DESCRIPTION AND PURPOSE OF THE CLINICAL SERVICE GUIDE

The Clinical Service Guide (CSG) contains protocols, clinical guidelines and standing orders 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 protocols, guidelines and standing orders 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. Sections of this document may contain medically approved guidelines or protocols as required by regulation. Guidelines are recommendations for patient management that identify and/or support the use of a range of patient care interventions and approaches. Standing orders 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 protocols, clinical guidelines and standing orders 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 protocols, guidelines and standing orders 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; 314.042; and 201 KAR 20:057 for Kentucky Nursing Practice
    a. KBN Advisory Opinion Statement #41-RN/LPN Scope and Practice Determination Guidelines
    b. KBN Guidelines for Determination of APRN Scope of Practice
2. KRS 314.021 Nurses responsible and accountable for their decisions
3. 201 KAR 20:400 Delegation of nursing tasks
    a. KBN Decision Tree for Delegation to Unlicensed Assistive Personnel
4. KBN AOS #14 – Roles of Nurses in the Implementation of Patient Care Orders
5. KBN AOS #15 – Role of Nurses in the Supervision and Delegation of Nursing Acts to Unlicensed Personnel
6. KBN AOS #16 Roles of Nurses in the Administration of Medication via Various Routes
7. KBN AOS #30 - Roles of Nurses in School Nursing Practice

Deputy Commissioner for Clinical Affairs
KY Department for Public Health

July 1, 2025

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
March of Dimes	www.marchofdimes.com/
Mayo Clinic	www.mayohealth.org
Medicine Net	www.medicinenet.com
Medline Plus 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.

Population Health

The Commonwealth faces many challenges in health outcomes, as evidenced by state health rankings, Kentucky Behavioral Risk Factor Survey (KyBRFS), and variations in health status between populations in Kentucky. The factors shaping Kentucky's overall health challenges stem from the environments where we live, work, and play, along with the underlying causes of imbalances in health access and outcomes. These contributing factors include education, physical and built environment, neighborhood conditions, socioeconomic status, social connectedness, and access to quality health care. Local health departments should continue to address variations in health outcomes, conditions and policies affecting health and other barriers to care. Focusing on these priorities strengthens connections to resources and services, ensuring all Kentuckians have the opportunity to achieve optimal health.

Please look to our website for additional information and resources regarding Population Health in Kentucky. Website updates **coming soon**. In the meantime, use this website:
https://www.chfs.ky.gov/agencies/dph/Pages/default.aspx

For more information, please contact the Population Health Program at 502-564-1303.

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Components of a Breast/Cervical Cancer Screening Visit

For information on cancer screening services beyond breast and cervical cancer screening, see

- *Kentucky Colon Cancer Screening and Prevention Program - Cabinet for Health and Family Services*
- *Lung Cancer Screening Program - Cabinet for Health and Family Services (ky.gov)*
- *Ovarian Cancer Screening- Patients may call this number to inquire about a free ovarian cancer screening offered through the University of Kentucky: 1-800-766-8279.*

A breast/cervical cancer screening visit has the following components; for KWCSP-eligible women these components (with approved CPT codes) are free:

- **Office visit**, which would include the following:
    - Comprehensive health history
    - Breast/cervical cancer review of risk factors and **risk assessment (program requirement)**
    - **Tobacco use assessment/referral to quit line (program requirement)**
    - Physical examination, which may include CBE and/or pelvic exam
    - Referral for mammogram, as appropriate
    - Pap/HPV test, as appropriate
    - Counseling: (Documentation in medical record is required)
        - CSEM given/counseled, and patient verbalized understanding
        - Basic information on lung and colon cancer screening, as appropriate (see links above for information)
        - Breast Self-Awareness (optional teaching sheet available)
        - Benefits/risks of mammography (optional teaching sheet available)
        - Pap/Mammogram rescreening recommendations
        - Breast/cervical cancer risks/risk reduction
        - Regular exercise
        - Adequate diet (low fat, high fiber, 5 fruits/vegetables daily)
        - Risks/benefits of HRT, if menopausal
        - Smoking risks/cessation and referral
        - HPV vaccination, as appropriate
    - Documentation of return clinic appointments
- Follow-up of abnormal test results

Helpful Links:

Kentucky Women's Cancer Screening Program

Administrative Reference

Breast Cancer Screening

Early diagnosis of breast cancer offers women more treatment options and greatly reduces mortality. Mammograms are the best way to screen for early breast cancer.

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 at 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 ACOG Practice Bulletin 179, July 2017; reaffirmed 2021)*

- A CBE is recommended for 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 40-74: Women ages 40-74 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. The RN should consult with a higher-level clinician to determine when and how often an individual in this population should be screened. For this population it is generally 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 (*Screening for breast cancer in transgender women | Gender Affirming Health Program (ucsf.edu)

- 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, simple ones can be found here and here (requires purchase of a license for clinic use; price based on patient volume).
        - ❖ 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 the KWCSP Nurse Consultant at KWCSP@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.

  **Note: Unless radiologist/provider recommends differently or contrast is contraindicated, MRI order will be without and with contrast.*

- 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; reaffirmed 2021.*

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 KWCSP@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. 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 (including surgical excision when clinically appropriate)

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**.**

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 developing cervical cancer. Not all risk factors will put a woman in the high-risk category. Women in the high-risk category would require more frequent screening than those who are at average risk. See "HIGH-RISK POPULATIONS" section to determine who is at high risk.

- 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 signs/symptoms (e.g., pelvic pain, painful intercourse, abnormal vaginal discharge or bleeding)

PELVIC EXAMINATION

**Information in this section (Pelvic Examination) adapted from ACOG Committee Opinion Number 754, Oct. 2018; reaffirmed 2020; 2024)*

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; guidelines are currently being updated. While the new guidelines are expected to be released later this year (2025), until the new ones are available these 2018 guidelines will continue to be used.

Ages 21-29: Pap test every 3 years

Ages 30-65: 3 options for screening women in this age group:

1. Pap test every 3 years,
   or
2. Primary hrHPV test (high-risk HPV 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, even for women in the average-risk population.

THE PRIMARY hrHPV (HIGH-RISK HPV) TEST

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.

The hrHPV test was recently approved by the FDA for self-collection of a vaginal specimen, while in a healthcare setting. The self-collected HPV test is not recommended for the high-risk population nor for those in surveillance. The KWCSP will reimburse for self-collected hrHPV tests using the current codes for HPV testing.

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

Abnormal screening results can lead to diagnostic testing and may alter a woman's screening schedule. 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.

HIGH-RISK POPULATIONS

Women with the following conditions are considered high-risk and should be screened according to orders from the contracted gynecologist, regardless of their age:

- immunosuppressed (i.e., renal transplant, HIV infection)

  Note: If uncertain whether a patient's condition/disease would cause immunosuppression, consult your medical director or contracted clinician.

- History of CIN2, CIN3, cervical cancer
- Diethylstilbestrol (DES) exposure in utero.

KWCSP funds can be used for annual cervical cancer screening among women who are considered high-risk.

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 KWCSP@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

The 2019 ASCCP Management Consensus Guidelines for Abnormal Cancer Screening Tests and Cancer Precursors provides the guidance for managing abnormal cervical cancer screenings. 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.
(The Pap test and Bethesda 2014 - Nayar - 2015 - Cancer Cytopathology - Wiley Online Library; See *Table)*

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 provider's or colposcopist's name, date, and source of the order (e.g., verbal order, provider's office note in chart, etc.) for the next screening or diagnostic procedure.

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: KWCSP@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 KWCSP@ky.gov . One-on-one training will be provided to each new NCM by a KWCSP nurse. 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 (provider'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.

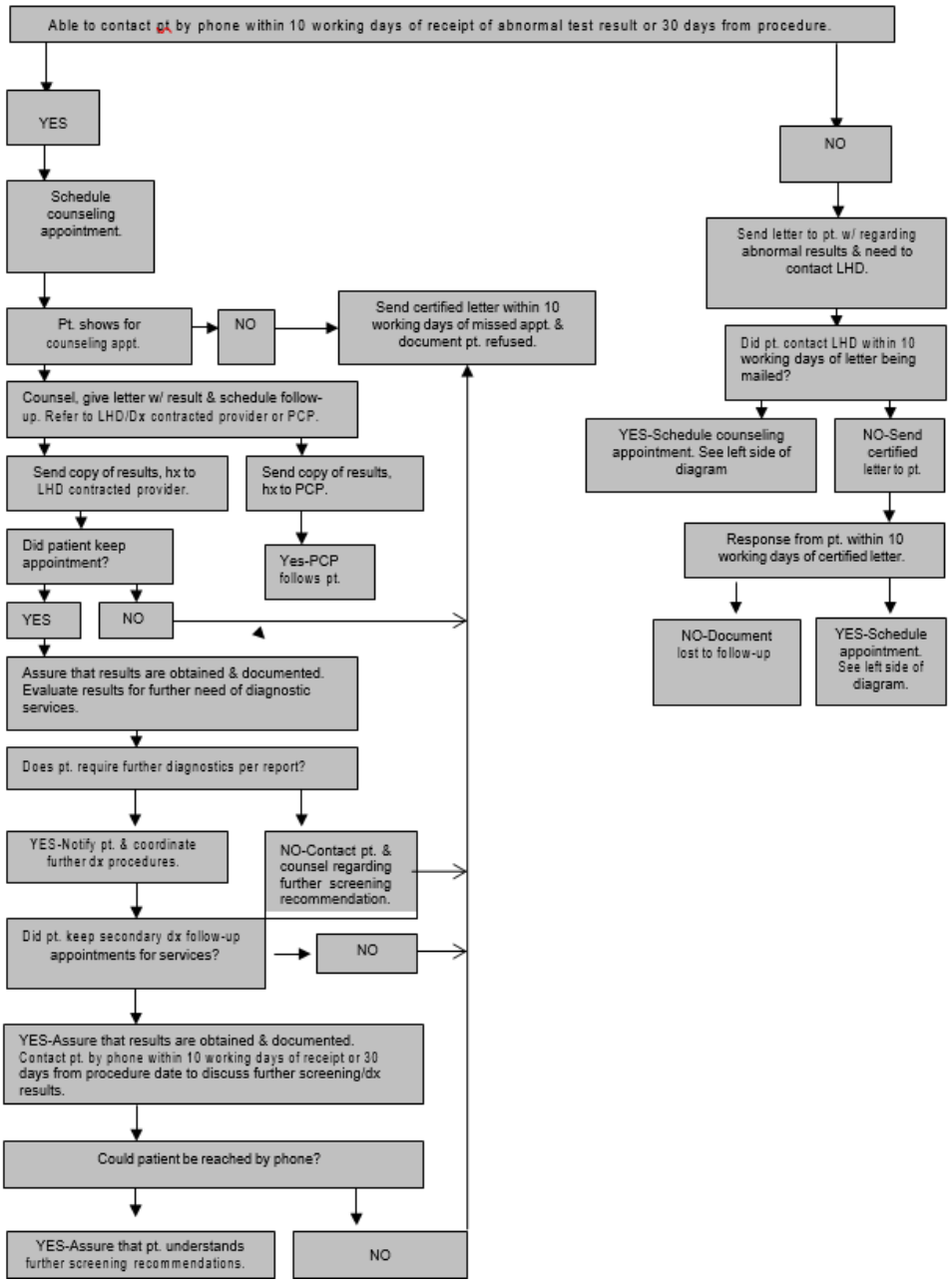
Work-up Refused: This occurs when a patient has been notified and counseled (by phone or in person) regarding an abnormal result and either fails to keep a referral appointment for diagnostics/treatment or verbalizes her desire not to seek follow-up. The date of final contact should be noted in the service record (CH3A) and on 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/or 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 which components of a cancer screening visit the patient will still need.
- 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 components of a breast/cervical cancer screening visit, the LHD is responsible for providing those services prior to referral for screening or diagnostic services.
- It is the responsibility of the LHD to educate providers as to the 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

CLINICAL PROTOCOLS

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, guidelines or standing orders 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.
- Other 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 single-dose intranasal spray containing 4 mg of naloxone hydrochloride in 0.1 mL or Naloxone hydrochloride 0.4mg/mL for intramuscular (IM) injection.
- Other Naloxone: _____
- 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, guidelines or standing orders.

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

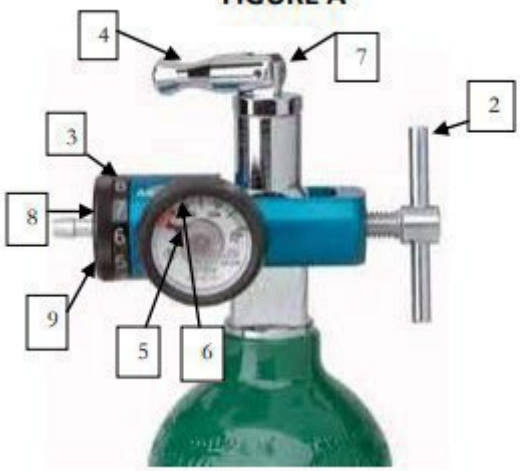
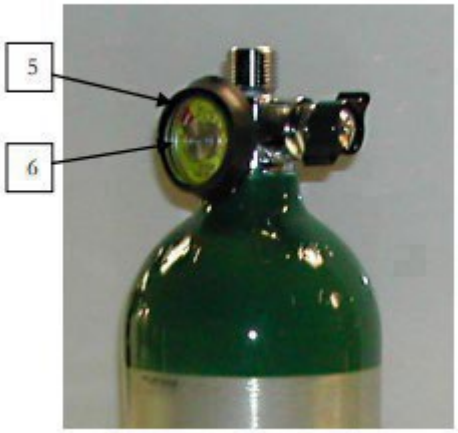


FIGURE B



(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!!

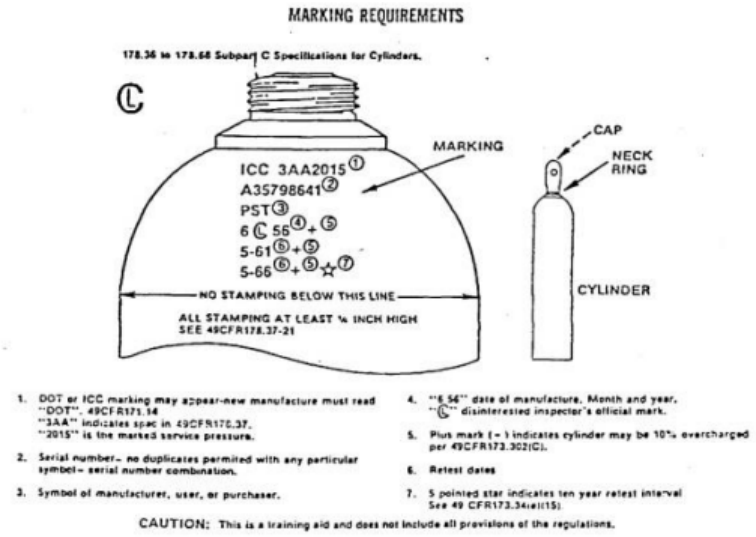
Oxygen Cylinder Markings

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” (syncope or loss of consciousness. 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. www.redcross.org

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 o Elevate legs 20-30 degrees if tolerated o 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. o 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: o Date o Time of occurrence o Vital signs o Medication(s)-time, dosage, response, administration by name o Immediate therapy o 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. www.redcross.org

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)	0.15mg 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

The following details procedures for clinical staff when responding to a suspected opioid overdose. Procedures for naloxone distribution by Local Health Department staff to the public for bystander use are detailed in the Administrative Reference for Local Health Departments, Training Guidelines.

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. Prolonged respiratory depression may result in damage to the central nervous system or death. Do not delay life-saving interventions.
- Make sure someone calls 911 to activate EMS as soon as an emergency has been identified. Assure 911 has been called immediately after administering the first dose of naloxone.

Signs and Symptoms of Opioid Overdose

All LHD nurses should be trained to recognize the signs and symptoms of an opioid overdose and to respond using naloxone and rescue breathing. Symptoms may include but are not limited to the following:

- Extreme sleepiness (inability to awaken verbally or upon tactile stimulation)
- Slow (less than 5 breaths per minute), 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
- HAVE SOMEONE CALL 911 IMMEDIATELY
- GET THE NALOXONE

Dosage and Intranasal Administration

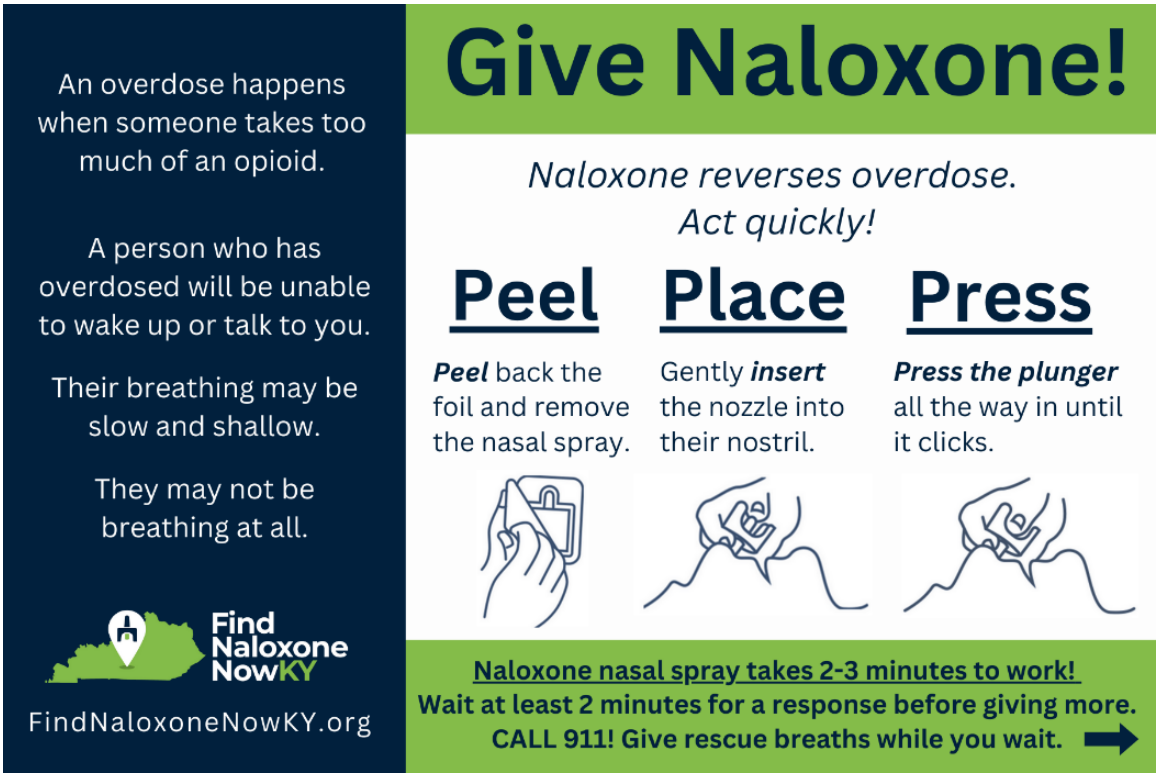
- **Naloxone Hydrochloride Nasal Spray: 4mg/0.1mL in carton containing two blister packages each with a single nasal spray.**
- **Other:_____**

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. Follow each dose with rescue breathing.

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

Administering intranasal naloxone:

1. Remove blister packs from carton.
2. Peel back the foil on one blister pack.
3. Remove the nasal spray device from the blister pack.
4. Hold the nasal spray device with index and middle finger on either side of the nozzle. Be careful not to press the plunger yet.
5. Insert the nasal spray device into a nostril. The index and middle fingers should be touching the bottom of the nostril.
6. Press the plunger all the way in until it clicks.
7. Remove the nasal spray device from the nostril.
8. Assure that 911 has been called.
9. Begin rescue breathing.
10. **Repeat every 2-3 minutes until the person begins breathing effectively or EMS arrives. Follow each dose with rescue breathing.** If the person begins to breathe effectively, wake up, or vomit, place the person on his/her side in the recovery position. Allow space between you and the individual to protect yourself.



A person who has overdosed may wake up after naloxone administration **or** they may remain unconscious.

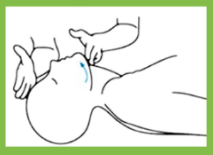
If someone who received naloxone is breathing slowly, shallowly or not at all, **rescue breathing is essential**.

Find Naloxone NowKY

Give Rescue Breaths!

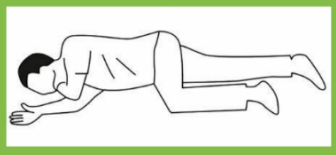
1. Place them on their back. Make sure nothing is their mouth.
2. Apply a barrier mask, if available. Tilt their head back, lift their chin and pinch their nose closed. This opens the airway.
3. **Give one breath slowly**, watching to see their chest rise.
4. Continue giving **one breath every five seconds.**
5. If they start to gurgle or breathe on their own, stop and roll them onto their side in recovery position.

Steps 1 - 2



Steps 3 - 4

Step 5



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)**
- **Other:** _____

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

Infant/Child/Adolescent (1 month - 17 years; > 20 kg) 0.01mg/kg/dose IM. After 2-3 minutes, if this dose does not result in the desired degree of clinical improvement, return of effective breathing, or EMS has not yet arrived, a subsequent dose of 0.1 mg/kg body weight may be administered and repeated 2-3 minutes if necessary

Neonate (<1 month) 0.1 mg/kg/dose IM/ After 2-3 minutes, if this dose does not result in the desired degree of clinical improvement, return of effective breathing, or EMS has not yet arrived, a subsequent dose of 0.01 mg/kg body weight may be administered and repeated 2-3 minutes if necessary Follow each dose with rescue breathing

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. Assure that 911 has been called.
13. Begin rescue breathing
14. **Repeat every 2-33 minutes until the person begins breathing effectivity or EMS arrives. Follow each dose with rescue breathing.** If the person begins to breathe effectively, wake up, or vomit, place the person on his/her side in the recovery position. Allow space between you and the individual to protect yourself.

Following naloxone administration, assure that 911 has been called and that EMS has been activated. Stay with the person and monitor and intervene for respiratory distress. If there is no breathing or breathing continues to be slow (less than 5 breaths/minute), continue to administer doses of naloxone every 2-3 minutes. , Between doses, continue to perform rescue breathing while waiting for the return of an effective breathing pattern, or the arrival of EMS. 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 overdose symptoms present again. . The duration of action of most opioids may 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. Repeated doses of naloxone should be administered, as necessary, while awaiting emergency medical assistance.
- Other supportive and/or resuscitative measures may be necessary 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.
- 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.NARCAN-US-Prescribing-Information.pdf

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
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CONTRACEPTIVES

Educate each client of the types of contraceptives available, so clients 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 contraceptives or other family planning services. A client's choice of contraceptive must be voluntary and without coercion. The Kentucky Family Planning Guide, also known as FPEM-19, may be utilized as an overview of each type of contraceptive; and may assist client to determine which contraceptive method is best for him/her.

The effectiveness of any contraceptive is optimal with consistent use according to manufacturer recommendations. See ACOG 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, storage and handling, and specific patient counseling information. **Package insert for specific manufacturer recommendations** are also best to screen for contraindications of 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 in Categories 3 or 4 by use of standing orders. A consultation with a provider should occur prior to initiation of Categories 3 or 4.

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

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

FAMILY PLANNING REQUIREMENTS MATRIX

The matrix should be followed regardless of funding.

Document Medical History on Adult H&P-14 or Electronic Medical Record

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

	Contraceptive Service Visit				
	Initial/Annual	**Supply/ Follow-up**	**ECP**	**Pregnancy Testing**	**STI Testing**
Physical Assessment	• Pelvic exam and Breast exam per QFP Guidelines or as clinically 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. as applicable • Specific method of contraceptive chosen by client • **Adolescent client counseling:** sexual abstinence, family involvement, consent and ways to resist coercion • 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's needs		Negative: • Benefits of planned pregnancy • Compliance with current contraceptive Positive: • Provide the opportunity for client to discuss non-directive, client-centered pregnancy options counseling as applicable: prenatal care and delivery; infant care, foster care or adoption; and pregnancy termination to the extent permitted by state law and other social services (e.g., HANDS, WIC, local pregnancy centers, DCBS, etc.); except with respect to any option(s) on which 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 as applicable:** • Kentucky Family Planning Guide or appropriate teaching sheets • Appropriate referrals as indicated (HANDS, Dietary, etc.) • Adolescents should receive information on abstinence, encourage family involvement, consent, and ways to resist coercion • 24-hour emergency number • Follow-up visit date for contraceptives or referral, as indicated • Contraceptive method of choice **unless contraindicated** (if not available provide RX or referral to provider as requested)				

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
- Risk factors for VTE, venous thromboembolism
- Postpartum <42 days with other risk for VTE
- Breastfeeding <42 days for COCs 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 a 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 of clotting, or active thrombosis, DVT, or PE; recent postpartum, HTN, CAD or CVD, or 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 or STIs, warnings, and other precautions
    - Smoking cessation
    - Use after administration of ECPs (Emergency Contraceptive Pills)
    - 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 referenced 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 provider 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 a 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 contraception injection may be given at other times than those listed above

- Negative pregnancy test prior to administration, and
- May offer additional emergency contraceptive pill, 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 a 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 a 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
- Breastfeeding – hormones may cross into breast milk (no difference in concentration of copper in human milk before and after insertion of copper IUDs)
- 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
- Pediatric use: Use of some IUDs is not indicated before menarche. Safety and efficacy have been established in women over 16 years of age.
- 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 a 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.

Potentially serious side effects can be referenced 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
- 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 a 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

- 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

HORMONAL VAGINAL RING

Contraindications/Precautions

- See package insert
- 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 a 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

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

NATURAL FERTILITY AWARENESS

Family planning providers and staff can use the RHNTC job aid to explain fertility indicators and fertility awareness-based methods (FABMs) to clients. FABMs are methods for avoiding unintended pregnancy or achieving intended pregnancy that require clients to monitor their fertility indicators.

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
- 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, and reported on the Kentucky Family Planning Sterilization Record. 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 Kentucky Womens Cancer Screening Program 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
- STIs—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 contraceptions:

Center for Disease Control and Prevention. (2024). Contraception and birth control methods. https://www.cdc.gov/contraception/about/index.html

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: https://rb.gy/ftg7y1

Center for Disease Control and Prevention. (2024). U.S. selected practice recommendations for contraceptive use, 2024. https://rb.gy/z5drfv

Code of Federal Regulations. (2025). Subpart B: sterilization of persons in federally assisted family planning projects. https://rb.gy/t72pw9

Zieman, M., Hatcher, R.A., Cohen, MAllen, A , Lapedis, M, & Haddad, L. (17th ed.) (2024). 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 on-site treatment or 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 the use of nonsterile injection equipment; 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-c/hcp/diagnosis-testing/?CDC_AAref_Val=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

EVERYONE should be tested at least once in their lifetime. Pregnant persons should be tested during each and every pregnancy. Individuals with risk factors should be tested more frequently.

Find testing recommendations for hepatitis C infection here: https://www.cdc.gov/hepatitis-c/hcp/diagnosis-testing/?CDC_AAref_Val=https://www.cdc.gov/Hepatitis/HCV/guidelinesc.htm

HCV diagnosis is typically done through a two-step testing process: a test to detect antibodies and an RNA test to confirm a current, active infection.

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 Services Programs (SSPs) 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 Testing Recommendations for Hepatitis C Virus Infection | CDC

There is also the possibility of on-site point of care confirmatory testing that returns results within 60 minutes. FDA approval was granted in June 2024 (https://www.fda.gov/news-events/press-announcements/fda-permits-marketing-first-point-care-hepatitis-c-rna-test) for the Cepheid Xpert HCV test system (https://www.cepheid.com/en-US/tests/blood-virology-womens-health-sexual-health/xpert-hcv-info.html). This machine allows for on-site, same day diagnosis confirmation and may be appropriate for some facilities based on testing volume and funding. However, it may be cost prohibitive for many. Insurance reimbursement for this test is not yet approved, and there is not funding available at this time from KDPH for the test machine or cartridges.

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 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 Services Programs (SSPs). Training on the HCV Rapid can be arranged by contacting the rapid test manufacturer. Contact the Viral Hepatitis Program for the contact information (vhp@ky.gov). 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.
- If on-site treatment services are not available, 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. Various viral hepatitis and hepatitis C trainings can be found on TRAIN Search - Kentucky TRAIN - an affiliate of the TRAIN Learning Network powered by the Public Health Foundation. Facilities may select the trainings that meet their needs.
- 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.

HCV Treatment

The best option for your patients is to offer HCV treatment on-site at your LHD. HCV treatment is now much easier than it has been in the past. Most individuals can be treated with a simplified course of treatment (For more information: https://www.hcvguidelines.org/ "Recommendations for Testing, Managing, and Treating Hepatitis C | HCV Guidance). Any medical provider (including advance practice providers) can prescribe HCV medications without a specialist consultation. The Kentucky Hepatitis Academic Mentorship Program (KHAMP) https://kyrha.org/khamp provides easily accessible training and ongoing mentoring to any provider who would like HCV training. Contact kentuckyruralhealthassociation@gmail.com or visit: https://kyrha.org/KHAMP . Additionally, your LHD may be able to partner with an organization that provides telehealth services (For example: UK Healthcare) so that patients can still access treatment services from your location.

Referral for HCV Management and Treatment

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

If on site treatment is not available, HCV-positive persons should be linked to care by referral or telehealth to a physician or mid-level clinician who treats hepatitis C. A hepatitis C treatment provider finder can be found on the CDC's website at Hepatitis C - FAQs, Statistics, Resources, Find Treatment, & More | CDC

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.

The Kentucky Hepatitis Academic Mentorship Program (KHAMP) (https://kyrha.org/KHAMP/) provides free training and ongoing mentoring to any provider who would like HCV training. Contact kentuckyruralhealthassociation@gmail.com or visit: https://kyrha.org/KHAMP/ .

Counseling Patients

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

- Harm reduction strategies are effective in preventing HCV transmission. Sterile supplies should always be used. Share information on local syringe services programs (SSPs) https://www.chfs.ky.gov/agencies/dph/Pages/harmreduction.aspx
- Sharing equipment used to inject drugs, not limited to syringes, can potentially spread HCV to others. This is the most common mode of HCV transmission in the U.S.
- Individuals should be informed about the risk for transmission to sex partners, although this is a less frequent route of transmission.
- Sharing personal items that might have blood on them, such as toothbrushes or razors, can pose a risk to others. Equipment used for tattooing and piercing can also spread HCV. Sterile supplies should always be used.
- 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.

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.
- Encourage hepatitis A and hepatitis B vaccinations.

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. All pregnant women should be tested during each and every pregnancy regardless of other risk factors. HCV infection in pregnant women and infants born to mothers with hepatitis C is reportable to public health officials. Electronic reporting preferred. If you have full NEDSS access, you can create an investigation, and no further reporting is needed. If you do not have NEDSS access, report electronically via Direct Data Entry (DDE). Email KHIEsupport@ky.gov to be onboarded for DDE if your facility is not yet using it. No EPID form is required if using either electronic option. EPID 200 and EPID 394 forms may be used as last resort.

Public Health Perinatal HCV Investigation Guidance can be found here: Hepatitis C, Positive Pregnant Female
https://www.chfs.ky.gov/agencies/dph/dehp/idb/Documents/Public%20Health%20Investigation%20Guidance%20for%20Hepatitis%20C,%20Positive%20Pregnant%20Female.pdf
https://www.chfs.ky.gov/agencies/dph/dehp/idb/Documents/Public%20Health%20Investigation%20for%20Perinatal%20Hepatitis%20C.pdf

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. Currently, no HCV treatment is approved for use during pregnancy. Transmission occurs during pregnancy or 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. However, it is important to obtain appropriate care, including follow-up testing and any necessary treatment. Testing at specified intervals will be needed (See Infants born to mothers with HCV infection Section below), and children may receive HCV treatment starting at age 3 for those who develop chronic infection. 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 between the ages of two months to six months. Updated recommendations can be found at CDC Recommendations for Hepatitis C Testing Among Perinatally Exposed Infants and Children — United States, 2023 | MMWR. An infant born to a mother with HCV infection is reportable to public health officials in Kentucky. Electronic reporting preferred. If you have full NEDSS access, you can create an investigation, and no further reporting is needed. If you do not have NEDSS access, report electronically via Direct Data Entry (DDE). Email KHIEsupport@ky.gov to be onboarded for DDE if your facility is not yet using it. No EPID form is required if using either electronic option. EPID 200 and EPID 394 forms may be used as last resort.

An alternative 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. Children for whom parental HCV status is unknown should be tested. Children in foster or kinship care, in particular, are at a higher risk of exposure and should be tested. See Appendix 3 the “Management of Infants Born to Mothers with Hepatitis C Virus Infection for Healthcare Providers: Guide for Testing Infants and Children Perinatally Exposed to 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 (vhp@ky.gov).

HCV Testing Provided at LHDs

Offer HCV testing to individuals requesting testing or who have risk factors. LHDs may 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 or if the LHD has billing capabilities, 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. HCV testing should occur regardless of the individual's ability to pay that day. 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.

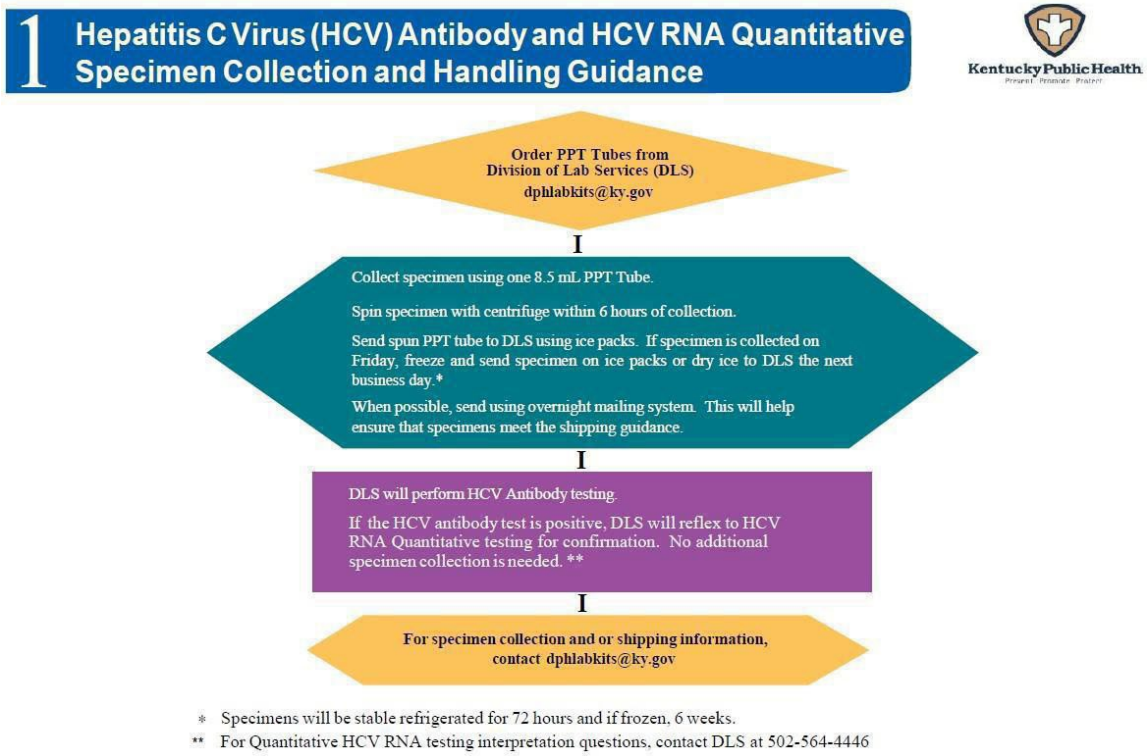
REPORTING

In addition to perinatal hepatitis C (see Pregnancy and HCV Infection section), Acute hepatitis C is a reportable condition Reportable disease link:
https://www.chfs.ky.gov/agencies/dph/dehp/idb/Documents/KYEPID200A.pdf

Regulation link: https://apps.legislature.ky.gov/law/kar/titles/902/002/020/

Electronic reporting preferred. If you have full NEDSS access, you can create an investigation, and no further reporting is needed. If you do not have NEDSS access, report electronically via Direct Data Entry (DDE). Email KHIEsupport@ky.gov to be onboarded for DDE if your facility is not yet using it. No EPID form is required if using either electronic option. EPID 200 and EPID 394 forms may be used as last resort.

