from adult intermittent dose of 25mg/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.

RIFAQUIN trial studied a 6-month regimen. Daily isoniazid was replaced by daily moxifloxacin 400mg for the first 2 months, followed by once-weekly doses of moxifloxacin 400mg and RPT 1200mg for the remaining 4 months. Two hundred twelve patients were studied {each dose 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 [164].

DOSES[a] OF ANTITUBERCULOSIS DRUGS FOR ADULTS AND CHILDREN[b]

TABLE 4. Suggested pyrazinamide doses, using whole tablets, for adults weighing 40–90 kilograms

	Weight (kg)*		
	40–55	56–75	76–90
Daily, mg (mg/kg)	1,000 (18.2–25.0)	1,500 (20.0–26.8)	2,000† (22.2–26.3)
Thrice weekly, mg (mg/kg)	1,500 (27.3–37.5)	2,500 (33.3–44.6)	3,000† (33.3–39.5)
Twice weekly, mg (mg/kg)	2,000 (36.4–50.0)	3,000 (40.0–53.6)	4,000† (44.4–52.6)

*Based on estimated lean body weight.
†Maximum dose regardless of weight.

TABLE 5. Suggested ethambutol doses, using whole tablets, for adults weighing 40–90 kilograms

	Weight (kg)*		
	40–55	56–75	76–90
Daily, mg (mg/kg)	800 (14.5–20.0)	1,200 (16.0–21.4)	1,600† (17.8–21.1)
Thrice weekly, mg (mg/kg)	1,200 (21.8–30.0)	2,000 (26.7–35.7)	2,400† (26.7–31.6)
Twice weekly, mg (mg/kg)	2,000 (36.4–50.0)	2,800 (37.3–50.0)	4,000† (44.4–52.6)

*Based on estimated lean body weight.
†Maximum dose regardless of weight.

Centers for Disease Control and Prevention. Treatment of Tuberculosis, American Thoracic Society, CDC, and Infectious Disease Society of America.

MMWR 2003; 52 (No. RR-11):5.

PYRIDOXINE (VITAMIN B6) SUPPLEMENTATION DURING TREATMENT OF LTBI OR ACTIVE TB

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[1, 2, 3]:

- Nutritional deficiencies
- Diabetes
- HIV infection
- Chronic renal failure
- Alcoholism
- Persons with seizure disorders
- Pregnant women
- Breastfeeding women

Infants, children, and adolescents[1, 2, 3, 4, 5, 6]**:** Routine administration of pyridoxine is not recommended for most children and adolescents taking INH[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 exclusivelybreastfed
- Children and adolescents on meat- and milk-deficient diets
- Children and adolescents with nutritional deficiencies
- Children who experience paresthesia 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[1]
Wisconsin TB Program guidelines – 10 to 50 mg/day[2]
The Harriet Lane Handbook[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;
- Breastfeeding 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;
- Adults, pregnant and breast-feeding women, over 18 years, 100 mg."

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[1] Centers for Disease Control and Prevention. Treatment of Tuberculosis. MMWR 2003;52 (No. RR-11), http://www.cdc.gov/MMWR/PDF/rr/rr5211.pdf

[2] 2016 Clinical Practice Guidelines for Diagnosis of Tuberculosis in Adults and Children.

[3] Wisconsin TB Program. "Frequently Asked Questions about Pyridoxine (Vitamin B-6)," http://www.dhs.wisconsin.gov/tb/resources/guidelines/pyridoxine_faq.pdf

[4] American Academy of Pediatrics. 2018 Red Book: Report of the Committee on Infectious Disease. Elk Grove Village, IL: American Academy of Pediatrics, p. 841.

[5] Robertson J, Shilkofski, N, editors. The Harriet Lane Handbook: A Manual for Pediatric House Officers, 17th Edition, Elsevier Mosby, 2005 p. 949.

[6] Nationwide Children's Hospital, Columbus OH. Pyridoxine Hydrochloride Oral Solution, http://www.nationwidechildrens.org/Document/Get/79362, accessed Nov 08, 2010.

[7] National Institutes of Health. Medline Plus: Pyridoxine (Vitamin B6), http://www.nlm.nih.gov/medlineplus/druginfo/natural/934.html, accessed Nov 08, 2010.

DOSAGE CHART*

Weight in Pounds	Weight in Kilograms	Dosage at 5 mg/kg	Dosage at 10 mg/kg	Dosage at 15 mg/kg	Dosage at 20 mg/kg	Dosage at 25 mg/kg	Dosage at 30 mg/kg
5	2.3	11.3	22.7	34.0	45.4	56.7	68.0
10	4.5	22.7	45.4	68.0	90.7	113.4	136.1
15	6.8	34.0	68.0	102.1	136.1	170.1	204.1
20	9.1	45.4	90.7	136.1	181.4	226.8	272.2
25	11.3	57	113	170	227	283	340
30	13.6	68	136	204	272	340	408
35	15.9	79	159	238	318	397	476
40	18.1	91	181	272	363	454	544
45	20.4	102	204	306	408	510	612
50	22.7	113	227	340	454	567	680
55	24.9	125	249	374	499	624	748
60	27.2	136	272	408	544	680	816
65	29.5	147	295	442	590	737	885
70	31.8	159	318	476	635	794	953
75	34.0	170	340	510	680	850	1021
80	36.3	181	363	544	726	907	1089
85	38.6	193	386	578	771	964	1157
90	40.8	204	408	612	816	1021	1225
95	43.1	215	431	646	862	1077	1293
100	45.4	227	454	680	907	1134	1361
105	47.6	238	476	714	953	1191	1429
110	49.9	249	499	748	998	1247	1497
115	52.2	261	522	782	1043	1304	1565
120	54.4	272	544	816	1089	1361	1633
125	56.7	283	567	850	1134	1417	1701
130	59.0	295	590	885	1179	1474	1769
135	61.2	306	612	919	1225	1531	1837
140	63.5	318	635	953	1270	1588	1905
145	65.8	329	658	987	1315	1644	1973
150	68.0	340	680	1021	1361	1701	2041
155	70.3	352	703	1055	1406	1758	2109
160	72.6	363	726	1089	1451	1814	2177
165	74.8	374	748	1123	1497	1871	2245
170	77.1	386	771	1157	1542	1928	2313
175	79.4	397	794	1191	1588	1984	2381
180	81.6	408	816	1225	1633	2041	2449
185	83.9	420	839	1259	1678	2098	2517
190	86.2	431	862	1293	1724	2155	2585
195	88.5	442	885	1327	1769	2211	2654
200	90.7	454	907	1361	1814	2268	2722
205	93.0	465	930	1395	1860	2325	2790
210	95.3	476	953	1429	1905	2381	2858
215	97.5	488	975	1463	1950	2438	2926
220	99.8	499	998	1497	1996	2495	2994
225	102.1	510	1021	1531	2041	2551	3062
230	104.3	522	1043	1565	2087	2608	3130
235	106.6	533	1066	1599	2132	2665	3198
240	108.9	544	1089	1633	2177	2722	3266
245	111.1	556	1111	1667	2223	2778	3334
250	113.4	567	1134	1701	2268	2835	3402

*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 12. Clinically significant drug–drug interactions involving the rifamycins*

Drug class	Drugs whose concentrations are substantially decreased by rifamycins (references)	Comments
Antiinfectives	HIV-1 protease inhibitors (saquinavir, indinavir, nelfinavir, amprenavir, ritonavir, lopinavir/ritonavir) (*1,20–25*)	Can be used with rifabutin. Ritonavir, 400–600 mg twice daily, probably can be used with rifampin. The combination of saquinavir and ritonavir can also be used with rifampin.
	Nonnucleoside reverse transcriptase inhibitors Delavirdine (*26,27*) Nevirapine (*28*) Efavirenz (*29*)	Delavirdine should not be used with any rifamycin. Doses of nevirapine (*28*) and efavirenz (*29*) need to be increased if given with rifampin, no dose increase needed if given with rifabutin (*5*).
	Macrolide antibiotics (clarithromycin, erythromycin) (*30–32*)	Azithromycin has no significant interaction with rifamycins.
	Doxycycline (*33*)	May require use of a drug other than doxycycline.
	Azole antifungal agents (ketoconazole, itraconazole, voriconazole) (*34–38*)	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.
	Atovaquone (*39*)	Consider alternate form of *Pneumocystis carinii* treatment or prophylaxis.
	Chloramphenicol (*40*)	Consider an alternative antibiotic.
	Mefloquine (*41*)	Consider alternate form of malaria prophylaxis.
Hormone therapy	Ethinylestradiol, norethindrone (*42–44*)	Women of reproductive potential on oral contraceptives should be advised to add a barrier method of contraception when taking a rifamycin.
	Tamoxifen (*45*)	May require alternate therapy or use of a nonrifamycin-containing regimen.
	Levothyroxine (*46,47*)	Monitoring of serum TSH recommended; may require increased dose of levothyroxine.
Narcotics	Methadone (*48,49*)	Rifampin and rifapentine use may require methadone dose increase; rifabutin infrequently causes methadone withdrawal.
Anticoagulants	Warfarin (*50*)	Monitor prothrombin time; may require two- to threefold dose increase.
Immunosuppressive agents	Cyclosporine, tacrolimus (*51–53*)	Rifabutin may allow concomitant use of cyclosporine and a rifamycin; monitoring of cyclosporine serum concentrations may assist with dosing.
	Corticosteroids (*54–57*)	Monitor clinically; may require two- to threefold increase in corticosteroid dose (*58*).
Anticonvulsants	Phenytoin (*59*), lamotrigine (*60*)	Therapeutic drug monitoring recommended; may require anticonvulsant dose increase.
Cardiovascular agents	Verapamil (*61*), nifedipine (*62,63*), diltiazem (a similar interaction is also predicted for felodipine and nisoldipine)	Clinical monitoring recommended; may require change to an alternate cardiovascular agent.
	Propranolol (*64*), metoporol (*65*)	Clinical monitoring recommended; may require dose increase or change to an alternate cardiovascular drug.
	Enalapril (*66*), losartan (*67*)	Monitor clinically; may require a dose increase or use of an alternate cardiovascular drug.
	Digoxin (among patients with renal insufficiency) (*68*), digitoxin (*69*)	Therapeutic drug monitoring recommended; may require digoxin or digitoxin dose increase.
	Quinidine (*70,71*)	Therapeutic drug monitoring recommended; may require quinidine dose increase.
	Mexilitine (*72*), tocainide (*73*), propafenone (*15*)	Clinical monitoring recommended; may require change to an alternate cardiovascular drug.
Bronchodilators	Theophylline (*74*)	Therapeutic drug monitoring recommended; may require theophylline dose increase.
Sulfonylurea hypoglycemics	Tolbutamide, chlorpropamide, glyburide, glimepiride, repaglinide (*75–79*)	Monitor blood glucose; may require dose increase or change to an alternate hypoglycemic drug.
Hypolipidemics	Simvastatin (*80*), fluvastatin (*81*)	Monitor hypolipidemic effect; may require use of an alternate hypolipidemic drug.
Psychotropic drugs	Nortriptyline (*82*)	Therapeutic drug monitoring recommended; may require dose increase or change to alternate psychotropic drug.
	Haloperidol (*83*), quetiapine (*84*)	Monitor clinically; may require a dose increase or use of an alternate psychotropic drug.
	Benzodiazepines (e.g., diazepam [*85*], triazolam [*86*]), zolpidem (*87*), buspirone (*88*)	Monitor clinically; may require a dose increase or use of an alternate psychotropic drug.

Centers for Disease Control and Prevention. Treatment of Tuberculosis. MMWR 2003;52 (No. RR-11) pg 47.

https://www.cdc.gov/mmwr/pdf/rr/rr5211.pdf

Dosing Recommendations for Adult Patients with Reduced Renal Function

Drug	Change in Frequency?	Recommended Dose and Frequency for Patients With Creatinine Clearance <30 mL/min, or Patients Receiving Hemodialysis
Isoniazid	No	300 mg once daily, or 900 mg 3 times/wk
Rifampin	No	600 mg once daily, or 600 mg 3 times/wk
Pyrazinamide	Yes	25–35 mg/kg/dose 3 times/wk (not daily)
Ethambutol	Yes	20–25 mg/kg/dose 3 times/wk (not daily)
Levofloxacin	Yes	750–1000 mg/dose 3 times/wk (not daily)
Moxifloxacin	No	400 mg once daily
Cycloserine	Yes	250 mg once daily, or 500 mg/dose 3 times/wk[b]
Ethionamide	No	250–500 mg/dose daily
Para-amino salicylic acid	No	4 g/dose twice daily
Streptomycin	Yes	15 mg/kg/dose 2-3 times/wk (not daily)
Capreomycin	Yes	15 mg/kg/dose 2-3 times/wk (not daily)
Kanamycin	Yes	15 mg/kg/dose 2-3 times/wk (not daily)
Amikacin	Yes	15 mg/kg/dose 2-3 times/wk (not daily)

- 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

TABLE 16. Potential regimens for the management of patients with drug-resistant pulmonary tuberculosis

Pattern of drug resistance	Suggested regimen	Duration of treatment (mo)	Comments
INH (± SM)	RIF, PZA, EMB (an FQN may strengthen the regimen for patients with extensive disease)	6	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 BIII). INH should be stopped in cases of INH resistance (see text for additional discussion).
INH and RIF (± SM)	FQN, PZA, EMB, IA, ± alternative agent	18–24	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).
INH, RIF (± SM), and EMB or PZA	FQN (EMB or PZA if active), IA, and two alternative agents	24	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).
RIF	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)	12–18	Daily and three times weekly regimens of INH, PZA, and SM given for 9 mo were effective in a BMRC trial‡ (Rating BI). 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 BIII). But for more extensive disease and/or to shorten duration (e.g., to 12 months), an injectable agent may be added in the initial 2 mo of therapy (Rating BIII).

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, clarithromycin, amoxicillin-clavulanate, linezolid.
* **Source:** Mitchison DA, Nunn AJ. Influence of initial drug resistance on the response to short-course chemotherapy of pulmonary tuberculosis. Am Rev Respir Dis 1986;133:423–430.
† **Source:** Hong Kong Chest Service, British Medical Research Council. Five-year follow-up of a controlled trial of five 6 month regimens of chemotherapy for tuberculosis. Am Rev Respir Dis 1987;136:1339–1342.
‡ **Source:** Hong Kong Chest Service, British Medical Research Council. Controlled trial of 6-month and 9-month regimens of daily and intermittent streptomycin plus isoniazid plus pyrazinamide for pulmonary tuberculosis in Hong Kong. Am Rev Respir Dis 1977;115:727–735.

Centers for Disease Control and Prevention. Treatment of Tuberculosis, American Thoracic Society, CDC, and Infectious Disease Society of America. MMWR 2003; 52(No.RR-11):69.

https://www.cdc.gov/mmwr/pdf/rr/rr5211.pdf

TB TREATMENT IN SPECIAL SITUATIONS

Treating Culture-Negative Pulmonary TB

Preferred Regimen: **RIF/INH/PZA/EMB (RIPE)**	**Initial Phase:** RIPE x 2 months 40 (M-F) doses	**Continuation Phase:** RIPE x 2 months 40 (M-F) doses
Alternate Regimen: **RIF/INH/PZA/EMB (RIPE)**	**Initial Phase:** RIPE x 2 months 40 (M-F) doses	**Continuation Phase:** RIF and INH x 2 months 40 (M-F) doses

CONSULT TB EXPERTS AT SNTC (800-4TB-INFO) about treatment recommendations for drug-resistant tuberculosis**.**

Centers for Disease Control and Prevention. MMWR December 30, 2005/Vol.54/No. RR-17. Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings, 2005.

Extra-Pulmonary Tuberculosis

Extra-pulmonary TB disease may cause symptoms related to the part of the body that is affected. For example, TB of the spine may cause back pain; TB of the kidney may cause blood in the urine; TB meningitis may cause headache or confusion. Extra-pulmonary TB disease should be considered in the differential diagnosis of ill persons who have systemic symptoms and who are at high risk for TB disease.

Both pulmonary and extra-pulmonary TB disease symptoms can be caused by other diseases; however, they should prompt the clinician to consider TB disease.

Symptoms of Pulmonary and Extra-pulmonary TB Disease

Symptoms of Pulmonary TB Disease (TB disease usually causes one or more of the symptoms)	**Symptoms of Possible Extra-pulmonary TB Disease** (Depends on the part of the body that is affected by the disease)
• Cough (especially if lasting for 3 weeks or longer) with or without sputum production • Coughing up blood (hemoptysis) • Chest pain • Loss of appetite • Unexplained weight loss • Night sweats • Fever • Fatigue	• TB of the kidney may cause blood in the urine • TB meningitis may cause headache or confusion • TB of the spine may cause back pain • TB of the larynx can cause hoarseness • Loss of appetite • Unexplained weight loss • Night sweats • Fever • Fatigue

***For diagnostic purposes, all persons suspected of having TB disease at any site should have sputum specimens collected for an AFB smear and culture, even those without respiratory symptoms.**

As a general rule, regimens for treating persons with pulmonary tuberculosis are also effective for treating extrapulmonary tuberculosis disease. With the exception of the meninges or central nervous system, 6 MONTHS of treatment is recommended for treating extrapulmonary tuberculosis.

A 9-to 12-month regimen is recommended for meninges or central nervous system tuberculosis; and a 6-to 9-month regimen is recommended for bone and joint tuberculosis.

As always, please consider extending treatment for any tuberculosis site of infection that is slow to respond to treatment.

Sources:

CDC. Core Curriculum on Tuberculosis: What the Clinician Should Know. 6th Edition, Chapter 4 Atlanta, GA: US Department of Health and Human Services, CDC, 2013. http://www.cdc.gov/tb/education/corecurr/default.htm

Self-Study Modules On Tuberculosis Module 4: Treatment of Latent Tuberculosis Infections and Tuberculosis Disease, pg 26. US Department of Health and Human Services. Centers for Disease and Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention. Atlanta, Georgia 2019.

FOR ANY SUSPECTED EXTRA-PULMONARY TB CASE, CONSULT TB EXPERTS AT SNTC (800-4TB-INFO).

CRITERIA TO DETERMINE NON-INFECTIOUSNESS

Criteria for determining when, during therapy, a patient with pulmonary tuberculosis (TB) has become noninfectious*

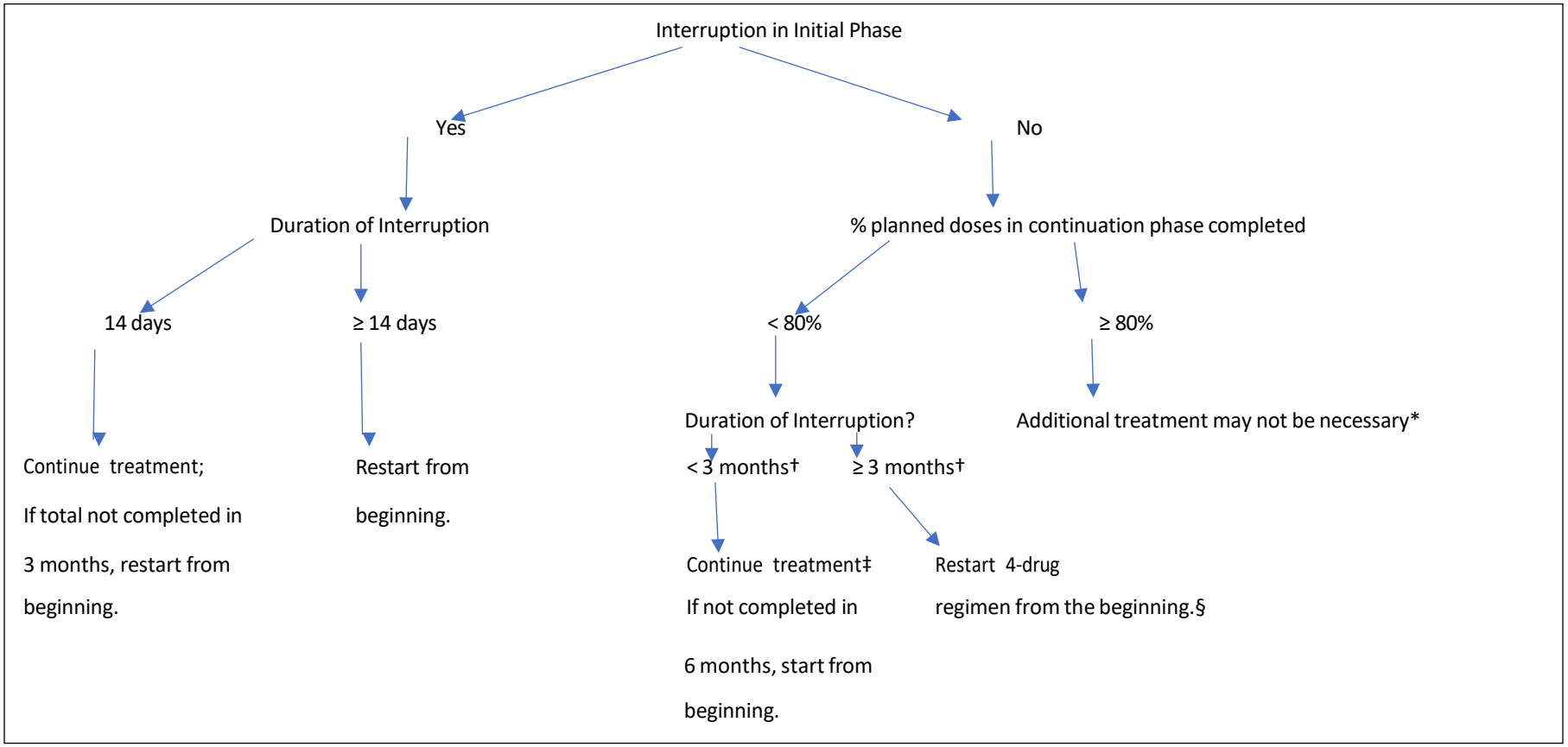
- Patient has negligible likelihood of multidrug-resistant TB (no known exposure to multidrug-resistant tuberculosis and no history of prior episodes of TB with poor compliance during treatment.)
- Patient has received standard multidrug anti-TB therapy for 2-3 weeks. (For patients with sputum acid-fast 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 patient 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, patient with pulmonary TB should remain in airborne infection isolation (AII) 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/rr/rr5412.pdf (Box 3, pg 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

MMWR, June 20, 2003 41



*Patients who were initially AFB smear-positive should receive additional therapy.

† Recheck smears and cultures (if positive, check drug susceptibility results). Start DOT if not already being used.

‡ If repeat culture is positive, restart four-drug regimen while waiting for drug susceptibility results. If repeat culture is negative, continue therapy to complete regimen within 9 months of original start date.

§If repeat culture is positive, continue four-drug regimen while waiting for drug susceptibility results. If repeat culture is negative, consider stopping therapy if patient has received a total of 9 months of therapy. *Centers for Disease Control and Prevention. Treatment of Tuberculosis, American Thoracic Society, CDC, and Infectious Diseases Society of America. MMWR 2003; 52(No.RR-11):5*

SECTION III

MANAGEMENT OF TB INFECTION (LTBI)

LATENT TUBERCULOSIS INFECTION

REPORTABLE CASES

In order to assist in the management of latent tuberculosis infection (LTBI), the following individuals with LTBI are required to be reported to the Kentucky Tuberculosis Program:

- Persons who are contacts of persons with active TB disease
- Health care workers
- Residents of long-term care facilities (LTCF)
- Refugees, refugee status

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)
- Healthcare workers who serve clients who are 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 person who abuse drugs or alcohol
- Infants, children, and adolescents exposed to adults who are at increased risk for latent *M. tuberculosis* infection or active tuberculosis.

Source: 2016 Clinical Practice Guidelines for Diagnosis of Tuberculosis in Adults and Children.

*Persons with these characteristics have an increased risk for *M. tuberculosis* infection compared to 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 (LTBI):

DOSES, TOXICITIES, AND MONITORING REQUIREMENTS

Drug	Oral dose (mg/kg) (maximum dose) Daily Adults	Daily Children	Twice weekly* Adults	Twice weekly* Children	Adverse reactions	Monitoring	Comments
Isoniazid	5 (300 mg)	10–20 (300 mg)	15 (900 mg)	20–40 (900 mg)	Rash Hepatic enzyme elevation Hepatitis Peripheral neuropathy Mild central nervous system effects Drug interactions resulting in increased phenytoin (Dilantin) or Disulfiram (Antabuse) levels	Clinical monitoring monthly 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	Hepatitis risk increases with age and alcohol consumption Pyridoxine (vitamin B_6, 10–25 mg/d) might prevent peripheral neurophathy and central nervous system effects
Rifampin	10 (600 mg)	10–20 (600 mg)	10 (600 mg)	—	Rash Hepatitis Fever Thrombocytopenia Flu-like symptoms Orange-colored body fluids (secretions, urine, tears)	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	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, coumadin derivatives, glucocorticoids, hormonal contraceptives, estrogens, oral hypoglycemic agents, digitalis, anticonvulsants, dapsone, ketoconazole, and cyclosporin) Might permanently discolor soft contact lenses
Rifabutin	5 (300 mg)¶	—	5 (300 mg)¶	—	Rash Hepatitis Fever Thrombocytopenia Orange-colored body fluids (secretions, urine, tears) With increased levels of rifabutin Severe arthralgias Uveitis Leukopenia	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¶	Rifabutin is contraindicated for HIV-infected patients taking hard-gel saquinavir or delavirdine; caution is also advised if rifabutin is adminis tered with soft-gel saquinavir Reduces levels of many drugs (e.g., PIs, NNTRIs, methadone, dapsone, ketoconazole, coumadin derivatives, hormonal contraceptive, digitalis, sulfonylureas, diazepam, ß-blockers, anticonvulsants, and theophylline) Might permanently discolor contact lenses
Pyrazinamide	15–20 (2.0 g)		50 (4.0 g)	—	Gastrointestinal upset Hepatitis Rash Arthralgias Gout (rare)	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	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

* 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, amprenavir, 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/d when used with nelfinavir, indinavir, or amprenavir; and to 150 mg (two or three times a week) when used with ritonavir. If 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.