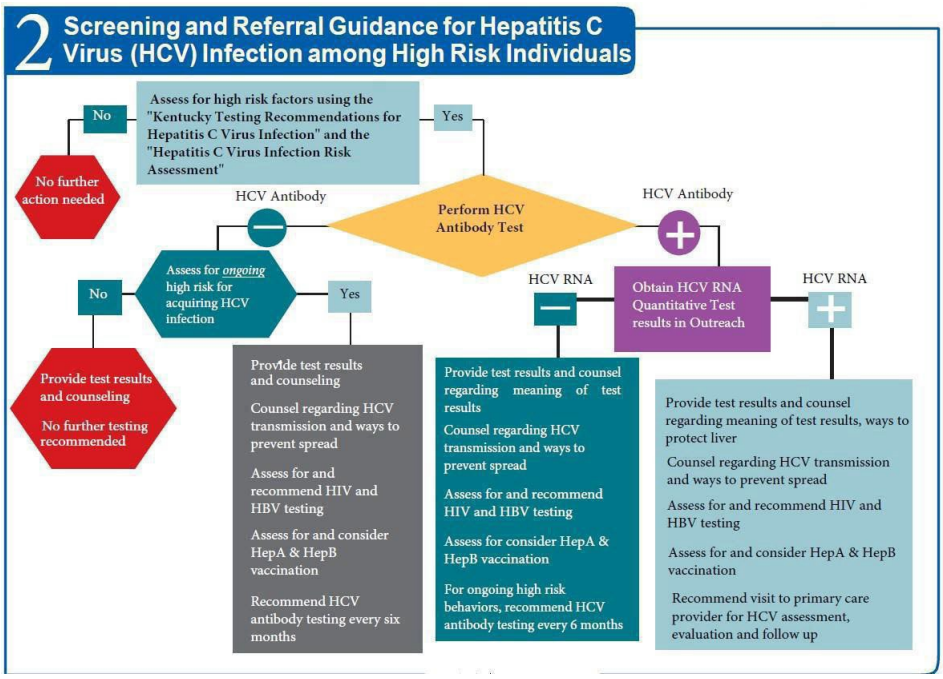
Specimen Collection and Handling



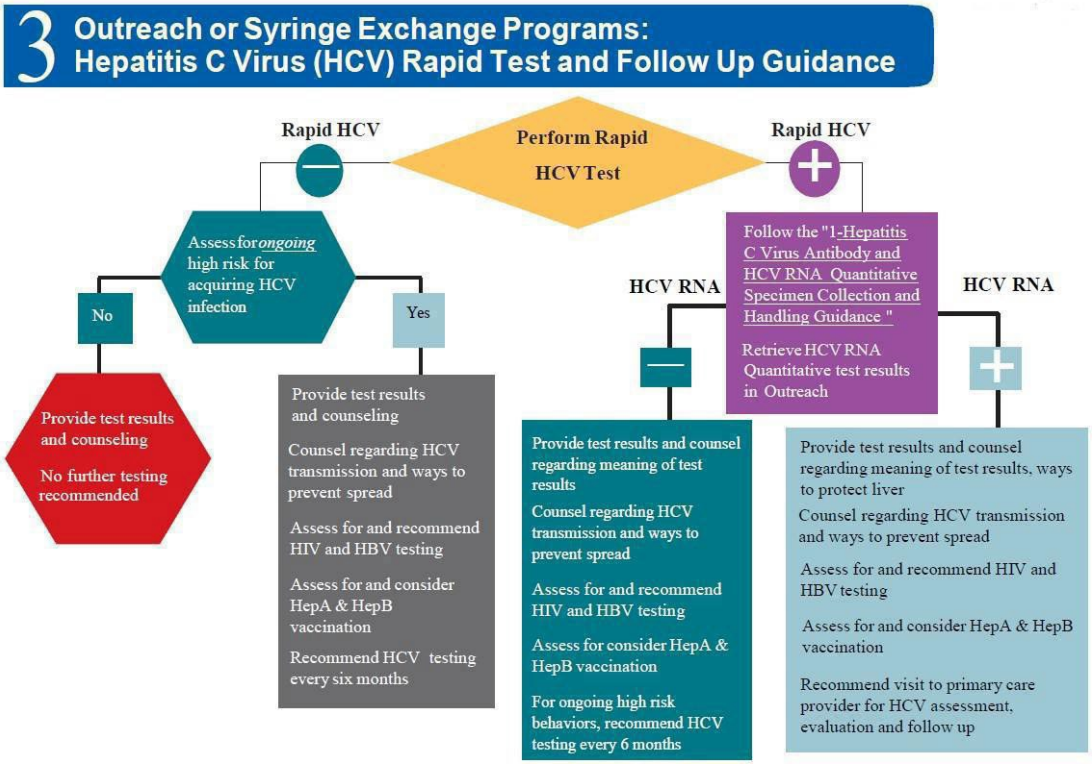
* Specimens will be stable refrigerated for 72 hours and if frozen, 6 weeks.

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

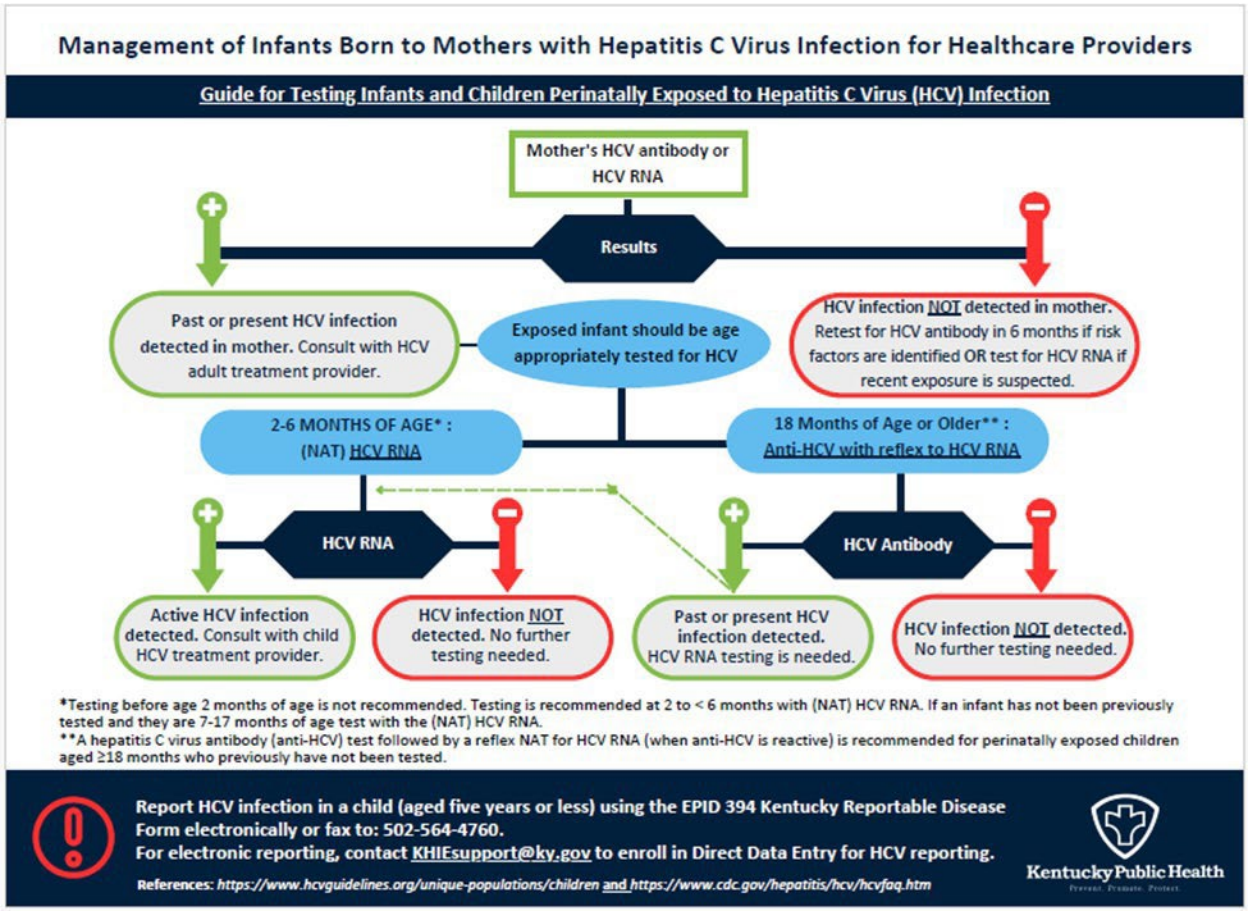
Screening and Referral Guidance



Outreach and Syringe Exchange Programs



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). LHDs may designate a self-pay fee at their own discretion.

Medicaid Preventive Billing Codes:

86803- Hepatitis C Antibody test,
87522- Hepatitis C, Quantification, includes reverse transcription when performed
99201- Office/ Outpatient Visit New
99202- Office/ Outpatient Visit New
99203- Office/ Outpatient Visit New
99204- Office/ Outpatient Visit New
99205- Office/ Outpatient Visit New
99211- Office/ Outpatient Visit Established (EST)
99212- Office/ Outpatient Visit EST
99213- Office/ Outpatient Visit EST
99214- Office/ Outpatient Visit EST
99215- Office/ Outpatient Visit EST

Partnerships with local substance use service providers

LHDs are encouraged to work with local substance use treatment facilities to develop HCV testing options for their clients.
A current list of Kentucky Opioid Treatment programs can be found at:
https://findhelpnowky.org/ky

Kentucky HCV Screening, Testing and Referral Guidance

Identify Individuals	HCV Pre-Test Counseling	HCV Testing	HCV RNA Confirmation & Referral
<u>Any person who requests hepatitis C testing should receive it, regardless of disclosure of risk, because many persons may be reluctant to disclose stigmatizing risks.</u> 1. All adults at least once in a lifetime 2. Baby boomers (born between 1945 and 1965) at least once in a lifetime 3. Pregnant Women (during every pregnancy) 4. Risk Factors Identified (routine periodic testing as frequent as every 8 weeks): 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, or transfusion or transplant before July 1992	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- 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-</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. Specialist (such as hepatologist, gastroentero logist, infectious disease) Note that specialist care is not required. **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

• who were ever on long- term hemodialysis • who have HIV infection • who have hepatitis B infection		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 B. Counsel regarding HCV transmission and ways to prevent spread	

HIV Non-Clinical and Clinical Protocols

Table of Contents

HIV Testing – Non-Clinical Settings

Non-Clinical Settings: Rapid Testing Fingerstick

TRAIN course 1104889, Implementing HIV Testing in Nonclinical Settings, a 3-part module is 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)
- 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 (pre-exposure prophylaxis) 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 Services Programs (SSP) 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 the Department of Laboratory Services (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 follow-up test result.
  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 Evaluation Web HIV Test form for all state-sponsored HIV tests within 2 weeks.

Complete Adult or Pediatric Case Report Form for all HIV positive tests and report to Frankfort within 5 business days of confirmation. See below for further details.

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 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 Evaluation Web 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://www.chfs.ky.gov/agencies/dph/dehp/hab/Pages/services.aspx#CareCoordinatorProgram.

For Kentucky HIV/AIDS Prevention Programs and EvaluationWeb HIV testing form go to https://www.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

- PrEP Locator
- Guidelines and Recommendations | HIV Partners | CDC
- HIV - STI Treatment Guidelines (cdc.gov)
- About HIV | HIV | CDC
- Getting Tested for HIV | HIV | CDC
- Together TakeMeHome

Immunizations
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These protocols are based on the recommendations of the Advisory Committee for Immunization Practices (ACIP), https://www.cdc.gov/acip-recs/hcp/vaccine-specific/?CDC_AAref_Val=https://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 https://www.cdc.gov/vaccines/hcp/imz-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.

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2024-2025 Pfizer-BioNTech COVID-19
Vaccine Standing Orders for
Administering Vaccine
6 months to 4 years old

Vaccine	Diluent	Dosage (amount)/Route
6 months through 4 years old (Multidose vial with yellow cap)	Dilute with 1.1 mL sterile 0.9% Sodium Chloride Injection, USP prior to use	0.3mL/(3mcq) 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-4 years old for 2024-2025 Pfizer- BioNTech COVID- 19 vaccine based on the following criteria:

<u>Children who ARE NOT moderately or severely immunocompromised</u>

- Children who have not been previously vaccinated with a mRNA COVID-19 vaccine should receive:
    - Administer dose 1 (one) of 2024-2025 Pfizer-BioNTech COVID-19 vaccine then dose 2 (two) administered 3-8 weeks apart
    - Dose 3 (three) of the 2024-2025 Pfizer- BioNTech COVID-19 vaccine should be administered at least 8 weeks after dose 2 (two).
- Children who have received 1 (one) dose of any Pfizer-BioNTech COVID-19 vaccine should receive:
    - Administer dose 1 (one) 2024-2025 Pfizer-BioNTechCOVID-19 vaccine 3-8 weeks after last dose of vaccine
    - Dose 2 (two) of the 2024-2025 Pfizer0BioNTech COVID-19 vaccine administered at least 8 weeks after Dose 1
- Children who have received 2 (two) doses of any Pfizer- BioNTechCOVID-19 vaccine should receive:
    - Administer dose 1 (one) 2024-2025 Pfizer-BioNTech COVID-19 vaccine at least 8 weeks after last dose of vaccine
- Children who have received 3 (three) or more doses of any Pfizer-BioNTechCOVID-19 vaccine

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should receive:

- Administer dose 1 (one) 2024-2025 Pfizer-BioNTech COVID-19 vaccine at least 8 weeks after last dose of vaccine

Children who ARE moderately or severely immunocompromised *

- Children who have not been previously vaccinated with a mRNA COVID-19 vaccine should receive:
  - Administer dose 1 (one) of 2024-2025 Pfizer-BioNTech COVID-19 vaccine then dose 2 (two) administered 3 weeks apart
  - Dose 3 (three) of the 2024-2025 Pfizer- BioNTech COVID-19 vaccine should be administered at least 8 weeks after dose 2 (two).
  - Dose 4 (four) of the 2024-2025 Pfizer- BioNTech COVID-19 vaccine should be administered 6 months (minimum interval 2 months) after dose 3.
- Children who have received 1 (one) dose of any Pfizer-BioNTech COVID-19 vaccine should receive:
  - Administer dose 1 (one) 2024-2025 Pfizer-BioNTechCOVID-19 vaccine 3 weeks after last dose of vaccine
  - Dose 2 (two) of the 2024-2025 Pfizer0BioNTech COVID-19 vaccine administered at least 8 weeks after Dose 1
  - Dose 3 (three) of the 2024-2025 Pfizer- BioNTech COVID-19 vaccine should be administered 6 months (minimum interval 2 months) after 2024-2025 dose 2.
- Children who have received 2 (two) doses of any Pfizer-BioNTech COVID-19 vaccine should receive:
  - Administer dose 1 (one) 2024-2025 Pfizer-BioNTech COVID-19 vaccine 8 weeks after last dose of vaccine
  - Dose 2 (two) of the 2024-2025 Pfizer- BioNTech COVID-19 vaccine should be administered 6 months (minimum interval 2 months) after 2024-2025 dose 1.
- Children who have received 3 (three) doses of any Pfizer-BioNTech COVID-19 vaccine, should receive:
  - Administer dose 1 (one) 2024-2025 Pfizer-BioNTech COVID-19 vaccine 8 weeks after last dose of vaccine
  - Dose 2 (two) of the 2024-2025 Pfizer- BioNTech COVID-19 vaccine should be administered 6 months (minimum interval 2 months) after 2024-2025 dose 1.

* **Note**: The child may receive additional doses with at least 2-month minimum interval after last 2024-2025 Pfizer-BioNTech dose, based on shared clinical decision making. For more information, see: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html.

Special situation: Children ages 6 months–4 years should receive all doses of COVID-19 vaccine from the same manufacturer; this includes children who are moderately or severely immunocompromised and those who are not.

In the following exceptional situations, a different age-appropriate COVID-19 vaccine may be administered:

- Same vaccine not available
- Previous dose unknown

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- Person would otherwise not complete the vaccination series
- Person starts but unable to complete a vaccination series with the same COVID-19 vaccine due to a contraindication

A Vaccine Adverse Event Reporting System (VAERS) report is not indicated for these exceptional situations.

If mRNA vaccine doses are administered from different manufacturers because of a circumstance described above, a 3-dose schedule should be followed:

Children ages 6 months–4 years

- The second dose is administered 4–8 weeks after the first dose.
- The third dose of either 2024–2025 Moderna vaccine or 2024–2025 Pfizer-BioNTech vaccine is administered at least 8 weeks after the second dose.

People ages 6 months and older who are moderately or severely immunocompromised

- The second dose is administered 4 weeks after the first dose.
- The third dose of either 2024–2025 Moderna vaccine or 2024–2025 Pfizer-BioNTech vaccine is administered as follows:
  - Ages 6 months–4 years: at least 8 weeks after the second dose
  - Ages 5 years and older: at least 4 weeks after the second dose

NOTE: Children ages 6 months–4 years who are moderately or severely immunocompromised have the option to receive 1 (one) additional dose of a homologous updated 2024-2025 mRNA vaccine at least 2 months following the last recommended updated 2024-2025 mRNA vaccine dose. Further additional homologous updated 2024-2025 mRNA 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 updated 2024-2025 Formula mRNA vaccine dose. For Pfizer- BioNTech COVID-19 vaccine, administer 0.3 mL/3 ug IM injection.

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

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. However, for children who transition from age 4 years to age 5 years and children who are moderately or severely immunocompromised and transition from age 11 years to age 12 years, **the option to administer the lower dosage is no longer authorized.**

Myocarditis or pericarditis after a dose of COVID-19 vaccine

Development of myocarditis or pericarditis within 3 weeks after a dose of any COVID-19 vaccine is a precaution to a subsequent dose of any COVID-19 vaccine, and subsequent doses should generally be avoided. Experts advise that these people should:

- Generally, **not receive** a subsequent dose of any COVID-19 vaccine
- If, after a risk assessment, the decision is made to administer a subsequent COVID-19 vaccine dose, wait until at least their episode of myocarditis or pericarditis has resolved (resolution of symptoms, no evidence of ongoing heart inflammation or sequelae as determined by patient's clinical team)

Considerations for subsequent COVID-19 vaccination might include:

- Myocarditis or pericarditis considered unrelated to vaccination (e.g., due to SARS-CoV-2 or other viruses)

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- Personal risk of severe acute COVID-19 (e.g., age, underlying conditions)
- Timing of any immunomodulatory therapies; ACIP's General Best Practice Guidelines for Immunization can be consulted for more information
- History of myocarditis or pericarditis that occurred prior to COVID-19 vaccination or more than 3 weeks after a COVID-19 vaccine dose

People who have a history of myocarditis or pericarditis that occurred before COVID-19 vaccination or more than 3 weeks after a COVID-19 vaccine dose may receive any currently FDA-approved or FDA-authorized COVID-19 vaccine after the episode of myocarditis or pericarditis has completely resolved (i.e., resolution of symptoms, no evidence of ongoing heart inflammation or sequelae as determined by the person's clinical team). This includes people who had myocarditis or pericarditis due to SARS-CoV-2 or other viruses.

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/clinical-considerations/interim-considerations-us-appendix.html.
- 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/interim-considerations-us.html.

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. However, for children who transition from age 4 years to age 5 years and children who are moderately or severely immunocompromised and transition from age 11 years to age 12 years, **the option to administer the lower dosage is no longer authorized.**

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 0.3 mL of 2024-2025 Pfizer-BioNTech COVID-19 vaccine for children 6 months through 4 years of age as outlined above.
- VIS https://www.cdc.gov/vaccines/hcp/current-vis/covid-19.html.

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 (if applicable): 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.

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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 and Precautions

Medical condition or history	**Guidance**	**Recommended action(s)**
History of a severe allergic reaction* (e.g., anaphylaxis†) after a previous dose or to a component of the COVID-19 vaccine‡	Contraindication	Do not vaccinate with the same COVID- 19 vaccine type. May administer the alternate COVID-19 vaccine type. See Considerations for people with a history of allergies and allergic reactions for additional information.
History of a diagnosed non-severe allergy* to a component of the COVID-19 vaccine‡	Precaution	May administer the alternate COVID-19 vaccine type. For additional information, see Considerations for people with a history of allergies and allergic reactions.
History of a non-severe, immediate (onset less than 4 hours) allergic reaction* after administration of a previous dose of one COVID-19 vaccine type§	Precaution	
Moderate or severe acute illness, with or without fever	Precaution	Defer vaccination until the illness has improved.
History of MIS-C or MIS-A	Precaution	See COVID-19 vaccination and MIS-C and MIS-A.
History of myocarditis or pericarditis within 3 weeks after a dose of **any COVID-19 vaccine**	Precaution	A subsequent dose of any COVID-19 vaccine should generally be avoided. See COVID-19 vaccination and myocarditis and pericarditis.

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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 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), 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 myocarditis, pericarditis, Multisystem inflammatory syndrome (MIS) in adults and children or cases of COVID-19 that result in hospitalization/death.

*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.

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2024-2025 Pfizer-BioNTech COVID-19 Standing Orders for Administering Vaccine 5 years through 11 years old

Vaccine	Diluent	Dosage (amount)/Route
5 years through 11 years old (Blue cap single dose vial)	DO NOT DILUTE	0.3mL/(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 5 years through 11 years old for 2024-2025 Pfizer-BioNTech COVID-19 vaccine based on the following criteria:

Children who ARE NOT moderately or severely immunocompromised

- Children who have not been previously vaccinated for COVID-19 should receive 1 (one) dose of the 2024-2025 Pfizer-BioNTech COVID-19 vaccine.
- Children who have received 1 (one) or more doses of any mRNA vaccine should receive 1 (one) dose of 2024-2025 Pfizer-BioNTech COVID-19 vaccine 8 weeks after the last dose.

Children who ARE moderately or severely immunocompromised *

- Children who have not been previously vaccinated with a COVID-19 vaccine should receive:
  - Administer dose 1 (one) of 2024-2025 Pfizer-BioNTech COVID-19 vaccine then dose 2 (two) administered 3 weeks apart
  - Dose 3 (three) of the 2024-2025 Pfizer- BioNTech COVID-19 vaccine should be administered at least 4weeks after dose 2 (two).
  - Dose 4 (four) of the 2024-2025 Moderna **or** Pfizer- BioNTech COVID-19 vaccine should be administered 6 months (minimum interval 2 months) after dose 3.
- Children who have received 1 (one) dose of any Pfizer-BioNTech COVID-19 vaccine should receive:
  - Administer dose 1 (one) 2024-2025 Pfizer-BioNTechCOVID-19 vaccine 3 weeks after last dose of vaccine
  - Dose 2 (two) of the 2024-2025 Pfizer0BioNTech COVID-19 vaccine administered at least 4 weeks after Dose 1
  - Dose 3 (three) of the 2024-2025 Moderna **or** Pfizer- BioNTech COVID-19 vaccine should be administered 6 months (minimum interval 2 months) after 2024-2025 dose 2.

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- Children who have received 2 (two) doses of any Pfizer- BioNTechCOVID-19 vaccine should receive:
    - Administer dose 1 (one) 2024-2025 Pfizer-BioNTech COVID-19 vaccine at least 4 weeks after last dose of vaccine
    - Dose 2 (two) of the 2024-2025 Moderna **or** Pfizer- BioNTech COVID-19 vaccine should be administered 6 months (minimum interval 2 months) after 2024-2025 dose 1.
- Children who have received 3 (three) or more doses of any mRNA COVID- 19 vaccine should receive:
    - Administer dose 1 (one) 2024-2025 Moderna **or** Pfizer-BioNTech COVID-19 vaccine at least 8 weeks after last dose of vaccine
    - Dose 2 (two) of the 2024-2025 Moderna **or** Pfizer- BioNTech COVID-19 vaccine should be administered 6 months (minimum interval 2 months) after 2024-2025 dose 1.

*** Note**: The child may receive additional doses (Moderna **or** Pfizer- BioNTech) with at least 2- month minimum interval after last 2024-2025 mRNA dose, based on shared clinical decision making. For more information, see: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#routine-vaccination-guidance

If mRNA vaccine doses are administered from different manufacturers because of a circumstance described above, a 3- dose schedule should be followed:

Children ages 6 months–4 years

- The second dose is administered 4–8 weeks after the first dose.
- The third dose of either 2024–2025 Moderna vaccine or 2024–2025 Pfizer-BioNTech vaccine is administered at least 8 weeks after the second dose.

People ages 6 months and older who are moderately or severely immunocompromised

- The second dose is administered 4 weeks after the first dose.
- The third dose of either 2024–2025 Moderna vaccine or 2024–2025 Pfizer-BioNTech vaccine is administered as follows:
    - Ages 6 months–4 years: at least 8 weeks after the second dose
    - Ages 5 years and older: at least 4 weeks after the second dose
- **Individuals who will turn from 4 years old to 5 years old**
- 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. However, for children who transition from age 4 years to age 5 years and children who are moderately or severely immunocompromised and transition from age 11 years to age 12 years, **the option to administer the lower dosage is no longer authorized.**

NOTE: Children ages 5–11 years who are moderately or severely immunocompromised have the option to receive 1 (one) additional dose of updated 2024-2025 Moderna COVID-19 Vaccine, 0.25mL/25 ug or updated 2024-2025 Pfizer-BioNTech COVID-19 Vaccine, 0.3 mL/10 ug at least 2 months following the last recommended updated 2024-2025 Formula COVID-19 vaccine dose. Further additional 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 updated 2024-2025 COVID-19 vaccine dose.

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Myocarditis or pericarditis after a dose of COVID-19 vaccine

Development of myocarditis or pericarditis within 3 weeks after a dose of any COVID-19 vaccine is a precaution to a subsequent dose of any COVID-19 vaccine, and subsequent doses should generally be avoided. Experts advise that these people should:

- Generally, **not receive** a subsequent dose of any COVID-19 vaccine
- If, after a risk assessment, the decision is made to administer a subsequent COVID-19 vaccine dose, wait until at least their episode of myocarditis or pericarditis has resolved (resolution of symptoms, no evidence of ongoing heart inflammation or sequelae as determined by patient's clinical team)

Considerations for subsequent COVID-19 vaccination might include:

- Myocarditis or pericarditis considered unrelated to vaccination (e.g., due to SARS-CoV-2 or other viruses)
- Personal risk of severe acute COVID-19 (e.g., age, underlying conditions)
- Timing of any immunomodulatory therapies; ACIP's General Best Practice Guidelines for Immunization can be consulted for more information

History of myocarditis or pericarditis that occurred prior to COVID-19 vaccination or more than 3 weeks after a COVID-19 vaccine dose

People who have a history of myocarditis or pericarditis that occurred before COVID-19 vaccination or more than 3 weeks after a COVID-19 vaccine dose may receive any currently FDA-approved or FDA-authorized COVID-19 vaccine after the episode of myocarditis or pericarditis has completely resolved (i.e., resolution of symptoms, no evidence of ongoing heart inflammation or sequelae as determined by the person's clinical team). This includes people who had myocarditis or pericarditis due to SARS-CoV-2 or other viruses.

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/clinical-considerations/interim-considerations-us-appendix.html.
- 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/interim-considerations-us.html#routine-vaccination-guidance.

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. However, for children who transition from age 4 years to age 5 years and children who are moderately or severely immunocompromised and transition from age 11 years to age 12 years, **the option to administer the lower dosage is no longer authorized.**

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Screen for Contraindications and Precautions

Medical condition or history	Guidance	Recommended action(s)
History of a severe allergic reaction* (e.g., anaphylaxis†) after a previous dose or to a component of the COVID-19 vaccine‡	Contraindication	Do not vaccinate with the same COVID-19 vaccine type. May administer the alternate COVID-19 vaccine type. See Considerations for people with a history of allergies and allergic reactions for additional information.
History of a diagnosed non-severe allergy* to a component of the COVID-19 vaccine‡	Precaution	May administer the alternate COVID-19 vaccine type. For additional information, see Considerations for people with a history of allergies and allergic reactions.
History of a non-severe, immediate (onset less than 4 hours) allergic reaction* after administration of a previous dose of one COVID-19 vaccine type§	Precaution	
Moderate or severe acute illness, with or without fever	Precaution	Defer vaccination until the illness has improved.
History of MIS-C or MIS-A	Precaution	See COVID-19 vaccination and MIS- C and MIS-A.
History of myocarditis or pericarditis within 3 weeks after a dose of **any COVID-19 vaccine**	Precaution	A subsequent dose of any COVID- 19 vaccine should generally be avoided. See COVID-19 vaccination and myocarditis and pericarditis.

Vaccine Administration

- Prepare to administer 2024-2025 Pfizer-BioNTech COVID-19 vaccine by IM injection.
  - Needle gauge and length: Use a 22–25-gauge, 1 inch
- Follow dose and schedule regimen outlined above
- VIS https://www.cdc.gov/vaccines/hcp/current-vis/covid-19.html
- 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 (if applicable): 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.

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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/interim-considerations-us.html#myocarditis-pericarditis)

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.

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

- While this vaccine is under Emergency Use Authorization (EUA), 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 myocarditis, pericarditis, Multisystem inflammatory syndrome (MIS) in adults and children or cases of COVID-19 that result in hospitalization/death.

*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.

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2024-2025 Pfizer-BioNTech COVID-19 (COMIRNATY) Standing Orders for Administering Vaccine

12 years of Age and Older

Vaccine	Diluent	Dosage (amount)/Route
Pfizer- BioNTech **- (12 years old and older)** (Manufacturer-filled syringe)	**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 12-64 years of age who **are not** moderately or severely immunocompromised for vaccination with 2024-2025 Pfizer- BioNTech COVID-19 vaccine based on the following criteria:

- Unvaccinated individuals should receive 1 dose of 2024-2025 Pfizer-BioNTech COVID-19 vaccine
- Individuals who have received 1 (one) or more doses of any mRNA COVID-19 vaccine administer 1 (one) dose of 2024-2025 Pfizer-BioNTech COVID-19 vaccine at least 8 weeks after last dose

Assess persons 65 years of age and older who **are not** moderately or severely immunocompromised for vaccination with 2024-2025 Pfizer- BioNTech COVID-19 vaccine based on the following criteria:

- If the recipient has never received a COVID-19 vaccine, administer dose 1 (one) of 2024- 2025 Pfizer-Bio-NTech COVID-19 Vaccine then another dose 2024-2025 (Moderna, Novavax or Pfizer- BioNTech) COVID-19 vaccine 6 months (minimum interval 2 months) after dose 1.
- If the recipient has previously been vaccinated before 2024-2025 vaccine with 1 or more doses of mRNA vaccine (Moderna or Pfizer-BioNTech), 2 or more doses of Novavax, 1 dose of Novavax[§] or 1 or more doses of Janssen COVID-19 vaccines: Administer dose 1 (one) of 2024-2025 Pfizer- BioNTech COVID-19 Vaccine at least 8 weeks after last dose then dose 2 (two) 2024-2025 (Moderna, Novavax or Pfizer-BioNTech) COVID-19 vaccine 6 months (minimum interval 2 months) after dose 1.

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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 with a COVID-19 vaccine should receive:
  - Administer dose 1 (one) of 2024-2025 Pfizer-BioNTech COVID-19 vaccine then dose 2 (two) administered 3 weeks apart
  - Dose 3 (three) of the 2024-2025 Pfizer- BioNTech COVID-19 vaccine should be administered at least 4 weeks after dose 2 (two).
  - Dose 4 (four) of the 2024-2025 (Moderna, Novavax **or** Pfizer-BioNTech) COVID-19 vaccine should be administered 6 months (minimum interval 2 months) after 2024-2025 dose 3.
- Individuals who have received 1 (one) dose of any mRNA COVID-19 vaccine should receive:
  - Administer dose 1 (one) 2024-2025 Pfizer-BioNTech COVID-19 vaccine 3 weeks after last dose of vaccine
  - Dose 2 (two) of the 2024-2025 Pfizer0BioNTech COVID-19 vaccine administered at least 4 weeks after Dose 1
  - Dose 3 (three) of the 2024-2025 (Moderna, Novavax, **or** Pfizer-BioNTech) COVID-19 vaccine should be administered 6 months (minimum interval 2 months) after 2024-2025 dose 2.
- Individuals who have received 2 (two) doses of any mRNA COVID-19 vaccine should receive:
  - Administer dose 1 (one) dose of 2024-2025 Pfizer-BioNTech COVID-19 vaccine at least 4 weeks after last dose of vaccine
  - Dose 2 (two) of the 2024-2025 (Moderna, Novavax **or** Pfizer- BioNTech) COVID-19 vaccine should be administered 6 months (minimum interval 2 months) after 2024-2025 dose 1.
- Individuals who have received 3 (three) or more doses of any mRNA COVID-19 vaccine should receive:
  - Administer dose 1 (one) 2024-2025 (Moderna, Novavax **or** Pfizer-BioNTech) COVID-19 vaccine at least 8 weeks after last dose of vaccine
  - Dose 2 (two) of the 2024-2025 (Moderna, Novavax **or** Pfizer- BioNTech) COVID-19 vaccine should be administered 6 months (minimum interval 2 months) after 2024-2025 dose 1.

§ If recipient was previously vaccinated before 2024-2025 vaccine with only 1 dose of Novavax and it has been less than 8 weeks since 1st dose of Novavax: administer 1 dose 2024-2025 Novavax vaccine 3-8 weeks after last dose then administer dose 2 (two) 6 months (minimum interval 2 months) of 2024-2025 (Moderna, Novavax or Pfizer-BioNTech) COVID-19 vaccine after 2024-2025 dose 1 *(see standing order for Novavax COVID-19 Vaccine).*

* May receive additional doses (Moderna, Novavax **or** Pfizer- BioNTech) with at least 2-month minimum interval after last dose any 2024-2025 vaccine, based on shared clinical decision making. For more information, see: *https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations- us.html#immunocompromised*.

Preparation for Administration

- 2024-2025 Pfizer- BioNTech COVID-19 vaccine 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 2024-2025 Pfizer- BioNTech COVID-19 Vaccine.

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- Withdraw a single 0.3 mL dose from vial. Discard the vial and any excess contents.

Myocarditis or pericarditis after a dose of COVID-19 vaccine

Development of myocarditis or pericarditis within 3 weeks after a dose of any COVID-19 vaccine is a precaution to a subsequent dose of any COVID-19 vaccine, and subsequent doses should generally be avoided. Experts advise that these people should:

- Generally, **not receive** a subsequent dose of any COVID-19 vaccine
- If, after a risk assessment, the decision is made to administer a subsequent COVID-19 vaccine dose, wait until at least their episode of myocarditis or pericarditis has resolved (resolution of symptoms, no evidence of ongoing heart inflammation or sequelae as determined by patient's clinical team)

Considerations for subsequent COVID-19 vaccination might include:

- Myocarditis or pericarditis considered unrelated to vaccination (e.g., due to SARS-CoV-2 or other viruses)
- Personal risk of severe acute COVID-19 (e.g., age, underlying conditions)
- Timing of any immunomodulatory therapies; ACIP's General Best Practice Guidelines for Immunization can be consulted for more information

History of myocarditis or pericarditis that occurred prior to COVID-19 vaccination or more than 3 weeks after a COVID-19 vaccine dose

People who have a history of myocarditis or pericarditis that occurred before COVID-19 vaccination or more than 3 weeks after a COVID-19 vaccine dose may receive any currently FDA-approved or

FDA-authorized COVID-19 vaccine after the episode of myocarditis or pericarditis has completely resolved (i.e., resolution of symptoms, no evidence of ongoing heart inflammation or sequelae as determined by the person's clinical team). This includes people who had myocarditis or pericarditis due to SARS-CoV-2 or other viruses.

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/clinical-considerations/interim-considerations-us-appendix.html
- 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

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. However, for children who transition from age 4 years to age 5 years and children who are moderately or severely immunocompromised and transition from age 11 years to age 12 years, the option to administer the lower dosage is no longer authorized.

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 and Precautions

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Medical condition or history	Guidance	Recommended action(s)
History of a severe allergic reaction* (e.g., anaphylaxis†) after a previous dose or to a component of the COVID-19 vaccine‡	Contraindication	Do not vaccinate with the same COVID- 19 vaccine type. May administer the alternate COVID-19 vaccine type. See Considerations for people with a history of allergies and allergic reactions for additional information.
History of a diagnosed non-severe allergy* to a component of the COVID-19 vaccine‡	Precaution	May administer the alternate COVID-19 vaccine type. For additional information, see Considerations for people with a history of allergies and allergic reactions.
History of a non-severe, immediate (onset less than 4 hours) allergic reaction* after administration of a previous dose of one COVID-19 vaccine type§	Precaution	
Moderate or severe acute illness, with or without fever	Precaution	Defer vaccination until the illness has improved.
History of MIS-C or MIS-A	Precaution	See COVID-19 vaccination and MIS-C and MIS-A.
History of myocarditis or pericarditis within 3 weeks after a dose of **any COVID-19 vaccine**	Precaution	A subsequent dose of any COVID-19 vaccine should generally be avoided. See COVID-19 vaccination and myocarditis and pericarditis.

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

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- Provide all recipients with a copy of VIS https://www.cdc.gov/vaccines/hcp/current-vis/covid-19.html

Prepare to administer the 2024-2025 Pfizer-BioNTech COVID-19 vaccine. Choose the correct needle gauge, needle length, and injection site for persons:

  - 12years of age:
    - Needle gauge/length: 22-25 gauge, 1-inch.
    - Site: Deltoid muscle of arm.
  - 19 years of age and older: See chart.
- Administer 2024-2025 Pfizer-BioNTech COVID-19 Vaccine by intramuscular (IM) injection
  - 0.3 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 (if applicable): 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/imz-best-practices/preventing-managing-adverse-reactions.html

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        - **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#covid19euas) 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 or children

      (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#covid19-vaccination-misc-misa)

* 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.

§ 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**).

2024-2025 Moderna COVID-19 Vaccine Standing Orders for Administering Vaccine 6 months to 4 years old

Vaccine	Diluent	Dosage (amount)/Route
6 months through 4 years (Manufacturer-filled syringe)	**DONOT 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 months-4 years old for 2024-2025 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 2024-2025 Moderna COVID-19 vaccine and dose 2 (two), 4-8 weeks later
- If the recipient has received 1 (one) previous dose of Moderna COVID-19 vaccine, administer 1 (one) dose of the 2024-2025 Moderna COVID-19 vaccine at least 4–8 weeks after the receipt of the vaccine
- If the recipient has received 2 (two) or more doses of the Moderna COVID-19 vaccine (not including the 2024-2025 formula), administer 1 (one) dose of the 2024-2025 Moderna COVID-19 vaccine at least 8 weeks after the last dose of vaccine.

Children who ARE moderately or severely immunocompromised*

- If the recipient has never received a COVIID-19 vaccine, administer 1(one) dose of the 2024-2025 Moderna COVID-19 vaccine and dose 2 (two), 4 weeks after receipt of dose 1(one). Administer dose 3 (three) 4 weeks after dose 2 (two). Administer dose 4 (four) of the 2024-2025 Moderna COVID-19 vaccine 6 months (minimum interval 2 months) after 2024-2025 dose 3 (three).
- If the recipient has received 1 (one) previous dose of Moderna COVID-19 vaccine, administer 1 (one) dose of the 2024-2025 Moderna COVID-19 vaccine at least 4 weeks after the receipt of dose 1 (one). Administer dose 3 (three) at least 4 weeks after dose 2 (two). Administer dose 4 (four) of the 2024-2025 Moderna COVID-19 vaccine 6 months (minimum interval 2 months) after 2024-2025 dose 3 (three).
- If the recipient has received 2 (two) doses of the Moderna COVID-19 vaccine, administer 1 (one) dose of the 2024-2025 Moderna COVID-19 vaccine at least 4 weeks after the last vaccine. Administer dose 4 (four) of the 2024- 2025 Moderna COVID-19 vaccine 6 months (minimum interval 2 months) after 2024-2025 dose 3 (three).
- If the recipient has received 3 (three) or more doses of the Moderna COVID- 19 vaccine Administer 1 (one) dose of the 2024-2025 Moderna COVID-19 vaccine 8 weeks after the receipt of the last dose of vaccine. Administer dose 4 (four) of the 2024-2025 Moderna COVID-19 vaccine 6 months (minimum interval 2 months) after 2024-2025 dose 3 (three).

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* The child may receive additional doses 2024-2025 Moderna with at least 2-month minimum interval after last dose 2024-2025 Moderna vaccine, based on shared clinical decision making. For more information, see: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim- considerations-us.html#immunocompromised.

NOTE: Children ages 6 months–4 years who are moderately or severely immunocompromised have the option to receive 1 (one) additional dose of a homologous updated 2024-2025 mRNA vaccine at least 2 months following the last recommended updated 2024-2025 mRNA vaccine dose. Further additional homologous updated 2024- 2025 mRNA 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 updated 2024-2025 mRNA vaccine dose.

Special situation: Children ages 6 months–4 years should receive all doses of COVID-19 vaccine from the same manufacturer; this includes children who are moderately or severely immunocompromised and those who are not.