Centers for Disease Control, Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection, MMWR 2000; 49(No.RR-6) pgs 28-29. https://www.cdc.gov/mmwr/PDF/rr/rr4906.pdf

Recommendations for Regimens to Treat Latent Tuberculosis Infection (LTBI)

Priority rank*	Regimen	Recommendation (strong or conditional)	Evidence (high, moderate, low, or very low)
Preferred	3 mos isoniazid plus rifapentine given once weekly	Strong	Moderate
Preferred	4 mos rifampin given daily	Strong	Moderate (HIV negative)†
Preferred	3 mos isoniazid plus rifampin given daily	Conditional	Very low (HIV negative)
		Conditional	Low (HIV positive)
Alternative	6 mos isoniazid given daily	Strong§	Moderate (HIV negative)
		Conditional	Moderate (HIV positive)
Alternative	9 mos isoniazid given daily	Conditional	Moderate

Abbreviation: HIV = human immunodeficiency virus.

* *Preferred*: excellent tolerability and efficacy, shorter treatment duration, higher completion rates than longer regimens and therefore higher effectiveness; *alternative*: excellent efficacy but concerns regarding longer treatment duration, lower completion rates, and therefore lower effectiveness.

† No evidence reported in HIV-positive persons.

§ Strong recommendation for those persons unable to take a preferred regimen (e.g., due to drug intolerability or drug-drug interactions).

Centers for Disease Control, Guidelines for the Treatment of Latent Tuberculosis Infection: Recommendations from the National Tuberculosis Controllers Association and CDC, 2020; MMWR Vol 69/No.1/Pg 6, February 14, 2020.

https://www.cdc.gov/mmwr/volumes/69/rr/pdfs/rr6901a1-H.pdf

Dosages for Recommended Latent Tuberculosis Infection Treatment Regimens

Drug	Duration	Dose and age group	Frequency	Total doses
Isoniazid* and rifapentine†	3 mos	**Adults and children aged ≥12 yrs** Isoniazid: 15 mg/kg rounded up to the nearest 50 or 100 mg; 900 mg maximum Rifapentine: 10–14.0 kg, 300 mg 14.1–25.0 kg, 450 mg 25.1–32.0 kg, 600 mg 32.1–49.9 kg, 750 mg ≥50.0 kg, 900 mg maximum **Children aged 2–11 yrs** Isoniazid*: 25 mg/kg; 900 mg maximum Rifapentine†: see above	Once weekly	12
Rifampin¶	4 mos	**Adults:** 10 mg/kg **Children:** 15–20 mg/kg** **Maximum dose:** 600 mg	Daily	120
Isoniazid* and rifampin¶	3 mos	**Adults** Isoniazid*: 5 mg/kg; 300 mg maximum Rifampin¶: 10 mg/kg; 600 mg maximum **Children** Isoniazid*: 10–20 mg/kg††; 300 mg maximum Rifampin¶: 15–20 mg/kg; 600 mg maximum	Daily	90
Isoniazid*	6 mos	**Adults:** 5 mg/kg **Children:** 10–20 mg/kg†† **Maximum dose:** 300 mg	Daily	180
		Adults:15 mg/kg **Children:** 20–40 mg/kg†† **Maximum dose:** 900 mg	Twice weekly§	52
	9 mos	**Adults:** 5 mg/kg **Children:** 10–20 mg/kg†† **Maximum dose:** 300 mg	Daily	270
		Adults: 15 mg/kg **Children:** 20–40 mg/kg†† **Maximum dose:** 900 mg	Twice weekly§	76

* Isoniazid is formulated as 100-mg and 300-mg tablets.
† Rifapentine is formulated as 150-mg tablets in blister packs that should be kept sealed until use.
§ Intermittent regimens must be provided via directly observed therapy (i.e., a health care worker observes the ingestion of medication).
¶ Rifampin (rifampicin) is formulated as 150-mg and 300-mg capsules.
** The American Academy of Pediatrics acknowledges that some experts use rifampin at 20–30 mg/kg for the daily regimen when prescribing for infants and toddlers (**Source:** American Academy of Pediatrics. Tuberculosis. In: Kimberlin DW, Brady MT, Jackson MA, Long SS, eds. Red Book: 2018 Report of the Committee on Infectious Diseases. 31st ed. Itasca, IL: American Academy of Pediatrics; 2018:829–53).
†† The American Academy of Pediatrics recommends an isoniazid dosage of 10–15 mg/kg for the daily regimen and 20–30 mg/kg for the twice-weekly regimen.

Centers for Disease Control, Guidelines for the Treatment of Latent Tuberculosis Infection: Recommendations from the National Tuberculosis Controllers Association and CDC, 2020; MMWR Vol 69/No.1/Pg 6, February 14, 2020.

https://www.cdc.gov/mmwr/volumes/69/rr/pdfs/rr6901a1-H.pdf

SECTION IV

CONTACT INVESTIGATIONS

The Goals of a Contact Investigation:

- Rapid identification of individuals who are high priority contacts to a known or suspected case of pulmonary, laryngeal, or pleural TB;
- Timely initiation of appropriate treatment for those persons determined to be recently infected or exposed with a significant risk for progression to disease;
- 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).

PLANNING A CONTACT INVESTIGATION

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 will delay the initiation of contact investigations, any delays 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.

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.**

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 prolongedillness).

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;
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.

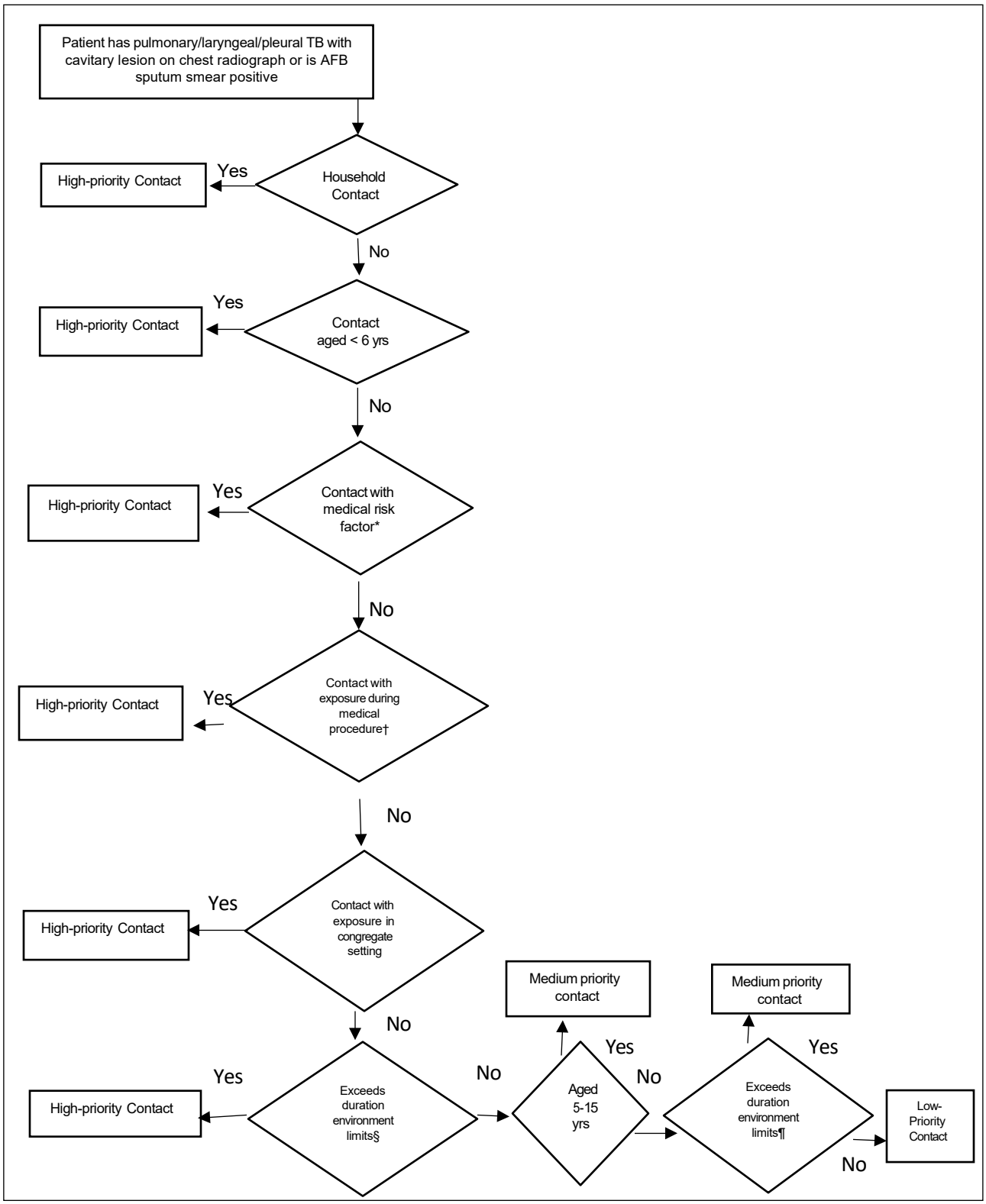
Initial Assessment of Contacts

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 during 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- antagonists, systemic corticosteroids equivalent to 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 TBdisease;
    - 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



*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:

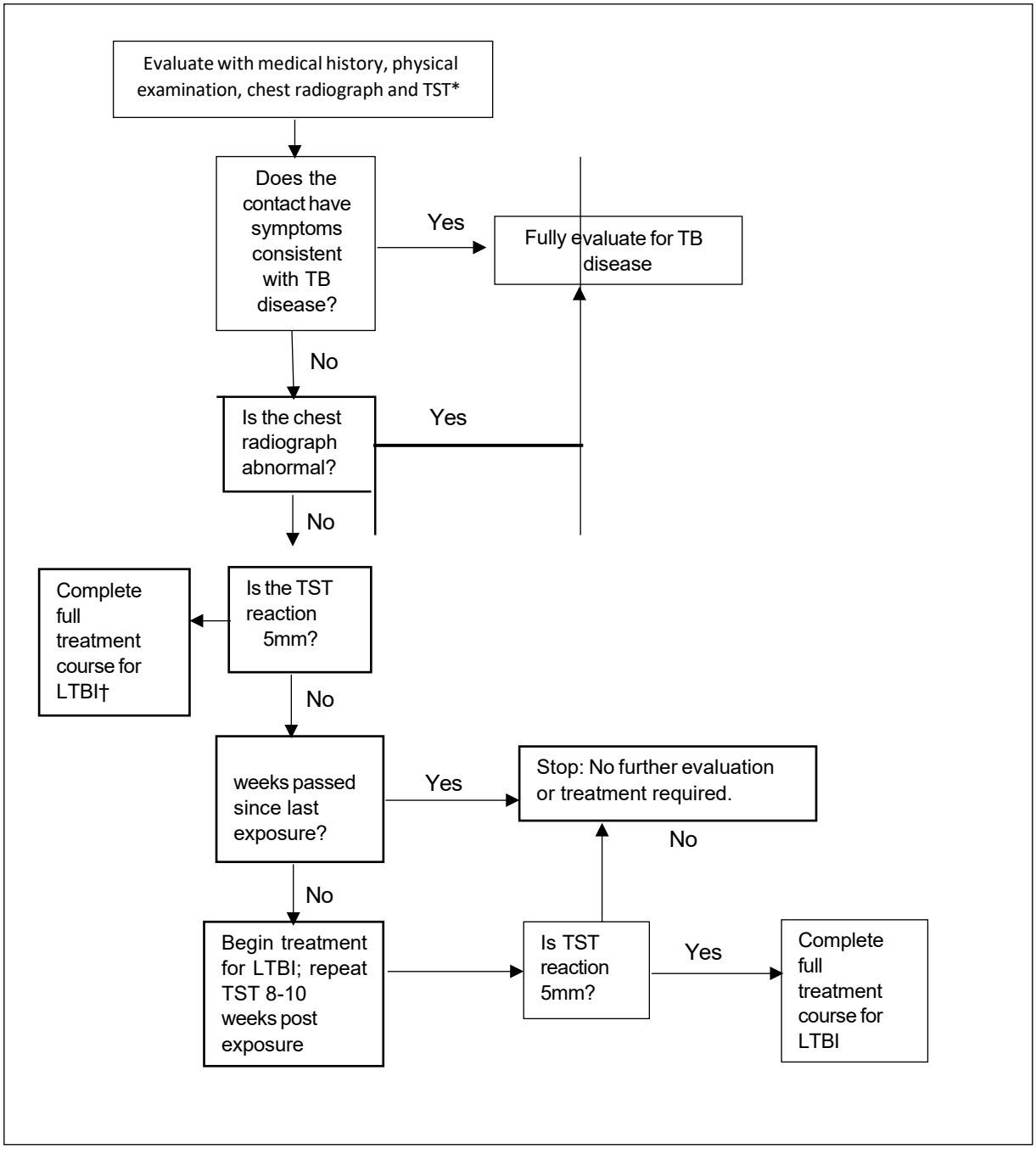
- Aged <5 years;
- Aged 5 through 15 years, at the clinician's discretion; or
- HIV-infected or otherwise immunocompromised.

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

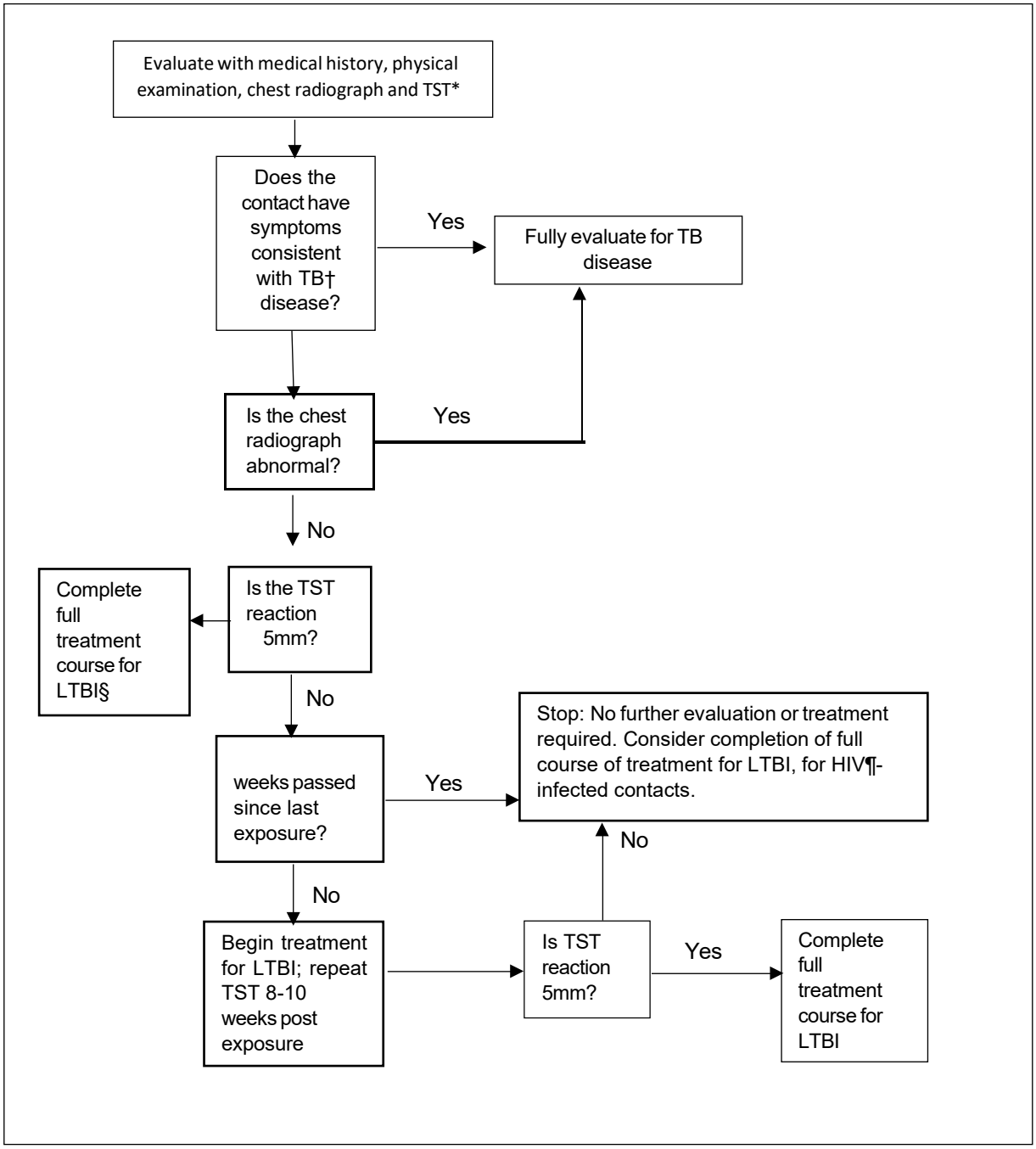


***Tuberculin skin test.**

†Latent TB Infection.

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 Immunocompromised Contacts



***Tuberculin skin test.**

†Tuberculosis

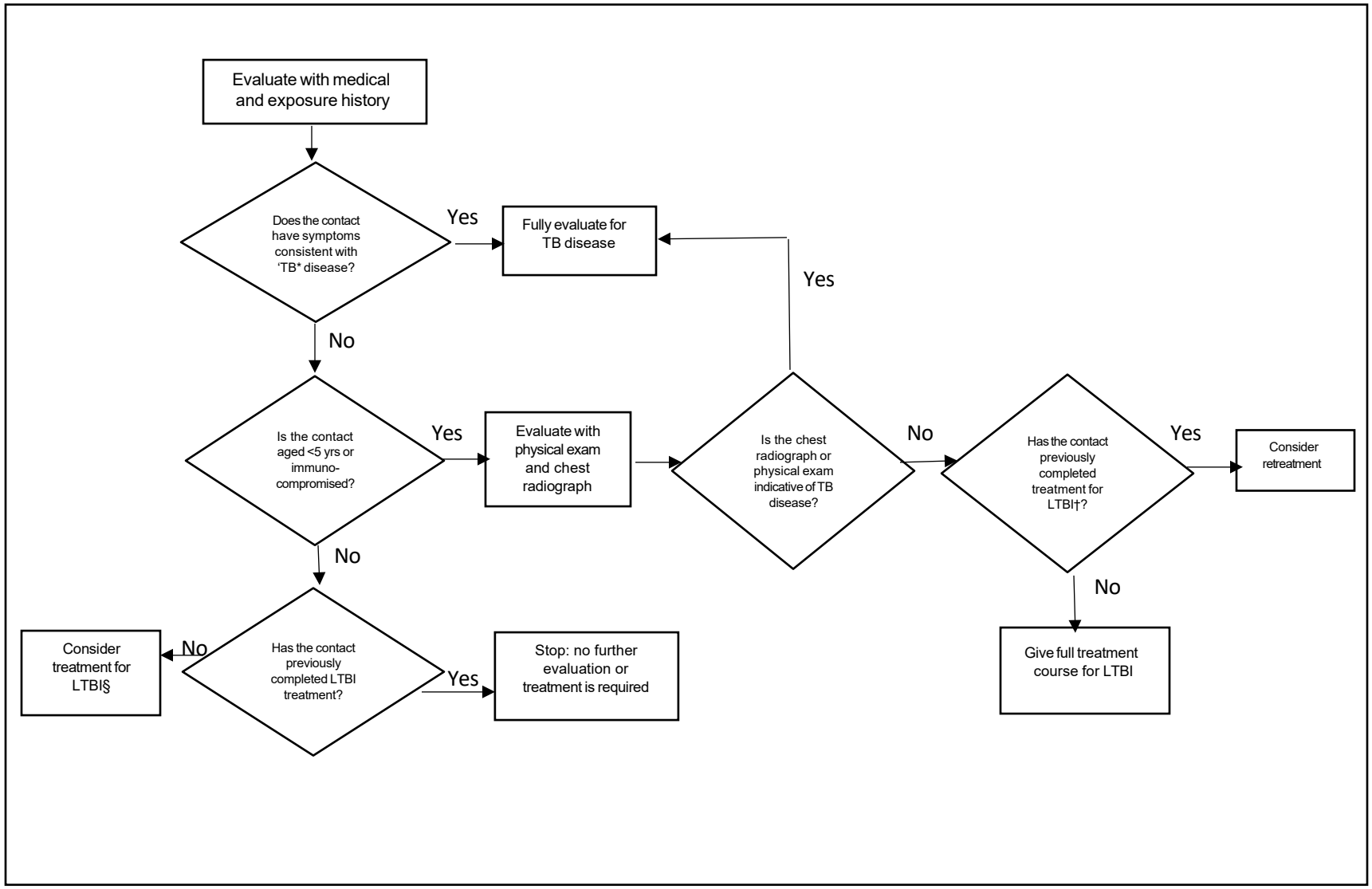
§Latent TB Infection

¶Human immunodeficiency virus

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 16.

Evaluation, Treatment, and Follow-Up of Contacts

With a Documented Previously Positive Tuberculin Skin Test



*Tuberculosis †Latent TB Infection §Before initiation of treatment, contacts should be evaluated fully for TB disease.

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 19.

Time Frames for Initial Follow-Up of Contacts of Persons Exposed to Tuberculosis (TB)

Type of Contact	Business days from listing of a contact to initial encounter*	Business days from initial encounter to completion of medical evaluation†
High-priority contact: index case AFB§ sputum smear positive or cavitary disease on chest radiograph (see Figure 2)	7	5
High-priority contact: index case AFB sputum smear negative (see Figure 3)	7	10
Medium-priority contact: regardless of AFB sputum smear or culture results (see Figures 2-4)	14	10

SOURCE: California Department of Health Services Tuberculosis Control Branch; California Tuberculosis Controllers Association. Contact Investigation guidelines. Berkeley, CA: California Department of Health Services; 1998.

*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 Characteristics

Characteristic			
TB Symptoms	**AFB* sputum smear positive**	**Cavitary chest radiograph**	**Recommended minimum beginning of likely period of infectiousness**
Yes	No	No	3 months before symptom onset or first positive finding (e.g., abnormal chest radiograph) consistent with TB disease, whichever is longer
Yes	Yes	Yes	3 months before symptom onset or first positive finding consistent with TB disease, whichever is longer
No	No	No	4 weeks before date of suspected diagnosis
No	Yes	Yes	3 months before first positive finding consistent with TB

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.

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3. Diagnosis of TB in Adults and Children Clin Infect Dis 2017; 64:111-115. https://academic.oup.com/cid/article/64/2/el/2629583/Official-American-Thoracic-Society-Infectious

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5. Tuberculosis Laws as found in the Kentucky Revised Statutes, Chapter 215.511 – 600. http://chfs.ky.gov/dph/epi/tb

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CDC TB Guidelines published in MMWR are available online. Http://www.cdc.gov/tb/publications/guidelines/default.htm This information is listed in the forms and teaching sheets listing of the CSG at http://chfs.ky.gov/dph/Local+Health+Department.htm

SECTION V

BLOOD ASSAYS and IGRAs

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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-

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 tobenefit 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 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 IGRAs 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 IGRAs 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 IGRAs 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. IGRAs offer the possibility of detecting *M. tuberculosis* infection with greater specificity than with a TST. Also, unlike TSTs, IGRAs do not boost subsequent test results and can be completed following a single patient visit. However, data on the ability of IGRAs to predict subsequent active tuberculosis are limited. If IGRAs 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, IGRAs offer technical, logistic, and possible economic advantages compared with TSTs but also have potential disadvantages. Advantages include the ability to get results following a single visit. Two- step testing is not required for IGRAs, because IGRA testing does not boost subsequent test results. Disadvantages of IGRAs 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 IGRAs. TST conversion is defined as a change n 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 IGRAs 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- N 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- 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."

INTERPRETATION CRITERIA for the QuantiFERON-TB Gold (QFT-G) And QuantiFERON-TB Gold In-Tube (QFT-GIT)

TABLE 1. Interpretation criteria for the QuantiFERON-TB Gold Test (QFT-G)

Interpretation	Nil*	TB Response†	Mitogen Response§
Positive¶	Any	≥0.35 IU/ml and ≥50% of Nil	Any
Negative**	≤0.7	<0.35 IU/ml	≥0.5
Indeterminate††	≤0.7	<0.35 IU/ml	<0.5
	>0.7	<50% of Nil	Any

Source: Based on Cellestis Limited. QuantiFERON-TB Gold [Package insert]. Available at http://www.cellestis.com/IRM/Company/ShowPage.aspx?CPID=1247.

* The interferon gamma (IFN-γ) concentration in plasma from blood incubated with saline.

† The higher IFN-γ concentration in plasma from blood stimulated with a cocktail of peptides representing early secretory antigenic target-6 (ESAT-6) or a cocktail of peptides representing culture filtrate protein 10 (CFP-10) minus Nil.

§ The IFN-γ concentration in plasma from blood stimulated with mitogen minus Nil.

¶ Interpretation indicating that *Mycobacterium tuberculosis* infection is likely.

** Interpretation indicating that *M. tuberculosis* infection is not likely.

†† Interpretation indicating an uncertain likelihood of *M. tuberculosis* infection.

TABLE 2. Interpretation criteria for the QuantiFERON-TB Gold In-Tube Test (QFT-GIT)

Interpretation	Nil*	TB Response†	Mitogen Response§
Positive¶	≤8.0	≥0.35 IU/ml and ≥25% of Nil	Any
Negative**	≤8.0	<0.35 IU/ml or <25% of Nil	≥0.5
Indeterminate††	≤8.0	<0.35 IU/ml or <25% of Nil	<0.5
	>8.0	Any	Any

Source: Based on Cellestis Limited. QuantiFERON-TB Gold In-Tube [Package insert]. Available at http://www.cellestis.com/IRM/content/pdf/QuantiFeron%20US%20VerG–Jan2010%20NO%20TRIMS.pdf.

* The interferon gamma (IFN-γ) concentration in plasma from blood incubated without antigen.

† The IFN-γ concentration in plasma from blood stimulated with a single cocktail of peptides representing early secretory antigenic target-6 (ESAT-6), culture filtrate protein-10 (CFP-10), and part of TB 7.7 minus Nil.

§ The IFN-γ concentration in plasma from blood stimulated with mitogen minus Nil.

¶ Interpretation indicating that *Mycobacterium tuberculosis* infection is likely.