In the following exceptional situations, a different age-appropriate COVID-19 vaccine may be administered:

- Same vaccine not available
- Previous dose unknown
- Person would otherwise not complete the vaccination series
- Person starts but unable to complete a vaccination series with the same COVID-19 vaccine due to a contraindication

A Vaccine Adverse Event Reporting System (VAERS) report is not indicated for these exceptional situations.

If mRNA vaccine doses are administered from different manufacturers because of a circumstance described above, a 3-dose schedule should be followed:

Children ages 6 months–4 years

- The second dose is administered 4–8 weeks after the first dose.
- The third dose of either 2024–2025 Moderna vaccine or 2024–2025 Pfizer-BioNTech vaccine is at least 8 weeks after the second dose.

People ages 6 months and older who are moderately or severely immunocompromised

- The second dose is administered 4 weeks after the first dose.
- The third dose of either 2024–2025 Moderna vaccine or 2024–2025 Pfizer-BioNTech vaccine is administered as follows:
    - Ages 6 months–4 years: at least 8 weeks after the second dose
    - Ages 5 years and older: at least 4 weeks after the second dose

Individuals who will turn from 4 years old to 5 years old
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. However, for children who transition from age 4 years to age 5 years and children who are moderately or severely immunocompromised and transition from age 11 years to age 12 years, **the option to administer the lower dosage is no longer authorized.**

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Myocarditis or pericarditis after a dose of COVID-19 vaccine

- Development of myocarditis or pericarditis within 3 weeks after a dose of any COVID-19 vaccine is a precaution to a subsequent dose of any COVID-19 vaccine, and subsequent doses should generally be avoided. Experts advise that these people should:
    - Generally, **not receive** a subsequent dose of any COVID-19 vaccine
    - If, after a risk assessment, the decision is made to administer a subsequent COVID-19 vaccine dose, wait until at least their episode of myocarditis or pericarditis has resolved (resolution of symptoms, no evidence of ongoing heart inflammation or sequelae as determined by patient's clinical team)
- Considerations for subsequent COVID-19 vaccination might include:
    - Myocarditis or pericarditis considered unrelated to vaccination (e.g., due to SARS-CoV-2 or other viruses)
    - Personal risk of severe acute COVID-19 (e.g., age, underlying conditions)
    - Timing of any immunomodulatory therapies; ACIP's General Best Practice Guidelines for Immunization can be consulted for more information

History of myocarditis or pericarditis that occurred prior to COVID-19 vaccination or more than 3 weeks after a COVID-19 vaccine dose

People who have a history of myocarditis or pericarditis that occurred before COVID-19 vaccination or more than 3 weeks after a COVID-19 vaccine dose may receive any currently FDA-approved or FDA-authorized COVID-19 vaccine after the episode of myocarditis or pericarditis has completely resolved (i.e., resolution of symptoms, no evidence of ongoing heart inflammation or sequelae as determined by the person's clinical team). This includes people who had myocarditis or pericarditis due to SARS-CoV-2 or other viruses.

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/clinical-considerations/interim-considerations-us-appendix.html#appendix-a
- 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/interim-considerations-us.html#infection

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Screen for Contraindications and Precautions

Medical condition or history	Guidance	Recommended action(s)
History of a severe allergic reaction* (e.g., anaphylaxis†) after a previous dose or to a component of the COVID-19 vaccine‡	Contraindication	Do not vaccinate with the same COVID-19 vaccine type. May administer the alternate COVID-19 vaccine type. See Considerations for people with a history of allergies and allergic reactions for additional information.
History of a diagnosed non-severe allergy* to a component of the COVID-19 vaccine‡	Precaution	May administer the alternate COVID-19 vaccine type. For additional information, see Considerations for people with a history of allergies and allergic reactions.
History of a non-severe, immediate (onset less than 4 hours) allergic reaction* after administration of a previous dose of one COVID-19 vaccine type§	Precaution	
Moderate or severe acute illness, with or without fever	Precaution	Defer vaccination until the illness has improved.
History of MIS-C or MIS-A	Precaution	See COVID-19 vaccination and MIS-C and MIS-A.
History of myocarditis or pericarditis within 3 weeks after a dose of **any COVID-19 vaccine**	Precaution	A subsequent dose of any COVID-19 vaccine should generally be avoided. See COVID-19 vaccination and myocarditis and pericarditis.

Vaccine Administration

- Prepare to administer 2024-2025 Moderna COVID-19 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 years through 4 years: Deltoid muscle in the upper arm
- See guidance provided above for dosing and schedule regimen

VIS https://www.cdc.gov/vaccines/hcp/current-vis/covid-19.html

- 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 (if applicable): 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.

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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)

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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 or children (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#covid19-vaccination-misc-misa)
- 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.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.gov/):
  - Clinically important adverse events that occur after vaccination, even if you are not sure whether the vaccine caused the adverse event

*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.

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2024-2025 Moderna COVID-19 Vaccine
Standing Orders for Administering Vaccine 5 years through 11 years old

Vaccine	Diluent	Dosage (amount)/Route
5 Years through 11 Years (Manufacturer-filled syringe)	**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 5 years through 11 years old for 2024-2025 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 2024-2025 Moderna COVID-19 vaccine.
- Recipients who have received 1 (one) or more doses of any mRNA vaccine should receive 1 (one) dose of 2024-2025 Moderna COVID-19 vaccine at least 8 weeks after last the last dose

Children who ARE moderately or severely immunocompromised*

- If the recipient has never received a COVID-19 vaccine, administer dose 1 (one) of 2024-2025 Moderna COVID-19 vaccine and dose 2 (two) at least 4 weeks later and dose 3 (three) at least 4 weeks past dose 2 (two). Administer dose 4 (four) of the 2024-2025 Moderna **or** Pfizer-BioNTech COVID-19 vaccine 6 months (minimum interval 2 months) after dose 3 (three).
- If the recipient has received 1(one) previous dose of Moderna mRNA COVID-19 vaccine, administer 1(one) dose of the 2024-2025 Moderna COVID-19 vaccine at least 4 weeks after the receipt of the vaccine and dose 2 (two) at least 4 weeks later. Administer dose 3 (three) of the 2024-2025 Moderna **or** Pfizer-BioNTech COVID-19 vaccine 6 months (minimum interval 2 months) after 2024-2025 dose 2 (two).
- If the recipient has received 2 (two) doses of Moderna COVID-19 vaccine, administer 1 (one) dose of the 2024-2025 Moderna COVID-19 vaccine at least 4 weeks after the last dose. Administer dose 2 (two) of the 2024-2025 Moderna **or** Pfizer-BioNTech COVID-19 vaccine 6 months (minimum interval 2 months) after 2024-2025 dose 1 (one).
- If the recipient has received 3 (three) doses of any mRNA COVID-19 vaccine, administer 1 (one) dose of the 2024-2025 Moderna **or** Pfizer-BioNTech COVID-19 vaccine at least 8 weeks after last dose of vaccine. Administer dose 2 (two) of the 2024-2025 Moderna **or** Pfizer-BioNTech COVID-19 vaccine 6 months (minimum interval 2 months) after 2024-2025 dose 1 (one).

* The child may receive additional doses (Moderna **or** Pfizer- BioNTech) with at least 2-month minimum interval after last 2024-2025 mRNA dose, based on shared clinical decision making. For more information:

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https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#immunocompromised.

NOTE: Children ages 5–11 years who are moderately or severely immunocompromised have the option to receive 1 (one) additional dose of updated 2024-2025 Moderna COVID-19 Vaccine, 0.25mL/25 ug **or** updated 2024-2025 Pfizer- BioNTech COVID-19 Vaccine, 0.3 mL/10 ug at least 2 (two) months following the last recommended updated any 2024-2025 mRNA COVID-19 vaccine dose. Further additional 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 (two) months after the last updated 2024-2025 mRNA COVID-19 vaccine dose.

If mRNA vaccine doses are administered from different manufacturers because of a circumstance described above, a 3-dose schedule should be followed:

Children ages 6 months–4 years

- The second dose is administered 4–8 weeks after the first dose.
- The third dose of either 2024–2025 Moderna vaccine or 2024–2025 Pfizer-BioNTech vaccine is administered at least 8 weeks after the second dose.

People ages 6 months and older who are moderately or severely immunocompromised

- The second dose is administered 4 weeks after the first dose.
- The third dose of either 2024–2025 Moderna vaccine or 2024–2025 Pfizer-BioNTech vaccine is administered as follows:
  - Ages 6 months–4 years: at least 8 weeks after the second dose
  - Ages 5 years and older: at least 4 weeks after the second dose

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

- 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. However, for children who transition from age 4 years to age 5 years and children who are moderately or severely immunocompromised and transition from age 11 years to age 12 years, **the option to administer the lower dosage is no longer authorized.**

Myocarditis or pericarditis after a dose of COVID-19 vaccine

Development of myocarditis or pericarditis within 3 weeks after a dose of any COVID-19 vaccine is a precaution to a subsequent dose of any COVID-19 vaccine, and subsequent doses should generally be avoided. Experts advise that these people should:

- Generally, **not receive** a subsequent dose of any COVID-19 vaccine
- If, after a risk assessment, the decision is made to administer a subsequent COVID-19 vaccine dose, wait until at least their episode of myocarditis or pericarditis has resolved (resolution of symptoms, no evidence of ongoing heart inflammation or sequelae as determined by patient's clinical team)

Considerations for subsequent COVID-19 vaccination might include:

- Myocarditis or pericarditis considered unrelated to vaccination (e.g., due to SARS-CoV-2 or other viruses)
- Personal risk of severe acute COVID-19 (e.g., age, underlying conditions)
- Timing of any immunomodulatory therapies; ACIP's General Best Practice Guidelines for Immunization can be consulted for more information

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History of myocarditis or pericarditis that occurred prior to COVID-19 vaccination or more than 3 weeks after a COVID-19 vaccine dose

People who have a history of myocarditis or pericarditis that occurred before COVID-19 vaccination or more than 3 weeks after a COVID-19 vaccine dose may receive any currently FDA-approved or FDA-authorized COVID-19 vaccine after the episode of myocarditis or pericarditis has completely resolved (i.e., resolution of symptoms, no evidence of ongoing heart inflammation or sequelae as determined by the person's clinical team). This includes people who had myocarditis or pericarditis due to SARS-CoV-2 or other viruses.

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/clinical-considerations/interim-considerations-us-appendix.html#appendix-a

- Moderna COVID-19 Vaccine may be co-administered with other vaccines without regard to timing,
- 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

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. However, for children who transition from age 4 years to age 5 years and children who are moderately or severely immunocompromised and transition from age 11 years to age 12 years, the option to administer the lower dosage is no longer authorized.

Screen for Contraindications and Precautions

Medical condition or history	Guidance	Recommended action(s)
History of a severe allergic reaction* (e.g., anaphylaxis†) after a previous dose or to a component of the COVID-19 vaccine‡	Contraindication	Do not vaccinate with the same COVID-19 vaccine type. May administer the alternate COVID-19 vaccine type. See Considerations for people with a history of allergies and allergic reactions for additional information.
History of a diagnosed non-severe allergy to a component of the COVID-19 vaccine‡	Precaution	May administer the alternate COVID-19 vaccine type. For additional information, see Considerations for people with a history of allergies and allergic reactions.
History of a non-severe, immediate (onset less than 4 hours) allergic reaction after administration of a previous dose of one COVID- 19 vaccine type§	Precaution	
Moderate or severe acute illness, with or without fever	Precaution	Defer vaccination until the illness has improved.
History of MIS-C or MIS-A	Precaution	See COVID-19 vaccination and MIS-C and MIS-A.
History of myocarditis or pericarditis within 3 weeks after a dose of any COVID-19 vaccine	Precaution	A subsequent dose of any COVID-19 vaccine should generally be avoided. See COVID-19 vaccination and myocarditis and pericarditis.

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Vaccine Administration

- Prepare to administer vaccine by IM injection.
  - Needle gauge and length: Use a 22–25-gauge, 1 inch
- See guidance provided above for dosing and schedule regimen
- VIS https://www.fda.gov/emergency-preparedness-and-response/coronavirus- disease-2019-covid-19/covid-19-vaccines-2024-2025
- **Docu**ment 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 (if applicable): 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)

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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#covid19euas) 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/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#covid19-vaccination-misc-misa

- 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.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#covid19euas) conditions for use of an authorized vaccine throughout the duration of the EUA

- Healthcare professionals are encouraged to report to VAERS (https://vaers.hhs.gov/):
    - Clinically important adverse events that occur after vaccination, even if you are not sure whether the vaccine caused the adverse event.

*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.

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2024-2025 Moderna COVID-19 Vaccine (SPIKEVAX)

Standing Orders for Administering Vaccine 12 Years of Age and Older:

Vaccine	Dosage (amount)/Route
Moderna- (12 years old and older) (Manufacturer-filled syringe)	**0.5mL (50 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 for vaccination with 2024-2025 Moderna COVID- 19 Vaccine based on the following criteria:

Persons who ARE NOT moderately or severely immunocompromised

For people ages 12 years -64 years:

- If the recipient has never received a COVID-19 vaccine, administer 1 (one) dose of 2024- 2025 Moderna COVID-19 Vaccine
- If the recipient has received 1 (one) or more previous dose/s of any mRNA administer 1 (one) dose of 2024- 2025 Moderna COVID-19 vaccine at least 8 weeks after last dose.

For people ages 65 years and older:

- If the recipient has never received a COVID-19 vaccine, administer dose 1 (one) of 2024- 2025 Moderna COVID-19 Vaccine then another dose 2024-2025 (Moderna, Novavax or Pfizer-BioNTech) COVID-19 vaccine 6 months (minimum interval 2 months) after dose 1.
- If the recipient has previously been vaccinated before 2024-2025 vaccine with 1 or more doses of mRNA vaccine (Moderna or Pfizer-BioNTech), 2 or more doses of Novavax, 1 dose of Novavax[§] or 1 or more doses of Janssen COVID-19 vaccines: Administer dose 1 (one) of 2024-2025 Moderna COVID-19 Vaccine at least 8 weeks after last dose then dose 2 (two) 2024-2025 (Moderna, Novavax or Pfizer-BioNTech) COVID-19 vaccine 6 months (minimum interval 2 months) after dose 1.

Person who ARE moderately or severely immunocompromised*

- If the recipient has never received any mRNA vaccine, administer dose 1 (one) of 2024-2025 Moderna COVID-19 vaccine and dose 2 (two) at least 4 weeks later and dose 3 (three) at least 4 weeks after dose 2 (two). Administer Dose 4 (four) of the 2024-2025 (Moderna, Novavax **or** Pfizer-BioNTech) COVID-19 vaccine should be administered 6 months (minimum interval 2 months) after 2024-2025 dose 3.

- If the recipient has received 1(one) previous dose of any mRNA COVID-19 vaccine, administer 1(one) dose of the 2024-2025 Moderna COVID-19 vaccine at least 4 weeks after the receipt of the last vaccine and dose 2 (two) at least 4 weeks later. Administer dose 3 (three) of the 2024-2025 (Moderna, Novavax **or** Pfizer- BioNTech) COVID-19 vaccine should be administered 6 months (minimum interval 2 months) after 2024-2025 dose 2.

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- If the recipient has received 2 (two) doses of any mRNA COVID-19 vaccine, administer 1 (one) dose of the 2024-2025 Moderna COVID-19 vaccine at least 4 weeks after the last vaccine. Administer dose 2 (two) of the 2024-2025 (Moderna, Novavax or Pfizer- BioNTech) COVID-19 vaccine should be administered 6 months (minimum interval 2 months) after 2024-2025 dose 1.
- If the recipient has received 3 (three) doses of any mRNA COVID-19 vaccine, administer 1 (one) dose of the 2024-2025 (Moderna, Novavax **or** Pfizer- BioNTech) COVID-19 vaccine at least 8 weeks after last dose. Administer dose 2 (two) of the 2024-2025 (Moderna, Novavax **or** Pfizer-BioNTech) COVID-19 vaccine should be administered 6 months (minimum interval 2 months) after 2024-2025 dose 1.

§ If recipient was previously vaccinated before 2024-2025 vaccine with only 1 dose of Novavax and it has been less than 8 weeks since 1st dose of Novavax: administer 1 dose 2024-2025 Novavax vaccine 3-8 weeks after last dose then administer dose 2 (two) 6 months (minimum interval 2 months) of 2024-2025 (Moderna, Novavax **or** Pfizer- BioNTech) COVID-19 vaccine after 2024-2025 dose 1 *(see standing order for Novavax COVID-19 Vaccine)*.

***** May receive additional doses (Moderna, Novavax or Pfizer- BioNTech) with at least 2-month minimum interval after last dose any 2024-2025 vaccine, based on shared clinical decision making. For more information, see: https://www.cdc.gov/vaccines/covid-19/clinical- considerations/interim-considerations-us.html#immunocompromised. 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. **Receipt of the lower dose is no longer authorized.**

Myocarditis or pericarditis after a dose of COVID-19 vaccine

Development of myocarditis or pericarditis within 3 weeks after a dose of any COVID-19 vaccine is a precaution to a subsequent dose of any COVID-19 vaccine, and subsequent doses should generally be avoided. Experts advise that these people should:

- Generally, **not receive** a subsequent dose of any COVID-19 vaccine
- If, after a risk assessment, the decision is made to administer a subsequent COVID-19 vaccine dose, wait until at least their episode of myocarditis or pericarditis has resolved (resolution of symptoms, no evidence of ongoing heart inflammation or sequelae as determined by patient's clinical team)

Considerations for subsequent COVID-19 vaccination might include:

- Myocarditis or pericarditis considered unrelated to vaccination (e.g., due to SARS- CoV-2 or other viruses)
- Personal risk of severe acute COVID-19 (e.g., age, underlying conditions)
- Timing of any immunomodulatory therapies; ACIP's General Best Practice Guidelines for Immunization can be consulted for more information

History of myocarditis or pericarditis that occurred prior to COVID-19 vaccination or more than 3 weeks after a COVID-19 vaccine dose

People who have a history of myocarditis or pericarditis that occurred before COVID-19 vaccination or more than 3 weeks after a COVID-19 vaccine dose may receive any currently FDA-approved or FDA-authorized COVID-19 vaccine after the episode of myocarditis or pericarditis has completely resolved (i.e., resolution of symptoms, no evidence of ongoing heart inflammation or sequelae as determined by the person's clinical team). This includes people who had myocarditis or pericarditis due to SARS-CoV-2 or other viruses.

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For persons who received a COVID-19 vaccine:

- Outside of the United States
- Not currently authorized/approved in the United States
- See clinical guidance, at https://www.cdc.gov/vaccines/covid-19/clinical- considerations/covid-19-vaccines-us.

2024-2025 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

Screen for Contraindications and Precautions**Medical condition or history**	**Guidance**	**Recommended action(s)**
History of a severe allergic reaction* (e.g., anaphylaxis†) after a previous dose or to a component of the COVID-19 vaccine‡	Contraindication	Do not vaccinate with the same COVID- 19 vaccine type. May administer the alternate COVID-19 vaccine type. See Considerations for people with a history of allergies and allergic reactions for additional information.
History of a diagnosed non-severe allergy* to a component of the COVID-19 vaccine‡	Precaution	May administer the alternate COVID-19 vaccine type. For additional information, see Considerations for people with a history of allergies and allergic reactions.
History of a non-severe, immediate (onset less than 4 hours) allergic reaction* after administration of a previous dose of one COVID-19 vaccine type§	Precaution	
Moderate or severe acute illness, with or without fever	Precaution	Defer vaccination until the illness has improved.
History of MIS-C or MIS-A	Precaution	See COVID-19 vaccination and MIS-C and MIS-A.
History of myocarditis or pericarditis within 3 weeks after a dose of **any COVID-19 vaccine**	Precaution	A subsequent dose of any COVID-19 vaccine should generally be avoided. See COVID-19 vaccination and myocarditis and pericarditis.

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
Male260+ lbs.	22-25	1 ½”	Deltoid muscle of arm

Vaccine Administration

- Provide all recipients with a copy VIS https://www.cdc.gov/vaccines/hcp/current-vis/covid-19.html
- Prepare to administer the vaccine. Choose the correct needle gauge, needle length, and injection site for persons:
  - 12years of age:
    - Needle gauge/length: 22-25 gauge, 1-inch.
    - Site: Deltoid muscle of arm.
  - 19years of age and older: See chart.

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- **Follow the manufacturer's guidance for storing/handling punctured vaccine vials.**
- Administer 2024-2025 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 (if applicable): 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/imz-best-practices/preventing-managing-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).

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2024-2025 NOVAVAX COVID-19 Vaccine

Standing Orders for Administering Vaccine

Vaccine	Diluent	Dosage (amount)/Route
12 years old and older (Manufacturer-filled syringe)	DO NOT DILUTE	5mcq SARS-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 (CDC) 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.

- Individuals 12 Years– 64 years of age and older previously vaccinated with any COVID-19 vaccine: administer a single 0.5 mL dose of 2024-2025 Novavax COVID-19 vaccine at least 2 (two) months after receipt of the last previous dose of COVID-19 vaccine.
- Individuals 12 Years-64 years of age and older not previously vaccinated with any COVID-19 Vaccine: administer a series of two doses of 2024-2025 Novavax COVID-19 vaccine (0.5 mL each) 3-8 weeks apart.
- People ages 65 years old and older and previously unvaccinated should receive 2 doses of 2024-2025 Novavax COVID-19 vaccine (0.5 mL each) 3-8 weeks apart§ An additional dose of any 2024-2025 COVID- 19 vaccine (Moderna, Pfizer-BioNTech or Novavax), should be administered at least 6 (six) months (minimum interval 2 months) following the previous dose of 2024-2025 Novavax COVID-19 vaccine.
- People ages 65 years old and older previously vaccinated‡ with 1 or more doses before 2024-2025 vaccine should receive 1 dose of 2024-2025 Novavax COVID-19 vaccine (0.5 mL each) with first dose administered at least 8 weeks after last dose. An additional dose of any 2024-2025 COVID-19 vaccine (Moderna, Pfizer- BioNTech or Novavax), should be administered at least 6 (six) months (minimum interval 2 months) following the previous dose of 2024-2025 Novavax COVID-19 vaccine.

Those who ARE moderately or severely immunocompromised*

- Individuals 12 Years of age and older previously completed the initial series before 2024-2025 vaccine: administer dose 1 (one) 0.5 mL of 2024-2025 Novavax COVID-19 vaccine at least 8 weeks after receipt of the last dose of COVID- 19 vaccine. Administer dose 2 (two) 6 months (minimum interval 2 months) after 2024-2025 dose 1.
- Individuals 12 Years of age and older who previously initiated series with Novavax but did not complete the initial series before 2024–2025 vaccine: Administer dose 1 (one) 0.5 mL of 2024-2025 Novavax COVID-19 vaccine at least 3 weeks after last dose. Administer dose 2 (two) of any 2024-2025 COVID-19 vaccine (Moderna, Pfizer-BioNTech or Novavax) at least 6 months (minimum interval 2 months) after 2024- 2025 dose 1.
- Individuals 12 Years of Age and older not previously vaccinated with any COVID-19 vaccine: administer a series of two doses (0.5 mL each) 3 weeks apart of the 2024-2025 Novavax COVID-19 vaccine. An additional dose of any 2024-2025 COVID-19 vaccine (Moderna, Pfizer-BioNTech or Novavax), should be administered at least 6 (six) months (minimum interval 2 months) following the previous dose of 2024-2025 Novavax COVID-19 vaccine.

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- Additional doses of 2024-2025 COVID-19 (Novavax, Moderna **or** Pfizer-BioNTech) vaccine may be administered at the discretion of the healthcare provider, taking into consideration the individual's clinical circumstances. The timing of the additional doses may be based on the individual's clinical circumstances. For more information, see: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#immunocompromised

‡ People ages 65 years and older who received 1 or more doses of Janssen COVID-19 Vaccine should receive a first dose of any 2024–2025 COVID-19 vaccine followed by a second dose of any 2024–2025 COVID-19 vaccine 6 months (minimum interval 2 months) after the first dose.

- People ages 18 years and older who received 1 or more doses of Janssen COVID-19 Vaccine should receive 1 dose of any 2024–2025 COVID-19 followed by a second dose of any 2024–2025 COVID-19 vaccine 6 months (minimum interval 2 months) after the first dose. Additional doses of any 2024–2025 COVID-19 vaccine may be administered under shared clinical decision-making at least 2 months after last dose of any 2024–2025 vaccine.

Additional Clinical Considerations

- For the patient who has never received a COVID-19 vaccine, 2024-2025 Novavax COVID-19 vaccine should be used for both dose 1 and dose 2 separated by 3 weeks.
  - If a mixed 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 2-dose series with 2024-2025 Novavax COVID-19 vaccine due to a contraindication, any other age-appropriate COVID-19 vaccine may be administered to complete the series. Follow the vaccine interval guidance for those previously vaccinated provided in the Moderna or Pfizer CSG Additional resource: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#contraindications
  - 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.

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

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Precautions

Screen for Contraindications and Precautions

Medical condition or history	Guidance	Recommended action(s)
History of a severe allergic reaction* (e.g., anaphylaxis†) after a previous dose or to a component of the COVID-19 vaccine‡	Contraindication	Do not vaccinate with the same COVID-19 vaccine type. May administer the alternate COVID-19 vaccine type. See Considerations for people with a history of allergies and allergic reactions for additional information.
History of a diagnosed non-severe allergy to a component of the COVID-19 vaccine‡	Precaution	May administer the alternate COVID-19 vaccine type. For additional information, see Considerations for people with a history of allergies and allergic reactions.
History of a non-severe, immediate (onset less than 4 hours) allergic reaction after administration of a previous dose of one COVID-19 vaccine type§	Precaution	
Moderate or severe acute illness, with or without fever	Precaution	Defer vaccination until the illness has improved.
History of MIS-C or MIS-A	Precaution	See COVID-19 vaccination and MIS-C and MIS-A.
History of myocarditis or pericarditis within 3 weeks after a dose of **any COVID-19 vaccine**	Precaution	A subsequent dose of any COVID-19 vaccine should generally be avoided. See COVID-19 vaccination and myocarditis and pericarditis.

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 (if applicable): 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) or “registry”: Report the vaccination to the appropriate state/local IIS, if available.

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

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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)

M**yocarditis 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*).

Sy**ncope**
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 FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE:).

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) (FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE:), 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 (FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE:) conditions for use of an authorized vaccine throughout the duration of the EUA
- Healthcare professionals are encouraged to report to VAERS (https://vaers.hhs.gov):
  - Clinically important adverse events that occur after vaccination, even if you are not sure whether the vaccine caused the adverse event

2024–2025 COVID-19 Vaccine Immunization Schedule for People 6 Months of Age and Older
Staying Up to Date with COVID-19 Vaccines | COVID-19 | CDC

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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

- **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
- **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).
  - Use tetanus and diphtheria vaccine (Td) off-label for children aged <7 years who develop a contraindication to pertussis-containing vaccine *(for more information, visit: (https://www.cdc.gov/pertussis/hcp/vaccine-recommendations/td-offlabel.html?CDC_AAref_Val=https://www.cdc.gov/vaccines/vpd/dtap-tdap-td/hcp/td-offlabel.html)*.
  - If Td is used, follow the same schedule that would be used for DTaP.
  - Children who receive Td in place of DTaP may have sub-optimal protection against diphtheria.
    - 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
- **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.")

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- **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 than12 months	22-25	1”	Anterolateral thigh muscle
12 through 35 months	22-25	⅝**-1” 1-1 ¼”	Anterolateralthigh muscle* or deltoid muscle of arm
3 through 6 years	22-25	⅝**-1” 1-1 ¼”	Anterolateralthigh muscle or deltoid muscle of arm*

*Preferred site.

** A ⅝” 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.

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

VACCINEAND DOSE NUMBER	RECOMMENDED AGE FOR THIS DOSE	MINIMUMAGE FOR THIS DOSE	RECOMMENDED INTERVAL TO NEXT DOSE	MINIMUM INTERVALTO 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	MINIMUMINTERVAL BETWEEN DOSES OF DTAPVACCINE 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				5 months[3]

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

2- 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.

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- **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.
- **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 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://vaers.hhs.gov/ event.html. Further assistance is available at (800) 822-7967.

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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.

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- 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 of DTaP to dose 5 using Kinrix 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 Gauge	Needle Length	Vaccine Site
4-6 years old	22-25	⅝"*-1"	Deltoid muscle of arm (preferred)

* ⅝" may be used 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 at 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 the next visit.

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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

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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 whose previous DTaP vaccine doses have been with Pentacel, DAPTACEL, and/or VAXELIS 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:
    - 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 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

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given, see section 6 titled “Document Vaccination.”)

Dosage and Route

- Just before use, shake the vial well, until a uniform, white, cloudy suspension results. Administer Quadracel® vaccine 0.5 mL intramuscularly (IM) into the deltoid muscle of the upper arm. Quadracel should not be combined through reconstitution or mixed with any other 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.

Age	Needle Gauge	Needle Length	Preferred Site
Children 4-6 years old	22-25	5/8*-1”	Deltoid muscle of arm

* ⅝” may be used If the skin is stretched tightly and the subcutaneous tissues are not bunched.

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.

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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

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- **Precautions**
  - In clinical trials, PEDIARIX was associated with higher rates of fever, relative to separately administered vaccines.
  - If Guillain-Barré syndrome occurs within 6 weeks of receipt of a prior vaccine containing tetanus toxoid, the decision to give PEDIARIX should be based on potential benefits and risks.
  - Syncope (fainting) can occur in association with administration of injectable vaccines, including PEDIARIX. 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 PEDIARIX 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 PEDIARIX.
  - Apnea following intramuscular vaccination has been observed in some infants born prematurely. Decisions about when to administer an intramuscular vaccine, including PEDIARIX, 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

- 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. Per ACIP guidance, PEDIARIX may be used in infants born to women whose HBsAg status is positive or unknown beginning no earlier than age 6 weeks. 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.
- DTaP-HepB-IPV can be administered simultaneously with other vaccines given at separate injection sites. Please refer to the section below on **Adverse Events** for additional information.

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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*

*16 weeks from Dose 1 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

- Shake vigorously to obtain a homogeneous, turbid, white suspension. Do not use if resuspension does not occur with vigorous shaking. Give **PEDIARIX®** vaccine 0.5 mL intramuscularly (IM). Do not administer this product intravenously, intradermally, or subcutaneously.
- **Always check the package insert prior to administration of any vaccine**.

Anatomical Site

The preferred administration site is the anterolateral aspect of the thigh for children younger than 1 year. In older children, the deltoid muscle is usually large enough for an intramuscular injection. The vaccine should not be injected in the gluteal area or areas where there may be 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"**:**

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- 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.

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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 (e.g., 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.

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- 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. When Pentacel is administered at ages 2, 4, 6, and 15-18 months, an additional booster dose of IPV vaccine should be administered at age 4-6 years, resulting in a 5-dose IPV series. 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

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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.

Reconstitutionof Freeze-Dried Product and Withdrawal from Stoppered Vial

- Gently shake the vial of DTaP-IPVcomponent
- 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.
- Gently swirl the vial now containing Pentacel until a cloudy, uniform, white to off-white (yellow tinge) suspension results. 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.

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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.

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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

- **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.)*
- **Screen for contraindications and precautions**

Contraindications

- Do not give HepA vaccine 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).

Precautions

- Moderate or severe acute illness with or without fever

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**

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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	⅝*-1” 1-1 ¼”	Anterolateralthigh muscle** Deltoid muscle of arm
Children (3-10 years)	22-25	⅝*-1” 1-1 ¼”	Deltoid muscle of arm** Anterolateral thigh muscle
Adolescents and Teens (11-18years)	22-25	⅝*-1” 1-1 ½ “	Deltoid muscle of arm** Anterolateral thigh muscle

* A ⅝ " 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.

- **Administer HepA 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 through 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 months	Healthy	1 dose[2]	None
1 through 18 years	Healthy&notpreviously vaccinated	1 dose	None
All ages ≥12 months	Immunocompromised &not previously vaccinated	1 dose	0.1 or 0.2 mL/kg[1]

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FOOTNOTES

- 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 months' 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. Because IG might interfere with live virus vaccines, when MMR or varicella vaccine is indicated, give at least 2 weeks before giving IG or at least 6 months after giving IG.
- A dose given at age 6–11 months does not count toward the routine 2-dose series given after the first birthday.

- **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.

- **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 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.

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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 aged 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),
- **Precautions**
  - Moderate or severe acute illness with or without fever

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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 Weightof Patients	**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 152–200 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 ⅝ " 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 HepA Vaccine

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

History of Previous HepA Vaccination	**Dose and Schedule for Administration of HepA**
0documenteddoses,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.

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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 travel of >2 months duration) may also be administered simultaneously at a separate anatomic 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.

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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**
  - Th○e 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

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- 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

- Standard dosing schedule consists of 3 doses (1-mL each), given intramuscularly at 0, 1, and 6 months. Alternatively, an accelerated schedule of 4 doses (1-mL each), given intramuscularly on Days 0, 7, and 21 to 30 followed by a booster dose at Month 12 may be used.

Dosage and Route

- Suspension for injection available in 1-mL prefilled TIP-LOK syringes
- The vaccine should be re-suspended before use. When re-suspended, the vaccine will have a uniform hazy white appearance.
- TWINRIX should be administered by intramuscular injection only as a 1-mL dose. Administer in the deltoid region. Do not administer in the gluteal region; such injections may result in a suboptimal response.
- Attach a sterile needle to the prefilled syringe and administer intramuscularly.
- Do not administer this product intravenously, intradermally, or subcutaneously.

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*:*

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        - 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.

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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 https://www.cdc.gov/pinkbook/hcp/table-of-contents/chapter-10-hepatitis-b.html#cdc_report_pub_study_section_8-hepatitis-b-vaccine 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.")

1. **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
Newborns (1st 28 days)	22-25	⅝"	Anterolateral thigh muscle
Infants (1-12 months)	22-25	1"	Anterolateral thigh muscle
Toddlers (1-2 years)	22-25	⅝*-1" 1-1¼"	Anterolateral thigh muscle** Deltoid muscle of arm

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Children (3-10 years)	22-25	⅝*-1” 1-1 ¼ “	Deltoid muscle of arm** Anterolateral thigh muscle
Adolescents and Teens (11-18 years)	22-25	⅝*-1” 1-1 ½ “	Deltoid muscle of arm** Anterolateral thigh muscle

* A ⅝ " 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.

2. **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	RECOMMENDEDAGE FOR THIS DOSE	MINIMUM AGE FOR THIS DOSE	RECOMMENDEDINTERVAL TO NEXT DOSE	MINIMUM INTERVAL TO NEXT DOSE
Hep B #1	Birth	Birth	4 weeks–4 months	4 weeks
Hep B #2	1–2 months	4 weeks	8 weeks–17 months	8 weeks[2]
Hep B #3	6–18 months	24 weeks		

Schedule for catch-up vaccination

NUMBER OF PRIOR DOCUMENTED DOSES	MINUMUMAGE FOR DOSE 1	MINUMUM INTERVAL BETWEEN DOSESOF 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	8weeks and at least 16 weeks between Dose 1 and Dose 3[2]
1		4 Weeks	8 weeks and at least 16 weeks between Dose 1 and Dose 3[2]
2			8weeks and at least 16 weeks between Dose 1 and Dose 3[2]

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.

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3. 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.

4. 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.

5. 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.

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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 aged 19 through 59 years
  - All adults aged 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.

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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 https://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 https://www.cdc.gov/pinkbook/hcp/table-of-contents/chapter-10-hepatitis-b.html#cdc_report_pub_study_section_8-hepatitis-b-vaccine).
- ***Precautions***
  - Moderate or severe acute illness with or without fever
  - ***Pregnancy***
  - Pregnancy testing is not needed before vaccination; however, data on 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, Heplisav-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	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	1"*–1½"	Anterolateral thigh

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

- ⅝" need for patients weigh less than 130 lbs. (<60 kg)

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- 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

HISTORYOF 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-B[1,2]	Schedule for administration of Engerix- B, Recombivax HB, or PreHevbrio[1,2]
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, 6-month schedule. The safety and effectiveness of Heplisav-B and PreHevbrio have not been established in adults on hemodialysis.
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.

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- 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.

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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 https://www.cdc.gov/pinkbook/hcp/table-of-contents/index.html?CDC_AAref_Val=https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.
- Do not give ActHIB (Sanofi), Hiberix (GSK), or Pedvax HIB (Merck) to a child or teen who has a history of a severe allergic reaction to dry natural latex.
- Do not give Hib vaccine to an infant younger than age 6 weeks.

Precaution

- Moderate or severe acute illness with or without fever

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.")

3. **Prepare to Administer Vaccine**

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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 weeks-11 months)	22-25	1”	Anterolateral thigh muscle
Toddlers (1-2 years)	22-25	⅝*-1” 1-1 ¼”	Anterolateral thigh muscle** Deltoid muscle of arm
Children (3-10 years)	22-25	⅝*-1” 1-1 ¼”	Deltoid muscle of arm** Anterolateral thigh muscle
Adolescents and Teens (11-18years)	22-25	⅝*-1” 1-1 ½ “	Deltoid muscle of arm** Anterolateral thigh muscle
Adolescents and Teens (11-18years)	22-25	⅝*-1” 1-1 ½ “	Deltoid muscle of arm** Anterolateral thigh muscle

** Preferred site.

* A ⅝” 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.

4. **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 ADMINISTRATIONOF HIB VACCINE
0 documented doses, or none known	Younger than age 1 year	Follow schedule as per above.
0 documented doses, or none known	12 through 59 months	Give dose #1, followed by final dose in 8 weeks. (no more)
1dosebeforeage 1 year		Give dose #2 at least 8 weeks after dose #1. (no more)
2 doses before age 1 year		Give dose #3 at least 8 weeks after dose #2. (no more)

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c. Schedule for catch-up vaccination of children with certain medical conditions[2] Note: Children younger than age 12 months with special medical conditions should follow routine Hib vaccination recommendations (see 5a above).

MEDICAL CONDITION OR PROCEDURE	AGE AND VACCINATION HISTORY		
	CHILDRENAGED 12–59 MONTHS WHO ARE UNVACCINATED[2] OR HISTORY OF ONLY 1 DOSE	CHILDREN AGE12–59 MONTHS WITH HISTORY OF 2 OR MORE DOSES	CHILDREN AGED 5 YEARS OR OLDER WHO ARE UNVACCINATED[2]
Functional or anatomic asplenia	Give2doses, 8 weeks apart.	Give 1 dose at least 8 weeks after previous	Give 1 dose
HIV-infected	Give2doses, 8 weeks apart.	Give 1 dose at least 8 weeks after previous	Give 1 dose
Immunoglobulin deficiency, early component complement deficiency	Give2doses, 8 weeks apart.	Give 1 dose at least 8 weeks after previous	
Chemotherapy or radiation therapy[3]	Give2doses, 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 Hiberix, GSK) are given as a 3-dose primary series (age 2, 4, and 6 mos) with a booster at age 12–15 mos. PedvaxHIB o r V ax el i s is preferred for American Indian/Alaska Native infants.