** Interpretation indicating that *M. tuberculosis* infection is not likely.

†† Interpretation indicating an uncertain likelihood of *M. tuberculosis* infection.

Centers for Disease Control, Updated Guidelines for Using Interferon Gamma Release Assays…MMWR 2010; Vol.59 (RR-5)

https://www.cdc.gov/mmwr/PDF/rr/rr5905.pdf

INTERPRETATION of QFT-Plus TEST RESULTS

Nil (IU/ml)	TB1 minus Nil (IU/ml)	TB2 minus Nil (IU/ml)	Mitogen minus Nil (IU/ml)*	QFT-Plus Result	Report/interpretation
≤8.0	≥0.35 and ≥25% of Nil	Any	Any	Positive†	*M. tuberculosis* infection likely
	Any	≥0.35 and ≥25% of Nil			
	<0.35 or ≥0.35 and <25% of Nil	<0.35 or ≥0.35 and <25% of Nil	≥0.50	Negative	*M. tuberculosis* infection NOT likely
	<0.35 or ≥0.35 and <25% of Nil	<0.35 or ≥0.35 and <25% of Nil	<0.50	Indeterminate‡	Likelihood of *M. tuberculosis* infection cannot be determined
>8.0§	Any				

* 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.

QuantiFERON-TB Gold Plus (QFT-PLUS) Package Insert 08/2017, pg 35
https://quantiferon.com/wp-content/uploads/2017/10/QFT-Plus-ELISA-IFU-L1095849-R02.pdf

INTERPRETATION CRITERIA for the T-SPOT TB TEST (TST)

Interpretation	Nil*	TB Response†	Mitogen§
Positive¶	≤10 spots	≥8 spots	Any
Borderline**	≤10 spots	5, 6, or 7 spots	Any
Negative††	≤10 spots	≤4 spots	
Indeterminate**	>10 spots	Any	Any
	≤10 spots	<5 spots	<20 spots

Source: Based on Oxford Immunotec Limited. T-Spot.TB [Package insert]. Available at http://www.oxfordimmunotec.com/USpageInsert.

* 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.

Source: Based on Oxford Immunotec Limited. T-SPOT.*TB* [Package insert]. Available at http://www.oxfordimmunotec.com.

CDC. Recommendations and Reports. Updated Guidelines for Using Interferon Gamma Release Assays to Detect *Mycobacterium tuberculosis* Infection. MMWR 2010; 59 (No. RR-5)

SECTION VI

IMMIGRANTS & REFUGEES

TB Evaluation of Immigrants &Refugees

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CASE MANAGEMENT

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:

   Step 1 – Make a telephone call within 24 hours of receipt of documents.

   Step 2 – Send a letter within 7 working days if no response to phone call.

   Step 3 – Make a home visit within 10 working days if no response to call or letter.

2. Conduct an assessment work-up:
   - Assess for signs and symptoms of TB using the TB Risk Assessment.
   - Repeat tuberculin skin test (TST) and/or administer a tuberculin skin test (TST) or perform a blood assay for *Mycobacterium tuberculosis* (BAMT).
   - 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. Forward all completed TB Follow-up worksheets to the KY TB Program within 90 days.

TB Follow-up Recommendations for Arrivals with a TB Class Condition – October 2010

Arrival's Class Status	TB Follow-up Recommendations
TB Class A – active TB disease • **Pulmonary TB disease** • **Sputum smear or TB culture positive** • **Requires a waiver for travel (i.e., on treatment and smear negative prior to travel)**	❑ Consider this patient to have active TB disease (suspected or confirmed). ❑ Review overseas medical exam and treatment documentation. ❑ Assess the patient clinically and do additional diagnostic testing, such as repeat chest x-ray (CXR), sputum collection, and other tests, if indicated. ❑ Provide HIV counseling, testing, and referral. If HIV test is refused, reoffer HIV testing monthly while on treatment for active TB disease ❑ Continue or revise treatment regimen, as indicated. ❑ Report a case of active TB disease to the Kentucky TB Program by calling 502-564-4276 within one business day. ❑ Directly observed therapy (DOT) is the standard of practice for treating persons with active TB.
TB Class B1 – • **Evidence of pulmonary or extrapulmonary TB disease** • **Sputum smear-negative** • **Includes "old healed TB," and previously treated TB**	❑ Evaluate for signs and symptoms of TB disease that may have developed since their overseas exam. ❑ Administer a tuberculin skin test (TST) or blood assay for *Mycobacterium tuberculosis* (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. ❑ Obtain a chest x-ray (CXR) regardless of TST/BAMT result. Repeat the CXR if done previously outside the United States. ❑ 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). ❑ 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

TB Follow-up Recommendations for Arrivals with a TB Class Condition – October 2010	
Arrival's Class Status	**TB Follow-up Recommendations**
TB Class B2 – LTBI • **(TST ≥ 10 mm induration)**	❑ Consider this patient to have latent TB infection (LTBI). Evaluate for signs and symptoms of activeTB disease that may have developed since their overseas exam. ❑ Repeat TST or BAMT to confirm or rule-out an overseas diagnosis ofLTBI. ❑ 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. ❑ Obtain a CXR for those who have signs or symptoms compatible with TB disease, regardless of previous results. ❑ Provide HIV counseling, testing, and referral. If HIV test is refused, reoffer HIV testing monthly while on LTBI treatment ❑ 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).
TB Class B3 – TB Contact • **Contact overseas to aconfirmed case of TB**	❑ 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 overseasexam. ❑ 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 BAMTresult. ❑ If more information is needed about the source case, call the Kentucky TB Program at 502-564-4276.

TB Follow-up Recommendations for Arrivals with a TB Class Condition – October 2010

Arrival's Class Status	TB Follow-up Recommendations

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 cancertherapy).
- 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 negativeresult.
- 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:

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.

Sections A & B **Demographic & Jurisdictional**	• Pre-populated
Section C **U.S. Evaluation**	• Record date of the initial evaluation.
▪ **TST and/or BAMT**	• Administer a tuberculin skin test (TST) or draw blood for BAMT. • Record the TST date, mm induration (not redness), and interpretation. ▪ *For persons with TB Class B1 Conditions or TB-related abnormalities on CXR, a TST reading of ≥ 5 mm is considered positive.* • Record date and results of BAMT, if used. BAMTs (i.e., IGRAs) are not widely available in KY.
▪ **Review of Overseas CXR**	• Arrivals should bring their overseas CXR film(s) with them to their exam. Record your (or your radiologist's) interpretation of the overseas CXR. **NOTE: Call the KY TB Program if overseas CXR is not available.**
▪ **Domestic CXR**	• For Class B1 TB - Repeat CXR, regardless of TST or BAMT results. • For Class B2 or B3 - Perform a CXR if positive TST or positive BAMT.
▪ **CXR Comparison**	• Compare overseas to U.S. CXR and document the results.
▪ **Microscopy/ Bacteriology**	• If active TB disease cannot be ruled out by TST/BAMT and CXR, collect specimen/sputum for AFB smear and culture. Document results. ***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.***

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** ▪ **Diagnosis**	• 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 isrecommended. ◦ 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.* *KT 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:

Kentucky Department for Public Health
TB Prevention and Control Program
275 East Main Street, HS2E-B
Frankfort, KY 40621

Fax# 502-564-3772

Phone# 502-564-4276

Vital Signs (Body Temperature, Pulse Rate, Respiration Rate, Blood Pressure)

CLINICAL PROTOCOLS

Temperature

Pulse Rate

Respiration Rate

Blood Pressure

Vital Signs

Vital signs are measurements of the body's most basic functions. The 4 main vital signs routinely checked by LHD providers include: Body temperature, pulse rate, breathing rate (respirations) and blood pressure. Vital signs help detect or monitor medical problems.

Body Temperature

The normal body temperature of a patient **can range from 97.8° F (36.5°C) to 99°F (37.2°C)** for a healthy adult. A person's body temperature can be taken in any of the following ways:

- **Orally**. Temperature can be taken by mouth using a digital thermometer that uses an electronic probe to measure body temperature.
- **Rectally**. Temperatures taken rectally tend to be 0.5°F to 0.7°F higher than when taken by mouth. This is more common in babies because their body doesn't regulate temperature the way an older child or adult's body does.
- **Armpit (axillary)**. Temperatures can be taken under the arm using a digital thermometer. Temperatures taken by this route tend to be 0.3°F to 0.4°F lower than those temperatures taken by mouth.
- **By ear (tympanic).** A special thermometer can quickly measure the temperature of the eardrum, which reflects the body's core temperature (the temperature of the internal organs).
- **By skin**. A special thermometer can quickly measure the temperature of the skin on the forehead. Some thermometers don't require contact with the skin to get a temperature reading.

Age	Temperature	Management
Birth to 10 years	• 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 • Temperature between 101–102 is considered a mild fever. • Temperature between 102–103 is considered a moderate fever. • Temperature around 104 or above is considered a high fever, and delirium or convulsions may occur.	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.
11 years to Adult	• Temperature above 100.4 is considered a fever. • If temperature is taken rectally, it would register one degree higher and a reading of 101 would be considered a fever. • Temperature between 101–102 is considered a mild fever. • Temperature between 102–103 is considered a high fever, and delirium or convulsions may occur.	

Pulse

The normal pulse for healthy adults ranges from 60 to 100 beats per minute. The pulse rate may fluctuate and increase with exercise, illness, injury, and emotions. The pulse rate is a measurement of the heart rate. This is the number of times the heart beats per minute. As the heart pushes blood through the arteries, the arteries expand and contract with the flow of the blood. Taking a pulse not only measures the heart rate, but also can indicate the heart rhythm and strength.

Age	Pulse	Management
Newborn	100-170	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. 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 strength. Also, record whether the pulse is normal, bounding (very strong), or thready (weak). When reviewing the resting heart or pulse rate in each of the age groups, if the rate is not within the normal limits: • Repeat to confirm. • Review history for appropriate age group to determine if patient is taking medication that may alter the heart rate or if the patient is active in sports or exercise programs (i.e., runner, jogger, football, basketball, tennis, etc.). • If heart or pulse rate is outside the normal range and there is no appropriate rationale, refer for medical evaluation.
6 months-1 years	90-130	
2-3 years	80-120	
4-9 years	70-110	
10 years-Adult	60-100	

Respirations

The respiration rate is the number of breaths you take each minute. The rate is usually measured when you are at rest. It simply involves counting the number of breaths for one minute by counting how many times your chest rises. Respiration rates may increase with exercise, fever, illness, and with other medical conditions. **Normal respiration rates for an adult person at rest range from 12 to 20 breaths per minute**.

Age	Respirations	**Management**
Newborn	30-60	The procedure for measuring a child's respiratory rate is essentially the same as for an adult. However, keep in mind these points. • Since a child's respiration rate is diaphragmatic observe abdominal movement to count the respiration rate. • Abdominal movement in a child will be irregular. • Count for one full minute. 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.
6 months	24-36	
1 year	20-40	
2-3 years	20-30	
4-6 years	16-22	
6-10 years	16-20	
11-20 years	12-20	

Blood Pressure

Blood pressure is the force of the blood pushing against the artery walls during contraction and relaxation of the heart. Two numbers are recorded when measuring blood pressure. The higher number is called systolic pressure. It refers to the pressure inside the artery when the heart contracts and pumps blood through the body. The lower number is called diastolic pressure. It refers to the pressure inside the artery when the heart is at rest and is filling with blood. Both pressures are recorded as "mm Hg" (millimeters of mercury). Blood pressure measurement for a child is basically the same as for an adult. **The size of the blood pressure cuff is extremely important**. The size of the blood pressure cuff is determined by the size of the patient'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.

Age	Min Systolic/Diastolic	Normal Systolic/Diastolic	Max Systolic/Diastolic
1-12 months	75/50	90/60	100/75
1-5 years	80/55	95/65	110/79
6-13 years	90/60	105/70	115/80
14-19 years	105/73	117/77	120/81
20-24 years	108/75	102/79	132/83
25-29 years	109/76	121/80	133/84
30-34 years	110/77	122/81	134/85
35-39 years	111/78	123/82	135/86
40-44 years	112/79	125/83	137/87
45-49 years	115/80	127/84	139/88
50-54 years	116/81	129/85	142/89
55-59 years	118/82	131/86	144/90
60-64 years	121/83	134/87	147/91

*Modified from the AAP 50th -90th Percentile and American Heart Association 2021 Guidelines

CLASSIFICATON AND MANAGEMENT OF BLOOD PRESSURE FOR ADULTS Ages 18 and Older

Blood pressure is categorized as normal, elevated, or stage 1 or stage 2 high blood pressure:

BP Classification	SBPmmHg	DBPmmHg	Management*
Normal	<120	And <80	1. Detailed education regarding weight management, salt restriction, smoking management, adequate management of obstructive sleep apnea and exercise. 2. Recheck BP annually at minimum.
Elevated	120-139	<80	1. Detailed education on needed lifestyle modifications including therapeutic BMI, healthy diet with reduced sodium, fatty foods and sugars, aerobic physical activity, moderation of alcohol consumption and smoking cessation. 2. Elevated BP confirmed twice using contralateral arm. 3. Refer for medical evaluation and treatment.
Stage 1 Hypertension	130-139	80-89	1. Detailed education on needed lifestyle modifications including therapeutic BMI, healthy diet with reduced sodium, fatty foods and sugars, aerobic physical activity, moderation of alcohol consumption and smoking cessation. 2. Elevated BP confirmed twice using contralateral arm. 3. Assess for risk factors. 4. Refer for medical evaluation and treatment. 5. Refer or provide medical nutrition therapy.
Stage 2 Hypertension	>140	>90	1. Detailed education on needed lifestyle modifications including therapeutic BMI, healthy diet with reduced sodium, fatty foods and sugars, aerobic physical activity, moderation of alcohol consumption and smoking cessation. 2. Elevated BP confirmed twice using contralateral arm. 3. Assess for risk factors. 4. Refer for medical evaluation and treatment. 5. Refer or provide medical nutrition therapy.