[2] Children who have not received a primary series and booster or at least 1 dose of Hib vaccine 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**.

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). 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.

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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 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/ Further assistance is available at (800) 822-7967.

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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 (prior to 5th birthday) 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.")

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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), https://www.cdc.gov/pinkbook/hcp/table-of-contents/chapter-8-haemophilus-influenzae.html?CDC_AAref_Val=https://www.cdc.gov/vaccines/pubs/pinkbook/hib.html

Dosage and Route

- Administer HIBERIX vaccine 0.5 mL intramuscularly (IM) after reconstitution using only the accompanying saline diluent.

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 Gauge	Needle Length	Injection Site
Infants Ages 6 weeks - 11 months	22-25	1”	Anterolateral Thigh Muscle
Toddler 1-2 years	22-25	1–1¼"	Anterolateral Thigh Muscle**
	22-25	⅝ *-1”	Deltoid muscle of arm
Children 3-4 years	22-25	⅝ *-1”	Deltoid muscle of arm**
	22-25	1–1¼"	Anterolateral Thigh Muscle

* A ⅝” 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.

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.

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- 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.

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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 https://www.cdc.gov/vaccine-safety/vaccines/hib.html
- ***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.")

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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	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

*Preferred site.

** A ⅝" 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 https://www.immunize.org/wp-content/uploads/catg.d/p3082.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.

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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.

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Standing Order 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 a 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)

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	⅝**-1" 1-1 ¼ ''	Deltoid muscle of arm* Anterolateral thigh muscle
11 through 18 years	22-25	⅝**-1" 1-1 ½ ''	Deltoid muscle of arm* Anterolateral thigh muscle

* Preferred site.

**A ⅝" needle may be used for children for IM injection in the deltoid muscle only if the skin is stretched right, the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle.

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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[1,2]	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 15 years	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

https://www.cdc.gov/pinkbook/hcp/table-of-contents/chapter-11-human-papillomavirus.html#cdc_report_pub_study_section_9-contraindications-and-precautions-to-vaccination

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:

GENDERAND 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	1–1 ½"	Deltoid muscle of arm
Male 153–260 lbs	22–25	1–1 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

* 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° angle to the skin.

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 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 (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

- **Review package insert.**
- **Assess Adults for Need of Vaccination against Influenza**
- All adults 18 years and older are recommended to receive influenza vaccination each year.
- Adults aged 65 and older should preferentially receive any one of the following higher doses or adjuvanted influenza vaccines: trivalent high-dose inactivated influenza vaccine (HD-IIV3-Fluzone) or trivalent adjuvanted IIV (aIIV3, Fluad). If none of these three vaccines are 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 (IIV3) or RIV3 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- can be found at https://www.cdc.gov/vaccines/hcp/imz-best-practices/timing-spacing-immunobiologics.html?CDC_AAref_Val=https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/timing.html or https://www.immunize.org/catg.d/p2030.pdf
- **Screen for Contraindications and Precautions**

Not a contraindication or precaution

ACIP and CDC do not consider egg allergy of any severity to be a contraindication or a precaution to administration of any influenza vaccine (egg-based or non-egg-based). People with any type of egg allergy may receive any IIV, RIV, or live attenuated influenza vaccine (LAIV) that is otherwise appropriate for their age and health status. Safety measures beyond those recommended for receipt of any vaccine are not recommended.

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.

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- 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 LAIV only

- Do not give LAIV to a person who:
  - is pregnanth as 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 50years 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 LAIV, revaccinate with IIV or RIV;
  - 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 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 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 (of any valency) Associated with Previous Serious or Anaphylactic Reaction	**Available 2024-2025 Influenza Vaccines**		
	Egg-Based IIVs and LAIV	**ccIIV**	**RIV**
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 ccIIV and RIV 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.

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Precautions for use of LAIV 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])
- **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	1–1 "	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 **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.

Manufacturer	Trade Name (vaccine abbreviation)[1]	How Supplied	Mercury Content (mcg Hg/0.5mL)	Age Range	CVX Code	Vaccine Product Billing Code[2] CPT
AstraZeneca	FluMist (LAIV3)	0.2 mL (single-use nasal spray)	0	2 through 49 years	111	90660
GSK	Fluarix (IIV3)	0.5 mL (single-dose syringe)	0	6 months & older[3]	140	90656
	FluLaval (IIV3)	0.5 mL (single-dose syringe)	0	6 months & older[3]	140	90656
Sanofi	Flublok (RIV3)	0.5 mL (single-dose syringe)	0	18 years & older	155	90673
	Fluzone (IIV3)	0.5 mL (single-dose syringe)	0	6 months & older[3]	140	90656
		0.5 mL (single-dose vial)	0	6 months & older[3]	140	90656
		5.0 mL multi-dose vial (0.25 mL dose)	25	6 through 35 months[3]	141	90657
		5.0 mL multi-dose vial (0.5 mL dose)	25	6 months & older	141	90658
	Fluzone High-Dose (HD-IIV3)	0.5 mL (single-dose syringe)	0	65 years & older[4]	135	90662
CSL Seqirus	Afluria (IIV3)	5.0 mL multi-dose vial (0.25 mL dose)	24.5	6 through 35 months[3]	141	90657
		5.0 mL multi-dose vial (0.5 mL dose)	24.5	3 years & older[5]	141	90658
		0.5 mL (single-dose syringe)	0	3 years & older[3]	140	90656
	Fluad (aIIV3)	0.5 mL (single-dose syringe)	0	65 years & older[4]	168	90653
	Flucelvax (ccIIV3)	0.5 mL (single-dose syringe)	0	6 months & older[3]	153	90661
		5.0 mL multi-dose vial (0.5 mL dose)	25	6 months & older[3]	320	90661

NOTES

1. All 2024–2025 seasonal influenza vaccines are trivalent. IIV = egg-based inactivated influenza vaccine (injectable); where necessary to refer to cell culture-based vaccine, the prefix "cc" is used (e.g., ccIIV); RIV = recombinant hemagglutinin influenza vaccine (injectable); aIIV = adjuvanted inactivated influenza vaccine.
2. An administration code should always be reported in addition to the vaccine product code. Note: Third party payers may have specific policies and guidelines that might require providing additional information on their claim forms.
3. Dosing for infants and children age 6 through 35 months:
   - Afluria 0.25 mL
   - Fluarix 0.5 mL
   - Flucelvax 0.5 mL
   - FluLaval 0.5 mL
   - Fluzone 0.25 mL or 0.5 mL
4. Solid organ transplant recipients age 18 through 64 years who are on immunosuppression medication regimens may receive HD-IIV influenza vaccine as options for influenza vaccination, without a preference over other age-appropriate IIVs or RIVs.
5. Afluria is approved by the Food and Drug Administration for intramuscular administration with the PharmaJet Stratis Needle-Free Injection System for persons age 18 through 64 years.

Immunize.org

FOR PROFESSIONALS www.immunize.org / FOR THE PUBLIC www.vaccineinformation.org

www.immunize.org/catg.d/p4072.pdf
Item #P4072 (7/30/2024)

Scan for 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.
  - 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.

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- **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. For Immunize.org's Medical Management of Vaccine Reactions in Adults in a Community Setting, go to https://www.immunize.org/wp- content/uploads/catg.d/p3082.pdf. For Immunize.org's Medical Management of Vaccine Reactions in Children and Teens in a Community Setting, go to https://www.immunize.org/wp-content/uploads/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 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.

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Administering Influenza Vaccine to Children and Adolescents

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

Review package insert

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 aged 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 https://www.cdc.gov/vaccines/hcp/imz-best-practices/timing-spacing-immunobiologics.html?CDC_AAref_Val=https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/timing.html.
- IIV or RIV may be administered at any time before, after, or simultaneously with other recommended vaccines. Live attenuated influenza vaccine (LAIV) may be administered without regard to timing of non-live vaccines but should be administered on the same day or at least 4 weeks apart from another injectable vaccine.

Screen for Contraindications and Precautions

Not a contraindication or precaution

ACIP and CDC do not consider egg allergy of any severity to be a contraindication or a precaution to administration of any influenza vaccine (egg-based or non-egg-based). People with any type of egg allergy may receive any IIV, RIV, or live attenuated influenza vaccine (LAIV) that is otherwise appropriate for their age and health status. Safety measures beyond those recommended for receipt of any vaccine are not recommended.

Contraindications for use of all influenza vaccines

- Do not give any egg-based inactivated influenza vaccine (IIV) 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 ccIIV 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.

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- Do not give any RIV to a teen age 18 years or older who has experienced a serious systemic or anaphylactic reaction to any component of RIV or to a prior dose of RIV.
- Do not give any LAIV 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).

Additional contraindications for use of LAIV only

Do not give LAIV 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* LAIV, revaccinate with IIV or RIV.
- 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 (of any valency) Associated with Previous Serious or Anaphylactic Reaction	**Available 2024-2025 Influenza Vaccines**		
	Egg-Based IIV and LAIV	**ccIIV**	**RIV**
Any Egg-Based IIV Or LAIV	Contraindication	Precaution*	Precaution*
Any ccIIV	Contraindication	Contraindication	Precaution
Any RIV	Precaution	Precaution*	Contraindication
Unknown Influenza Vaccine	Allergist Consultation Recommended		

* Use of ccIIV and RIV 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.

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Precautions for use of LAIV 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])

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 aged 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.

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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 (IIV)	6–35 months	Afluria: 0.25 mL Fluarix: 0.5 mL Flucelvax: 0.5 mL 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 (IIV)	3 years and older	0.5 mL	Intramuscular (IM)	Administer vaccine in deltoid muscle or, alternatively, in anterolateral thigh muscle.
Recombinant influenza vaccine (RIV)	18 years and older	0.5 mL	Intramuscular (IM)	Administer vaccine in deltoid muscle.
Live attenuated influenza vaccine (LAIV)	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.
Adjuvanted IIV (aIIV)	SOTR and 18 years and older[‖]	0.5 mL	Intramuscular (IM)	Administer vaccine in deltoid muscle.
High-dose IIV (HD-IIV)	SOTR and 18 years and older[‖]	0.5 mL	Intramuscular (IM)	Administer vaccine in deltoid muscle.

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.

‖ A solid organ transplant recipient (SOTR) age 18 years or older who is on an immunosuppressive medication regimen may receive either HD-IIV or aIIV without a preference over other IIVs or RIV.

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 (if used)** Record the date of vaccination and the name/location of the administering clinic.
- ***Imm*unization 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.

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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 aged 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 https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/common-ingredients-fda-approved-vaccines.

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.

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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	⅝*-1” 1-1 ¼”	Anterolateral thigh muscle** Deltoid muscle of arm
Children (3-10 years)	22-25	⅝*-1” 1-1 ¼”	Deltoid muscle of arm** Anterolateral thigh muscle
Adolescents and Teens (11-18 years)	22-25	⅝*-1” 1-1 ½ “	Deltoid muscle of arm** Anterolateral thigh muscle

** Preferred site.

* A ⅝ " 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	⅝ "	Fatty tissue over triceps or fatty tissue over anterolateral thigh

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[1] DOSE
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.

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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[2,3]
Unknown	4 weeks	4 weeks	6 months
0	4 weeks	4 weeks	6 months
1	4 weeks	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. This excludes people whose 4th dose was administered prior to August 6, 2009.

[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.

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 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)

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 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 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 Vaccine Adverse Event Reporting System (VAERS) Further assistance is available at (800) 822-7967.

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Standing Orders for Polio Vaccination for Adults

Purpose: To reduce morbidity and mortality from poliomyelitis by vaccinating all persons who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP), the Food and Drug Administration (FDA) product labeling.

Policy: Under these standing orders, eligible nurses and other health care professionals working within their scope of practice may vaccinate patients who meet the criteria below.

Procedure:

1. Identify persons ≥18 years of age in need of vaccination against poliovirus based on the following criteria:
   - Routine poliovirus vaccination of adults in the United States is not necessary. Most adults have a minimal risk for exposure to polioviruses and are immune as a result of childhood vaccination. Vaccination is recommended for certain adults who are at greater risk for exposure to polioviruses than the general population, including the following:
   - Travelers who are going to countries where polio is epidemic or endemic (For additional information, see Polio Vaccination for International Travelers | Polio | CDC)
   - Laboratory and healthcare workers who handle specimens that might contain polioviruses.
   - Healthcare workers or other caregivers who have close contact with a person who could be infected with poliovirus.
   - Unvaccinated or incompletely vaccinated adults whose children will be receiving oral poliovirus vaccine (for example, international adoptees or refugees).
   - Unvaccinated or incompletely vaccinated adults living or working in a community where poliovirus is circulating.

Note: *Receipt of the primary series of IPV may be assumed unless there is a reason to believe otherwise (e.g., childhood spent in a developing country, childhood immunizations not received, etc.)

2. Screen all patients for contraindications and precautions to inactivated polio vaccine (IPV):

Contraindications:

- A history of a serious reaction (e.g., anaphylaxis) after a previous dose of IPV or to a vaccine component (to include neomycin, streptomycin, or polymyxin B)
- For information on vaccine components, refer to the manufacturer's package insert or go to Table of Contents | Pink Book | CDC

Precautions:

- Moderate or severe acute illness with or without fever
- Syncope (fainting) can occur in association with administration of injectable vaccines. Procedures should be in place to avoid a falling injury (e.g., 15 minute observation after administration)

3. Provide all patients (or their parent/legal representative) with a copy of the most current federal Vaccine Information Statement (VIS). You must document, in the patient's medical record, 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 available and preferred.

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4. Provide IPV as follows:
   - Unvaccinated adults: a 3-dose series (0, 1-2 and 6-12 months)
     - Administer 0.5mL intramuscularly in the deltoid muscle for adults
   - Adults who are incompletely vaccinated (previously received one or two doses of either IPV or tOPV) and who are at increased risk of exposure to poliovirus administer the remaining doses of IPV to complete the three-dose series at the recommended interval:
     - If the adult has received Dose 1, and
     - It has been ≥4 weeks since Dose 1, then give Dose 2 today. Dose 3 (final) should be given at least 6 months after Dose 2.
     - It has been <4 weeks since Dose 1, then wait to give Dose 2 at least 4 weeks after Dose 1.
     - If the adult has received Dose 2 and It has been ≥ 6 months since Dose 2, then give Final Dose 3 today.
     - This will complete the person's primary polio vaccination series.
     - It has been <6 months since Dose 2, then wait to give Final Dose 3 at least 6 months after Dose 2.
   - Adults who have had three or more doses of polio vaccine in the past and are at increased risk – of exposure to poliovirus may get one lifetime booster dose of IPV.
   - In some circumstances, when there is not enough time to give three doses of IPV according to the above recommended intervals, then an accelerated schedule can be used:
     - If protection is needed in ≥8 weeks, three doses of IPV can be administered at least 4 weeks apart (e.g., at weeks 0, 4, and 8).
     - If protection is needed in ≥4 but <8 weeks, two doses of IPV should be administered at least 4 weeks apart (e.g., at weeks 0 and 4).
     - If protection is needed in fewer than 4 weeks, a single dose of IPV should be administered.

- Resource: https://www.cdc.gov/vaccines/vpd/polio/hcp/recommendations.html

Needle Length and Injection Site of IM Injections for Adults		
Use a 22 – 25-gauge needle. Choose needle gauge and length appropriate to administration route and the patient's age and body mass.		
Age Group	**Needle Length**	**Injection Site**
Men and Women (<130 lbs)	1 inch†	Deltoid Muscle of Arm
Men and Women (130-152 lbs)	1 inch	
Men (152-260 lbs)	1-1.5 inches	
Women (152-200 lbs)		
Men (> 260 lbs)	1.5 inches	
Women (>200 lbs)		

Adapted from General Best Practice Guidelines for Immunization: Vaccine Administration https://www.cdc.gov/vaccines/hcp/imz-best-practices/vaccine-administration.html?CDC_AAref_Val=https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/administration.html

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† Some experts recommend a ⅝ inch needle for men and women who weigh <130 lbs, skin must be stretched tightly (do not bunch subcutaneous tissue)

5. Document all immunizations administered in the patient's electronic health record andthe appropriate immunization tracking system. Include date, immunization given, dose, anatomical location of administration, lot number, manufacturer, Vaccine Information Sheet (VIS) date, and the identification of the person administering the vaccine. If vaccine was not given, record the reason for non-receipt.

6. Be prepared to manage a medical emergency related to the administration of vaccines by having a written emergency medical protocol available, as well as equipment and medications.

7. Adverse events occurring after administration of any vaccine should be reported to the Vaccine Adverse Event Reporting System (VAERS). Reports can be submitted to VAERS online, by fax, or by mail. Additional information about VAERS is available by telephone (800-822-7967) or online at https://vaers.hhs.gov.

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Protocol for Administration of JYNNEOS Adults 18 Years of Age and Older Children 6 months of age to 18 years old

JYNNEOS Standing Orders for Administering Vaccine

Vaccine	Dosage (Amount) Route
JYNNEOS	**Adults and children assessed need for Mpox vaccination who have been never vaccinated against *smallpox* or do not recall receiving a *smallpox vaccine*:** • **Recommended: 0.5mL subcutaneous 2 doses 4 weeks (28 days) apart** **Adults ONLY** • **Alternative Regimen: 0.1mL intradermal 2 doses 4 weeks (28 days) apart**

Purpose: JYNNEOS is a vaccine indicated for prevention of smallpox and monkeypox disease in adults AND children 6 months of age and older determined to be at high risk for smallpox or monkeypox infection.

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 for Need of Vaccination** against smallpox and monkeypox based on current guidance provided by CDC and state or local public health authorities. Refer to Interim Clinical Considerations for Use of JYNNEOS and ACAM2000 Vaccines during the 2022 U.S. Monkeypox Outbreak- Monkeypox – Poxvirus- CDC for current CDC guidance.
- ***Healthcare professionals must monitor this website for updates and comply with any such posted updates.*** https://www.cdc.gov/mpox/?CDC_AAref_Val=https://www.cdc.gov/poxvirus/mpox/vaccines/vaccine-recommendations.html
- **Screen for Contraindications and Precautions**
  - Contraindications:
    - Severe allergic reaction (e.g., anaphylaxis) after a previous dose of JYNNEOS vaccine or any of its components.
  - Precautions:
    - Moderate or severe acute illness with or without fever.

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.

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Preparation and Administration

- Allow the vaccine to thaw and reach room temperature before use. Once thawed, the vaccine may be kept at +2°C to +8°C (+36°F to +46°F) for 12 hours. Do not refreeze.
- When thawed, JYNNEOS is a milky, light yellow to pale white colored suspension.
- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. If either of these conditions exists, the vaccine should not be administered.
- Swirl the vial gently before use for at least 30 seconds. Withdraw appropriate dose into a sterile syringe for injection.

Prepare to Administer the Vaccine

- **Follow the manufacturer's guidance for storing/handling punctured vaccine vials.**
- For individuals with a history of keloid scarring, administer the vaccine via the subcutaneous route.
- **STANDARD REGIMEN FOR ADULTS AND CHILDREN**
- Administer JYNNEOS by subcutaneous (sq) injection.
- 0.5 mL for all doses
- Choose the correct needle gauge, needle length, and injection site for persons:
- 5/8th inch needle, 23-25 gauge inserted at a 45-degree angle
- Administer posterior upper arm (preferred site) for individuals 12 months and older
- Administer anterolateral thigh for people younger than the age of 12 months.
- **UNVACCINATED**: Give a 2-dose series. Dose 1 now. Administer Dose 2 at least 4 weeks (28 days) after Dose 1
- **1 PREVIOUS DOSE OF JYNNEOS**-Give dose 2 at least 4 weeks (28 days) after Dose 1
- **ALTERNATIVE REGIMEN (ADULTS ONLY)**
- Administer JYNNEOS by intradermal (ID) injection
    - ml for all doses
- Choose the correct needle gauge, needle length and injection site for persons:
- ¼ inch needle 25-27 gauge inserted at @ 5-15 degree angle with the bevel facing up

Administer inner surface of forearm or the upper back under the scapula.

https://www.cdc.gov/mpox/hcp/vaccine-considerations/intradermal-administration.html?CDC_AAref_Val=https://www.cdc.gov/poxvirus/mpox/interim-considerations/jynneos-ID.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 card: Date of vaccination, product name/manufacturer, lot number, and

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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 for 30 minutes.

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/translations/ (For information about how to document that the VIS was given, see section 5 titled “Document Vaccination.

Report Adverse Events to VAERS

The Vaccine Adverse Event Reporting System (VAERS) is the nation’s early warning system that monitors the safety of vaccines after they are authorized or licensed for use by the U.S. Food and Drug Administration. VAERS accepts and analyzes reports of adverse events following vaccination. The following requirements are stipulated as part of the HHS Mpox vaccine provider agreement:

- For JYNNEOS vaccine administered under the HHS Mpox Vaccination Program Provider Agreement, the vaccination provider is responsible for mandatory reporting of the following listed events after JYNNEOS vaccination to VAERS**:**

  » Vaccine administration errors, whether or not associated with an adverse event

  » Serious* adverse events (irrespective of attribution to vaccination)

  » Cases of cardiac events, including myocarditis and pericarditis

  » Cases of thromboembolic events and neurovascular events

*Serious adverse events are defined as:

  - Death
  - A life-threatening adverse event
  - Inpatient hospitalization or prolongation of existing hospitalization
  - A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
  - A congenital anomaly/birth defect
  - An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above

- Providers are encouraged to also report to VAERS any additional clinically significant adverse events following vaccination, even if they are not sure if vaccination caused the event.
- When submitting a VAERS report, ensure that you document the Route of Vaccination in Section 17 of the VAERS form (e.g., ‘’subcutaneous”) from the selection menu.

For information on how to submit a report to VAERS, visit VAERS—Report an Adverse Event (hhs.gov) or call 1-800-822-7967

Pregnancy

Available human data on JYNNEOS administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy

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Lactation

Data are not available to assess the effects of JYNNEOS in the breastfed infant or on milk production/excretion.

For more information:

- Mpox Vaccination Basics : Mpox Vaccination | Mpox | CDC
- Mpox Vaccine Recommendations: Interim Clinical Considerations for Use of Vaccine for Mpox Prevention in the United States | Mpox | CDC
- Mpox Vaccination: https://www.cdc.gov/mpox/hcp/vaccine-considerations/vaccination-overview.html?CDC_AAref_Val=https://www.cdc.gov/poxvirus/mpox/interim-considerations/overview.html

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STANDING ORDERS FOR

Measles IGIM (GamaSTAN)

Purpose

- To reduce morbidity and mortality from measles

Policy

- Where allowed by state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess the need for and provide intramuscular immunoglobulin (IGIM)
- **Review the package insert prior to administration and confirm storage and handling guidance**

Procedure

- **Assess Children in Need for IGIM**
  - IG administered intramuscularly (IGIM) is recommended for infants <12 months of age
- IG administered intravenously (IGIV) for severely immunocompromised persons and pregnant women who are exposed to measles.
- For infants 6 through 11 months of age, MMR vaccine can be given in place of IG, if administered within 72 hours of exposure.
  - IGIM can be given to other persons who do not have evidence of measles immunity, but priority should be given to persons exposed in settings with intense, prolonged, close contact (e.g., household, daycare, classroom). However, postexposure use of IGIM might be limited because of volume limitations; persons who weigh >30 kg will receive less than the recommended dose and will have lower titers than recommended.
  - PEP should only be given to a person without any evidence of immunity. Acceptable evidence of immunity (for purposes of PEP decision making) includes at least one of the following:
- One or more documented doses of live measles virus-containing vaccine administered on or after the first birthday for children and adults who are not severely immunocompromised; or
- Laboratory evidence of immunity; or
- Birth before 1957 regardless of nationality; or
- Laboratory evidence of disease.
- *NOTE:*
  - *After receipt of IG, individuals cannot return to health care settings. In other settings such as childcare, school, or work, factors such as immune status, intense or prolonged contact, and presence of populations at risk, should be taken into consideration before allowing these individuals to return. These factors may decrease the effectiveness of IG or increase the risk of disease and complications depending on the setting to which they are returning*.
  - Receipt of MMR after IG or IG after MMR:
- MMR after IG: Any susceptible person exposed to measles who received IG should subsequently receive MMR vaccine provided the person is 12 months of age or older and the vaccine is not otherwise contraindicated. MMR vaccine should be administered:
- No earlier than 6 months after IGIM administration
- No earlier than 8 months after IVIG administration

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Screen for Contraindications and Precautions

- **Contraindications**
  - IG should not be given to people with immunoglobulin A (IgA) deficiency. Persons with IgA deficiencies have the potential for developing antibodies to IgA and therefore could experience an anaphylactic reaction when IG is administered.
  - IGIM should not be administered to persons with severe thrombocytopenia or any coagulating disorder that would contraindicate intramuscular injections.
  - Anaphylactic or severe systemic hypersensitivity reactions to Immune Globulin (Human).
  - Do not give GamaSTAN and measles vaccine at the same time.
  - IGIM is not indicated for persons who have received 1 dose of measles-containing vaccine at age ≥12 months, unless they are severely immunocompromised.
- **Precautions**
  - Administer GAMASTAN cautiously to patients with a history of prior systemic allergic reactions following the administration of human immunoglobulin preparations. Have epinephrine available for treatment of acute allergic symptoms, should they occur.

Prepare to Administer Vaccine

- Administer 0.5 mL/kg of intramuscular IG (IGIM) in the anterolateral aspect of the upper thigh(s).
  - *Do not follow package inserts that indicate a 0.25 mL/kg dose as this lower dose does not reflect current ACIP recommendations*.
- Do not administer more than 3mL of IGIM per injection site; for infants and children weighing >6 kg, multiple injections are required.
- The maximum total dose per IGIM administration is 15 mL.
  - Note: Persons weighing >30 kg (66 lbs) who receive IGIM are unlikely to receive an effective dose and will still be recommended exclusion and social distancing; IVIG can be used, but only in special situations.

- 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

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:

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- Record the date of vaccination and the name/location of the administering clinic.

Be Prepared to Manage Medical Emergencies

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

Additional Tools

CHFS Measles IG Protocol https://www.chfs.ky.gov/agencies/dph/dehp/idb/Documents/Measles_PEP.pdf

Centers for Disease Control and Prevention (2013, June 14). Prevention of measles, rubella, congenital rubella syndrome, and mumps, 2013. Summary recommendations of the Advisory Committee on Immunization Practices (ACIP). *Morbidity and Mortality Weekly Report* 62(4). https://www.cdc.gov/mmwr/pdf/rr/rr6204.pdf

Guidelines for Intramuscular and Subcutaneous Injection Administration

Intramuscular Injections[2]

SITE[1]	Infant	Toddler	Preschool-Aged	School-Aged	Adolescent/Adult
Vastus lateralis	Needle length: 5/8 inch Volume: 0.5 mL **recommended for infants < 7 months of age	Needle length: 5/8 – 1 inch Volume: 0.5 – 1 mL	Needle length: 1 inch Volume: 1 mL	Needle length: 1 inch Volume: 1.5 –2 mL	Needle length:1-3 inches Volume: 1-5 mL
Ventrogluteal	Needle length:5/8 inch Volume: 0.5 mL **recommended for infants > 7 months of age	Needle length: 5/8 – 1 inch Volume: 1 mL	Needle length: 1 inch Volume: 1.5 mL	Needle length: 1-1.5 inches Volume: 1.5-2 mL	Needle length: 1-3 inches Volume: 1-5 mL
Deltoid	Not recommended	Needle length: 5/8 – 1 inch Volume: 0.5 mL	Needle length: 5/8 – 1 inch Volume: 0.5 mL	Needle length: 5/8 – 1 inch Volume: 0.5 – 1 mL	Needle length: 1-3 inches Volume: 0.5 –2 mL
Dorsogluteal	Not recommended	Not recommended	Not recommended	Needle length: 1/2-1.5 inches Volume: 1.5-2 mL	Needle length: 1-3 inches Volume: 1-5 mL

Subcutaneous Injections[2]: May be given in upper outer arm, anterior thigh, abdomen, upper back, or buttocks

Infant or Child	Adolescent or Adult	Obese Person
Needle length: 3/8 inch Needle gauge: 25 Volume: *no more than 0.1 mL for intradermal *no more than 0.5 mL for small child * no more than 1 mL preschool or school-aged child	Needle length: ½ - 5/8 inch Needle gauge: 25-27 Volume: 0.5 – 1 mL	Needle length: 7/8 inch Needle gauge: 25-27 Volume: 0.5 – 1 mL

[1]Follow manufacture's instructions for required administration sites.

[2]Needle length should be sufficient to reach muscle.

References:

Bowden, V, R., & Greenberg, C. S. (2003). Medication administration: Intramuscular. *Pediatric Nursing Procedures* (pp. 374-375). Philadelphia: Lippincott, Williams, & Wilkins.
Bowden, V, R., & Greenberg, C. S. (2003). Medication administration: Subcutaneous. *Pediatric Nursing Procedures* (pp. 37415-416). Philadelphia: Lippincott, Williams, & Wilkin
(2000). Intramuscular injections. *Nursing Procedures*. Philadelphia: Lippincott, Williams, & Wilkins.

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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 https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use- united-states
- 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 (20 mg daily or 2 mg/kg body weight of prednisone or its equivalent), 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]. For additional information regarding HIV laboratory parameters and use of live vaccines, see the General Best Practice Guidelines for Immunization, "Altered Immunocompetence," at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/immunocompetence.html and Table 4-1 (footnote J) at www.cdc.gov/vaccines/hcp/acip-recs/general- recs/contraindications.html.)*

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- 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 (require evaluation before vaccination)

- 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)
- 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

MMR II (Merck) may be administered via either the intramuscular (IM) or subcutaneous (Subcut) route; Priorix (GSK) may only be administered by the Subcut route.

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
Age 1 through 2 years	22-25	1–1¼"	Anterolateral thigh muscle*
		⅝†–1"	Deltoid muscle of arm
Age 3 through 10 years	22-25	⅝†–1"	Deltoid muscle of arm*
		1–1¼"	Anterolateral thigh muscle
Age 11 years and older	22-25	⅝†–1"	Deltoid muscle of arm*
		1–1½"	Anterolateral thigh muscle

* Preferred site.

† A ⅝" 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, choose the needle gauge, needle length, and injection site according to the following chart:

NEEDLE GAUGE	NEEDLE LENGTH	INJECTION SITE
23–25	⅝ "	Fatty tissue over triceps or fatty tissue over anterolateral thigh

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Reconstitute the vaccine with the manufacturer-supplied diluent just prior to administration.

5. **Administer Measles, Mumps, and Rubella Vaccine (MMR),** 0.5 mL, 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	4yearsand older	Give dose #1. Give dose #2 at least 4 weeks later.
1 previous dose given before age 12 months	12monthsand older	Give dose #1. Give dose #2 at least 4 weeks later.
1 previous dose of MMR given at age 12 months or older	4yearsand 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); discuss the need for the vaccine with the patient (or, int case of a minor, their parent or legal representative) at the next visit and offer the vaccine again.

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.

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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 https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/common-ingredients-fda-approved-vaccines
   - 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).

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- 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).

Note: Susceptible individuals living with HIV are at increased risk for serious illness if infected with measles. HIV+ adults who are not severely immunocompromised should receive MMR vaccine as recommended. For additional information regarding HIV laboratory parameters and use of live vaccines, see the General Best Practice Guidelines for Immunization, "Altered Immunocompetence," at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/immunocompetence.html and Table 4-1 (footnote J) at www.cdc.gov/vaccines/hcp/acip-recs/general- recs/contraindications.html.

- 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

MMRII (Merck) may be administered via either the intramuscular (IM) or subcutaneous (Subcut) route; Priorix (GSK) may only be administered by the Subcut route.

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

BIOLOGICAL SEX & 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	1"*–1½"	Anterolateral thigh muscle

* Alternative needle lengths may be used for IM injections if the skin is stretched tightly, the subcutaneous tissues are not bunched, and the injection is made at a 90° angle to the skin as follows: a) a ⅝ " needle for adults weighing less than 130 lbs (<60 kg) or b) a 1" needle for administration in the thigh muscle for adults of any weight.

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	⅝ "	Fatty tissue over triceps

Reconstitute the vaccine with the manufacturer-supplied diluent just prior to administration.

ADMINISTER MMR VACCINE, 0.5 ML, ACCORDING TO THE FOLLOWING CRITERIA AND SCHEDULE: HISTORY OF PREVIOUS MMRVACCINATION	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.

5. 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.

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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 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.

7. 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.

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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 old 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. Exercise caution when administering ProQuad to persons with an individual or family history of febrile seizures.
  - Use caution when administering ProQuad to children with anaphylaxis or immediate hypersensitivity to eggs.
  - 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.
  - Do not administer ProQuad to individuals who are pregnant or planning on becoming pregnant in the next 3 months.

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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.")

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, providers may use either MMR vaccine and varicella vaccine or MMRV vaccine. Providers who are considering administering MMRV vaccine should discuss the benefits and risks of both vaccination options with the parents or caregivers. Unless the parent or caregiver expresses a preference for MMRV vaccine, CDC recommends that providers administer MMR vaccine and varicella vaccine for the first dose 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 or intramuscularly

MMRV vaccine is supplied in single-dose vials of lyophilized vaccine to be reconstituted using only the separately packaged supplied 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 immediately after reconstitution. Discard reconstituted vaccine if not used within 30 minutes.

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Prepare and Administer MMRV (Proquad)

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	⅝ "	Fatty tissue over triceps or fatty tissue over anterolateral thigh muscle

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
Age 1 through 2 years	22-25	1–1¼"	Anterolateral thigh muscle*
		⅝†–1"	Deltoid muscle of arm
Age 3 through 10 years	22-25	⅝†–1"	Deltoid muscle of arm*
		1–1¼"	Anterolateral thigh muscle
Age 11 through 12 years	22-25	⅝†–1"	Deltoid muscle of arm*
		1–1½"	Anterolateral thigh muscle

* Preferred site.

† A ⅝" 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.

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.

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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.

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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, or whose most recent dose, if given at age 16 or older, was administered more than 5 years earlier.

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, particularly if contact with the local population will be prolonged

***** *MenABCWY vaccine may be given to adolescents ages 10 and over as an option when receiving MenACWY* ***and*** *MenB vaccines at the same visit.*

MenABCWY contains Trumenba and may not be interchanged with individuals needing Bexsero. See MenABCWY CSG for further guidance.

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 including diphtheria toxoid, CRM197 (for Menveo), or tetanus toxoid (for MenQuadfi). For information on vaccine components, refer to the manufacturer's package insert (www.immunize.org/fda) or go to https://www.cdc.gov/pinkbook/hcp/table-of-contents/index.html

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Precautions

- Moderate or severe acute illness with or without fever
- Preterm birth if younger than age 9 months (for Menveo Two-Vial only)

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	1–1¼"	Anterolateral thigh**
		⅝***–1"	Deltoid muscle of arm
Children (3 through 10 years)	22–25	⅝***–1"	Deltoid muscle of arm**
		1–1¼"	Anterolateral thigh
Adolescents and Teens (11 through 18 years)	22–25	⅝***–1"	Deltoid muscle of arm**
		1–1½"	Anterolateral thigh muscle

* Only Menveo Two-Vial vaccine can be used for infants aged 2 through 23 months; MenQuadfi may be used beginning at age 2 years; Menveo One-Vial may be used beginning at age 10 years. For directions on use, please refer to manufacturer package insert for vaccine being used.

** Preferred site

*** A ⅝" 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.

Administer 0.5 mL vaccine via the intramuscular (IM) route Schedule and criteria for routine vaccination with MenACWY

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 years.)
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 18 years	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, or if given after the 16th birthday but more than 5 years previously, give dose #2 of 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.

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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.

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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.
    - Military recruits
    - 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*

* *MenABCWY vaccine may be given to adolescents and young adults ages 10-25 as an option when receiving MenACWY **and** MenB vaccines at the same visit. MenABCWY contains Trumenba and may not be interchanged with individuals needing Bexsero. See MenABCWY CSG for further guidance.*

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 https://www.cdc.gov/pinkbook/hcp/table-of-contents/?CDC_AAref_Val=https://www.cdc.gov/vaccines/pubs/pinkbook/

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downloads/appendices/B/excipient-table-2.pdf.

- **Precautions**

Moderate or severe acute illness with or without fever provide vaccine information statements.

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	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	1*-1½"	Anterolateral thigh muscle

* Alternate needle lengths may be used for IM injections if the skin is stretched tightly, the subcutaneous tissues are not bunched, and the injection is made at a 90º angle to the skin, as follows: a) a ⅝" needle for adults weighing less than 130 lbs (<60 kg) or b) a 1" needle for administration in the thigh muscle for adults of any weight.

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

** Persons with immunocompromising conditions or functional or anatomic asplenia should receive a 2nd dose at least 8 weeks after dose #1 followed by a dose every 5 years thereafter if they remain immunocompromised.

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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.

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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*

* *MenABCWY vaccine may be given to adolescents and young adults ages 10-25 as an option when receiving MenACWY **and** MenB vaccines at the same visit. MenABCWY contains Trumenba and may not be interchanged with individuals needing Bexsero. See MenABCWY CSG for further guidance.*

2. **Screen for contraindications and precautions**

Contraindications

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 https://www.immunize.org/official-guidance/fda/pkg-inserts/ or go to https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/common-ingredients-fda-approved-vaccines.

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.

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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	⅝ *–1" 1–1¼"	Deltoid muscle of arm** Anterolateral thigh muscle
11–18 years	22–25	⅝ *–1" 1–1½"	Deltoid muscle of arm** Anterolateral thigh muscle
Age 19 years and older			
• 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
• Female153–200 lbs	22–25	1–1½"	Deltoid muscle of arm
• Male 153–260 lbs	22–25	1–1½"	Deltoid muscle of arm
• Female200+ lbs	22–25	1½"	Deltoid muscle of arm
• Male 260+ lbs	22–25	1½"	Deltoid muscle of arm

* 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° 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 risk[1] for meningococcal serogroup B disease, based on shared clinical decision-making.

TYPE OF VACCINE	AGE GROUP	DOSE	SCHEDULE
Bexsero (MenB-4c, GlaxoSmithKline) ***OR*** 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 for persons who desire more rapid protection against serogroup B (e.g., students initiating vaccination <6 months before college entry) may receive the 3 dose series to optimize rapid protection.

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 determined, 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
Bexsero (MenB-4c, GlaxoSmithKline) ***OR*** Trumenba (MenB-FHbp, Pfizer)	10 Years and older	0.5 mL	Three doses at 0, 1–2, and 6 months[3]	If risk is ongoing, give MenB booster dose 1 year[4] following completion of primary series, followed by boosters every 2–3 years thereafter.

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[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 or Bexsero series is administered earlier than 6 months after Dose #1, a third dose should be administered at least 4 months after Dose #2.
[3]If dose #2 was administered at least 6 months after dose #1, dose #3 is NOT needed; if dose #3 is administered earlier than 4 months after dose #2, a 4th dose should be administered at least 4 months after dose #3.
[4]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.

8. 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.

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STANDING ORDERS FOR

Administering Meningococcal ABCWY (Penbraya) Vaccine to Adolescents and Adults

Purpose

To reduce morbidity and mortality from meningococcal disease caused by *Neisseria meningitidis* serogroups A, B, C, W, and Y 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 MenABCWY vaccination*:**

MenABCWY vaccine may be used only when both MenACWY and MenB vaccines are indicated at the same visit:

* People must get the same vaccine brand for all doses of MenB vaccine. MenABCWY (Penbraya) is interchangeable with all MenACWY vaccine products and Trumenba only MenB vaccine product. It is not interchangeable with Bexsero. If a patient receives MenABCWY vaccine, which includes the MenB vaccine Trumenba®, then administer Trumenba® for their additional MenB dose(s).

*MenABCWY vaccine can be used only when both MenACWY **and** MenB vaccines are indicated at the same visit. Otherwise, MenACWY and MenB vaccines should be given separately as appropriate).*

✓ **Assess adolescents and adults 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, or whose most recent dose, if given at age 16 or older, was administered more than 5 years earlier.

✓ **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, at increased risk:
- Diagnosis of persistent complement component deficiency (e.g., inherited chronic deficiencies

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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

Contraindications

Do not give meningococcal vaccine to an adolescent or adult who has experienced a serious systemic or anaphylactic reaction to a prior dose of meningococcal vaccine or to any of its components. For information on vaccine components, refer to the manufacturers' package insert for Penbraya at: labeling.pfizer.com/ShowLabeling.aspx?id=19937#S11.

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; MenACWY (English/ Other Languages) MenB (English / Other Languages) which can be found at https://www.immunize.org/vaccines/vis/menb/#Current-Translations

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	⅝*–1" 1–1¼"	Deltoid muscle of arm** Anterolateral thigh muscle
11–18 years	22–25	⅝*–1" 1–1½"	Deltoid muscle of arm** Anterolateral thigh muscle
Age 19 years and older			
• 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

* 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° angle to the skin.

** Preferred site

Penbraya (MenABCWY) is supplied in a kit that includes a vial of Lyophilized MenACWY Component (a sterile white powder), a prefilled syringe containing the MenB Component and a vial adapter.

To form PENBRAYA (MenABCWY), reconstitute the Lyophilized MenACWY Component with the MenB Component as directed below: *(see labeling.pfizer.com/ShowLabeling.aspx?id=19937#S11)*

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Step 1. Preparation of vial and vial adapter

- ✓ Remove plastic flip-off cap from vial containing the Lyophilized MenACWY Component.
- ✓ Cleanse the rubber stopper.
- ✓ Without removing the vial adapter from its packaging, peel off the top cover.

Step 2. Attachment of vial adapter

- ✓ Hold the base of the vial on a flat surface.
- ✓ Keep the vial adapter in the packaging and orient it vertically over the center of the vial so that the adapter spike aligns with the center of the vial's rubber stopper.
- ✓ Connect the vial adapter to the vial with a straight downward push. The vial adapter will lock into place.
- ✓ Do not push vial adapter in at an angle as this may result in leaking during use.
- ✓ Remove the vial adapter packaging.

Step 3. Resuspension of the MenB Component

- ✓ Shake the syringe vigorously to obtain a white homogenous suspension. Do not use if the contents cannot be resuspended.

Step 4. Removal of syringe cap

- ✓ For all syringe assembly steps, hold the syringe only by the Luer lock adapter located at the tip of the syringe. This will prevent the Luer lock adapter from detaching during use.
- ✓ Remove the syringe cap by slowly turning the cap counterclockwise while holding the Luer lock adapter.

Step 5. Connection of syringe to vial adapter

- ✓ Hold the syringe's Luer lock adapter and connect it to the vial adapter by turning clockwise.
- ✓ Stop turning when you feel resistance, overtightening the syringe may result in leaking during use.
- ✓ Once the syringe is securely attached to the vial adapter, there will be a small space between the top of the vial adapter and the Luer lock adapter of the syringe.

Step 6. Reconstitution of Lyophilized MenACWY Component with MenB Component to form PENBRAYA

- ✓ Inject the entire contents of the syringe containing the MenB Component into the vial.
- ✓ Do not remove the empty syringe.
- ✓ While holding the plunger rod down, gently swirl the vial in a circular motion until the powder is completely dissolved (less than 1 minute).

Step 7. Withdrawal of PENBRAYA

- ✓ Invert the vial completely with the vial adapter and syringe still attached.
- ✓ Slowly withdraw the entire contents into the syringe to ensure an approximately 0.5 mL dose of PENBRAYA for administration.
- ✓ Do not pull the plunger rod out.

Step 8. Disconnection of syringe

- ✓ Hold the Luer lock adapter of the syringe and disconnect the syringe from the vial adapter by turning counterclockwise.

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Step 9. Attachment of needle

- ✓ Attach a sterile needle suitable for intramuscular injection to the syringe containing PENBRAYA.

Step 10. Visual inspection

- ✓ PENBRAYA is a homogeneous white suspension. If the vaccine is not a homogenous suspension, shake to resuspend prior to administration.
- ✓ Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.
- ✓ Discard if either condition is present.

5. Administer MenABCWY vaccine*, approximately 0.5 mL, via the intramuscular (IM) route, *(After reconstitution, administer PENBRAYA immediately or store between 2°C and30°C (36°F and 86°F) and use within 4 hours. Discard reconstituted vaccine if not used within 4 hours.)*

* **NOTE:** As stated previously, people must get the same vaccine brand for all doses of MenB vaccine. If a patient receives MenABCWY vaccine, which includes the MenB vaccine Trumenba®, then administer Trumenba® for their additional MenB dose(s).

Adolescents and adults with certain medical conditions and risk factors** may get more than one dose of MenABCWY vaccine.
If a patient is receiving MenACWY and MenB vaccines at the same visit, MenABCWY may be given instead. If a patient receives MenABCWY vaccine, which includes Trumenba®, then administer:

- Trumenba® for additional MenB dose(s) when MenACWY isn't indicated
- Any MenACWY vaccine when MenB isn't indicated

The minimum interval between MenABCWY doses is 6 months. People with prolonged increased risk for serogroup A, C, W, or Y **and** B meningococcal disease need regular boosters. Booster doses should be given:
For MenACWY: Single dose at 5 years after primary vaccination and every 5 years thereafter

For MenB: Single dose at 1 year after completion of primary vaccination and every 2–3 years thereafter.

** Medical conditions and risk factors *(for more details, visit Meningococcal Vaccination:Recommendations of the Advisory Committee on ImmunizationPractices,UnitedStates, 2020 | MMWR(cdc.gov):*

- ✓ Persons with persistent complement component deficiencies.
- ✓ Persons who use complement inhibitors
- ✓ Persons with anatomic or functional asplenia
- ✓ Microbiologists routinely exposed to *N. meningitidis* isolates
- ✓ Persons at increased risk during an outbreak of meningococcal disease

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 (if applicable): 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.

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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 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.

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STANDING ORDERS FOR
Administering Pneumococcal Vaccines
(PCV15, PCV20, PCV21 andPPSV23) 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 50 years or older

Risk-Based Pneumococcal Vaccination

Age 19 through 49 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]Latrogenic 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).

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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

All PCVs (PCV15, PCV20, PCV21) 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	⅝*–1"	Deltoid muscle of arm
Female or male130–152 lbs	22–25	1"	Deltoid muscle of arm
Female 153–200 lbs	22–25	1–1 1/2"	Deltoid muscle of arm
Male 153–260 lbs	22–25	1–1 1/2"	Deltoid muscle of arm
Female 200+ lbs	22–25	1 1/2"	Deltoid muscle of arm
Male 260+ lbs	22–25	1 1/2"	Deltoid muscle of arm
Female or male, any weight	22–25	1*–1 1/2"	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 ⅝ " 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, ⅝ " needle for injection into the fatty tissue overlying the triceps muscle.

5. **Administer PCV15, PCV20, PCV21 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.

Table 1. Recommendations for all adults 50 years or older

PRIOR VACCINES	OPTION A	OPTION B
None, unknown, or PCV7 only	PCV20 or PCV21	PCV15 followed by PPSV23 in at least 1 year**
PPSV23 only (at any age)	PCV20 or PCV21 at least 1 year after PPSV23	PCV15 at least 1 year after PPSV23
PCV13 only (at any age)	PCV20 or PCV21 at least 1 year after PCV13	No option B
PCV13 (at any age) & PPSV23 before age 65 years	PCV20 or PCV21 at least 5 years after last pneumococcal vaccine dose	
Complete series of PCV13 at any age & PPSV23 at age 65 years or older	May administer PCV20 or PCV21 at least 5 years after most recent pneumococcal vaccination	

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**Consider minimum interval (8 weeks) for adults with an immunocompromising condition, cochlear implant, or cerebrospinal fluid leak (CSF).

Table 2. Recommendations for adults aged 19 through 49 years with specified immunocompromising conditions‡

PRIOR VACCINES	OPTION A	OPTION B
None, unknown, or PCV7 only	PCV20 or PCV21	PCV15 followed by PPSV23 in at least 8 weeks
PPSV23 only	PCV20 or PCV21 at least 1 year after PPSV23	PCV15 at least 1 year after PPSV23
PCV13 only	PCV20 or PCV21 at least 1 year after PCV13	No option B
PCV13 & 1 dose PPSV23	PCV20 or PCV21 at least 5 years after last pneumococcal dose	
PCV13 & 2 doses PPSV23	PCV20 or PCV21 at least 5 years after last pneumococcal dose§	

‡ See list of immunocompromising conditions on page 1.

§ If PCV20 or PCV21 is not given, CDC recommends that you review pneumococcal vaccine recommendations again when your patient turns 50 years old (see https://www.cdc.gov/pneumococcal/downloads/Vaccine-Timing-Adults-JobAid.pdf).

Table 3. Recommendations for adults age 19 through 49 years with a cochlear implant or cerebrospinal leak‡

PRIOR VACCINES	OPTION A	OPTION B
None, unknown, or PCV7 only	PCV20 or PCV21	PCV15 followed by PPSV23 in at least 8 weeks
PPSV23 only	PCV20 or PCV21 at least 1 year after PPSV23	PCV15 at least 1 year after PPSV23
PCV13 only	PCV20 or PCV21 at least 1 year after PCV13	No option B
PCV13 & 1 dose PPSV23	May administer PCV20 or PCV21 at least 5 years after last pneumococcal dose§	

‡ Recommendations for vaccination in the presence of these conditions differ slightly from other non-immunocompromising chronic health conditions.
§ If PCV20 or PCV21 is not given, CDC recommends that you review pneumococcal vaccine recommendations again when your patient turns 50 years old (see https://www.cdc.gov/pneumococcal/downloads/Vaccine-Timing-Adults-JobAid.pdf).

Table 4. Recommendations for adults age 19 through 49 years with a non-immunocompromising chronic health condition¶

PRIOR VACCINES	OPTION A	OPTION B
None, unknown, or PCV7 only	PCV20 or PCV21	PCV15 followed by PPSV23 in at least 1 year
PPSV23 only	PCV20 or PCV21 at least 1 year after PPSV23	PCV15 at least 1 year after PPSV23
PCV13 only	PCV20 or PCV21 at least 1 year after PCV13	No option B

PCV13 & 1 dose PPSV23	No additional pneumococcal vaccines are recommended at this time[§§]

[¶] See list of non-immunocompromising chronic health conditions on page 1. Excluding cochlear implant and cerebrospinal fluid leak (see table 3).

[§§] CDC recommends that you review pneumococcal vaccine recommendations again when your patient turns 50 years old (see https://www.cdc.gov/pneumococcal/downloads/Vaccine- Timing-Adults-JobAid.pdf).

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 https://www.immunize.org/wp-content/uploads/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 Pneumococcal Vaccines to Children and Teens
(PCV15, PCV20 and PPSV23)

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, pharmacists and other healthcare professionals 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 (PCV) series (either PCV15 or PCV 20) * should be administered routinely to all children ages 2 through 59 months. Either PCV15 or PCV20 may be used any time pneumococcal conjugate vaccination of a child younger than 19 years is indicated. Children who have completed vaccination with PCV13 are not recommended to receive an additional dose of PCV15 or PCV20

Risk-based pneumococcal vaccination

Risk-based pneumococcal vaccination recommendations are divided by type of risk condition (also listed in **Table 3**):

- Non-Immunocompromising: age 2 years and older with chronic heart disease (particularly cyanotic congenital heart disease and cardiac failure); chronic lung disease (including moderate persistent or severe persistent); chronic liver disease, diabetes mellitus, cerebrospinal fluid (CSF) leak; cochlear implant, and chronic kidney disease (excluding maintenance dialysis and nephrotic syndrome which are included in immunocompromising conditions)
- Immunocompromising: age 2 years and older with chronic kidney disease and on maintenance dialysis or with nephrotic syndrome, congenital or acquired immunodeficiency, treatment with immunosuppressive drugs or radiation therapy, HIV infection, solid organ transplant, and sickle cell disease or other hemoglobinopathies. **Hematopoietic stem cell transplant (HSCT):** specific recommendations for children of any age following HSCT **(see Table 5)**

***Note:** If only PCV13 is available when the child is scheduled to receive a PCV, PCV13 may be given as previously recommended

2. **Screen for contraindications and precautions**

Contraindications

Do not give pneumococcal conjugate vaccine (PCV15, Vaxneuvance, Merck; PCV15, Prevnar20, Pfizer) or pneumococcal polysaccharide vaccine (PPSV23, Pneumovax 23, Merck) to a person who has experienced a serious reaction or anaphylactic reaction to a prior dose of the vaccine or to any of its components (including diphtheria toxoid, which is in pneumococcal conjugate vaccines). For a list of vaccine components, refer to the manufacturers' package insert (www.immunize.org/official-guidance/fda/pkg-inserts/) or go to https://www.cdc.gov/pinkbook/hcp/table-of-contentsindex.html

Precautions

Moderate or severe acute illness with or without fever

3. **Provide Vaccine Information Statements**

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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. All English and translated VISs can be accessed at https://www.immunize.org/vaccines/vis/about-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 intramuscularly (IM). PPSV23 may be administered 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:

AGE OF CHILD/TEEN	NEEDLE GAUGE	NEEDLE LENGTH	INJECTION SITE
Younger than 12 months	22–25	1"	Anterolateral thigh muscle
12 through 35 months	22–25	1–1¼"	Anterolateral thigh muscle*
		⅝**–1"	Deltoid muscle of arm
Children (3 through 10 years)	22–25	⅝**–1"	Deltoid muscle of arm*
		1–1¼"	Anterolateral thigh muscle
Adolescents and Teens (11 through 18 years)	22–25	⅝**–1"	Deltoid muscle of arm*
		1–1½"	Anterolateral thigh muscle

* Preferred site.

**A ⅝ " 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.

When administering PPSV23, if you prefer Subcut injection, choose a 23–25 gauge, ⅝" needle for injection into the fatty tissue overlying the triceps muscle.

5. Administer pneumococcal conjugate vaccine

Refer to the tables below to determine the appropriate vaccine based on age, vaccination history, and presence or absence of risk conditions, then, administer the appropriate vaccine as follows:

- PCV15 or PCV20, 0.5 mL, via the IM route, to all healthy children to children or to children with a risk condition, age 2 months and older
- PPSV23, 0.5 mL, via the IM or Subcut route, as an option when PCV20 is not available, for certain children with risk conditions, age 2 years and older

Follow the guidance in the tables below for choosing the vaccine type, appropriate age, number of doses, and dosing intervals.

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Table 1. Recommended Schedule for Administering Pneumococcal Conjugate Vaccine (PCV) to all children (healthy and those with risk conditions) age 2 through 23 months

Child's age now	Vaccination history of PCV13, PCV15 or PCV20 doses	Recommended PCV15 or PCV20 doses to complete series by age 24 mos*†
2‡ through 6 months	0	4 doses: 3 doses 8 weeks apart; last dose at age 12–15 months
	1	3 additional doses: 2 doses, 8 weeks apart; last dose at age 12–15 months
	2	2 additional doses: 1 dose 8 weeks after most recent dose; last dose at least 8 weeks later at age 12–15 months
	3	1 additional dose at age 12–15 months
7 through 11 months	0 before age 7 months	3 doses; 2 doses 8 weeks apart; last dose at age 12–15 months
	1 or 2 before age 7 months	2 additional doses: 1 dose 8 weeks after most recent dose; last dose at least 8 weeks later, at age 12–15 months
	3 before age 7 months or older	1 additional dose at age 12–15 months
	1 at age 7 months or older	2 additional doses; 1 dose 8 weeks after most recent doses; last dose at least 8 weeks later, at age 12–15 months
	2 at age 7months or older	1 additional dose at least 8 weeks later, at age 12–15 months
12 through 23 months	0 before age 12 months	2 doses, at least 8 weeks apart
	1before age 12 months	2 doses, at least 8 weeks apart
	2 or 3 before age 12 months	1 additional dose, at least 8 weeks after most recent dose
	1 at age 12 months or older	1 additional dose, at least 8 weeks after the most recent dose

*(see **Table 1** Footnotes on next page)*

* If only PCV13 is available when the child is scheduled to receive PCV, PCV13 may be given as previously recommended.

† Minimum interval between doses: for children younger than age 12 months = 4 weeks; for children aged 12 months or older = 8 weeks

‡ Minimum age for dose 1 is 6 weeks.

Table 2. Recommended schedule for administering pneumococcal conjugate vaccine (PCV) to healthy children aged 24 months through 18 years

Child's age now	Number of previous PCV13, PCV15 or PCV20 doses	Number of PCV15 or PCV20 doses needed*
24 through 59 months	Completed any PCV schedule, including an all-PCV13 schedule by 24 mos	No additional doses
	No previous doses, or any incomplete PCV schedule by age 24 months	1 additional dose, at least 8 wks after most recent PCV dose
5 through 18 years	No previous doses or any incomplete PCV schedule by 24 months	No additional doses

* If only PCV13 is available when the child is scheduled to receive PCV, PCV13 may be given as previously **recommended.**

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Table 3. Risk conditions for which additional doses of PCV15, PCV20, or pneumococcal polysaccharide (PPSV23) vaccines are indicated for children age 24 months through 18 years

Non-immunocompromising conditions (non-IC)	Immunocompromising conditions (IC)
Chronic lung disease (including moderate persistent or severe persistent asthma)	Asplenia or splenic dysfunction
Chronic heart disease	Congenital or acquired immunodeficiency
Chronic liver disease	Treatment with immunosuppressive drugs or radiation therapy
Diabetes mellitus	HIV infection
Cerebrospinal fluid leak	Solid organ transplant
Cochlear implant	Sickle cell disease or other hemoglobinopathies
Chronic kidney disease (except as specified in the IC list)	Kidney disease and on maintenance dialysis
	Kidney disease with nephrotic syndrome

Table 4. Recommended schedule for administering pneumococcal vaccine to children aged 24 months through 18 years with immunocompromising (IC) and non-immunocompromising (non-IC) risk conditions (see Table 3 for risk conditions)

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Child's age now	Number of previous PCV13, PCV15, or PCV20 doses	Option A	Option B (if applicable)
24 through 71 months (any risk condition)	Any incomplete schedule of 0, 1 or 2 PCV doses by age 24 months	2 doses of PCV20 or PCV15‡, given at least 8 weeks apart	
24 through 71 months (any risk condition)	3 doses of PCV, all before 12 months	1 dose of PCV20 or PCV15‡	
2 through 18 years (any risk condition)	Completed PCV series before age 6 years, including one or more doses of PCV20	No additional doses	
2 through 18 years (non-IC only)	Completed PCV series before age 6 years with PCV13 and/or PCV15 (no PCV20, no PPSV23§)	1 dose of PCV20 at least 8 weeks after most recent PCV dose	1 dose of PPSV23 at least 8 weeks after most recent PCV dose
2 through 18 years (IC only)	Completed PCV series before age 6 years with PCV13 and/or PCV15 (no PCV20, no PPSV23‖)	1 dose of PCV20 at least 8 weeks after most recent PCV dose	1 dose of PPSV23 at least 8 weeks after most recent PCV dose; at least 5 years later, give 1 dose of PCV20 or a second dose of PPSV23‖
6 through 18 years (non-IC)	No previous dose of PCV13, PCV15 or PCV20	1 dose of PCV20 at least 8 weeks after most recent pneumococcal vaccination	1 dose of PCV15 at least 8 weeks after most recent pneumococcal vaccination. At least 8 weeks later, give 1 dose of PPSV23, if PPSV23 not previously given. If PPSV23 previously given, do not give another dose of PPSV23
6 through 18 years (IC)	No previous dose of PCV13, PCV15 or PCV20	1 dose of PCV20 at least 8 weeks after most recent pneumococcal vaccination	1 dose of PCV15 at least 8 weeks after most recent pneumococcal vaccination. At least 8 weeks later, give 1 dose of PPSV23, if PPSV23 not previously given. If PPSV23 previously given, do not give another dose of PPSV23.
6 through 18 years (non-IC)	PCV13 only, given at or after age 6 years	1 dose of PCV20 at least 8 weeks after most recent PCV13 dose	1 dose of PPSV23 at least 8 weeks after most recent PCV13 dose
6 through 18 years (IC)	PCV13 only, given at or after age 6 years	1 dose of PCV20 at least 8 weeks after most recent PCV13 dose	1 dose of PPSV23 at least 8 weeks after most recent PCV13 dose; at least 5 years after the first PPSV23 dose, give 1 dose of PCV20 or a second dose of PPSV23

‡ If PCV15 is used, one or two additional pneumococcal vaccine doses will be needed. For options, refer to the appropriate row of this table for a child aged 2 through 18 years (IC or non-IC) who completed the PCV series before age 6 years without a dose of PCV20.

§ If PPSV23 previously given, then child is complete.

‖ If PPSV23 previously given, options are (a) give one dose of PCV20 at least 8 weeks after most recent pneumococcal vaccination, or (b) give a second dose of PPSV23 five years after the first dose of PPSV23

Table 5. Recommended schedule for administering pneumococcal conjugate vaccine to any child

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younger than age 19 years following a hematopoietic stem cell transplant (HSCT)

Current age	Previous pneumococcal vaccination	Recommended schedule
Younger than 19 years	Any	4 doses of PCV20, beginning 3 to 6 months after HSCT: give 3 doses 4 weeks apart, then a 4th dose at least 6 months after dose 3 and at least 12 months after HSCT¶

¶ If PCV20 is unavailable: give 3 doses of PCV15, beginning 3 to 6 months after HSCT (administer 4 weeks apart), then give a dose of PPSV23 at least 12 months after HSCT. If the patient has chronic graft-versus- host disease (GVHD), administer a 4th dose of PCV15 at least 12 months after HSCT, instead of PPSV23.

Note: For additional decision support, use the CDC PneumoRecsVaxAdvisor mobile app for vaccination providers. To learn more or download the app, visit https://www.cdc.gov/pneumococcal/hcp/vaccine-recommendations/app.html?CDC_AAref_Val=https://www.cdc.gov/vaccines/vpd/pneumo/hcp/pneumoapp.html

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.

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 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.

7. 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.

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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 6 weeks 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)
- 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 given by mouth. Never inject these vaccines.

Note: RV1 (Rotarix) may be packaged as either (a) an oral dosing applicator only (does not need reconstitution or dilution before use), or (b) a lyophilized vaccine powder with an oral dosing applicator containing diluent (requires reconstitution not more than 24 hours before use).

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The schedule for administering each vaccine is as follows:

Schedule for routine vaccination:

VACCINE PRODUCT	SCHEDULE
Rotarix (RV1)	Ages 2 months[1], 4 months[2,3]
RotaTeq (RV5)	Ages 2 months[1], 4 months[2], 6 months[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 per the package inserts or can be obtained at https://www.immunize.org/official-guidance/fda/pkg-inserts/
- 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 https://www.immunize.org/wp-content/uploads/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.

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STANDING ORDERS FOR
Administering Adult Respiratory Syncytial Virus (RSV) Vaccine AREXVY, ABRYSVO and mRESVIA
For Adults 60 years old and older

Purpose

To reduce morbidity and mortality from meningococcal disease caused RSV in adults 60 years old and older 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 60 years older and who meet any of the criteria below.

Procedure
Read package insert
Assess adults for need of vaccination against RSV according to the following criteria:

Routine RSV Vaccination

- All adults ages 75 and older with no history of RSV vaccination

Risk-Based Vaccination

- Age 60 through 74 years with no history of RSV vaccination and meet criteria for being at increased risk of RSV based on one or more of the conditions listed below. The patient's self-report of a high-risk condition is sufficient. ACIP recommends that RSV vaccination should not be denied to a person because of lack of medical documentation.
- Cardiovascular disease (e.g., heart failure; coronary artery disease; congenital heart disease, excluding isolated hypertension).
- Lung disease (e.g., chronic obstructive pulmonary disease [COPD], emphysema, asthma, interstitial lung disease, cystic fibrosis),
- Advanced chronic kidney disease (e.g., stages 4–5, dependence on hemodialysis or other renal replacement therapy),
- Diabetes mellitus with end-organ damage (e.g., diabetic nephropathy, neuropathy, retinopathy, or cardiovascular disease),
  - Severe obesity (body mass index ≥40 kg/m^2),
  - Liver disorders (e.g., cirrhosis),
- Neurologic or neuromuscular conditions (e.g., neuromuscular conditions causing impaired airway clearance or respiratory muscle weakness, excluding history of stroke without impaired airway clearance),
  - Hematologic disorders (e.g., sickle cell disease, thalassemia
- Moderate or severe immune compromise (either attributable to a medical condition or receipt of immunosuppressive medications or treatment);
  - People who are frail
- People who reside in nursing homes or other long-term care facilities providing assistance with activities of daily living
- People with other chronic medical conditions or risk factors that a healthcare provider determines might increase the risk of severe disease due to respiratory infection.

- For patients who have not already received an RSV vaccine and decide to get one, CDC encourages healthcare providers to maximize the benefit of RSV vaccination by giving them their RSV vaccine in late summer or early fall.

- The RSV vaccine is not currently an annual vaccine, meaning eligible adults do not need to get a dose every RSV season. Currently, CDC recommends only a single dose of RSV vaccine for all adults ages 75 and older and adults ages 60-74 with increased risk of severe RSV disease.

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Note: *If a person age 60–74 does not have a medical condition or risk factor that increases their risk of severe RSV disease, RSV vaccination is not recommended.*

Screen for contraindications and precautions

Contraindications

History of severe allergic reaction to any component of**:**

- AREXVY
- ABRYSVO
- MRESVIA

Precautions

- Prevent and manage allergic reactions
  - Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of the vaccine
    - Syncope
  - Syncope may occur in association with administration of injectable vaccines. Procedures should be in place to avoid injury from fainting
    - Altered Immunocompetence
  - Immunocompromised persons, including those receiving immunosuppressive therapy, may have a diminished immune response to the vaccine

Provide Vaccine Information Statements

- Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS) available at https://www.cdc.gov/vaccines/hcp/vis/vis- statements/rsv.html. 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.

Prepare vaccine

- Administer a single dose (0.5mL) of the vaccine intramuscularly

ABRYSVO

- **Reconstitution and preparation guidance: https://www.fda.gov/media/168889/download**
  - ABRYSVO is supplied in a kit that includes a vial of Lyophilized Antigen Component (a sterile white powder), a prefilled syringe containing Sterile Water Diluent Component and a vial adapter
  - To form ABRYSVO, reconstitute the Lyophilized Antigen Component with the accompanying Sterile Water Diluent Component
  - ABRYSVO is a clear and colorless solution
  - Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Discard if either condition is present

AREXVY

- **Reconstitution and preparation guidance:** https://www.fda.gov/media/167805/download
  - AREXVY is supplied in 2 vials that must be combined prior to administration.
  - Prepare AREXVY by reconstituting the lyophilized antigen component (a sterile white powder) with the accompanying adjuvant suspension component (an opalescent, colorless to pale brownish sterile liquid).

- Use only the supplied adjuvant suspension component for reconstitution.
- The reconstituted vaccine should be an opalescent, colorless to pale brownish liquid.
- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. If either of these conditions exists, the vaccine should not be administered

mRESVIA

- **Reconstitution and preparation guidance:** **https://www.fda.gov/media/179005/download?attachment**
  - MRESVIA is supplied as a pre-filled syringe that contains a frozen suspension that must be thawed prior to administration.
  - Thaw each syringe before use, either in the refrigerator or at room temperature, following the instructions
  - Do not refreeze
  - Do not shake

Prepare to Administer Vaccine

- Prepare the vaccine according to the manufacturer's instructions. Note: Arexvy (GSK) and Abrysvo (Pfizer) require reconstitution; mResvia (Moderna) does not.
- Choose the needle gauge, needle length, and injection site according to the following chart:

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

† 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.

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.

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- **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.

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.

- For more information: https://www.cdc.gov/vaccines/vpd/rsv/hcp/older-adults.html

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STANDING ORDERS FOR

Administering Adult Respiratory Syncytial Virus (RSV) Vaccine ABRYSVO For Pregnant Women *32-36 weeks Gestation*

Purpose

To reduce morbidity and mortality from RSV in infants who meet the criteria established by the Centers for Disease Control and Prevention's (CDC) 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 vaccination and to vaccinate pregnant women who meet the criteria below.

Procedure

- **Read package insert** https://labeling.pfizer.com/ShowLabeling.aspx?id=19589
- **Assess pregnant women** for need of vaccination against RSV according to ALL of the following criteria:
    - **Time of Year:** Maternal RSV vaccine administration is recommended September 1 through January 31 in Kentucky, most infants of vaccinated mothers will be born during RSV season (i.e., born during October-March).
    - **Gestational age:** between 32 weeks and 0 days through 36 weeks and 6 days of gestation.
    - **Vaccination history:**
        - No history of a previous dose of any RSV vaccine. If there is a history of a previous dose, do not vaccinate during this pregnancy: counsel them about the need for their infant to receive RSV preventive antibody after birth.
        - Mothers of most infants born outside of RSV season (i.e., born during April through September) will not have been vaccinated, counsel them about the need for their infant to receive RSV preventive antibody after birth.
- **Maternal preference:** Either maternal Abrysvo vaccination or nirsevimab preventive antibody administration to the infant is recommended. Both Abrysvo and nirsevimab are not needed for most infants. If both products are options, the pregnant person may choose maternal vaccination or infant immunization.

Screen for contraindications and precautions:

Contraindications

- History of severe allergic reaction to any component of**:**
    - **ABRYSVO**

Precautions

- Moderate or severe acute illness with or without fever
- Prevent and mange allergic reactions
    - Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of the vaccine
- Syncope
    - Syncope may occur in association with administration of injectable vaccines. Procedures should be in place to avoid injury from fainting

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- Altered Immunocompetence
    - Immunocompromised persons, including those receiving immunosuppressive therapy, may have a diminished immune response to the vaccine

Provide Vaccine Information Statements

- Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS) available at https://www.cdc.gov/vaccines/hcp/vis/vis- statements/rsv.html. 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.

Prepare vaccine

- Administer a single dose (0.5mL) of the vaccine intramuscularly

ABRYSVO

Reconstitution and preparation guidance: https://www.fda.gov/media/168889/download

- ABRYSVO is supplied in a kit that includes a vial of Lyophilized Antigen Component (a sterile white powder), a prefilled syringe containing Sterile Water Diluent Component and a vial adapter
- To form ABRYSVO, reconstitute the Lyophilized Antigen Component with the accompanying Sterile Water Diluent Component
- ABRYSVO is a clear and colorless solution
- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Discard if either condition is present

Prepare to Administer Vaccine

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

Weight	Needle gauge	Needle size	Injection site
Less than 130 lbs	22–25	⅝†-1”	Deltoid muscle of arm
130–152 lbs	22–25	1”	
153–200 lbs	22–25	1”	
More than 200 lbs	22–25	1½"	
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 5/8” needle for patients weighing less than 130 lbs (<60 kg) ***or*** a 1” needle for administration in the thigh muscle for adults of any weight.

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 (if applicable):** 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.

Report Adverse Events to VAERS

- Report all adverse events to ABRYSVO 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 Nirsevimab RSV Preventive Antibody to Infants

Purpose

To reduce morbidity and mortality from severe respiratory syncytial virus (RSV) lower respiratory tract disease by administering a long-acting monoclonal antibody against RSV (nirsevimab, brand name Beyfortus by Sanofi) to all infants who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

RSV Vaccine Note: CDC recommends one dose of RSVpreF vaccine (Abrysvo, Pfizer) for previously unvaccinated pregnant people who are 32 through 36 weeks 6 days' gestation during RSV season as an alternative to nirsevimab. Only one lifetime RSV vaccine dose is recommended. Generally, vaccination during pregnancy is recommended as an option between September and the end of January, although local RSV seasonality and public health guidance may vary, especially in tropical areas and Alaska. The standing order template for maternal vaccination with Abrysvo is available at Standing Orders for Administering Maternal RSV Vaccine.

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 who meet any of the criteria below.

Procedure

1. **Assess infants and children for the need of nirsevimab against respiratory syncytial virus in their first or second RSV season according to the following criteria:**

1a. Routine dose for infants younger than 8 months and 0 days (must meet all criteria):

Timing: Generally, October 1 through March 31, unless use of nirsevimab outside of this time is currently recommended by regional experts or health authorities in response to local RSV activity. This seasonality is less likely outside the continental United States.

Infant immunization history: No history of nirsevimab; no history of palivizumab in the past 30 days

No history of effective maternal RSVpreF vaccination for one of the following reasons:

- RSVpreF vaccine was not administered, or
- RSVpreF administration history is unknown, or
- RSVpreF administration occurred less than 14 days before delivery, or
- RSVpreF administration occurred 14 or more days before delivery, but protection may be inadequate for one of the following reasons (evaluation may require referral):
  - Mother is immunocompromised or living with HIV, or
  - Infant has undergone cardiopulmonary bypass or extracorporeal membrane oxygenation, or
  - Infant has hemodynamically significant congenital heart disease, or
  - Infant has had an intensive care admission requiring oxygen at hospital discharge

Note: If maternal vaccination with RSVpreF was considered effective (i.e., none of the preceding criteria were met), do not give nirsevimab.

1b. **Risk-based immunization of children aged 8 months through 19 months during their second RSV season** (must be in at least one high risk category):

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Timing: Generally, October 1 through March 31, unless use of nirsevimab outside of this time is currently recommended by regional experts or health authorities in response to local RSV activity. This seasonality is less likely outside the continental United States.

High risk and eligible for palivizumab:

- Children with chronic lung disease of prematurity who require medical support (chronic corticosteroid therapy, or supplemental oxygen) at any time during the 6-month period before the start of their second RSV season
- Children who are severely immunocompromised
- Children with evidence of severe cystic fibrosis (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest imaging that persist when stable) or have weight-for-length that is less than the 10th percentile

If nirsevimab is unavailable, palivizumab should be administered to children who are eligible per AAP recommendations for palivizumab for RSV prevention (see https://publications.aap.org/redbook/resources/25379). Refer for palivizumab until nirsevimab becomes available.

High risk and ineligible for palivizumab:

- American Indian or Alaskan Native children in this age group

2. Screen for contraindications and precautions

Do not give nirsevimab to persons with a history of severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a nirsevimab component. For a list of nirsevimab components, refer to the manufacturer's package insert (www.immunize.org/fda).

3. Provide Immunization Information Statement

Provide each patient's parent or legal representative a copy of the most current federal nirsevimab Immunization Information Statement (IIS, a VIS-like document). At this time, the RSV preventive antibody is not part of the National Vaccine Injury Compensation Program (VICP), therefore, use of the IIS is not required by federal law. However, Vaccines for Children (VFC) program providers must give the IIS to parents in the same way that a VIS is provided. Provide non-English speaking parents/legal representatives with a copy of the IIS in their native language if one is available and desired; available translations can be found at www.immunize.org/vis. (For information about how to document that the IIS was given, see section 6 titled "Document Immunization.")

4. Prepare to Administer Nirsevimab

Verify proper storage per manufacture package insert. Do not freeze. Do not shake. Do not expose to heat. Keep in original carton to protect from light until time of use. After removal from the refrigerator, nirsevimab must be used within 8 hours or discarded.

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

AGE OF CHILD	NEEDLE GAUGE	NEEDLE LENGTH	INJECTION SITE
Newborns (1st 28 days)	22–25	⅝"	Anterolateral thigh
Infants age 2 through 11 months	22-25	1"	Anterolateral thigh
Age 12 through 19 months	22–25	1–1¼"	Anterolateral thigh*
		⅝†–1"	Deltoid muscle of arm

* Preferred site
† A ⅝" 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.

5. Administer the Appropriate Dose of Nirsevimab

Administer by the intramuscular (IM) route, according to the tables below, to eligible infants and toddlers. Nirsevimab is available in two formulations: a 50-mg (0.5 mL) manufacturer-filled syringe (MFS) or a 100-mg (1.0 mL) MFS. The 50-mg MFS should be reserved for use in infants weighing less than 5 kg: do not administer two 50-mg MFS doses to an infant weighing 5 kg or more.

Schedule and Criteria for Routine Vaccination with Nirsevimab (BEYFORTUS)

Recommended Dosage of Nirsevimab (BEYFORTUS) in Neonates and Infants	
Born during or entering their first RSV season and are younger than 8 months, 0 days	
Body Weight at Time of Dosing	**Recommended Dosage**
Less than 5 kg (11 lbs)	50 mg/0.5 mL (MFS with purple plunger rod)
Greater than or equal to 5 kg (11lbs)	100 mg/1 mL (MFS with light blue plunger rod)
Children ages 8-19 months old who remain at increased risk for severe RSV disease during their second RSV season[+]	
Any weight	200 mg/2 mL[++] (total) (PFS with light blue plunger rod)

\+ Children with chronic lung disease of prematurity who required medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) any time during the 6-month period before the start of the second RSV season; Children with severe immunocompromise; Children with cystic fibrosis who have either 1) manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest imaging that persist when stable), or 2) weight-for-length <10th percentile; American Indian or Alaska Native children
++ Two 100 mg/1 mL PFS (light blue plunger) injections given at the same time at different injection sites

Note: Only one dose of nirsevimab is recommended for any child for a single RSV season. Nirsevimab may be co-administered with any recommended live or non-live vaccines, at separate injection sites, or at any time before or after administration of any live or non-live vaccine.

6. Document Nirsevimab Administration

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

Medical record: Record the date nirsevimab was administered, the manufacturer and lot number, the injection 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 date that patient information sheet was given to the patient or the publication date of the VIS once produced by the CDC 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 nirsevimab was not administered, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal); discuss the need for immunization 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 nirsevimab administration 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 monoclonal antibody (e.g., a risk of anaphylaxis) 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. To prevent syncope in older children, administer monoclonal antibody while they are seated or lying down and consider observing them for 15 minutes after receipt of the immunization.