Hypertensive Crisis	>180	>120	**Seek emergency medical treatment immediately.**
***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 for medical evaluation.**			

https://newsroom.heart.org/news/high-blood-pressure-redefined-for-first-time-in-14-years-130-is-the-new-high

Iqbal AM, Jamal SF. Essential Hypertension. [Updated 2022 May 1]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK539859/

KENTUCKY DEPARTMENT FOR PUBLIC HEALTH CLINICAL PROTOCOL FOR EPINEPHRINE AUTO-INJECTORS IN THE SCHOOL SETTING

Kentucky Public Health
Prevent. Promote. Protect.

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, and KRS 158.832 clarifies definitions. Changes to KRS158.836 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 reaction.
- 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 <u>all</u> 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.

<u>Responding to Anaphylaxis</u>

This is a life and death decision. Act promptly.

<u>Go to the student</u>. <u>Never</u> 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

- Medication Administration Training Program - Kentucky Department of Education Updated 2021
- KDE Medication Administration Training Manual (ky.gov) Module III, Emergency Medications
- National Association for School Nurses (NASN) NASN Allergies and Anaphylaxis (updated March 2019)
- American Academy of Allergy Asthma & Immunology (AAAAI) Anaphylaxis Symptoms, Diagnosis, Treatment & Management | AAAAI
- ANAPHYLAXIS EMERGENCY ACTION PLAN 2016 (aaaai.org)
- Food Allergy and Anaphylaxis Network (FAAN) Back-to-School Resource Hub | Food Allergy Research & Education
- CDC Food Allergies Food Allergies | Healthy Schools | CDC
- CDC Voluntary Guidelines for Managing Food Allergies In Schools and Early Care and Education Programs (cdc.gov)
- Epi Pen Auto-Injector Epinephrine in Schools | EpiPen4Schools®
- Auvi-Q Epinephrine Auto-Injector AUVI-Q® (epinephrine injection, USP) for Anaphylaxis
- Management of Food Allergy in the School Setting, *Pediatrics*, *2010* Sicherer, et al : Management of Food Allergy in the School Setting | Pediatrics | American Academy of Pediatrics (aap.org)

APPENDIX B:

- **NALOXONE AUTO INJECTOR PROTOCOL IN THE SCHOOL SETTING**

KENTUCKY DEPARTMENT FOR PUBLIC HEALTH
CLINICAL PROTOCOL FOR NALOXONE
AUTO- INJECTORS IN THE SCHOOL SETTING

Kentucky Public Health
Prevent. Promote. Protect.

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 217.186 186 186 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 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 formanaging opioid overdose, developed and approved by the local school board.
- Administration of appropriate CPRmeasures may be needed if the individual does not have respirations or a heartbeat.

Link to updated KRS 217.186: http://www.lrc.ky.gov/Statutes/statute.aspx?id=42420.

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.***

<u>WHO MAY BE AT RISK</u>

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) 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 <u>all</u> 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]

REALLY HIGH	OVERDOSE
Muscles become relaxed	Pale, clammy skin
Speech is slowed/slurred	Very infrequent or no breathing
Sleepy looking	Deep snoring or gurgling (death rattle)
Responsive to stimuli (such as shaking, yelling, vigorous sternal rub, etc…)	Not responsive to stimuli (such as shaking, yelling, vigorous sternal rub, etc…)
Normal heart beat/pulse	Slow heart beat/pulse
Normal skin tone/color	Blue lips and/ or fingertips

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**[1] 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 opioidoverdose 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. ***ADMINISTER NALOXONE***

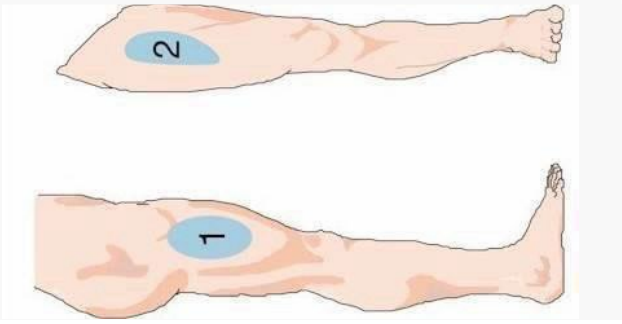
   There are multiple routes of administration for FDA approved naloxone: intramuscular, subcutaneous and intravenous. Schools may choose to use

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 viaprefilled 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]

Preparingnaloxone in apre-filled syringe

a) Quickly open the box and pull out the pre-filled 1 milliliter syringe
b) Attach the 1-1½ inch needle to the syringe
c) Remove the safety cap on the needle
d) Quickly push the needle straight down into the outer mid-thigh muscle, through the clothes if necessary and push down on the plunger
e) Put the needle/syringe in a sharps container



Use of the naloxone auto injector

a) Pull auto injector from theouter case
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.
c) Removethe safety cap, pull firmly.
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.

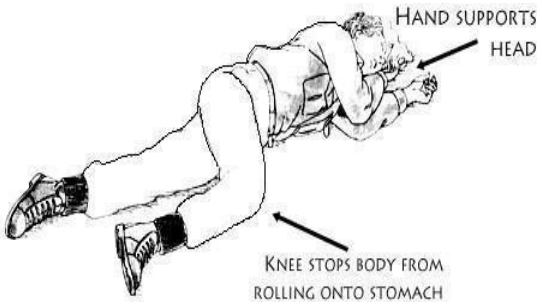
To reduce the chance of an accidental injection to yourself, do not touch the base of the auto-injector, which is where the needle comes out. If an accidental injection happens, getmedical helpright away.

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 emergencymedical assistance (911) after delivering the first dose of naloxone, keep the patient under continued surveillance, and repeat doses of naloxone as necessary.
6. **REPEAT NALONONE 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 incidentand complete school incident report.
9. Replace naloxone in-stock medication as appropriate as soon as possible.

NALOXONE[2]
Generic Name: naloxone (nah LOX own) Brand Names: *Evzio, Narcan*

INDICATIONS AND USAGE[2]

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[2]

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[1]

Store naloxone at controlled room temperature 15°C to 25°C (59°F to 77°F) and in a dark area.

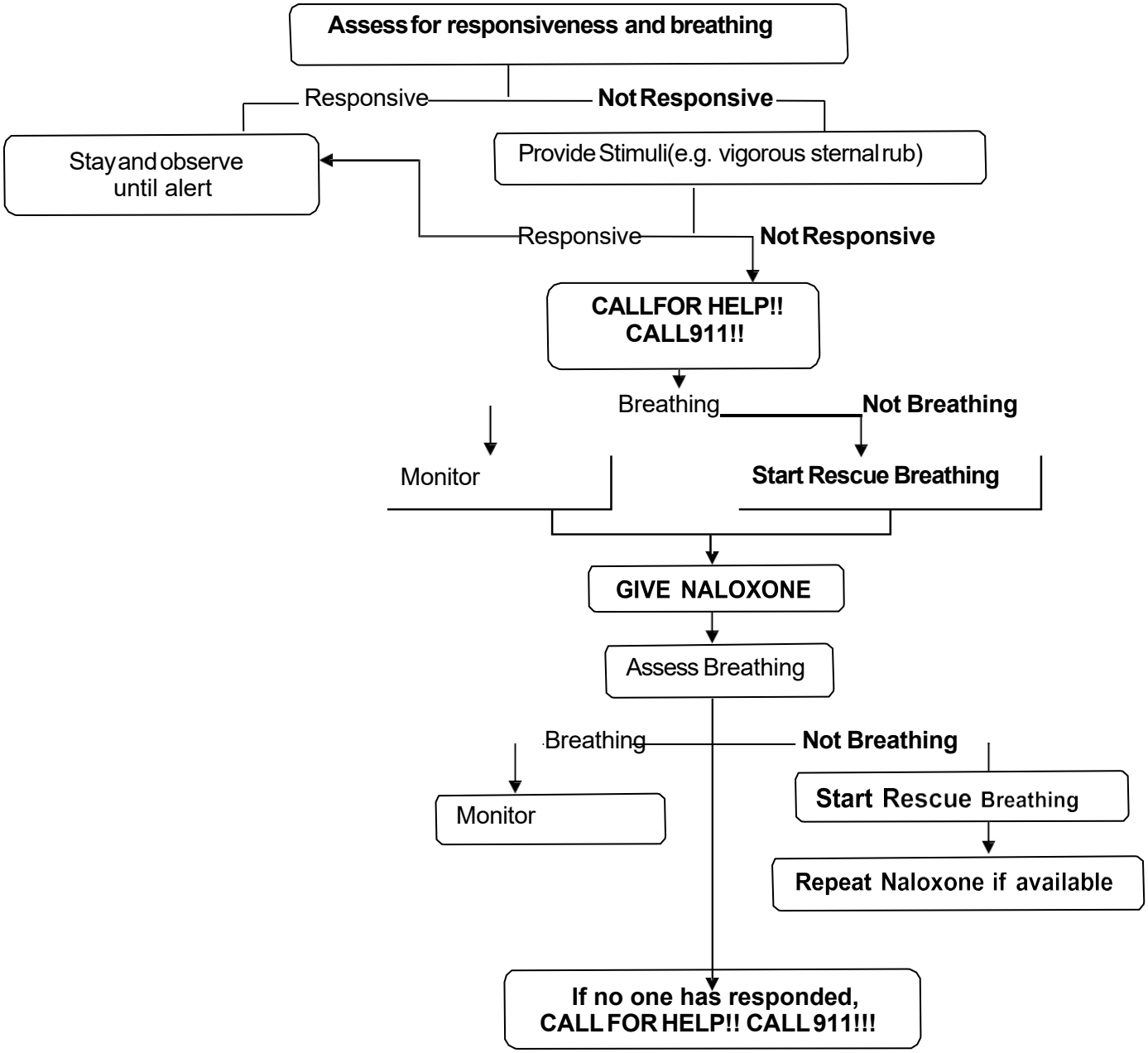
The naloxone should be checked monthly to ensure proper storage, expiration date, and medication stability. Expired naloxone or those with discolored solution or solid particles should not be used. Discard them in a sharps container.

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 [4]

The following flow-chart illustrates the steps that are taken depending on the victim's responsiveness.



REFERENCESAND SOURCES

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16. EVZIO Naloxone AutoInjector FDA PackageInsert: http://evzio.com/pdfs/Evzio%20PI.PDF
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18. Massachusetts Department for Public Health Opioid Overdose Education and Naloxone Distribution, http://www.mass.gov/eohhs/docs/dph/substance-abuse/core-competencies-for-naloxone-pilot-participants.pdf.
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Additional Resources

27. National Association for School Nurses (NASN) Medication Administration in the School Setting:http://www.nasn.org/PolicyAdvocacy/PositionPapersandReports/NASNPositionStatementsFullView/tabid/462/smid/824/ArticleID/86/Default.aspx
28. KDE Medication Administration Training Manual for Non-Licensed School Personnel, Chapter 3, Emergency Medications
29. Substance Abuse and MentalHealth Services Administration. Opioid overdose toolkit: informationfor prescribers. Accessed April 29, 2015.
30. http://store.samhsa.gov/shin/content//SMA14-4742/Overdose_Toolkit.pdf
31. Howto Use EVZIO: http://evzio.com/hcp/about-evzio/how-to-use-evzio.php
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.

KENTUCKY DEPARTMENT FOR PUBLIC HEALTH CLINICAL PROTOCOL FOR INTRANASAL NALOXONE IN THE SCHOOL SETTING

Kentucky Public Health
Prevent. Promote. Protect.

Background

In 2015, SB 192, section 8, an amendment to KRS 217.186 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:

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 naloxone. ***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?

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.

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

- 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) 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.

It is important to note that not <u>all</u> 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.

REALLY HIGH	OVERDOSE
Muscles become relaxed	Pale, clammy skin
Speech is slowed/slurred	Very infrequent or no breathing
Sleepy looking	Deep snoring or gurgling (death rattle)
Responsive to stimuli (such as shaking, yelling, vigorous sternal rub, etc…)	Not responsive to stimuli (such as shaking, yelling, vigorous sternal rub, etc…)
Normal heartbeat/pulse	Slow heartbeat/pulse
Normal skin tone/color	Blue lips and/ or fingertips

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.

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***
   I*f* 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 airtight mouth to mouth seal on the victim's mouth.

d) Take a regular (not deep) breath and give a breath over 1

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. ***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.

Important: Intranasal naloxone is for use in the nose only.