8. **Report Adverse Events to MedWatch or VAERS**

Adverse events that occur after administration of nirsevimab alone: Report to MedWatch online (www.fda.gov/medwatch), by fax, by mail or by contacting FDA at 1-800-FDA-1088.

Adverse events that occur after coadministration of nirsevimab with one or more vaccines: Report to the Federal Vaccine Adverse Event Reporting System (VAERS). Submit a VAERS report online (preferred) or download a writable PDF form at www.vaers.hhs.gov/reportevent.html. Further help is available by calling (800) 822-7967. Note: After reporting to VAERS, additional reporting of the same adverse reaction to MedWatch is not necessary.

Standing Order for
Tamiflu (oseltamivir)

Purpose

- To reduce mortality and prevent further spread of highly pathogenic avian influenza (HPAI) A(H5N1) associated with severe human disease if there are infected persons in the United States.
- Tamiflu (oseltamivir) is indicated for treatment or post-exposure prophylaxis (PEP) highly pathogenic avian influenza (HPAI) A(H5N1) virus of individuals 1 year of age and older in an outpatient clinical setting.

Policy

- Where allowed by state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess the need for and dispense to individuals one year of age or older 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.
- Refer to the Center for Disease Control and Prevention (CDC) Emergency Use Instructions (EUI) for Oseltamivir for further information about emergency use of FDA-approved medical products that differ from or go beyond the information provided in the FDA-approved labeling (package insert).

Procedure

- **Assess need for treatment or PEP:**

1. Treatment: Symptomatic outpatients 1 year of age and older with confirmed, probable, or suspected infection with highly pathogenic avian influenza (HPAI) A(H5N1) virus should receive oseltamivir treatment.
    - Oseltamivir treatment is recommended as soon as possible for symptomatic outpatients with confirmed, probable, or suspected novel influenza A virus infection associated with severe disease in infected persons.
2. PEP: Persons who are:
    - Close contacts of a confirmed or probable highly pathogenic avian influenza A(H5N1) virus case-patient.
    - Exposed to animals infected with highly pathogenic avian influenza A(H5N1) virus may be offered oseltamivir for PEP as soon as possible according to risk of exposure (i.e., highest-risk, moderate-risk, and low-risk exposure groups) as described in Highly Pathogenic Avian Influenza A(H5N1) Virus in Animals: Interim Recommendations for Prevention, Monitoring, and Public Health Investigations Risk Exposure Table.

- Signs/Symptoms of avian influenza A virus infection in humans may include
    - uncomplicated upper respiratory tract signs and symptoms also referred to as influenza-like illness (ILI) [fever ≥100°F plus cough or sore throat],
    - fever (temperature of 100°F [37.8°C] or greater) or feeling feverish,
    - cough,
    - sore throat,
    - runny or stuffy nose,

- muscle or body aches,
- headaches,
- fatigue,
- eye redness (or conjunctivitis),
- shortness of breath or difficulty breathing,
- Less common signs and symptoms are diarrhea, nausea, vomiting, or seizures,
- It is important to remember that infection with influenza viruses, including avian influenza A viruses, does not always cause fever. Fever may not occur in infected persons of any age, particularly in persons aged 65 years and older or people with immunosuppression. The absence of fever should not supersede clinical judgment when evaluating a patient for illness compatible with avian influenza A virus infection.

Screen for Contraindications and Precautions

- Persons with a known serious hypersensitivity or allergy to oseltamivir or to any of the components should not receive this drug.
- Consult physician/APP for persons with the following:
  - Pediatric patients less than 1 year of age.
  - Symptoms for greater than 48 hours.
  - Persons with severe influenza disease.
  - Persons with renal impairment.
    - Oseltamivir is not recommended for patients with end-stage renal disease not undergoing dialysis. See special dosage instructions below for patients who are undergoing dialysis.
  - Persons requiring hospitalization.
  - Persons in moderate- and low-risk exposure groups.
    - Initiation of oseltamivir PEP for persons in moderate- and low-risk exposure groups should be based on clinical judgment, with consideration given to the type of exposure and to whether the close contact is at higher risk for complications from influenza. Refer to Interim Guidance for Follow-up of Close Contacts of Persons Infected with Novel Influenza A Viruses and Use of Antiviral Medications for Chemoprophylaxis for recommendations regarding use of alternative antivirals.
  - Confirmed, probable, or suspected cases with uncomplicated disease, in whom fever is absent and symptoms are nearly resolved.
    - Decisions to initiate antiviral treatment for untreated outpatients who are confirmed, probable, or suspected cases with uncomplicated disease, in whom fever is absent and symptoms are nearly resolved, should be based on clinical judgment as described in CDC's Interim Guidance on the Use of Antiviral Medications for Treatment of Human Infections with Novel Influenza A Viruses Associated with Severe Human Disease.

Provide Education

- Provide Emergency Use Instructions (EUI) Fact Sheet for Recipients and Caregivers: Oseltamivir to Prevent or Treat Novel Influenza A to persons.
  - EUI Fact Sheet for Recipients and Caregivers: Spanish version
- **Tamiflu (oseltamivir) Beyond Labeled Expiry Date**

- For any Tamiflu-branded product (oseltamivir) that is past its original manufacturer-labeled expiration date, look up the lot number at the following website: https://aspr.hhs.gov/SNS/Pages/Access-to-Influenza-Countermeasure.aspx. If the lot number appears on this website, you may inform recipients that FDA has determined that the Tamiflu they have received can be used for up to 20 years beyond its manufacture date, provided it has been stored under labeled storage conditions. Expiration dates may be extended based on data that may have been generated as part of the federal government's Shelf-Life Extension Program or as a result of data provided by the manufacturer. FDA reviews available data to determine if product remains stable and potent and continues to meet the specifications for continued use.

- The number of bottles of oral suspension or capsules to dispense indicated may be greater than the recommended dosing. Patients should be instructed to properly dispose of any remaining medication.
- The most common adverse events are gastrointestinal symptoms (i.e., nausea and vomiting), headache, and pain. Nausea and vomiting may be less severe if oseltamivir is taken with food. Rare cases of anaphylaxis and serious skin reactions including toxic epidermal necrolysis, Stevens-Johnson syndrome, and erythema multiforme have been reported in postmarketing experience with oseltamivir.
- Oseltamivir should be stopped and appropriate treatment instituted if an allergic-like reaction occurs or is suspected. Patients with influenza may be at an increased risk of hallucinations, delirium, and abnormal behavior early in their illness. Monitor patients for signs of abnormal behavior.

Dosage and Route

Treatment: The FDA-approved treatment duration is 5 days for acute uncomplicated influenza.

- Adults and children ≥ 13 years and older:
  - Treatment: 75mg twice daily for 5 days (10 capsules)
- Pediatric patients ages 1 to 12 years:
  - Treatment dosing regimens are listed in table and are based on weight or age for 5 days. Weight-based dosing is preferred.

Oseltamivir Treatment
Dosage and Duration for Pediatric Patients 1–12 Years of Age (Weight-based Dosing Preferred) Under EUI

Body Weight (kg)	Body Weight (lbs)	Age (years)	Dosage for Treatment for 5 days	Volume of Oral Suspension (6mg/mL) for each dose	# Bottles Oral Suspension to Dispense	# of Capsules and Strength to Dispense[3]
≤15 kg	≤33 lbs	1–2 years	30 mg twice daily	5 mL	1 bottle for 5 days	10 capsules (30 mg) for 5 days
>15–23 kg	>33–51 lbs	>2–5 years	45 mg twice daily	7.5 mL	2 bottles for 5 days	10 capsules (45 mg) for 5 days
>23 –40 kg	>51–88 lbs	>5–9 years	60 mg twice daily	10 mL	2 bottles for 5 days	20 capsules (30 mg) for 5 days
>40 kg	> 88 lbs	>9–12 years	75 mg twice daily	12.5 mL	3 bottles for 5 days	10 capsules (75 mg) for 5 days

Post-Exposure Prophylaxis PEP: CDC recommends that PEP duration should be 5 or 10 days based on exposure. If exposure was time-limited and not ongoing, 5 days of medication from the last known exposure is recommended. If exposure is likely to be ongoing (e.g., household setting), 10 days is recommended because of the potential for prolonged infectiousness in the novel influenza A case.

- Adults and children ≥ 13 years and older:
  - Time-limited, not ongoing: 75mg twice daily for 5 days (10 capsules)
  - Ongoing exposure (e.g., household setting): 75mg twice daily for 10 days (20 capsules)
- Pediatric patients ages 1 to 12 years:
  - Time-limited, not ongoing exposure PEP dosing regimens are listed in table and are based on weight or age for 5 days. Weight-based dosing is preferred.

Oseltamivir Post-Exposure Prophylaxis (PEP) Time-limited, Not Ongoing Exposure Dosage and Duration for Pediatric Patients 1–12 Years of Age (Weight-based Dosing Preferred) Under EUI						
Body Weight (kg)	**Body Weight (lbs)**	**Age (years)**	**Dosage for PEP for 5 days**	**Volume of Oral Suspension (6mg/mL) for each dose**	**# Bottles Oral Suspension to Dispense**	**# of Capsules and Strength to Dispense Exposure time-limited, not ongoing**
≤15 kg	≤33 lbs	1–2 years	30 mg twice daily	5 mL	1 bottle for 5 days	10 capsules (30 mg) for 5 days
>15–23 kg	>33–51 lbs	>2–5 years	45 mg twice daily	7.5 mL	2 bottles for 5 days	10 capsules (45 mg) for 5 days
>23 –40 kg	>51–88 lbs	>5–9 years	60 mg twice daily	10 mL	2 bottles for 5 days	20 capsules (30 mg) for 5 days
>40 kg	> 88 lbs	>9–12 years	75 mg twice daily	12.5 mL	3 bottles for 5 days	10 capsules (75 mg) for 5 days

  - Ongoing exposure (e.g., household setting) PEP dosing regimens are listed in table and are based on weight or age for 10 days. Weight-based dosing is preferred.

Oseltamivir Post-Exposure Prophylaxis (PEP) for Ongoing Exposure Dosage and Duration for Pediatric Patients 1–12 Years of Age (Weight-based Dosing Preferred) Under EUI						
Body Weight (kg)	**Body Weight (lbs)**	**Age (years)**	**Dosage for PEP 10 days**	**Volume of Oral Suspension (6mg/mL) for each dose**	**# Bottles Oral Suspension to Dispense**	**# of Capsules and Strength to Dispense Exposure is likely to be ongoing**
≤15 kg	≤33 lbs	1–2 years	30 mg twice daily	5 mL	1 bottle for 5 days	20 capsules (30 mg) for 10 days
>15–23 kg	>33–51 lbs	>2–5 years	45 mg twice daily	7.5 mL	3 bottles for 10 days	20 capsules (45 mg) for 10 days
>23 – 40 kg	>51–88 lbs	>5–9 years	60 mg twice daily	10 mL	4 bottles for 10 days	40 capsules (30 mg) for 10 days
>40 kg	> 88 lbs	>9–12 years	75 mg twice daily	12.5 mL	5 bottles for 10 days	20 capsules (75 mg) for 10 days

Dosing in Special Populations:

- *Adults 65 years of age and older:* No dose modification is recommended. Follow adult dosing schedule.
- *Pregnant persons:* Oseltamivir is the preferred antiviral for treatment and PEP in pregnant persons up to 2 weeks postpartum. Follow adult dosing schedule.
- *Lactation:* Oseltamivir has been shown to be present in human milk.
  The benefits of breastfeeding should beconsidered along with the mother's clinical need for TAMIFLU and any potential adverse effects on the breastfed child from the drug or from the underlying maternal condition.
- *Hepatic impairment:* No dose modification is recommended.

Reconstitution Instructions for Preparing Oseltamivir for Oral Suspension (360 mg base, final concentration 6 mg/mL) use sterile water. The reconstituted oseltamivir for Oral Suspension (6 mg/mL) should be used within 17 days of preparation when stored under refrigeration (10 days at controlled room temperature).

- An oral suspension is available for children or adults who are unable to swallow capsules. The oral suspension is provided as powder that must be reconstituted by a pharmacist or healthcare provider. Refer to the Center for Disease Control and Prevention (CDC) Emergency Use Instructions (EUI) for Oseltamivir for instructions in Preparing Oseltamivir for Oral Suspension.
- During emergency situations when commercially manufactured oral suspension is not available, pharmacists may prepare an oral suspension (6 mg/mL) from oseltamivir 75 mg capsules.

Reporting and Monitoring Adverse Events

- Report adverse events or medication errors to MedWatch at www.fda.gov/medwatch, by submitting a MedWatch Form 3500 or by calling 1-800-FDA-1088.
- The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by certain medicines or vaccines, which may include certain oseltamivir products. Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving.

***While Tamiflu (Oseltamivir) is an available asset from the federal Strategic National Stockpile (SNS) during an emergency response or incident, when local resources are low or have been exhausted, LHDs are highly encouraged to source locally. Requests for Tamiflu should follow the local health department's/jurisdiction's SNS resource request guidance. If further guidance is needed, contact your Regional Preparedness Center (RPC).**

Instructions for Highly Pathogenic Avian Influenza (HPAI) Specimen Collection and Shipping

If there is suspicion for HPAI with relevant animal exposure call the Kentucky Department for Public Health (KDPH) at 502-564-3261 during regular business hours or 888-973-7678 after hours and on weekends to expedite testing of specimens.

If you have access to Outreach, please order the test code "FPCR". Print a copy of the requisition and submit with the specimen. Each specimen will require a separate order in Outreach and individual requisition form.

If you do not have access to Outreach, please complete the Virology paper requisition (Lab Form 275) available on the Department of Laboratory Services (DLS) website and submit with the specimen. Please complete one form per specimen.

Currently, acceptable specimens for testing are respiratory specimens and conjunctival swabs. All swabs used for collection must be synthetic tip swabs with aluminum or plastic shafts. Calcium alginate swabs or swabs with cotton tips and wooden shafts are unacceptable. Ensure all specimens are labeled with two identifiers, as well as specimen type and date of collection, and that all collection materials are not expired.

- If patient has conjunctivitis symptoms only:
    - Collect conjunctival swab and nasopharyngeal (NP) swab in separate tubes of sterile viral transport media (VTM) or universal transport media (UTM)
    - For collection guidance see the CDC's collection graphic
    - Swabs may be referred out for confirmation testing
- If patient has both conjunctivitis and respiratory symptoms:
    - Collect total of three specimens 1) conjunctival swab, 2) NP swab, 3) combined nasal and oropharyngeal (OP) swab, each in separate tube of VTM or UTM
- Alternative respiratory specimens:
    - A minimum of one respiratory specimen is required per patient
    - A single nasal swab, nasal wash/aspirate or single OP swab may be collected if cannot collect an NP swab
    - For patients with severe lower respiratory tract illness, a lower respiratory tract specimen (e.g. endotracheal aspirate or bronchoalveolar lavage fluid) should be collected

Store all specimens at 2-8°C after collection and ship overnight to DLS on ice pack to the following address: Kentucky Division of Laboratory Services, Attn: Virology, 100 Sower Blvd, Suite 204, Frankfort, KY 40601.

Specimens must reach DLS to be tested within 72 hours of collection when stored at 2-8°C. See Collection and Packaging Guidance on the DLS website for "Multishipper with Cold Pack Virus-Swab" for detailed instructions regarding swab collection and illustrated steps of packaging. The requisition form for ordering additional collection kits and packaging materials is also available on the DLS website.

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

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 https://www.cdc.gov/pinkbook/hcp/table-of-contents/index.html?CDC_AAref_Val=https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/
- 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 or controlled 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). 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	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	1*–1½"	Anterolateral thigh muscle

*Alternate needle lengths may be used for IM injections if the skin is stretched tightly, the subcutaneous tissues are not bunched, and the injection is made at a 90º angle to the skin, as follows: a) a ⅝" 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 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 prophylaxis for wound management sooner or if patient is pregnant (see below).

**Either Td or Tdap may be given for catch-up and booster dose.

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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. (see Standing Orders for Administering Tdap During Pregnancy)

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.

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.

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.

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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 https://www.cdc.gov/pinkbook/hcp/table-of-contents/index.html
  - 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.")

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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	⅝ "*–1"	Deltoid Muscle of Arm
130–152 Lbs.	22–25	1"	Deltoid Muscle of Arm
153–200 Lbs.	22–25	1–1½"	Deltoid Muscle of Arm
200+ Lbs.	22–25	1½"	Deltoid Muscle of Arm
Any weight	22-25	1"*–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.

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 trimester of each pregnancy, 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.

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STANDING ORDERS FOR
Administering Tdap/Td Vaccine to Children and Teens 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

- **Assess Children in Need of Vaccination** against diphtheria, tetanus, and pertussis based on the following criteria:
  - Do not give Tdap during pregnancy to any person who has experienced encephalopathy within 7 days following DTP/DTaP/Tdap not attributable to another identifiable cause.
  - 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
- **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 https://www.cdc.gov/pinkbook/hcp/table-of-contents/index.html
    - 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 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
    - 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
- **Provide Vaccine Information Statements**

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- 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 following chart

AGE OF CHILD/TEEN	NEEDLE GAUGE	NEEDLE LENGTH	INJECTION SITE
Children (7 through 10 years)	22–25	⅝*–1"	Deltoid muscle of arm**
		1–1¼"	Anterolateral thigh muscle
Adolescents and Teens (11 through 18 years)	22–25	⅝*–1"	Deltoid muscle of arm**
		1–1½"	Anterolateral thigh muscle

* A ⅝" 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

- **Administer Td/Tdap vaccine,** 0.5 mL, via the intramuscular (IM) route, according to the following tables:

Schedule for routine vaccination

RECOMMENDED AGE FOR ROUTINE DOSE	MINIMUMAGE FOR ADOLESCENT DOSE	RECOMMENDED INTERVAL TO NEXT DOSE	MINIMUM INTERVALTO NEXT DOSE
11–12years[1,2,3] (Tdap)	10years[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.

- **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.
- **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 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 4 weeks *(Note: the recommended minimum dosing interval for children age 12 months through 12 years is at least 12 weeks, but a documented dose inadvertently administered after at least 4 weeks may be counted as valid.)*
   - 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).
  - 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 with severe immunodeficiency (e.g., hematologic and solid tumors, receipt of chemotherapy, congenital immunodeficiency, long-term immunosuppressive therapy or patients with HIV infection who are severely immunocompromised).
  - Note: Long-term immunosuppressive therapy is defined as at least 2 weeks of daily receipt of 20 mg or 2 mg/kg body weight of prednisone or its equivalent.
  - Note: Susceptible individuals living with HIV infection are at increased risk for serious illness from varicella infection. Eligible HIV-infected children age 12 months or older should receive 2 doses of single-component varicella vaccine with a 3-month interval between doses. For additional information regarding HIV laboratory parameters and use of live vaccines, see the General Best Practice Guidelines for Immunization, "Altered Immunocompetence," at https://www.cdc.gov/vaccines/hcp/imz-best-practices/altered-immunocompetence.html?CDC_AAref_Val=https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/immunocompetence.html

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- 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 *(required evaluation before vaccination)*

- 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
- Use of aspirin or aspirin-containing products
- 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

Varivax (Merck) may be administered via either the intramuscular (IM) or subcutaneous (Subcut) route. 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
Age 1 through 2 years	22-25	1–1¼"	Anterolateral thigh muscle*
		⅝†–1"	Deltoid muscle of arm
Age 3 through 10 years	22-25	⅝†–1"	Deltoid muscle of arm*
		1–1¼"	Anterolateral thigh muscle
Age 11 years and older	22-25	⅝†–1"	Deltoid muscle of arm*
		1–1½"	Anterolateral thigh muscle

* Preferred site.

† A ⅝" 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**, choose the needle gauge, needle length, and injection site according to the following chart:

NEEDLE GAUGE	NEEDLE LENGTH	INJECTION SITE
23-25	⅝ "	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, 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 through 12 years	Give dose #1. Give dose #2 at least 12 weeks later.
1 documented dose	12 months through 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 https://www.immunize.org/wp-content/uploads/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 https://www.cdc.gov/pinkbook/hcp/table-of-contents/?CDC_AAref_Val=
- 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 with severe immunodeficiency (e.g., hematologic and solid tumors, receipt of chemotherapy, congenital immunodeficiency, long-term immunosuppressive therapy or patients with HIV infection who are severely immunocompromised).
    - Note: Long-term immunosuppressive therapy is defined as at least 2 weeks of daily receipt of 20 mg or 2 mg/kg body weight of prednisone or its equivalent.
    - Note: Susceptible individuals living with HIV are at increased risk for serious illness from varicella infection. Eligible HIV-infected adults should receive 2 doses of single-component varicella vaccine with a 3-month interval between doses. For additional information regarding HIV laboratory parameters and use of live vaccines, see the General Best Practice Guidelines for Immunization, "Altered Immunocompetence," at https://www.cdc.gov/vaccines/hcp/imz-best-practices/altered-immunocompetence.html?CDC_AAref_Val=https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/immunocompetence.html_l and Table 4-1 (footnote J) at https://www.cdc.gov/vaccines/hcp/imz-best-practices/contraindications-precautions.html?CDC_AAref_Val=

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- 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 *(require evaluation before vaccination)*

- 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

Varivax (Merck) may be administered via either the intramuscular (IM) or subcutaneous (Subcut) route. If vaccine is to be administered by the intramuscular route, 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	1"*–1½"	Anterolateral thigh muscle

* Alternative needle lengths may be used for IM injections if the skin is stretched tightly, the subcutaneous tissues are not bunched, and the injection is made at a 90° angle to the skin as follows: a) a ⅝ " needle for adults weighing less than 130 lbs (<60 kg) or b) a 1" needle for administration in the thigh muscle for adults of any weight.

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	⅝ "	Fatty tissue over triceps

Reconstitute the vaccine with the manufacturer-supplied diluent just prior to administration.
Administer Varicella Vaccine, 0.5 mL, 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.

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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 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 https://www.immunize.org/wp-content/uploads/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). 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.

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STANDING ORDERS FOR Administering Vaxelis (Diphtheria and Tetanus Toxoids and Acellular Pertussis, Inactivated Poliovirus, Haemophilus b Conjugate and Hepatitis B Vaccine) in Children 6 weeks through 4 years of Age

Purpose

- To reduce morbidity and mortality from tetanus, diphtheria, pertussis, poliomyelitis, hepatitis B, and invasive disease due to Haemophilus influenzae type b (Hib) 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:
  - The3 dose immunization series should be administered at 2, 4 and 6 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:
  - 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 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.
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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

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 intramuscularly

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

Note: DTaP-IPV-Hib-HepB (Vaxelis®) is included with PRP-OMP (PedvaxHIB®) in the preferential recommendation for American Indian and Alaska Native infants based on the Haemophilus influenzae type b (Hib) component.

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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.

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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/hcp/vaccine-considerations/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 immunocompromised adults with no documented history of varicella, varicella vaccination, or herpes zoster, see www.cdc.gov/chickenpox/hcp/clinical-guidance/index.html
- 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 https://www.fda.gov/vaccines-blood-biologics/vaccines) or go to https://www.cdc.gov/pinkbook/hcp/table-of-contents/appendix-b-vaccines.html

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.

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- 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	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	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 ⅝" 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.

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

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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 https://www.immunize.org/wp-content/uploads/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.

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 Case Manager

- Determine pregnancy status on all reports of HBsAg-positive women aged 14 through 46 years.
- Follow-up with the reporting provider of an HBsAg-positive pregnant woman to obtain more information needed for case management.
- The case manager 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". (Figure 1) https://www.cdc.gov/hepatitis-b/media/pdfs/2025/03/ob-provider-hepb-tip-sheet-EO.pdf
- Obtain an EPID 394 form on all HBsAg-positive pregnant women.
- Submit patient information in the REDCap Perinatal Hepatitis Tracker
- Upload EPID 394 form into the REDCap Perinatal Hepatitis Tracker.
- 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 Clinical Overview of Perinatal Hepatitis B https://www.cdc.gov/hepatitis-b/hcp/perinatal-provider-overview/index.html
    - A letter may be sent (PHBPP-1 form).
- Determine sexual and household contacts of the HBsAg-positive woman and refer them to education, testing and/or hepatitis B immunizations.
- Document contacts and outcomes in the REDCap Perinatal Hepatitis Tracker.
- Refer all HBsAg-positive patients to a medical provider to monitor outcomes or progress of HBV infection.
- Document referrals in REDCap.
- Send reminder letters and contact the mother by phone during pregnancy to provide timely reminders about necessary lab tests, follow up appointments for hepatitis B care, and the post-delivery care required for her infant. All active REDCap records must be reviewed at least once per month to ensure timely interventions. (PHBPP-2 form-found in REDCap)
- Notify the delivering hospital of the mother's HBsAg status. Direct obstetrical care provider to forward supporting documents of the mother's HBsAg status to the delivering hospital. (PHBPP-3 form-found in REDCap)
- Once an infant is born to an HBsAg-positive mother, verify that the infant received HBIG and Hepatitis B vaccine after delivery.
- Birthing hospital should complete the EPID 399 form.
- Review all EPID 399 forms for missing information. All sections of the EPID 399 form must be completed.

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- 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 2024-2027 Red Book for Follow-up Management of Infants Whose Birthing Parent is HBsAg positive (PHBPP 4 form and PHBPP-5 forms- found in REDCap). https://www.cdc.gov/vaccines/programs/perinatal-hepb/downloads/HepB-Provider-tipsheet-508.pdf
- 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 found in REDCap).
- HBsAg negative infants with anti-HBs less than 10 mIU/mL should be revaccinated with a single dose of Hep B vaccine and receive PVST one to two months later.
- Infants who's anti-HBs remains less than 10 mIU/mL following single dose revaccination should receive two additional doses of Hep B vaccine, followed by PVST one to two months after the final dose **OR**
    - 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-found in REDCap)
- Case is closed if the results of PVST indicate that the infant is HBsAg-negative and anti-HBs-positive. Document results in REDCap. Upload results if not available in NEDSS. Notify the Perinatal Hepatitis B Coordinator of results and that exposure is to be closed.
- 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 and notify the Perinatal Hepatitis B Prevention Coordinator at the Kentucky Department for Public Health in Frankfort.
    - CASE MUST BE REPORTED IN NEDDS

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 Case Manager 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 Case Manager then begins case management for infants born to an HBsAg-positive woman.

Managing Missed Vaccination/ Serology Appointment

- Send a reminder card for missed appointments.
- Send a letter, conduct home visit, make a telephone call to the parent, guardian, provider, and/or WIC visit. For continued non-compliance send certified letter.
- The LHD PHBPP Case Manager maintains documentation of efforts in the REDCap Perinatal Hepatitis Tracker.

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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:
    - * Accurint/search engines) * WIC database/appointments *Medicaid records * Electronic medical records *Pediatrician's office *Obstetrical care provider

- Infants categorized as "Lost to Follow-Up" (LTF) are those who have been identified for PHBPP case management services but cannot be located, even after prior successful communication. These cases should remain open with continuous outreach efforts until the end of the second reporting period. If the infant has not been located by 24 months of age, the case should be referred to the PHBPP State Coordinator for evaluation and determination of whether the case can be officially classified as "Lost to Follow-Up". Documentation of efforts should 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.

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Figure 1

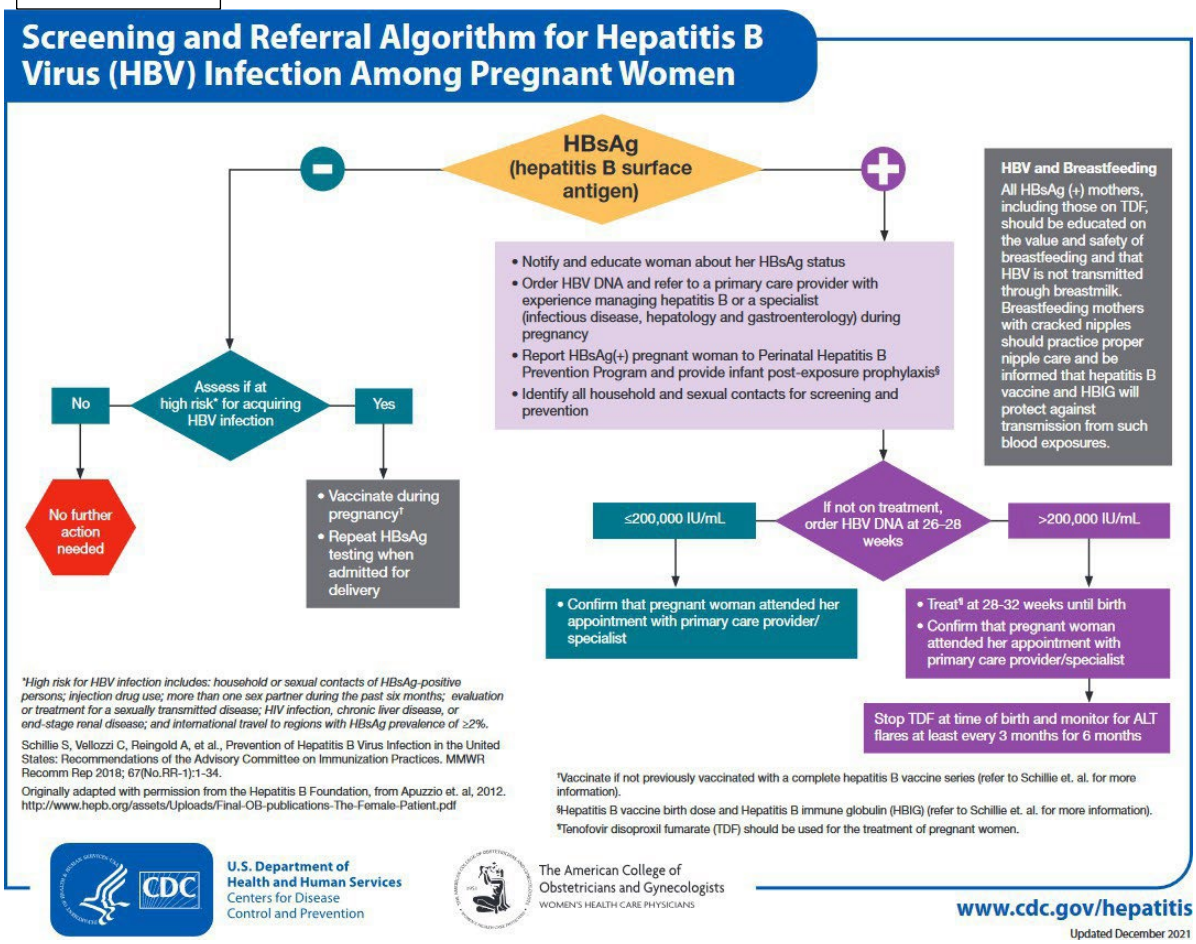

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Table 1: Hepatitis B Post Exposure Management of Infants with Birth Weight of 2,000 Grams or More

HEPATITIS B (Hep B) VACCINE SCHEDULES FOR NEWBORNS INFANTS BY MATERNAL HEPATITIS B SURFACE ANTIGEN (HBsAg) STATUS*

Maternal HBsAg Status	Monovalent (Single-antigen) Hep B vaccine		Monovalent (Single-antigen) Hep B 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
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
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

*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® and Vaxelis 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 or HBsAG status remains unknown, the infant should receive HBIG as soon as possible but no later than 7 days after birth.

Adapted from Committee on Infectious Diseases, American Academy of Pediatrics. David W. Kimberlin, MD, FAAP, ed. 2024. Red Book: 2024-2027 Report of the Committee on Infectious Diseases - 33rd Ed. American Academy of Pediatrics. ISBN 978-1-61002-734-2. eISBN 978-1-61002-735-9. ISSN 1080-0131. STAT!Ref Online Electronic Medical Library. https://online.statref.com/document/3-4yKzRRn_vNhkAUdBv8aD. 3/18/2025 2:54:40 PM CDT (UTC -05:00).

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Table 2. Hepatitis B Post Exposure Management of Preterm Infants, Birth Weight Less Than 2,000 grams, by Maternal Hepatitis B Surface Antigen (HBsAg) Status

Maternal HBsAg Status	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 Hep B 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 • 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 Hep B vaccine at 1, 2 through 3, and 6 months of age, or a hepatitis B combination vaccine at 2, 4, and 6 months of age For infants born to hepatitis B-infected mothers, postvaccination serologic testing, consisting of testing for HBsAg and quantitative anti-HBs, should be ordered at age 9 through 12 months (or 1 through 2 months after the final dose of the vaccine series, if delayed).
Negative	• Delay first dose of hepatitis B vaccine until age 1 month if medically stable or at hospital discharge. Complete the hepatitis B vaccine series with either monovalent Hep B vaccine at 1, 2 through 3, and 6 months, or a hepatitis B containing combination vaccine at 2, 4 and 6 months

*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 Committee on Infectious Diseases, American Academy of Pediatrics. David W. Kimberlin, MD, FAAP, ed. 2024. Red Book: 2024-2027 Report of the Committee on Infectious Diseases - 33rd Ed. American Academy of Pediatrics. ISBN 978-1-61002-734-2. eISBN 978-1-61002-735-9. ISSN 1080-0131. STAT!Ref Online Electronic Medical Library. https://online.statref.com/document/3-4yKzRRn_vNhkAUdBv8aD. 3/18/2025 2:54:40 PM CDT (UTC -05:00).

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Table 3: 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 Hep B vaccine and receive post vaccination serologic testing 1-2 months later. Infants whose anti-HBs remains less than 10 mIU/mL following single dose revaccination should receive two additional doses of HepB vaccine, followed by PVST 1-2 months after the final dose. • Based on clinical circumstances or family preference, HBsAg-negative infants with anti-HBs less than 10 mIU/mL may instead be revaccinated with a second, complete 3-dose series, followed by post vaccination serologic testing (PVST) performed 1-2 months after the final dose of vaccine.
HBsAg-positive and anti-HBs-negative	Infant is infected with Hepatitis B virus and will need medical follow up. Send a report to Kentucky Perinatal Hepatitis B Prevention Coordinator in accordance with 902 KAR 2:020 and CCSG protocol titled "Reportable Diseases Deadlines for Health Professionals and for Local Health Departments".

Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices MMWR. Recommendations and Reports / Vol. 67 / No. 1 / P. 1–31

Optional Forms and Templates for Perinatal Hepatitis B Prevention Program (PHBPP)
See CCSG Forms Section, https://www.chfs.ky.gov/agencies/dph/dpqi/hcab/Pages/ccsguide.aspx for the following forms:

EPID-399: Perinatal Hepatitis B Prevention Form for exposed Infants and Hepatitis B Positive Pregnant Mothers
EPID-394: Perinatal Hepatitis B Prevention Form for Pregnant Women and Positive Infant
PHBPP-1: Introduction Letter (for the Mother)
PHBPP-2: Reminder Letter Prior to Delivery (for Mothers
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 for tracking
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
PHBPP-10 Perinatal Hep B Letter to OB Provider

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References and Additional Resources

- Clinical Overview of Perinatal Hepatitis B
  - https://www.cdc.gov/hepatitis-b/hcp/perinatal-provider-overview/

- CHFS Perinatal Hepatitis B
  https://www.chfs.ky.gov/agencies/dph/dehp/idb/Pages/perinatal-hepatitis-b.aspx

  - KDPH | Perinatal Hep B Outreach Toolkit
    https://www.chfs.ky.gov/agencies/dph/dehp/idb/Documents/PeriHepB_Toolkit.pdf

    - Perinatal Hep B Case Management algorithm
    - Perinatal Hep B OB Provider algorithm
    - Perinatal Hep B Pediatric Provider algorithm
    - Perinatal Hep B Post Delivery Algorithm

- Management of Infants Born to Women with Hepatitis B Virus Infections
  - https://www.cdc.gov/vaccines/programs/perinatal-hepb/downloads/HepB-Provider-tipsheet-508.pdf

- Tip Sheet for Hepatitis B Screening, Testing, and Management of Pregnant Women
  - https://www.cdc.gov/hepatitis-b/media/pdfs/2025/03/ob-provider-hepb-tip-sheet-EO.pdf

- Algorithm – Maternal HBsAg Test Results AVAILABLE
  - https://www.cdc.gov/hepatitis-b/media/PerinatalAlgorithm-Avaliable.pdf

- Algorithm – Maternal HBsAg Test Results UNAVILABLE
  - https://www.cdc.gov/hepatitis-b/media/PerinatalAlgorithm-Unavailable.pdf

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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 two ways to report to VAERS, https://vaers.hhs.gov/reportevent.html:

1) Report Online via a secure website at https://vaers.hhs.gov/esub/index.jsp (Preferred method)
2) Report with a writable PDF : Download the VAERS form, https://vaers.hhs.gov/uploadFile/index.jsp, and review the instructions for completing and uploading the VAERS writable PDF.

To ensure that the Kentucky Immunization Program is aware of these events, please fax a copy to 502-564-4760.

Refer to the http://vaers.hhs.gov/resources/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf or the https://www.cdc.gov/pinkbook/hcp/table-of-contents/index.html 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, 2025 is available at https://www.cdc.gov/vaccines/hcp/imz-schedules/child-adolescent-age.html. The full ACIP recommendations for each vaccine are also available at https://www.cdc.gov/acip-recs/hcp/vaccine-specific/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.

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Laboratory Services

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CLINICAL PROTOCOLS

Overview

Laboratory tests may involve the testing of clinical and environmental specimens. Specimen types may include body fluids (plasma, serum, whole blood, urine, etc.) tissues, secretions, culture isolates, animal heads, food, milk, and water sources. Laboratory tests provide the Local Health Departments (LHD), clinicians and health care providers with indicators to possible health problems and to public health concerns from human, animal, and environmental exposures. Information from lab tests can help to identify changes in health condition and diagnose and track diseases or conditions. They can help guide decisions in treatment for a disease or condition, trigger mitigation to ensure safe food and water consumption and usage, evaluate treatment response, and help to monitor diseases, outbreaks, and pandemics in real time and 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's public heath reference laboratory; Division of Laboratory Services (DLS), and this CSG help 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 DLS website, Division of Laboratory Services - Cabinet for Health and Family Services (ky.gov), provides has the following information and resources:

- Contact numbers
- Business hours of operations (M - F 8:00am – 4:30pm) and for after-hours emergencies
- Laboratory Submission Forms and Requisitions
- CLIA Certification & Questions (includes the contact number for the Office of Inspector General)
- LIS registration and access for "Outreach" (lab's electronic information system for efficient submission of test orders and retrieval of test results)
- Ordering lab kits/supplies fillable/printable requisition Form (check periodically for updates).
- Reference list of tests (acceptable specimen sources, lab test and CPT codes, reference ranges, etc.)
- Collection and Packaging Guides (colorful graphics & user-friendly instructions)
- Newborn Screening reports KOG portal
- Cystic fibrosis 139 Variant Physician Insert (PDF)

Check the website for timely resources, guidance, and healthcare provider and patient facts posts for updates, especially during pandemics and other public health events, crisis, and emergencies.