- Do not remove or test the Naloxone Nasal Spray until ready to use.
- Each Naloxone Nasal Spray has 1 dose and cannot be reused.
- You do not need to prime Naloxone Nasal Spray.

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 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.

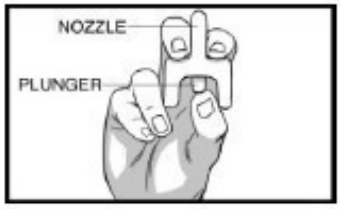
It is necessary to seek immediate emergency medical assistance (911) after delivering the first dose of naloxone, keep the patient under continued surveillance, and repeat doses of naloxone as necessary.

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.

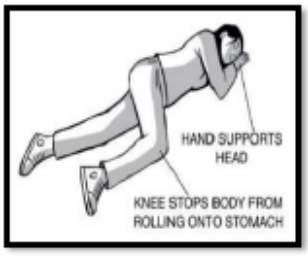


Step 4. Tilt the person's head back and provide support under the neck with your hand. Gently insert the tip of the nozzle into **one nostril** until your fingers on either side of the nozzle are against the bottom of the person's nose.

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.

6. REPEAT NALONONE 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.

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.
Document the incident and complete school incident report.
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).

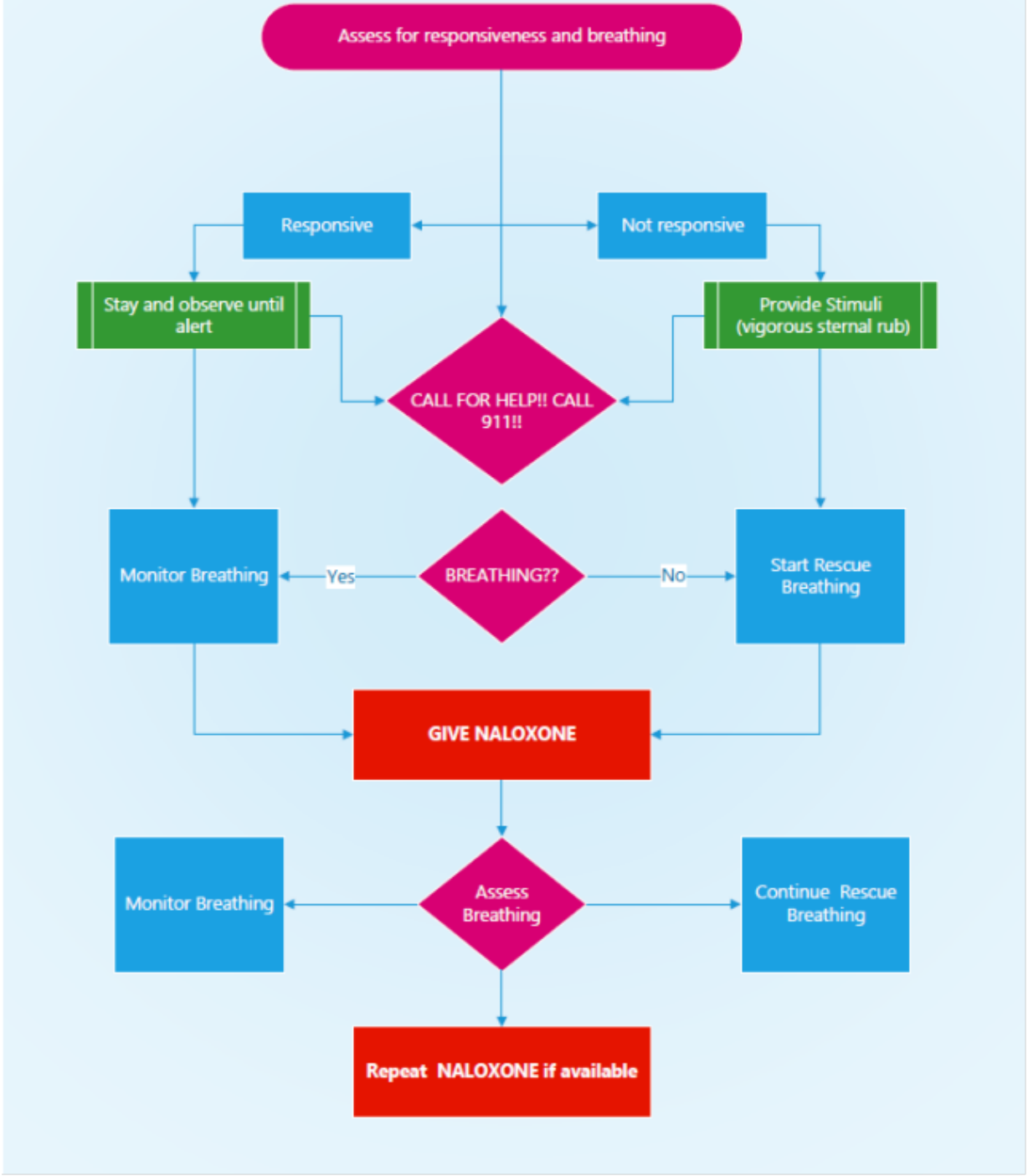
For questions regarding dosage or timing of the brand being used, please see product package insert instructions developed by the manufacturer.

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.



REFERENCES AND SOURCES

1. Kentucky Department for Public Health HARM REDUCTION PROGRAM

2. Substance Abuse and Mental Health Services Administration: Department of Health & Human Services
   SAMHSA Opioid Overdose Prevention TOOLKIT

3. Intranasal Naloxone nasal spray Package Insert

4. Massachusetts Department for Public Health Opioid Education and Naloxone Distribution

5. Narcan Training Program - Narcan.com

6. National Institute on Drug Abuse: Naloxone Drug Facts
   https://nida.nih.gov/publications/drugfacts/naloxone

7. Kentucky Department of Education: Medication Administration Training Program
   https://education.ky.gov/districts/SHS/Pages/Medication-Administration-Training-Program.aspx

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Kentucky Public Health
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KENTUCKY DEPARTMENT FOR PUBLIC HEALTH
CLINICAL PROTOCOL FOR BRONCHODILATOR RESCUE INHALER (BRI) IN THE SCHOOL SETTING

Background

2020 SB 127, an amendment to KRS 158.832 as used in Definitions for KRS 158.832 to KRS 158.838, makes provisions for students with asthma symptoms or respiratory distress to have access to a bronchodilator rescue inhaler (BRI) in school. Link to update: 21RS SB 127 (ky.gov)

- A student who has a documented life-threatening asthma symptoms or respiratory distress shall have:
  a) A BRI 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 a BRI in a minimum of two (2) locations in the school, including but not limited to the school office and athletic office so it may be administered to any student believed to be having asthma symptoms or respiratory distress. To minimize the spread of disease, the BRI's and spacers, if applicable, shall be used for one individual student and are not to be shared with any other student.

Stock BRIs

- Schools electing to keep stock BRI's to use for students without documented asthma symptoms or respiratory distress, shall maintain stock BRI's in a secure, accessible, but unlocked location. This shall apply to the extent that the BRI's are donated to a school, or a school has sufficient funding to purchase them. BRI's may only be purchased with a prescription from a medical provider. The school nurse or designee shall check the expiration date monthly and obtain a new prescription for replacement medication prior to expiration date.
- Each school electing to keep BRI's shall implement policies and procedures for managing student's asthma symptoms / respiratory distress reaction developed and approved by the local school board.
- Clinical protocols shall be developed by the Kentucky Department for Public Health to address BRI's kept by schools and to advise on clinical administration of BRI's.
- Any individual or entity who, in good faith and without compensation, renders emergency care or treatment by the use of a bronchodilator rescue inhaler shall be immune from civil liability for any personal injury as a result of the care or treatment, or as a result of any act or failure to act in providing or arranging further medical treatment, if the person acts as an ordinary, reasonable prudent person would have acted under the same or similar circumstances.
- The Department for Public Health, the Kentucky Board of Medical Licensure, the Kentucky Board of Nursing, the American Red Cross, or other training programs approved by the Department for Public Health may conduct in-person or on-line training for administering lifesaving treatment to persons believed in good faith to be experiencing severe allergic reactions and asthma symptoms or respiratory distress and issue a certificate of training to persons completing the training. The training shall include instructions for recognizing the symptoms of anaphylaxis and asthma and administering an injectable epinephrine device or a bronchodilator rescue inhaler.

ASTHMA means a respiratory condition marked by coughing, wheezing, or shortness of breath or chest tightness. Other symptoms may include struggling to breath, nasal flaring, increased breathing rate, blue or dusky lips/nail beds, agitation, or difficulty speaking.

Common triggers for asthma / respiratory distress:
Reduce Asthma Triggers | American Lung Association

- Respiratory infection
- Allergens, weather changes, pollen or air pollution
- Chemicals
- Odors – perfumes, deodorants and cleaning supplies, including but not limited to scented candles, incense, and air fresheners
- Physical activity
- Emotions
- Seasonal changes
- Smoking or exposure to secondhand smoke
- Animals – dander and saliva from fur or feathers
- Foods and medicines
- Pests – dust mites and cockroaches
- Mold

Signs and Symptoms of ASTHMA/Respiratory Distress:
Asthma Symptoms | American Lung Association

- Uncontrollable coughing, noisy breathing
- Wheezing-a high pitch, whistling sound during breathing out
- Rapid breathing
- Flaring (widening) of nostrils
- Feeling of tightness in the chest
- Not able to speak in full sentence
- Increased use of stomach and chest muscle during breathing
- Blueness around the lips or fingernails

ACTION STEPS FOR STAFF TO MANAGE AN ASTHMA ATTACK

Act fast! Warning signs and symptoms—such as coughing, wheezing, difficulty breathing, chest tightness or pressure, and low or falling peak flow readings—can worsen quickly and even become life threatening. They require quick action.

1. **Quickly assess the situation.**
   - **Call 911 or your local emergency service right away** if the student is struggling to breathe, talk, or stay awake; has blue lips or fingernails; or asks for an ambulance.
   - If accessible, use a peak flow meter to measure the student's lung function.

2. **Get help, but never leave the student alone.** Have an adult accompany the student to the health room or send for help from the school nurse or designee. Do not wait.

3. **Stop activity.** Help the student stay calm and comfortable.
   - If the asthma attack began after exposure to an allergen or irritant (such as furry animals, fresh cut grass, strong odors, or pollen) remove the student from the allergen or irritant, if possible.

4. **Treat symptoms**. Help the student locate and use his or her bronchodilator rescue inhaler (BRI) with a spacer or holding chamber (if available) or use the stock bronchodilator rescue inhaler (BRI).
    - Many students carry their medicine and can self-manage asthma attacks. They should follow their health care provider instructions. For s student without specific orders on file use the school policies and procedures to administer stock BRI provided by the medical director. Provide support as needed.
5. **Call the parent or guardian.**
6. **Repeat use of quick-relief inhaler per MD order / policy or if—**
    - Symptoms continue or return.
    - Student still has trouble breathing; or
    - Peak flow reading is below 80% of student's personal best peak flow number on asthma action plan.

Call 9–1–1 or your local emergency service if any of the following occur:

- The student is struggling to breathe, talk, or stay awake; has blue lips or fingernails; or asks for an ambulance.
- The student does not improve, or the student has a peak flow reading below 50% of the student's personal best peak flow number after two doses of quick-relief medication, and the nurse (or designee) or parent or guardian is not available.
- No quick-relief medicine is available; the student's symptoms have not improved spontaneously, and the nurse (or designee) or parent or guardian is not available.
- You are unsure what to do.

Managing Asthma: A Guide for Schools (nih.gov)

How to use an ASTHMA Metered Dose INHALER with Spacer:

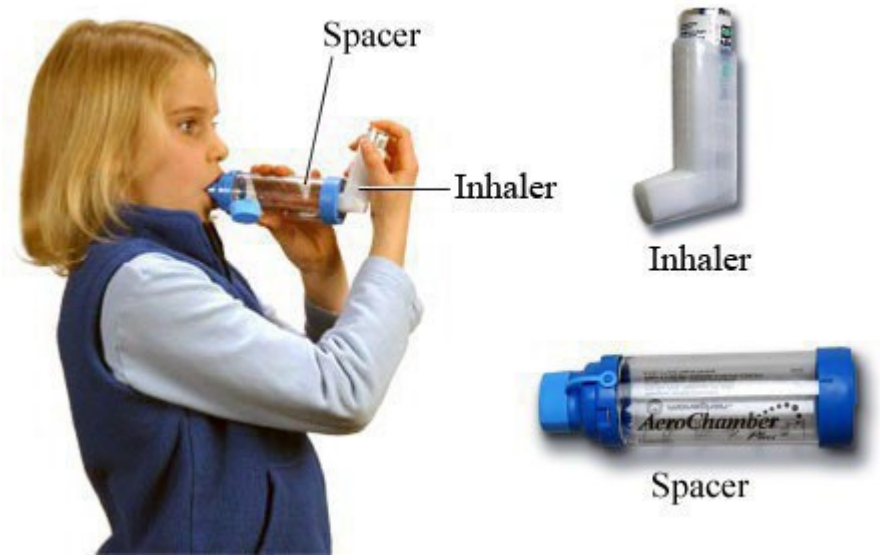
How to Use an MDI with Spacer: The Lung Association YouTube Video

1. Take off the caps from both spacer and inhaler.
2. Shake inhaler.
3. Insert inhaler into spacer.
4. Breathe out.
5. Seal lips around the mouthpiece.
6. Press the inhaler down once.
7. Breathe in slowly and deeply. If you hear a whistle, breathing is to fast.
8. Hold your breath for 5-10 seconds. If unable to hold breath, take 6 normal breathes instead.
9. Breathe out.
10. If another puff is required, wait as prescribed or 30-60 seconds and repeat.
11. Replace caps.
12. Rinse mouth with water.

Priming: Follow manufactures instructions

Cleaning: Clean the spacer about once a week, soak in warm, soapy water and let air dry.

Empty? Shake it. If it feels light or you do not feel liquid moving, it is empty and needs to be replaced. Some devices have counters. “0” means empty.

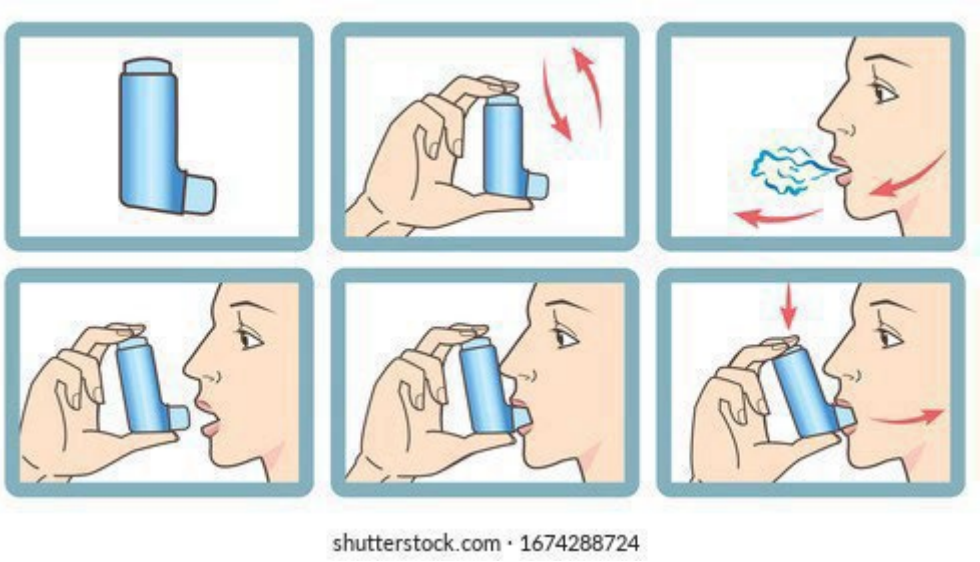


How to use an ASTHMA Metered Dose INHALER no Spacer:

Know How to Use Your Inhaler: CDC National Asthma Control: YouTube Video

1. Take off the cap from inhaler.
2. Shake inhaler.
3. Take a breath and breathe out all the way.
4. Hold the inhaler upright.
5. Put inhaler mouthpiece into your mouth above your tongue and between your teeth.
6. Seal lips around the mouthpiece.
7. Breathe in slowly and deeply.
8. Press the inhaler down once and keep breathing in.
9. Hold your breath for 5-10 seconds.
10. Breathe out slowly.
11. If another puff is required, wait as prescribed or 30-60 seconds and repeat.
12. Replace cap.
13. Rinse mouth with water.

Empty? Shake it. If it feels light or you do not feel liquid moving, it is empty and needs to be replaced. Some devices have counters. “0” means empty.



References and Additional Resources

- National Association for School Nurses (NASN) ASTHMA Resources Asthma - National Association of School Nurses (nasn.org)
- American Academy of Allergy Asthma & Immunology Asthma Symptoms, Diagnosis, Management & Treatment | AAAAI
- American Lung Association: What is Asthma? What Is Asthma? | American Lung Association
- American Lung Association "Asthma-Friendly Schools Initiative Toolkit" Asthma-Friendly Schools Initiative Toolkit | American Lung Association
- U.S. Department of Health and Human Services National Institutes of Health "Managing Asthma" A Guide for Schools: Managing Asthma: A Guide for Schools (nih.gov)
- CDC How to use an asthma inhaler CDC - Asthma - Using an Asthma Inhaler Videos
- Kentucky Department for education (KDE) Medication Administration Training Manual for Non-Licensed School Personnel, Module III, Emergency Medications Medication Administration Training Manual (ky.gov)
- KDE Module II Administration of Medications Medication Administration Training Manual (ky.gov)
- NIH 2020 Focused Updates to the Asthma Management Guidelines 2020 Focused Updates to the Asthma Management Guidelines: A Report from the National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group | NHLBI, NIH

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.

Section	Protocols
Oral Health (Nurse-Based)	Fluoride Supplement

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 web site, 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 https://bottledwater.org/list-of-brands-containing-fluoride/. 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 Division of Laboratory Services, 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 Division for Laboratory Services 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 are 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.

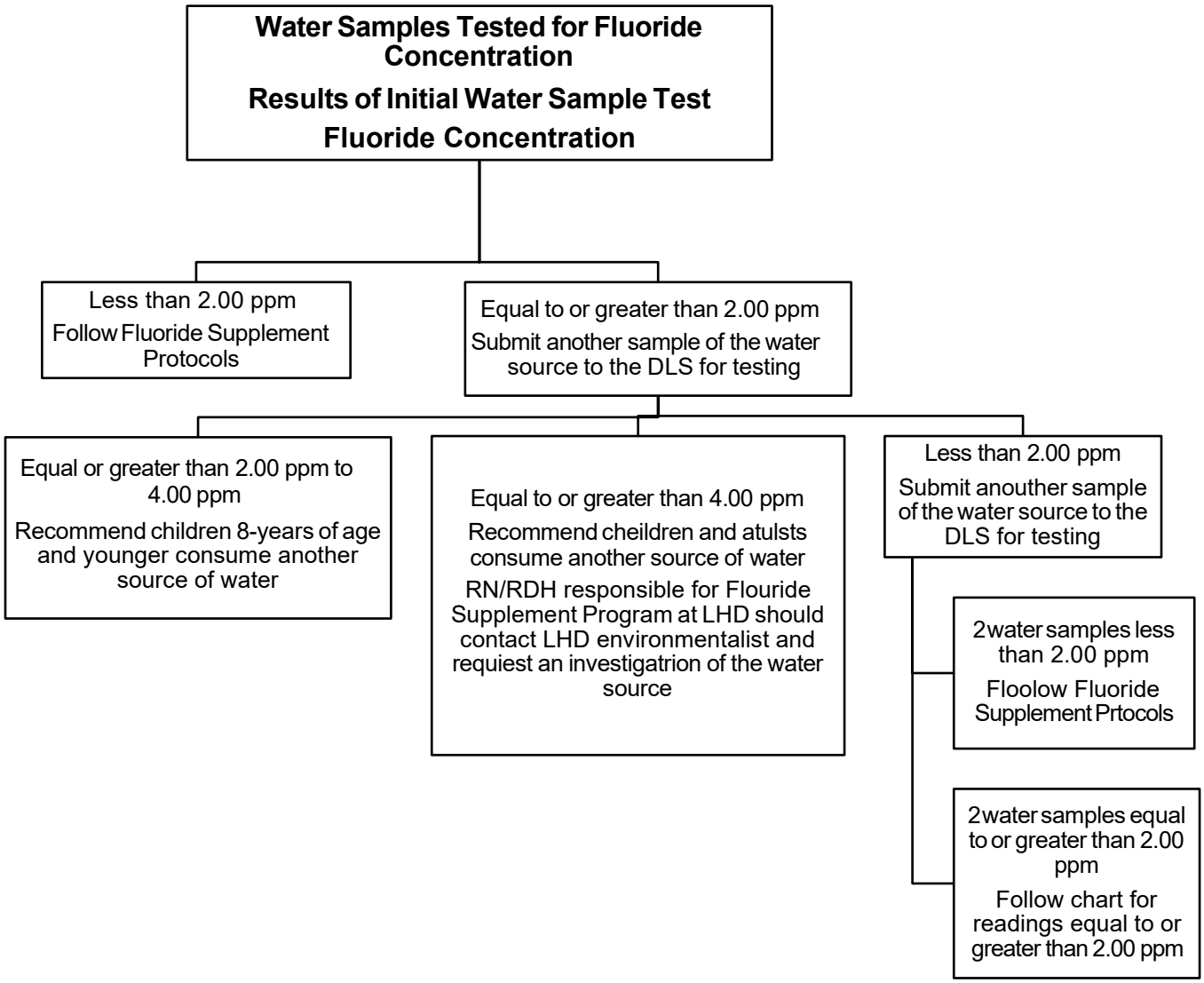
14. A 3-month supply of supplements may be provided for each child in a family. Empty containers should be returned before providing a replacement. At this time, a determination should be made whether circumstances affecting the amount of fluoride supplement to be provided have changed, such as change 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, https://www.ada.org/resources/research/science-and-research-institute/oral-health-topics/fluoride-topical-and-systemic-supplements

For additional information, please call the Oral Health Administrator at 502-564-3246, ext 4421.



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 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.

HEALTH RISK OR CONDITION	TREATMENT/ INTERVENTION	EDUCATON/ COUNSELING	FOLLOW-UP
Unfluoridated drinking water source may be: • Well • Cistern • Bottled • Spring	Distribute one (1) bottle of fluoride drops and/or one (1) bottle of fluoride tablets to each child with individualized doses as follows below.	NaFrinse Dropts-1 bottle has about 500 drops fluoride. NaFrinse Tablets-1 bottle contains 120 tablets. Children under 3 are not issued tablets. Dosage depends on age of the child and amount of fluoride in drinking water.	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" responses to 1 and 2-assess new water supply, if indicated. "Yes" response to 3-discontinue fluoride supplement.

DOSAGE:

Age of child	Fluoride in water 0 to 0.3 ppm	Fluoride in water 0.3 to 0.6 ppm	Fluoride in water 0.6 ppm and above
Birth – 6 months	None	None	None
6 months – 3 years	2 drops- 0.25mg 1 time per day (8-month supply)	None	None
3 – 6 years	4 drops- 0.50 mg 1 time per day (4-month supply) Or 1 tablet- 0.50mg 1 time per day (4-month supply)	2 drops- 0.25mg 1 time per day (8-month supply) **Must give drops there are NO 0.25mg tablets**.	None
6 – 16 years* *Children who do not attend school with a fluoridated water supply may continue in the program.	8 drops- 1 mg 1 time per day (2-month supply) Or 2 tablets- 0.50 mg 1 time per day (2-month supply)	4 drops- 0.50mg 1 time per day (4-month supply) Or 1 tablet- 0.50mg 1 time per day (4-month supply)	None

Dispose of unused drops or tablets by:
- Returning any unused liquid or tablets to the LHD
- Flushing unused liquid or tablets in commode
- Placing unused liquid or tablets in disposable trash container.

Source: American Dental Association's Council on Scientific Affairs: Fluoride Supplement Dosage Schedule: 2010

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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 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. Individual who benefits 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 caregiver's 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.

For additional information, please call the Oral Health Administrator at 502-564-3246, extension 4421.

References

Bawden JW. Fluoride varnish: a useful new tool for public health dentistry. J Public Health Dent 1999; 58:266-9.

Beltran-Aguilar E, Goldstein JW, Lockwood SA. Fluoride varnishes: a review of their clinical use, cariostatic mechanism, efficacy and safety. J Am Dent Assoc 2000; 131:589-596.

Cecil JC, Ferretti GA. Manual, Kids Smile: Oral Health Training Program. Frankfort, KY: Cabinet for Health Services, Department for Public Health; Lexington, KY: University of Kentucky, College of Dentistry, Division of Public Health, January 2003.

US Department of Health and Human Services. Oral Health in America: A Report of the Surgeon General. Rockville, MD: US Department of Health and Human Services, National Institute of Dental and Craniofacial Research, National Institutes of Health, 2000.

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.

HEALTH RISK OR CONDITION	TREATMENT/ INTERVENTION	FLUORIDE VARNISH/DOSAGE APPLIED	EDUCATION/COUNSELING	FOLLOW-UP
Children: • Ages 0 (eruption of first tooth) through 12 years • Decayed teeth • Family history of tooth decay • Low levels of fluoride in their drinking water • Limited access to dental care • Visible plaque on the front teeth • White-spot lesions	• Oral screening • Apply fluoride varnish • Referral to dentist for observed urgentcare needs	• 0.25 mL for primary dentition • 0.40 mL for mixed dentition • 0.50 mL for permanent dentition	• Discuss the procedure with the child and obtain consent from caregiver • 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. • 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. • Do not take a fluoride supplement the day of treatment. Do not provide any other at-home fluoride treatment that day (i.e., toothpaste, mouth rinse). • 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.	1. If NO DECAY, repeat oral screening exam and fluoride varnish application in six months. 2. If any WHITE SPOTS or UNTREATED DENTAL DECAY are noted, refer to a dentist **AND** repeat oral screening exam and fluoride varnish application in six months.

Physician, Dentist, Other **Date**

Fluoride References

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American Dental Association. Fluoride and Fluoridation. 5/13/02. http://www.ada.org/public/topics/fluoride/artcl-02.html

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

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