LIS – Outreach

Sign up to become a certified user to access Outreach, the laboratory's electronic information system, to efficiently submit test orders and retrieve timely laboratory results. Access helps to reduce turnaround time and decreases the risk for clerical errors. Sign up information is on the website.

- Contact the main DLS phone line at 502-564-446 for any questions or concerns
- Outreach e-mail: CHFS.CSCO@ky.gov

DLS Certificates

The DLS has the following downloadable certificates:

- CAP
- CLIA
- KY Medical Licensure

Requisition for Laboratory Supplies

A fillable electronic form that can be sent via email to HYPERLINK mailto:DPHLabkits@ky.gov DPHLabkits@ky.gov is on the DLS 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

Links to laboratory testing submission forms are on the DLS website. It is important to complete ALL ask at order entry questions, be thorough in answering submission questions, and include an email when requested (such as for water bacteriology requests). Having a contact enables the lab to contact the collector or a facility concerning questions and concerns about a submitted sample. Timely responses can help to avoid rejection of samples or the need for recollection.

NOTE: The laboratory submission forms listed on the DLS website are in PDF and serve only as a manual back-up if a submitting facility's electronic system is down and they cannot access Outreach.

Collection and Packaging

Links to collection and packaging guides are on the DLS website (listed below). These instruction guides include helpful colored graphics and contain crucial information on acceptable specimen types, storage, packaging, and shipment. These guides help to ensure the integrity and optimal conditions of specimens are preserved so they arrive to the DLS in an acceptable state for testing to produce accurate, reliable, and valid results. 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.

Collection and Packaging Instructions

- Multishipper Instructions
- Enteric and Norovirus Collection and Packaging Guidelines
- Food Collection
- Method for Sputum Collection
- Multishipper with Cold Pack Blood
- Multishipper with Cold Pack Hepatitis A
- Multishipper with Cold Pack Hepatitis C
- Multishipper with Cold Pack Virus-Swab
- Newborn Screening Collection
- Rabies Packaging
- Water Collection

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 the "Reference List of Tests" under the Test Menu on the home page of the DLS website

CLIA Certification, Training, and Resources

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. Certificate renewal fees occur biennially. Start renewal months in advance of the Certificate expiration to ensure no lapse in laboratory testing services. 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
- CLIA Certificate Information
- CLIA Certificate Quick start Guide https://www.cms.gov/files/document/laboratory-quick-start-guide-cms-clia-certification.pdf

Call the Office of Inspector General (OIG), for changes, questions, and issues with certification. Inform the OIG and 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.

- Phone (502) 564-7963 Ext 3322 / FAX: (502) 564-6546
- Email: KYCLIALabinquiries@ky.gov

The Centers for Disease Control and Prevention (CDC) provides basic eLearning laboratory training courses on how to safely and accurately perform CLIA-waived and PPM patient testing. Continuing education units (CEU) and P.A.C.E.® credits are available. Refer to the CDC Laboratory Training website for more information on training and educational resources.

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. Further information, resources, and a self-assessment checklist of good testing practices for those sites that have a certificate of waiver can be found in the above link. Information on this page includes the following:

  To Test or Not to Test Booklet
  Ready? Set? Test ! Booklet and Online Course
  Self-Assessment Checklist
  List of Website links to other useful information and resources.

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.

Helpful Resources:

- PPM Quality Practices
- CLIA and PPM Introduction Course

Laboratory Director/Site Coordinator Responsibilities

The Laboratory Director/Site Coordinator is a Local Health Department (LHD) staff member who is responsible for the overall operation and administration of the laboratory. They are responsible for CLIA compliance and ensuring their facility CLIA certification is renewed every (2 years), changes communicated to OIG, and updated with changes as required. They ensure 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.

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)

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.
- 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.
- 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.
- Maintain personnel records according to LHD records retention policy and in accordance with accreditations, local, state, and federal requirements as applicable. Records are to be readily available on current employees. Records may include, but are not limited to trainings, continuing education, competency assessments, proficiencies, HIPPA, confidentiality, and security agreements, health records, job duties, and applicable performance evaluations.

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 and with changes and revisions
- 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 committee for oversight of the program.
- Develop a system to identify, document, and monitor laboratory failures, incidents, deficiencies, and any non-compliance or non-conformances as they occur.
- Perform monthly record searches by reviewing a sampling of patient records. Ensure all relevant elements are documented, reports of results are accurate, and all required information is included. (CH-12 or equivalent quality assessment record search form may be used).
- Provide effective and measurable corrective and remedial action and resolution to prevent reoccurrence and promote quality improvement.
- Provide timely reviews of reports and follow-up reviews at 3 or 6 months and annually to help evaluate effectiveness of remedial action and resolutions.
- The tools and resources from CDC have many helpful sections on QA and QC for waived and PPM testing. Refer to the following website; Tools and Resources | CDC

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 and in date 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
- Maintain and retain records consistent with CLIA, OSHA, site policy, and any other applicable accreditation, licensure, and regulatory standards
- 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. Further resources of an assessment checklist, best practices, and safety plan information can be found within the tools and resources on the aforementioned CDC lab quality website.

General Laboratory Testing Recommendations

- 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/reviewed as documentation and to track reviews.
- 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 if the changes are major, such as a change in timing, results, or a procedural step.
- Use the test kits/reagents in the form they are received. For example, 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 and calibration documentation in accordance with LHD records retention policy and applicable accreditations and regulatory requirements..
- 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).
- Review reference lab specimen referral criteria. Confirm specimen collection requirements and follow up all testing results. Obtain a copy of the current CLIA and other testing certificates from all reference laboratories the LHD uses for testing referrals. These certifications are documentation that the laboratories performing the referral testing is an approved and certified laboratory for the tests that are being performed by them.
- 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 in accordance with LHD records retention policy and applicable accreditations and regulatory requirements.

See the CSG "Forms and Teaching Sheets" Lab Section and the tools and resources from the CDC: Tools and Resources | CDC further recommendations.

Shipping Laboratory Specimens to Division of Laboratory Services (DLS)

- Packaging and Shipping information can be found in the Administrative Reference.
- Questions on Packaging and Shipping - Call (502) 564-4446 or (502) 782-7703.

STANDING ORDER FOR MEASLES SPECIMEN COLLECTION AND TESTING

PURPOSE

To outline the procedures for specimen collection, testing, and reporting for suspected measles cases in alignment with the Kentucky Department for Public Health (KDPH) and Kentucky Division of Laboratory Services (DLS) guidelines. This standing order provides healthcare facilities with the necessary instructions on specimen types, collection methods, handling, storage, and shipping requirements to ensure timely and accurate laboratory diagnosis of measles. Measles is a reportable disease in Kentucky. All suspected and confirmed cases must be reported **immediately** to the Kentucky Department for Public Health (KDPH).

PROCEDURE

1. IDENTIFICATION OF SUSPECTED MEASLES CASES

All suspected or probable cases must be reported to the KDPH Immunization Program before laboratory testing. Testing is reserved for persons who are likely to have measles.
Healthcare providers should suspect measles in individuals presenting with:

- Fever
- Cough
- Coryza (runny nose)
- Conjunctivitis
- Generalized maculopapular rash

  (Rash usually appears about 14 days after exposure and spreads from the head to the trunk to the lower extremities. Sometimes immunocompromised patients do not develop the rash)

Obtain immunization status and travel history. Recent contact with individuals confirmed to have measles

2. INFECTION CONTROL AND PERSONAL PROTECTIVE EQUIPMENT (PPE)

(Adhere to Standard and Airborne Precautions)

- **Minimize potential measles exposures:**

  Before arrival: when scheduling appointments by phone:
  - For persons with signs or symptoms of measles, provide instructions for arrival, including entrance to facility and the precautions to take *(e.g., how to notify staff, don a facemask upon entry, triage procedures).*

  Upon arrival:
  - Persons with signs or symptoms of measles should be identified, provided a facemask to wear and separated from other patients prior to or as soon as possible after entry into a facility.
- **If an airborne infection isolation room (AIIR) is not available, follow these alternative airborne precautions:**
  - Collect specimens in a private room with door closed and limit entry.
  - If possible, use a room with mechanical ventilation to improve airflow.
  - Instruct staff to wear appropriate PPE *(N95 or higher-level respirator, gloves, gown and goggles or face shield).*
  - After patient departure, keep room vacant with door closed for at least 2 hours before disinfecting the room.

For more information on prevention and control recommendation for measles, visit: Interim Infection Prevention and Control Recommendations for Measles in Healthcare Settings | Infection Control | CDC

3. HEALTHCARE PERSONNEL IMMUNITY

- Ensure healthcare personnel (HCP) have documented evidence of immunity to measles. For more information, visit: https://www.cdc.gov/infection-control/hcp/measles/index.html

4. OBTAIN KDPH APPROVAL FOR MEASLES TESTING AT DLS

- Approval for measles testing at DLS must be obtained in advance from the KDPH Division of Epidemiology and Health Planning (DEHP).
- During business hours contact DEHP at (502) 564-3261
- After hours contact the epidemiologist on call at (888) 9REPORT, (888) 973-7678

5. SPECIMEN COLLECTION

SPECIMENS SHOULD BE COLLECTED AT THE FIRST CONTACT WITH A SUSPECTED CASE.

Preferred specimens: Nasopharyngeal (NP) or throat (oropharyngeal) swabs are the preferred samples for the detection of measles RNA by RT-PCR. Optimal timing for specimen collection is within the first 3 days of rash onset, though virus detection is possible up to 10-14days post-rash onset. If more than 10 days post-rash onset, only blood for serology (IgM and IgG) should be collected.

Specimen	Test	Volume	Shipment	Expected TAT
NP and/or Throat Swab *(preferred)*	PCR	2 mL VTM	Refrigerated (4°C/39.2°F), place on cold packs	PCR: 1-2 days
Serum	IgM and IgG EIA	1-3 mL	Refrigerated (4°C/39.2°F), place on cold packs	IgG: 1-2 days at DLS IgM: 4 days at Quest Diagnostics only

Testing Systems Employed:
Serological specimens will be evaluated at the Kentucky Division of Laboratory Services (DLS) using an Enzyme Immunoassay (EIA) to detect measles-specific IgG antibodies. IgM testing is available upon request at Quest Diagnostics if needed. Nasopharyngeal (NP) swabs and throat swabs will be processed for PCR testing at the Kentucky DLS.

Order Lab Specimen Collection Kits from DLS if needed:

- **Complete** DLS Requisition Ordering Form: https://www.chfs.ky.gov/agencies/dph/dls/Documents/LabForm275Virology.pdf
- **Email** completed form(s) to: dphlabkits@ky.gov

Collection Methods *(see Note)*:

- **Nasopharyngeal Swab**: Aseptically remove sterile swab from package and collect the nasopharyngeal swabs by gently inserting swab through each nostril deeply into the nasopharynx (aiming towards the ear). Place the swab tip into 2mL of viral transport medium (VTM) and break the shaft of the swab at the scored line. Screw the cap on tightly, ensuring a secure seal.
- **Throat Swab**: Aseptically remove sterile swab from package and collect epithelial cells by vigorously swabbing the posterior pharynx and tonsil regions of the throat, avoiding the tongue and buccal mucosa. Place the swab tip into 2mL of viral transport medium (VTM) and break the shaft of the swab at the scored line. Screw the cap on tightly, ensuring a secure seal.
- **Serum**: Collect 6-8 mL of whole blood in a serum separator tube. Let blood clot at room temperature for at least 30 minutes—do not shake, centrifuge to separate serum. Transfer 2-

3 mL serum into a screw-capped plastic vial to submit for testing. Hemolyzed, icteric, or lipemic serum is unacceptable.

Note: *Do not use expired media or swabs. Swabs must be synthetic (Dacron, Nylon, Polyester) with a non-wooden shaft. Swabs may be flocked. Do not use calcium alginate-tipped OR wooden-shafted swabs, as they may inactivate the virus. Ensure that the patient's first and last name, date-of-birth, specimen source and time/date of collection are recorded on the specimen tube.*

Specimen Timing:

- For optimal specimen collection timing, collect samples on the first day of rash onset through day 3; virus detection is possible up to days 10-14post-rash onset.
- For IgM testing, collect serum ≥3 days post-rash onset to avoid false-negative results due to undetectable levels of antibodies.

6. SPECIMEN STORAGE AND TRANSPORTATION:

- **Refrigerate (4° - 8°C or 39.2° - 46.4°F) all specimens immediately after collection.**
- If specimen cannot be shipped immediately, freeze at -70°C or -94°F and ship on dry ice. DO NOT store samples in a standard freezer
- Verify specimens are clearly labeled with patient's first and last name, date-of-birth, specimen source and collection date/time—matching the requisition form.
- Ship specimens cold to the Kentucky Division of Laboratory Services (DLS) the same day, using the fastest means available.

7. TEST REQUISITION FORMS

- **Serology (IgM and IgG):** Outreach code: MEAE or alternatively use Lab Form #275. (https://www.chfs.ky.gov/agencies/dph/dls/Documents/LabForm275Virology.pdf)
- **Swabs for PCR:** Outreach code: MEPCR or alternatively use Lab Form #275.
- Ensure all fields on the requisition form are completed, and that two patient identifiers match specimen labels.

If multiple specimens are submitted for the same patient, ensure a requisition form accompanies each type of specimen.

8. SHIPPING INSTRUCTIONS:

1) **Timely Shipment:**
   - Ship specimens cold to the Kentucky DLS on the same day of collection, using the fastest means possible.
2) **Primary Container Preparation:**
   - Wrap the properly labeled specimen (primary container) in absorbent material (e.g., paper towel).
   - Place it into a leak-proof secondary container (e.g., a sealed plastic bag or 95kPa-compliant bag.
3) **Specimen Preparation:**
   Single specimens:
   - Place the labeled specimen tube into a leak-proof secondary container (e.g., a sealed plastic bag) containing sufficient absorbent material to absorb the entire contents in case of leakage.

Multiple specimens:

- Individually wrap each specimen tube with absorbent material and place each into its own leak-proof secondary container.
- If available, use a tube shuttle or similar device to consolidate multiple specimens securely.
- Ensure that the combined packaging meets the 95kPa pressure differential requirement, as mandated for the transport of biological substances.

4) **Temperature Control:**

- Include two frozen gel/ice packs inside the shipping container to maintain the required cold temperature.

5) **Placement of Specimens:**
Place the secondary container(s) between the ice packs to ensure consistent cooling.

6) **Documentation:**
- Place completed requisition forms in a separate, sealed plastic bag.
- Position this bag outside the secondary container but within the outer shipping package to prevent contamination.

7) **Ship specimens to:**

Kentucky Division of Laboratory Services (DLS)
100 Sower Blvd, Suite 204
Frankfort, KY 40601
Phone: (502) 564-4446
https://chfs.ky.gov/agencies/dph/dls/Pages/default.aspx
Email DLS with tracking number if available

For DLS Specimen and Collection Shipping Instructions:

- Viral PCR Swab
https://www.chfs.ky.gov/agencies/dph/dls/Documents/Multishipperwithcoldpackvirusweb.pdf
- Blood Specimen for Immunity Testing
https://www.chfs.ky.gov/agencies/dph/dls/Documents/MultishipperwithcoldpackBlood.pdf

Note: PCR and serological samples received before 12:00 pm (EST) will be processed and tested the same day.

9. PATIENT INSTRUCTIONS

- **Isolation:** Suspected measles patients should remain at home and avoid contact with others until at least 4 days after rash onset.
- **Preventing Spread:** Practice hand hygiene and cover coughs/sneezes.
- **Medical Care:** If patient needs medical care at another facility, call ahead to alert the facility of potential measles exposure.

10. ROOM CLEANING AND DISINFECTION

- After patient departure, keep the room vacant with door closed for at least 2 hours before cleaning to allow airborne contaminants to settle and be removed properly.
- Perform terminal cleaning using standard hospital-grade disinfectants on all surfaces.

11. Test Result Interpretation Guidelines:

- **PCR Positive:** Indicates current measles infection.
- **IgM Positive:** Suggestive of acute measles infection; however, false positives can occur. Confirm with PCR.
- **IgG Seroconversion (negative to positive or 4x rise in titers in paired specimens):** Confirms measles infection.
- **IgM Negative & PCR Negative:** Likely no current measles infection, but retest if symptoms persist.

12. Exposure Management & Post-Exposure Prophylaxis (PEP) ***(see standing orders for Measles IG)***

For Unvaccinated or Non-Immune Contacts:

- MMR vaccine should be administered within 72 hours post-exposure to prevent infection.
- Immune globulin (IG) may be given within 6 days of exposure for high-risk individuals (e.g., infants <12 months, pregnant individuals, immunocompromised persons).

For Healthcare Personnel (HCP) Exposed to Measles Without Documented Immunity:

- Exclude from work from day 5 to day 21 post-exposure, regardless of symptoms.
- If symptoms develop, immediate testing and further isolation are required.

13. Additional Resources:

- Division of Laboratory Services - Cabinet for Health and Family Services (https://www.chfs.ky.gov/agencies/dph/dls/Pages/default.aspx)
  Main Laboratory number: (502)564-4446
  Laboratory Emergency after hours number: (502) 320-4501
  Epidemiology main number: (502) 564-3261
  Epidemiology after-hours number: (888) 9REPORT, (888) 973-7678
  Sentinel Laboratory Information: (502) 782-7703
- Measles - Cabinet for Health and Family Services (https://www.chfs.ky.gov/agencies/dph/dehp/idb/Pages/measles.aspx)
  Toll-free Measles Hotline: (855) 598-2246
  - 8 am – 4:30 pm (EST) Monday-Friday, for answers to general measles questions.
- KDPH Measles Testing Guidance (https://www.chfs.ky.gov/agencies/dph/dehp/idb/Documents/KDPHMeaslesTestingGuidance.pdf)
- KDPH Measles Post-Exposure Prophylaxis (PEP) (https://www.chfs.ky.gov/agencies/dph/dehp/idb/Documents/Measles_PEP.pdf)
- Measles (Rubeola) | Measles (Rubeola) | CDC (https://www.cdc.gov/measles/)

Lead

Kentucky Childhood Lead Poisoning Prevention Program (KYCLPPP)

Table of Contents:

Screening Guidelines and Specimen Collection

Lead Levels and Definitions

The amount of lead in blood is referred to as the blood lead level (BLL) is measured in micrograms of lead per deciliter (µg/dL) 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 reference value to 3.5 µg/dL based on these NHANES data. The CDC revised the BLRV to 3.5 µg/dL. **An elevated blood lead level (EBLL) is defined as a BLL greater or equal (≥) to 3.5 µg/dL.**

Lead Risk Assessment and Testing Guidelines

Any child or pregnant woman with a "Yes" or "I don't know" response on the lead risk assessment must be provided preventive lead education to prevent future exposures.

- All children should receive a lead risk assessment at 6, 9, 12, 18, and 24 months of age and at 3, 4, 5, and 6 year of age.
  - Any "Yes" or "I don't know" response should result in a blood lead test.
- All Medicaid enrolled children, regardless of funding through title XIX or XXI, are required to receive a blood lead test at 12 months and 24 months of age. Any child who did not receive a blood lead test, must receive one between the ages of 24 to 72 months of age. The Medicaid requirement is met when the child has these two lead tests, or the catch-up lead test mentioned. Completion of a risk assessment does not meet the Medicaid requirement for testing.
- All newly arriving refugee children aged 72 months and under: Infants and children should receive an initial blood lead test with a follow-up test 3 to 6 months later regardless of the initial blood lead test result.
- All newly arriving pregnant and lactating girls and women: Should receive an initial blood lead test. For those less than 18 years old who had an in initial BLL of ≥3.5 µg/dL, a follow-up lead test should be completed 3-6 months after the initial test.
- Pregnant women should receive a lead risk assessment. Any "Yes" or "I don't know" responses should result in a blood lead test. Refer to the Prenatal section for more information.

Blood Lead Specimen Collection

All LHD staff obtaining blood lead specimens must click the link Mission Unleaded: Blood Draw Collection 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 ≥3.5 µg/dL. LeadCare devices can only 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 ≥3.5 µg/dL, read the section below on confirmatory blood lead tests.

Confirmatory Venous 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 is ≥ to 3.5 µg/dL, a **confirmatory test must be completed through a venous sample per the CDC. If the child's primary care provider orders a capillary test, obtain written notification the provider ordered a capillary test, is following lead testing, and providing care for this child. This provider should be the one who sees the child for sick/well child visits.** 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.)*	Provide 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.** • If the child's primary care provider orders a capillary test, obtain written notification the provider ordered a capillary test, is following lead testing, and providing care for this child.	• Confirm BLL through a venous sample if the initial test was capillary. Venous is considered confirmed. • Confirmatory tests should be performed immediately, but no 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**, 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. • Although not considered elevated at <3.4 µg/dL, a BLL ≥2.3 µg/dL shall be reported to the cabinet within seven (7) days and to the local or district health officer. KRS 211.902	• 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 the case management form. *	• Complete a 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. If the child's primary care provider orders a capillary test, obtain written notification the provider ordered a capillary test, is following lead testing, and providing care for this child. • Establish a tracking system that ensures retesting and follow-up interventions. • Ensure that 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 µg/dL please provide PCP with information on lead specialist consult. • Recommend the provider 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)***
≥3.5–9	3 months*	6–9 months
10–19	1–3 months*	3–6 months
20–44	2 weeks–1 month	1–3 months
≥45	As soon as possible	As soon as possible

- If the child's primary care provider orders a capillary test, obtain written notification the provider ordered a capillary test, is following lead testing, and providing care for this child.
- 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.
- Seasonal weather changes may affect the BLLs. Increased exposure during the summer may require more frequent testing.

Lead Poisoning Prevention and Case Management

According to the 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 under the purview of a registered nurse. Some components of case management need to be completed by a nurse while other components may be delegated to a multi-disciplinary team (health educators, environmentalists, or community health workers).

- Completed by the nurse:
  - Individual assessment, diagnosis, and health education. If the child does not have a medical home or being managed by a primary care provider, a physical assessment and health education must be completed by the nurse either in the LHD or child's home.
  - Monitoring of service delivery
  - Evaluation
- Delegated to the multidisciplinary team:
  - Client identification and outreach
  - Service planning and resource identification
  - Linking of clients to needed services
  - Service implementation and coordination
  - Advocacy

When a blood lead result is ≥3.5 ug/dL, education should be provided on what lead is, 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**", even if they are or have been receiving direct clinical services elsewhere, when that level is identified through LHD screenings, are referred to LHDs by the primary care physician, or the EBLL is reported to the LHD by the state health department. They will remain a health department patient until case closure.

Reporting

- 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. KYCLPPP will notify LHDs of EBLLs reported to the state when available.
- The KYCLPPP Case Management form must be filled out for all children and pregnant women having a confirmed EBLL of ≥3.5 µg/dL. The original form is to be placed in the patient's chart. Updates on EBLLs and interventions must be clearly documented in notes section of the case management form. Appropriate follow-up interventions need to be dated when completed. Staff need to clearly write the

current BLL, method of testing, and date of specimen collection clearly in the BLL table on the notes page. The BLL table and notes need to be submitted to KYCLPPP when additional lead test results are received. The completed case management form, BLL table, and notes should be submitted to KYCLPPP when the case is closed.

- The Case Management form (and BLL table and notes) and Home Visit form may be submitted via an encrypted email to KYChildhoodLeadPoisoning@ky.gov, KYCLPPP established Teams channel, or fax to (502) 564-5766 Attn: KYCLPPP. The Case Management form (BLL table and notes) may also be submitted via REDCap at https://redcap.chfs.ky.gov/surveys/?s=8RFM3A79N83EX438.

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 can:

- Help the family visually identify potential lead hazards in the child's environment.
- Provide the family/guardian with educational materials/recommendations to reduce lead exposures and help guide the family in taking corrective action.
- Work to reduce patient's EBLL to <3.5 µg/dL by reducing/eliminating lead exposure.
- Ensure that patients with EBLLs receive timely and appropriate care.

Home Visit form:

- Part 1 and 2 of the Home Visit form must be completed within the appropriate timeframes according to the CDC's recommendations listed in Table 4. The form can be completed through a multidisciplinary approach.
- Part 1 of the home visit may be completed over the phone by the nurse or member of the multidisciplinary team prior to the visual investigation of the home. Part 2 (visual investigation) of the home visit must be completed in person and may be performed by the nurse, community health worker, environmentalist, or certified risk assessor. Every effort should be made to include an environmentalist for the visual inspection. It is the responsibility of the CLPPP nurse case manager to request assistance from a certified risk assessor or environmentalist.
- If the home visit is not completed by the nurse, any areas of concern should be documented and reported to the CLPPP nurse case manager for evaluation and case management. The CLPPP nurse case manager must review all portions of the Home Visit form and sign it prior to submitting it to the KYCLPPP state program. The form should not be submitted to the KYCLPPP until all portions are completed.

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

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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. Clinical related education such as physiological effects of lead and reasons for dietary changes should be provided by a 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 place 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, and daily clean up and vacuuming of work and walk off areas).

If the BLL remains ≥3.5 ug/dL, 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.

If the child's BLL should increase to a confirmed level of ≥15ug/dL, a certified risk assessment is required.

Certified Risk Assessments

According to KRS 211.905, **for confirmed BLLs ≥15µg/dL**, an inspection (with 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. The case should be referred to the environmentalist by the CLPPP nurse case manager.

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.

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. 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 CLPPP nurse case manager.

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, and 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.
- Visualizing 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.
- Ensuring 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.

Additional /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 CLPPP nurse case manager and relevant LHD staff. Some reasons why an additional or follow-up home visit might be completed:

- BLLs remain elevated or are increase over a period of months.
- The child moves to a new residence.
- Custody of the child changes and the new guardians need assistance controlling a lead exposure.
- A new lead source is discovered, and the family needs further assistance on controlling the exposure.

Case Closure

The case management form and case notes should be submitted to KYCLPPP as listed prior in the reporting section. 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 µg/dL: Case closure occurs when BLL is <3.5 µg/dL. Repeat at risk blood testing as indicated.
- For BLLs of 15 µg/dL and greater: Case closure occurs when BLL is <3.5 µg/dL, 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 ≥3.5 µg/dL.

The case should be closed based on a venous level. If the child's primary care provider orders a capillary test, obtain written notification the provider ordered a capillary test, is following lead testing, and providing care for this child.

A case may also be designated as ***administrative closure*** if all directives, as enumerated in the Elevated Blood Lead Response and Case Management sections have been completed. The CLPPP nurse case manager must follow and document all procedures for closure (listed below) in the case notes and complete the case closure section of the case management form if the case is "lost to follow-up".

Lost to follow-up should include at least 3 attempts at contact and a certified letter mailed to the family.

- Initial contact may be made by telephone if the number is available. Tip: Ask for all contact information from the referring agency or primary care provider.
- The second contact should be a regular mailed letter with directions for the patient to contact the LHD for follow-up.
- The third contact should be a certified or registered letter with directions for the patient to contact the LHD for follow-up.
- If after three of the above measures are made with no response, the LHD should document in the medical record that the case is closed, and the patient is lost to follow-up care.

At any point, a face-to-face visit with the family can be attempted to resolve the contact issue.

- 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 management form in area provided. If a case has been closed and a new EBLL is confirmed, please open a new case submit a new case management form with updated information. Please do not continue to use the old file and write "reopened".
- Notification to the primary care provider should be provided.

Referring a family to Department for Community Based Services (DCBS) based on non-compliance is at the discretion of the case-managing nurse and any specific health department guidance. If a referral to DCBS is made, please contact KYCLPPP to provide an update. 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.

Resources

Resources and information is available at the DPH/MCH Childhood Lead Poisoning Prevention website.

KYCLPP Forms: The case management form, home visit form and lead risk assessment form are available at Clinical Service Guide Forms and Teaching Sheets - CHFS. Fax the completed forms to (502) 564-5766 Attn: KYCLPPP.

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 MCHNBS program at (502) 564-1510.
    - If you have questions, call the MCH NBS program can be reached at (502) 564-2154.

ORAL HEALTH PROTOCOLS

The Oral Health Program - Cabinet for Health and Family Services (ky.gov) offers a variety of programs and services which include, but are not limited to, patient access to fluoride supplements, fluoride varnishes and hygiene services.

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 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)	"Study Your Sip" Fluoride Supplement Fluoride Varnish

“STUDY YOUR SIP” FLUORIDE SUPPLEMENT PROGRAM GUIDELINES

The program is primarily for pre-school children (6 months–6 years) but is 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.

A child may not be receiving enough fluoride for developing teeth if their drinking water is from a well, cistern or spring OR if the major source of drinking water is bottled water regardless of the source of household water. A simple question of “What type of water do you drink?” could point a family in the direction of the “Study Your SIP” program.

All children seen clinically should be provided with Study Your SIP information that the Oral Health Branch provides to each health department.

The information (postcard, flyer, poster) has a QR code that the family logs on to begin the assessment of any need for fluoride supplementation the children in the family. This program shifts the interaction from the public health clinic directly to the family. These informational resources can be ordered (at no cost to a health department) at Oral.Health@ky.gov

The Oral Health Branch, through the prescriptive authority of the state dental director (when a licensed dentist), assesses the need for any supplement and then prescribes and dispenses the correct dosage for each child in a family.

KIDS SMILE PROGRAM
FLUORIDE VARNISH PROGRAM

1. The Kentucky Oral Health Program provides supplemental 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.

   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 or high risk 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.
2. 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.

3. Instructions for applying cavity varnish for decay reduction vary among the brands of products, always read and follow manufacturer's instructions for any product.

4. 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.

5. Apply fluoride varnish:
   a. Order the materials for application of fluoride varnish from the University of Kentucky College of Dentistry. LHDs should use this address for ordering kits: kidsmiles@uky.edu
   b. The Oral Health Program uses 3M's formulation of Vanish that 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. For older children, laying down on a bench/couch with the head in the provider's lap is suggested.
   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 does 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
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.

6) The provider should offer a small drink of water to the patient immediately after the application procedure is finished.

7) 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.

8) Document procedures for the day in the personal medical record provided by the Kentucky Oral Health Program or current electronic health records.

For additional information, please call the Oral Health Program at 502-564-3604

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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 provides supplemental 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 502-564-3604 for additional information. Kits can be ordered through UK at this address: kidsmiles@uky.edu.

HEALTHRISKOR 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 urgent care 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 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 and fluoride varnish application in six months.

Physician, Dentist, Other **Date**

Pediatrics

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All standing orders should follow the recommendations of the AAP/Bright Futures.

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 their standing orders are 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 and that their established local standing orders are following the latest recommendations.

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 per ACOG guidelines

Component	Initial Workup	Initial Exam	Return Visits	15-20 Week	20-24 Weeks	28 Weeks	32 Week s	35-37 Weeks	Post-Partum Visit
History									
Comprehensive History (see ACOG antepartum or post-partum forms)		X	Review						X
Assess Immunization Status	X		Review						
Lead Risk Assessment	X								X
Assess Domestic Violence or IPV	X			X – second trimester		X- third trimester			X
Assess Depression or Post-Partum Depression	X	X	X					X-and after delivery	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 or Post-partum Forms		X	X						X
Document Fetal Movement	X	X	X						

Component	Initial Workup	Initial Exam	Return Visits	15-20 Week	20-24 Weeks	28 Weeks	32 Weeks	35-37 Weeks	Post-Partum Visit
Lab Tests/Procedures									
Hgb/Hct	X				If indicated	If indicated	X	X	
Blood Type/Rh Factor	X								
Rh Antibody Titer	X					If Rh negative			
Prenatal RhoGam						If Rh negative			
Hepatitis B surface Antigen (HBsAG) See guidelines	X							At risk	
Syphilis IGG (with reflex testing if positive)	X						X-and after delivery	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								

Component	Initial Workup	Initial Exam	Return Visits	15-20 Week	20-24 Weeks	28 Weeks	32 Weeks	35-37 Weeks	Post-Partum Visit
Lab Tests/Procedures									
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-and after delivery	X
Preterm Risk Status/Prevention/Referral	X		X						
Intimate Partner Violence (per trimester)	X			X- second trimester		X- third trimester (each visit)			X
HIV/AIDS & Other Prenatal Tests	X								
Environmental/Work Hazards/Toxoplasmosis	X								

Component	Initial Workup	Initial Exam	Return Visits	15-20 Week	20-24 Weeks	28 Weeks	32 Weeks	35-37 Weeks	Post-Partum Visit
Counseling									
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			PN-T2		PN-T3			PN-T4
	PAM-ACH 263								
	PN-2, PN-T1								
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. 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 Intimate Partner Violence Committee Opinion No. 518 and Reproductive and Sexual Coercion Committee Opinion No. 554 are available at: https://www.acog.org/search#q=Committee%20Opinion%20on%20%20Intimate%20partner%20violence&sort=relevancy at.
- 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. (2024). ACOG statement on 17p hydroxyprogesterone caproate. Find at: https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2023/04/updated-guidance-use-of-progesterone-supplementation-for-prevention-of-recurrent-preterm-birth
2. ACOG (2018; reaffirmed 2021). Committee opinion 741: Maternal immunization. Available at: https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2022/10/maternal-immunization
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 ≤ 18	750 mcg. RAE (3750 IU)	Age ≤18	2800 mcg. RAE (14,000 IU)
	Age 19-50	770 mcg. RAE (3850 IU)	Age 19-50	770 mcg. RAE (3850 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.	70 mg.		Age <18	1800 mg.
	Age 19-50	85 mg.			Age 19-50	2000 mg.
Vitamin K	Age ≤ 18	75 mg.			NA	
	Age 19-50	90 mg.				
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 B6	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 B12	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.	250 mg.		Age ≤ 18	3000 mg.
	Age 19-50	1000 mg.			Age > 18	2500 mg.

	1997-2011 Dietary Reference Intakes (DRI)		Minimal	Level	Maximum Level	
Choline	Age < 18	450 mg			Age < 18	550 mg.
	Age 19-50	450 mg			Age 19-50	550 mg.
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.	100 mg.		350 mg.	
	Age 19-30	350 mg.				
	Age 31-50	360 mg.				
Molybdenum	50 mcg.		50 mcg.		Age ≤ 18	1700 mcg.
					Age 19-50	2000 mcg.
Phosphorus	Age ≤ 18	1250 mg.	Age ≤ 18	1250 mg.	3500 mg.	
	Age 19-50	700 mg.	Age 19-50	700 mg.		
Selenium	60 mcg.		60 mcg.		400 mcg.	
Zinc	Age ≤ 18	12 mg.	9 mg.		Age ≤ 18	34 mg.
	Age 19-50	11 mg.			Age > 18	40 mg.

NA = Not available.
NOTE: Remember that vitamins are tolerated best if taken with food.

- 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 B6 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/womens-health/faqs/nutrition-during-pregnancy
4. *ACOG. (2021). Your pregnancy and childbirth month to month. Chapter 1: getting ready for pregnancy.* Washington, DC. The American College of Obstetricians and Gynecologists.
5. Jouanne, M., Oddux, S., Noel, A. and Voisin-Cheret, AS. (2021). Nutrition requirements during pregnancy and lactation. Nutrients, 13(2):692.

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 PCP, 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 than 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 2023). Weight gain during pregnancy: Committee Opinion 548. Available at: acog.org/clinical/clinical-guidance/committee-opinion/articles/2013/01/weight-gain-during-pregnancy.

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. Legend is as follows: Underweight= BMI < 19.8; Normal= BMI 19.8-26.0; Overweight= BMI 26.1-29.0; Obese= BMI ≥ 29.1

	Underweight		**Normal**						
BMI	19	19.8	20	21	22	23	24	25	26
4’10” (58”)	91	95	96	100	105	110	115	119	124
4’11” (59”)	94	98	99	104	109	114	119	124	128
5’0” (60”)	97	102	102	107	112	118	123	128	133
5’1” (61”)	100	105	106	111	116	122	127	132	137
5’2’ (62”)	104	108	109	115	120	126	131	136	142
5’3” (63”)	107	112	113	118	124	130	135	141	147
5’4” (64”)	110	116	116	122	128	134	140	145	151
5’5” (65”)	114	119	120	126	132	138	144	150	156
5’6” (66”)	118	123	124	130	136	142	148	155	161
5’7” (67”)	121	127	127	134	140	146	153	159	166
5’8” (68”)	125	130	131	138	144	151	158	164	171
5’9” (69”)	128	134	135	142	149	155	162	169	176
5’10” (70”)	132	138	139	146	153	160	167	174	181
5’11” (71”)	136	142	143	150	157	165	172	179	186
6’0” (72”)	140	146	147	154	162	169	177	184	191
6’1” (73”)	144	150	151	159	166	174	182	189	197
6’2” (74”)	148	154	155	163	171	179	186	194	202
6’3” (75”)	152	158	160	168	176	184	192	200	208
6’4” (76”)	156	162	164	172	180	189	197	205	213
6’5” (77”)	160	166	168	176	185	193	202	210	218
6’6” (78”)	164	170	172	181	190	198	207	216	224

	Overweight				Obese						
BMI	26.1	27	28	29	29.1	30	32	34	36	38	40
4’10” (58”)	125	129	134	138	>138	143	153	162	172	181	191
4’11” (59”)	129	133	138	143	>143	148	158	168	178	188	198
5’0” (60”)	134	138	143	148	>148	153	163	174	184	194	204
5’1” (61”)	138	143	148	153	>153	158	169	180	190	201	211
5’2’ (62”)	143	147	153	158	>158	164	175	186	196	207	218
5’3” (63”)	147	152	158	163	>163	169	180	191	203	214	225
5’4” (64”)	152	157	163	169	>169	174	186	197	209	221	232
5’5” (65”)	157	162	168	174	>174	180	192	204	216	228	240
5’6” (66”)	162	167	173	179	>179	186	198	210	223	235	247
5’7” (67”)	167	172	178	185	>185	191	204	217	230	242	255
5’8” (68”)	172	177	184	190	>190	197	210	223	236	249	262
5’9” (69”)	177	182	189	196	>196	203	216	230	243	257	270
5’10” (70”)	182	188	195	202	>202	209	222	236	250	264	278
5’11” (71”)	187	193	200	208	>208	215	229	243	257	272	286
6’0” (72”)	192	199	206	213	>213	221	235	250	265	279	294
6’1” (73”)	198	204	212	219	>219	227	242	257	272	288	302
6’2” (74”)	203	210	218	225	>225	233	249	264	280	295	311
6’3” (75”)	208	216	224	232	>232	240	256	271	287	303	319
6’4” (76”)	214	221	230	238	>238	246	262	279	295	312	328
6’5” (77”)	219	227	235	244	>244	252	269	286	303	319	336
6’6” (78”)	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.

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.

References:

1. CDC.gov, (2025). Childhood lead poisoning prevention. Available at: cdc.gov/lead-prevention/risk-factors/pregnancy.html.
2. ACOG, (2012, reaffirmed 2023). ACOG committee opinion no. 533: Lead screening during pregnancy and lactation. Available at:
    a. acog.org/clinical/clinical-guidance/committee-opinion/articles/2018/08/lead-screening-during-pregnancy-and-lactation .

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/womens-health/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, (2019, reaffirmed 2024). ACOG committee opinion no.762. Available at: acog.org/clinical/clinical-guidance/committee-opinion/articles/2019/01/prepregnancy-counseling.

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, (2024). 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: http://www.acog.org/womens-health/faqs/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: https://www.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 2023). Committee Opinion #691: *Carrier screening for genetic condition.* Available at acog.org/clinical/clinical-guidance/committee-opinion/articles/2017/03/carrier-screening-for-genetic-conditions.
2. ACOG FAQ guide available at: https://www.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 without 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, (2021). Group b strep and pregnancy. Available at: https://www.acog.org/womens-health/faqs/group-b-strep-and-pregnancy

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: ACOG, (2022). Genital Herpes FAQs. Available at: https://www.acog.org/womens-health/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, (2021). *Gestational Diabetes FAQ177.* Available at: https://www.acog.org/womens-health/faqs/gestational-diabetes

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 PCP 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) • PCP 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 PCP 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 PCP 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 PCP 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 PCP 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 PCP 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 PCP 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 PCP if preterm labor is suspected** • Refer to PCP 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 PCP 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 PCP; 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
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 PCP 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 PCP** • 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

DISCOMFORT	POSSIBLE CAUSE	NURSE ACTION
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 PCP 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 PCP** • 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
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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 for recognized†† 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	All domestic 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 POST EXPOSURE 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.

Previously Vaccinated Persons

Previously vaccinated persons are those with a history of preexposure vaccination with HDCV, PCECV, or rabies vaccine adsorbed (RVA); prior PEP with HDCV, PCECV or RVA, or previous vaccination with any other type of rabies vaccine and a documented history of antibody response to prior vaccination. Previously vaccinated persons should receive two vaccine doses, (1-mL of PCECV or HDCV administered IM in the deltoid on days 0 and 3 only). Administration of HRIG is unnecessary, and HRIG should not be administered to previously vaccinated persons to avoid possible inhibition of the relative strength or rapidity of an expected anamnestic response. Local wound care remains an important part of rabies PEP for any previously vaccinated persons.

Postvaccination Serologic Testing

Because the antibody response after the recommended postexposure vaccination regimen with PCECV or HDCV has been satisfactory, routine postvaccination serologic testing is not recommended for healthy persons to document seroconversion. Serologic testing is only indicated in unusual circumstances, as when the patient is known to be immunosuppressed. When titers are obtained, serum specimens collected 1--2 weeks after prophylaxis (after last dose of vaccine) should be <0.5 IU/ml.

Rabies Postexposure Prophylaxis Schedule, Kentucky Health 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	HRI 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 vaccination status	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]These regimens are applicable for all age groups, including children and pregnant women.

[2]The deltoid area is the only acceptable site of vaccination for adults and older children. For younger children, the outer aspect of the thigh may be used. Vaccine should never be administered in the gluteal area.

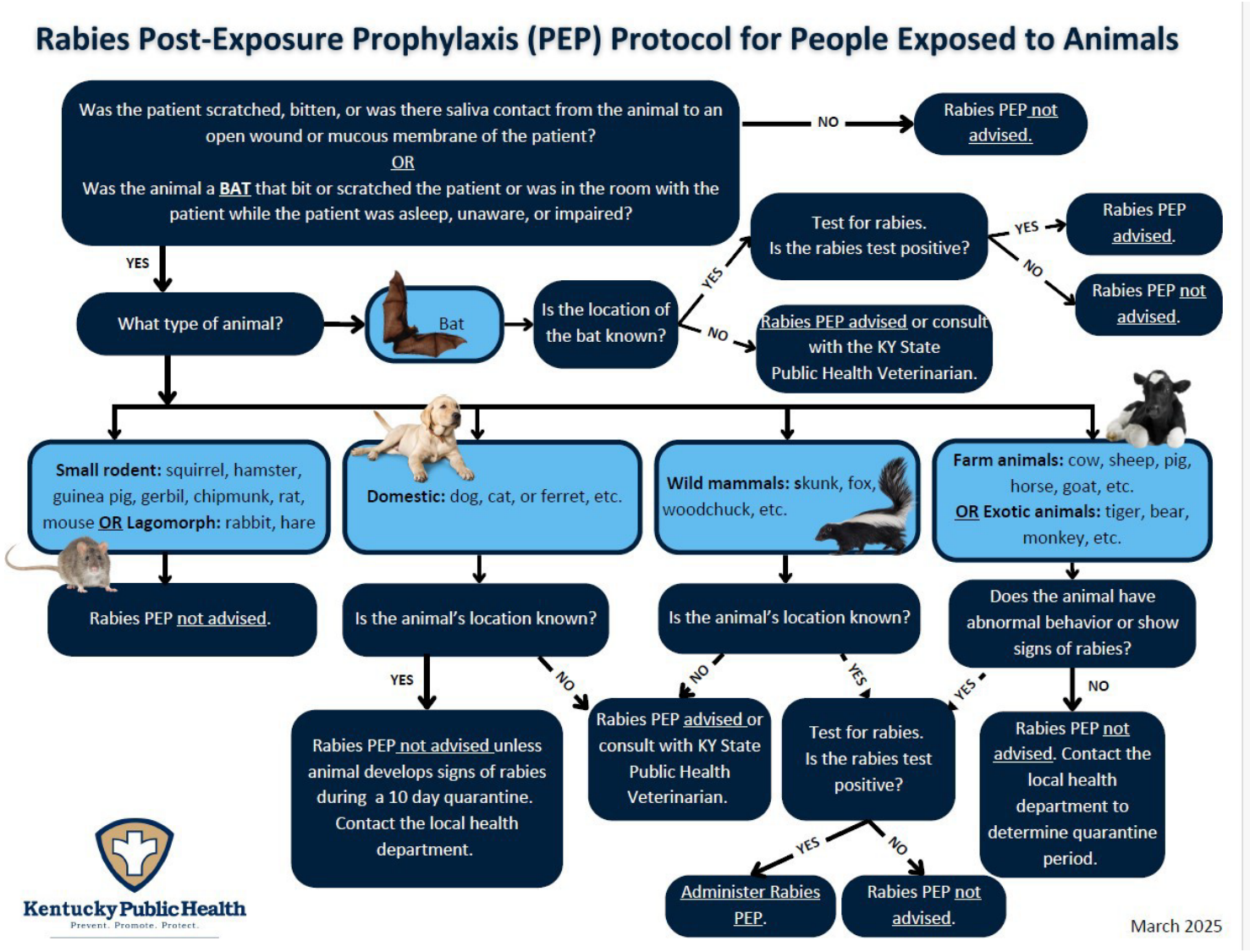
[3]Any person with a history of preexposure vaccination with HDCV, PCECV, or rabies vaccine adsorbed (RVA); prior PEP with HDCV, PCECV or RVA, or previous vaccination with any other type of rabies vaccine and a documented history of antibody response to prior vaccination.

For questions about PEP, call the Division of Epidemiology and Health Planning (502) 564-3418.

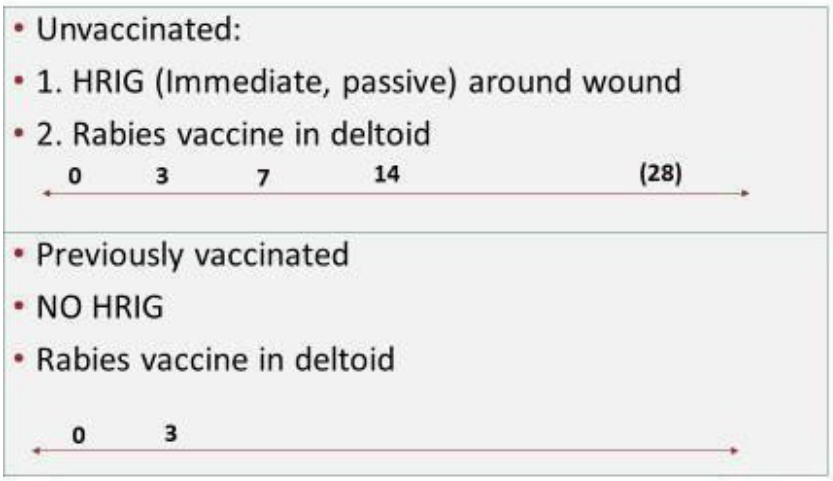
Rabies:
(New)Postexposure Prophylaxis Algorithm

For any questions, please contact:

Kelly H. Giesbrecht, DVM, MPH
STATE PUBLIC HEALTH VETERINARIAN
Kentucky Department for Public Health
Division of Epidemiology and Health Planning
Office: 502-564-6350
Cell: 502-682-4048
Kelly.Giesbrecht@ky.gov



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 balancing a number of criteria: the species of animal and the endemicity of rabies for that species in Kentucky, the observed health and behavior of the animal, and the circumstances of the bite.
2. This algorithm only addresses rabies post-exposure prophylaxis. Other treatment such as wound care, antibiotics, and tetanus immunization may be indicated.
3. In addition to obvious 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 the same room, an adult witnesses a bat in a room with a previously unattended child, mentally disabled person, or intoxicated individual) and rabies cannot be ruled out by testing of the bat. PEP would not be warranted 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 is predominantly a disease of carnivorous animals (animals hate at other animals) while carrion eaters like the opossum who eat dead or decaying flesh are seldom affected. Consultation with the state health department is strongly recommended for opossum human bites on rabies Post Exposure Prophylaxis.
5. Provoked exposures may include attempting to feed an animal, entering an animal's territory, petting or playing with an animal, handling an animal, attempting to break up a fight between animals, having contact with an injured animal, and walking, running, or riding a bicycle past an animal. Unprovoked exposures are rare and typically require an animal to cross neutral space and attack. The physician should attempt to get the patient to describe the scenario in order to establish the true nature or the circumstances surrounding the biting incident – DO NOT simply ask if the bite was provoked or unprovoked.
6. The severity and location of a wound (severe wounds or obvious wounds near the head and neck should be given highest priority), and the expected interval between the time of the bite and receipt of rabies test results should be considered when making a decision to begin PEP while awaiting test results.
7. Unless the person previously received rabies immunoprophylaxis, PEP consists of four (4) doses of vaccine (1.0 mL each administered IM in the deltoid region) on days 0, 3, 7 and 14 and one (1) dose of human rabies immune globulin (HRIG)administered on day 0,infiltrated into and around the bite wound as much as anatomically feasible, with the remainder administered IM at an anatomical site distant from vaccine administration. HRIG should not be administered in the same syringe or at the same site as vaccine. HRIG dosage is based on the weight of the patient, 20 IU/kg, and should not be given in more than the recommended dose, as it may suppress active production of antibody. A previously vaccinated person needs an abbreviated PEP schedule, specifically day 0 and day 3. Immunocompromised individuals should receive the 5 series of immunizations on days 0, 3, 7, 14-21 and 28 in addition to HRIG on day 0. Contact the health department for the schedule, if needed.
8. If the biting animal is captured and tests negative for rabies after PEP has begun, PEP may be discontinued.

Modified from: Kent County Health Department. Determining the need for rabies post-exposure prophylaxis (PEP)with human rabies immunoglobulin (RIG)and rabies vaccine; Ohio Department of Health. Rabies Post-Exposure Treatment (PET)Algorithm, December2000.

Reference: Centers for Disease Control and Prevention. Human Rabies Prevention–UnitedStates,1999: Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 1999;48(No. RR-1).

Reference: Centers for Disease Control and Prevention. Use of a Reduced (4-Dose) Vaccine Scheduled for Postexposure Prophylaxis to Prevent HumanRabies,2010: Recommendations of the Advisory Committee on Immunization Practices *(ACIP). MMWR2010; 59(No. RR-2)*

Reportable Diseases

Table of Contents

REPORTABLE DISEASES AND CONDITIONS IN KENTUCKY

Kentucky Public Health
Prevent. Promote. Protect.

902 KAR 2:020: Amended Table of Reportable Diseases and Conditions in Kentucky (Effective 02/10/2025)

https://apps.legislature.ky.gov/law/kar/902/002/020.pdf

** Select Any Disease/Condition to be redirected to the CDC Case Definition **

Updated: 2/10/2025

URGENT NOTIFICATION WITHIN 24 HOURS:

BY ELECTRONIC LABORATORY REPORTING AND REQUIRED EPID FORM

- **Anthrax**
- **Botulism**
- **Brucellosis** (multiple cases, temporally or spatially clustered)
- **Cronobacter spp,** invasive disease in an infant <12 months of age
- **Diphtheria**
- **Hepatitis A, acute**
- **Measles**
- **Melioidosis**
- **Meningococcal infections**
  - Neisseria meningitidis (isolate from sterile specimen site)
- **Middle East Respiratory Syndrome associated Coronavirus (MERS-CoV) disease**
- **Novel influenza A virus infections**
- **Orthopox virus infection, including:**
  - Mpox
  - Smallpox
  - Vaccinia
- **Plague**
- **Poliomyelitis**
- **Rabies, animal**
- **Rabies, human**
- **Rubella**
- **Severe Acute Respiratory Syndrome Associated Coronavirus (SARS-CoV)**
- **Tularemia**
- **Viral hemorrhagic fevers due to:**
  - Crimean-Congo Hemorrhagic Fever virus
  - Ebola virus
  - Lassa virus
  - Lujo virus
  - Marburg virus
  - New world arenaviruses including:
    - Guanarito virus
    - Junin virus
    - Machupo virus
    - Sabia virus
- **Yellow fever**

ROUTINE NOTIFICATION WITHIN 24 HOURS:

BY ELECTRONIC LABORATORY REPORTING VIA EPID 250

- **Candida auris**
- **Carbapenem-resistant - Acinetobacter**
- **Carbapenem-resistant – Enterobacterales (CRE)**
- **Carbapenem-resistant - Pseudomonas**
- **Vancomycin-intermediate Staphylococcus aureus (VISA)**
- **Vancomycin-resistant Staphylococcus aureus (VRSA)**

PRIORITY NOTIFICATION WITHIN ONE (1) DAY:

BY ELECTRONIC LABORATORY REPORTING AND REQUIRED EPID FORM

- **Arboviral diseases, neuroinvasive and non-neuroinvasive, including:**
  1. **California serogroup virus diseases, including diseases caused by:**
     - California encephalitis virus
     - Jamestown Canyon virus
     - Keystone virus
     - La Crosse virus
     - Snowshoe hare virus
     - 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**
  9. **Zika virus**, non-congenital or congenital
- **Brucellosis** (cases not temporally or spatially clustered)
- **Campylobacteriosis**
- **Carbon monoxide poisoning**
- **Cholera**
- **COVID-19 associated mortality** in a patient who is:
  - <18, OR Pregnant/postpartum (within 3 months of delivery)
- **Cryptosporidiosis**
- **Cyclosporiasis**
- **Dengue virus infections**
- **Foodborne disease outbreak**
- **Free-living amoeba infections:**
  - Acanthamoeba disease
  - Acanthamoeba keratitis
  - Balamuthia mandrillaris
  - Naegleria fowleri causing primary amebiv meningoencephalitis (PAM)
- **Giardiasis**
- **Haemophilus influenzae invasive disease**
- **Hantavirus infection, non-Hantavirus pulmonary syndrome**
- **Hantavirus pulmonary syndrome (HPS)**
- **Hemolytic uremic syndrome (HUS), postdiarrheal**
- **Hepatitis B, acute**
- **Hepatitis B infection** in a pregnant woman
- **Hepatitis B infection** in an infant or child aged two (2) years or less
- **Newborns born to Hepatitis B positive mothers at the time of delivery**
- **Influenza-associated mortality** in a patient who is:
  - <18, OR Pregnant/postpartum (within 3 months of delivery)
- **Legionellosis**, including Pontiac Fever and extrapulmonary disease
- **Leprosy** (Hansen's Disease)
- **Leptospirosis**
- **Listeriosis**
  - Listeria monocytogenes
- **Mumps**
- **Norovirus outbreak**
- **Pertussis**
- **Pesticide-related illness, acute**
- **Psittacosis**
- **Q fever**
- **Respiratory Syncytial virus (RSV)-associated mortality** in a patient who is:
  - <18, OR Pregnant/postpartum (within 3 months of delivery)
- **Rubella, congenital syndrome**
- **Salmonella**
- **Shiga toxin-producing E. coli (STEC)**
  - Shiga toxin-producing E. coli (STEC) or verotoxin-producing E.coli (VTEC) including E.coli O1457:H7
- **Shigellosis**
- **Streptococcal toxic-shock syndrome**
- **Streptococcus pneumoniae, invasive disease** (i.e. invasive pneumococcal disease)
- **Syphilis** - primary, secondary, or early latent
- **Tetanus**
- **Toxic-shock syndrome** (other than Streptococcal)
- **Tuberculosis**
  - mycobacterium tuberculosis (TB)
- **Typhoid fever**
- **Varicella**
- **Vibriosis**
  - **Vibrio species,** including those that cause cholera and other disease
- **Waterborne disease outbreak**

ROUTINE NOTIFICATION WITHIN FIVE (5) DAYS:

BY ELECTRONIC LABORATORY REPORTING AND REQUIRED EPID FORM

- **Acute Flaccid Myelitis**
- **Alpha-gal Syndrome**
- **Anaplasmosis**
- **Babesiosis**
- **Chancroid**
- **Chlamydia trachomatis infection**
- **Coccidioidomycosis**
- **Creutzfeldt-Jakob disease**
- **Ehrlichiosis**
- **Gonorrhea**
- **Granuloma inguinale**
- **Hepatitis C, acute**
- **Hepatitis C infection**
  - in a pregnant woman
  - in an infant or child aged three (3) years or less
- **Newborns born to Hepatitis C positive mothers at the time of delivery**
- **HIV infection or AIDS diagnosis**
- **Histoplasmosis**
- **Lead poisoning**
- **Lyme Disease**
- **Lymphogranuloma venereum**
- **Malaria**
- **Multi-system Inflammatory Syndrome in Children (MIS-C)**
- **Spotted Fever Rickettsiosis (Rocky Mountain Spotted Fever)**
- **Syphilis** - other than primary, secondary, early latent, or congenital
- **Toxoplasmosis**
- **Trichinellosis (Trichinosis)**

NOTIFICATION WITHIN 3 MONTHS OF DIAGNOSIS:

- **Asbestosis**
- **Pneumoconiosis,** including Coal worker's pneumoconiosis
- **Silicosis**

Submission of Clinical Isolates to the Kentucky Department for Public Health Division of Laboratory Services (DLS) Required

Routine Notification made by Electronic Laboratory Reporting and EPID 200

Routine Notification made by Electronic Laboratory Reporting and EPID 250

Routine Notification made by Electronic Laboratory Reporting and EPID 394

Routine Notification made by Electronic Laboratory Reporting and EPID 399

Review KDPH HIV/AIDS Section for reporting Requirements

Report Immediately by Telephone:

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
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 maypose a danger to the health of the public
   d. An epidemic
   e. A non-infectious chemical, biological, or radiological agent.

ROUTINE NOTIFICATION WITHIN FIVE (5) BUSINESS DAYS:

BY ELECTRONIC LABORATORY REPORTING

- **Hepatitis B & Hepatitis C laboratory test results whether reported as positive or negative;**
  - Include the serum bilirubin levels taken within ten (10) days of the test of a patient who has tested positive; or
  - include the serum alanine amino transferase levels taken within ten (10) days of the test of a patient who tested positive
- **Laboratory-confirmed influenza, detected by:**
  - Reverse transcriptase polymerase chain reaction (RT PCR)
  - Nucleic acid detection; or
  - viral culture
- **Laboratory confirmed Respiratory Syncytial virus (RSV), detected by**
  - Nucleic Acid Amplification Test (NAAT), including polymerase chain reaction (PCR)
- **Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-Co-V-2 detected by**
  - NAAT, including PCR; or
  - SARS-CoV-2 molecular sequencing
- **Varicella laboratory test results reported as positive for:**
  - Isolation of varicella virus from a clinical specimen
  - Varicella antigen detected by direct fluorescent antibody test
  - Varicella-specific nucleic acid detected by PCR
- **Multi-drug Resistant Organisms:**
  - Clostridioides (Formerly Clostridium) difficile (C. difficile)
  - Enterobacterales species resistant to ceftazidime, ceftriaxone, or cefotaxime
  - Methicillin-resistant Staphylococcus aureus (MRSA)
  - Vancomycin resistant Enterococcus species (VRE).

School Health

KRS 156.501 Student health services 7.15.2024-defines the responsibilities of Department of Education and Department of Public Health, and states while ***working in cooperation***, shall provide, contract for services, or identify resources to improve student health services, including but not limited to the following: (a) Standardized protocols and guidelines for health procedures to be performed by health professionals and school personnel.

This section contains protocols or medically approved guidelines as required by regulation.

KRS 217.186 Definition – Provider prescribing or dispensing opioid antagonist -- Administration by third party -- Use of opioid antagonist by person or agency authorized to administer medication -- Immunity from liability --Administrative regulations -- Use of opioid antagonist by schools -- Use of opioid antagonist by licensed health care provider.

- In collaboration with local health departments, local health providers, and local schools and school districts, the Kentucky Department for Public Health shall develop clinical protocols to address ***supplies of an opioid antagonist kept by schools*** under this section and to advise on the clinical administration of an opioid antagonist.

KRS 158.836 Possession and use of asthma or anaphylaxis medications -- Students with documented life-threatening allergies -- Schools electing to keep epinephrine injectable epinephrine devices and bronchodilator rescue inhalers on premises -- Limitation of liability.

- The Kentucky Department for Public Health shall develop clinical protocols in the school health section of the Core Clinical Service Guide manual that is maintained in the county or district public health department to address ***injectable epinephrine devices and bronchodilator rescue inhalers kept by schools*** under this subsection and to advise on clinical administration of the injectable epinephrine devices and bronchodilator rescue inhalers. The protocols shall be developed in collaboration with local health departments or local clinical providers and local schools and local school districts.

These protocols or medically approved guidelines were developed in collaboration with the Kentucky Department of Education, local school districts, local health departments, local clinical providers, and pharmacists, to provide advice on the clinical administration of the following emergency medications and to address their use in the school setting:

1. Epinephrine Auto-Injector
2. Bronchodilator Rescue Inhaler
3. Naloxone (Over-the-Counter)

- Clinical Protocol for Bronchodilator Rescue Inhaler Use in the School Setting
- Clinical Protocol for Epinephrine Auto-Injector Use in the School Setting
- Clinical Protocol for Naloxone (Opioid Antagonist) Use in the School Setting / Medically Approved Guideline for Over-the-Counter Use in the School Setting

Kentucky Public Health
Prevent. Promote. Protect.

Kentucky Department for Public Health
Clinical Protocol for Stock Bronchodilator Rescue Inhaler (BRI)
Emergency Use in the School Setting

Background

KRS 158.836, Possession and use of asthma or anaphylaxis medications -- Students with documented life-threatening allergies -- Schools electing to keep epinephrine injectable epinephrine devices and bronchodilator rescue inhalers on premises -- Limitation of liability. (June 29, 2021) states:

> (3) (a) Each school is encouraged to keep an injectable epinephrine device in a minimum of two (2) locations in the school, including but not limited to the school office and the school cafeteria, so that epinephrine may be administered to any student believed to be having a life-threatening allergic or anaphylactic reaction.
> (b) Each school is encouraged to keep a bronchodilator rescue inhaler in a minimum of two (2) locations in the school, including but not limited to the school office and athletic office, so that bronchodilator rescue inhalers may be administered to any student believed to be having asthma symptoms or respiratory distress.
> (c) Each school electing to keep injectable epinephrine devices or bronchodilator rescue inhalers shall implement policies and procedures for managing a student's life-threatening allergic reaction, anaphylactic reaction, or asthma developed and approved by the local school board.
> (d) The Kentucky Department for Public Health shall develop clinical protocols in the school health section of the Core Clinical Service Guide manual that is maintained in the county or district public health department to address injectable epinephrine devices and bronchodilator rescue inhalers kept by schools under this subsection and to advise on clinical administration of the injectable epinephrine devices and bronchodilator rescue inhalers.
> (4) Any school employee authorized under KRS 156.502 to administer medication shall not be liable for any civil damages for ordinary negligence in acts or omissions resulting from the administration or the assistance in the administration of epinephrine or a bronchodilator rescue inhaler to any student believed in good faith to be having a life-threatening allergic or anaphylactic reaction or asthma symptoms or respiratory distress.

KRS 311.646 Prescription injectable epinephrine auto-injectors and bronchodilator rescue inhalers states:

> (1) A health-care practitioner may prescribe injectable epinephrine devices and bronchodilator rescue inhalers in the name of an authorized entity or to a certified individual for use in accordance with this section.
> (2) A pharmacist may dispense injectable epinephrine devices and bronchodilator rescue inhalers pursuant to a prescription issued in the name of an authorized entity or to a certified individual.
> (3) 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.

(4) An individual who has a certificate issued under this section may:

(a) Receive a prescription for injectable epinephrine devices and bronchodilator rescue inhalers from a health-care practitioner.

(b) Possess prescribed injectable epinephrine devices and bronchodilator rescue inhalers; and

(c) In an emergency situation when a physician is not immediately available and the certified individual in good faith believes a person is experiencing a severe allergic reaction, asthma symptoms, or respiratory distress regardless of whether the person has a prescription for an injectable epinephrine device or a bronchodilator rescue inhaler or has previously been diagnosed with an allergy or asthma:

1. Administer an injectable epinephrine device or a bronchodilator rescue inhaler to the person; and

2. Provide an injectable epinephrine device or a bronchodilator rescue inhaler to the person for immediate self-administration.

(5) An authorized entity that acquires and stocks a supply of injectable epinephrine devices or bronchodilator rescue inhalers with a valid prescription shall:

(a) Store the injectable epinephrine devices and bronchodilator rescue inhalers in accordance with manufacturer's instructions and with any additional requirements established by the department; and

(b) Designate an employee or agent who holds a certificate issued under this section to be responsible for the storage, maintenance, and general oversight of injectable epinephrine devices and bronchodilator rescue inhalers acquired by the authorized entity.

(6) Any individual or entity who administers or provides an injectable epinephrine device to a person who is experiencing a severe allergic reaction shall contact the local emergency medical services system as soon as possible.

(7) Any individual or entity who acquires and stocks a supply of injectable epinephrine devices in accordance with this section shall notify an agent of the local emergency medical services system and the local emergency communications or vehicle dispatch center of the existence, location, and type of the injectable epinephrine devices acquired if a severe allergic reaction has occurred.

- An "Authorized entity" means an entity that may at any time have allergens present that are capable of causing a severe allergic reaction and has an individual who holds a certificate issued under KRS 311.646 on the premises or officially associated with the entity.
- 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.
- The school nurse or designee shall check the expiration date monthly and obtain a new prescription for replacement medication prior to expiration date.
- Any school employee authorized to administer medications should be aware of and understand their protections and liabilities as established in applicable regulations, including KRS 158.836 and KRS 156.502.

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ASTHMA means a respiratory condition marked by coughing, wheezing, or shortness of breath or chest tightness. Other symptoms may include struggling to breathe, nasal flaring, increased breathing rate, blue or dusky lips/nail beds, agitation, or difficulty speaking.

Common triggers for asthma / respiratory distress:

- 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:

- 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 sentences.
- 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's instructions. For students without specific orders on file use the school policies and procedures to administer stock BRI provided by the medical director. Provide support as needed.

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5. **Call the parent or guardian.**
6. **Repeat use of quick-relief inhaler per MD order / policy or if—**
   - Symptoms continue or return.
   - The 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.

How to use an ASTHMA Metered Dose INHALER without a Spacer:

1. **Prepare the Inhaler –** Shake the inhaler well for about 5 seconds and remove the cap.
2. **Positioning –** Have the child sit or stand up straight.
3. **Exhale First –** Ask them to breathe out completely to empty their lungs.
4. **Seal the Mouthpiece –** Place the inhaler's mouthpiece in their mouth, ensuring their lips form a tight seal around it.
5. **Inhale and Press –** As they start to take a slow, deep breath, press down on the inhaler to release the medication.
6. **Hold the Breath –** Encourage them to hold their breath for about 5 to 10 seconds to allow the medicine to reach their lungs.
7. **Exhale Slowly –** They should breathe out gently.
8. **Repeat if Needed –** If another dose is required, wait about a minute before repeating the process.
9. **Rinse Mouth**

- Cleaning: Clean the spacer about once a week, soak in warm, soapy water and let the 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.

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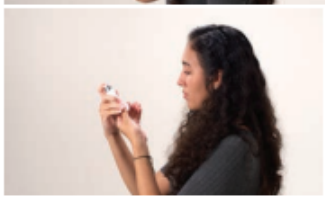
American Lung Association.

How to Use a Metered-Dose Inhaler without a Valved Holding Chamber or Spacer

Prime a brand-new inhaler: Before using it for the first time, if you have not used it for more than 7 days, or if it has been dropped.

1. Shake inhaler 10 seconds.



2. Take the cap off the inhaler and make sure it is clean and there is nothing inside of the mouthpiece.

3. Breathe out away from the device.

4. Put inhaler mouthpiece in mouth.

5. Press inhaler once and breathe in deep and steady.

6. Hold your breath for 10 seconds, then breathe out slowly.

   If you need another puff of medicine, wait 1 minute and repeat steps 3-6.

7. Rinse with water and spit it out.

Proper inhalation technique is important when taking your asthma medicine(s) and monitoring your breathing. Make sure to bring all your medicines and devices to each visit with your primary care provider or pharmacist to check for correct use, or if you have trouble using them.

For more videos, handouts, tutorials and resources, visit Lung.org.

Scan the QR Code to access How-To Videos

You can also connect with a respiratory therapist for one-on-one, free support from the American Lung Association's Lung HelpLine at **1-800-LUNGUSA**.

[How to Use a Metered Dose Inhaler CDC (YouTube Video 1:06)]

[Know How to Use Your Inhaler: CDC National Asthma Control: YouTube Video]

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How to use an ASTHMA Metered Dose INHALER with Spacer:

1. **Prepare the Inhaler and Spacer** – Shake the inhaler well and remove the cap. Attach the inhaler to the spacer.
2. **Positioning** – Have the child sit or stand up straight.
3. **Exhale First** – Ask them to breathe out completely.
4. **Seal the Mouthpiece or Mask** – If using a mask, place it over their nose and mouth, ensuring a tight seal. If using a mouthpiece, have them close their lips around it.
5. **Press and Breathe** – Press down on the inhaler to release the medication into the spacer. Then, have the child take slow, deep breaths in and out through the spacer for about 5 to 10 seconds.
6. **Repeat if Needed** – If another dose is required, wait about a minute before repeating the process.
7. **Rinse Mouth** – If the inhaler contains corticosteroids, have them rinse their mouth with water (without swallowing) to prevent irritation.

- Cleaning: Clean the spacer about once a week, soak in warm, soapy water and let the 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.

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Inhaler spacer with mouthpiece

This option is designed for school-age children who have learned to give the medication to themselves. (Adults should oversee the child's medication schedule and oversee each dose.) This spacer consists of a wide tube connecting the canister to a tapered mouthpiece. This video shows the steps your child will follow:

How to Use a Spacer-AAP-YouTube 1:27

Inhaler spacer with mask

This spacer is designed for babies and toddlers who take asthma medications. A wide tube connects the medicine canister to a small mask that fits over your child's nose and mouth. This video shows you how to make your child comfortable and release the dose while they take deep, slow breaths for about 10 seconds:

How to use a Spacer with a Mask-AAP YouTube_1:19

Respiratory Treatments: Digital Download: English Version (11” x 8 1/2”)

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References and Resources

American Academy of Allergy Asthma & Immunology

- School stock inhaler program (aaaai.org)
- Asthma Symptoms, Diagnosis, Management & Treatment | AAAAI

Asthma and Allergy Foundation of America

- Albuterol in Schools for Students with Asthma | AAFA.org

American Lung Association:

- Why Schools Should Stock Asthma Inhalers | American Lung Association
- Model-Policy-on-Stock-Bronchodilators_revDEC23.pdf (lung.org)
- What Is Asthma? | American Lung Association
- Asthma Symptoms | American Lung Association
- Reduce Asthma Triggers | American Lung Association
- Asthma Medication in Schools | American Lung Association
- Asthma-Friendly Schools Initiative Resources and Tools | American Lung Association
- How to Use Your Inhaler and Spacer (lung.org)

American Academy of Pediatrics

- Stock Inhaler Toolkit

Center for Disease Control (CDC)

- Asthma | CDC
- CDC - Asthma - School and Childcare Providers
- CDC - Asthma - Using an Asthma Inhaler Videos

Kentucky Department for education (KDE)

- Health Services Reference Guide - Kentucky Department of Education
- Medication Administration Training Manual for Non- Licensed School Personnel, Medication Administration Training Program - Kentucky Department of Education

National Association for School Nurses (NASN) ASTHMA Resources

- Asthma - National Association of School Nurses (nasn.org)

National Institutes of Health (NIH) 2020 Focused Updates to the Asthma Management Guidelines

- Ensuring Access to Albuterol in Schools: From Policy to Implementation. An Official ATS/AANMA/ALA/NASN Policy Statement - PMC (nih.gov)
- 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
- Managing Asthma: A Guide for Schools (nih.gov)

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)

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Resource Toolkits

Stock Asthma Medication Toolkit

The American Lung Association's Stock Asthma Medication Toolkit includes templates and forms that you can modify for use while implementing an emergency stock asthma medication program at your school. Get access to an Implementation Checklist, School Staff Tracking Form, Standing Medical Order and Prescription templates, data elements for documentation and reporting, a Usage Event Log, and a template email to Parents/Guardians about the program. Learn more about how to use the tools in this toolkit by taking the course, Stock Asthma Medication: Implementation guidance for schools.

AAAAI Stock Inhaler Toolkit for Schools

In 2023, the American Academy of Allergy Asthma Immunology in partnership with the American Academy of Pediatrics released the Stock Inhaler Toolkit for Schools. The American Lung Association reviewed this document and is pleased to make this available to you. Use this toolkit to: 1) Understand why stock inhalers are important for your campus - for those with and without diagnosed asthma; 2) Learn about stock inhaler laws in your state and develop a compliant school program; 3) Streamline the process of finding the right devices and finding evidence-based training materials for staff;
4) Save both time and money by utilizing our example documents and guidelines; and 5) Get started quickly on the path to help create a safer learning environment.

Other Resources

- Emergency Response for Life-Threatening Conditions in Schools: Asthma (utah.gov)
- Guidelines for Use of Undesignated Stock Albuterol in Schools (virginia.gov)
- Guidelines for Managing Asthma in Virginia Schools (Word)
- Guidelines for Use of Undesignated Stock Albuterol in Schools (Word)
- Asthma Action Plan (2020) (PDF)
- Order Albuterol Supplies for schools

Training Resources

- Learning Center for School Health Professionals (VAstudentservices-clc.org)
- Learning Center for School Health Professionals-Asthma
- Asthma Basics https://player.vimeo.com/video/642854554
- Use and Maintenance of the Stock Inhaler https://player.vimeo.com/video/642106466
- Use of Undesignated Stock Albuterol in Schools Training https://player.vimeo.com/video/644566364
- Stock Asthma Medication: Implementation Guidance for Schools (lung.training)
- Responding to Asthma Emergencies in Schools (lung.training)

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Kentucky Department for Public Health

Clinical Protocol for Stock Epinephrine Auto-Injector Emergency Use in the School Setting

Background

KRS 158.836, Possession and use of asthma or anaphylaxis medications -- Students with documented life-threatening allergies -- Schools electing to keep epinephrine injectable epinephrine devices and bronchodilator rescue inhalers on premises -- Limitation of liability. (June 29, 2021) states:

(3) (a) Each school is encouraged to keep an injectable epinephrine device in a minimum of two (2) locations in the school, including but not limited to the school office and the school cafeteria, so that epinephrine may be administered to any student believed to be having a life-threatening allergic or anaphylactic reaction.

(b) Each school is encouraged to keep a bronchodilator rescue inhaler in a minimum of two (2) locations in the school, including but not limited to the school office and athletic office, so that bronchodilator rescue inhalers may be administered to any student believed to be having asthma symptoms or respiratory distress.

(c) Each school electing to keep injectable epinephrine devices or bronchodilator rescue inhalers shall implement policies and procedures for managing a student's life-threatening allergic reaction, anaphylactic reaction, or asthma developed and approved by the local school board.

(d) The Kentucky Department for Public Health shall develop clinical protocols in the school health section of the Core Clinical Service Guide manual that is maintained in the county or district public health department to address injectable epinephrine devices and bronchodilator rescue inhalers kept by schools under this subsection and to advise on clinical administration of the injectable epinephrine devices and bronchodilator rescue inhalers.

(4) Any school employee authorized under KRS 156.502 to administer medication shall not be liable for any civil damages for ordinary negligence in acts or omissions resulting from the administration or the assistance in the administration of epinephrine or a bronchodilator rescue inhaler to any student believed in good faith to be having a life-threatening allergic or anaphylactic reaction or asthma symptoms or respiratory distress.

KRS 311.646 Prescription injectable epinephrine auto-injectors and bronchodilator rescue inhalers states:

(1) A health-care practitioner may prescribe injectable epinephrine devices and bronchodilator rescue inhalers in the name of an authorized entity or to a certified individual for use in accordance with this section.

(2) A pharmacist may dispense injectable epinephrine devices and bronchodilator rescue inhalers pursuant to a prescription issued in the name of an authorized entity or to a certified individual.

(3) 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.

(4) An individual who has a certificate issued under this section may:

(a) Receive a prescription for injectable epinephrine devices and bronchodilator rescue inhalers from a health-care practitioner.

(b) Possess prescribed injectable epinephrine devices and bronchodilator rescue inhalers; and

(c) In an emergency situation when a physician is not immediately available and the certified individual in good faith believes a person is experiencing a severe allergic reaction, asthma symptoms, or respiratory distress regardless of whether the person has a prescription for an injectable epinephrine device or a bronchodilator rescue inhaler or has previously been diagnosed with an allergy or asthma:

1. Administer an injectable epinephrine device or a bronchodilator rescue inhaler to the person; and

2. Provide an injectable epinephrine device or a bronchodilator rescue inhaler to the person for immediate self-administration.

(5) An authorized entity that acquires and stocks a supply of injectable epinephrine devices or bronchodilator rescue inhalers with a valid prescription shall:

(a) Store the injectable epinephrine devices and bronchodilator rescue inhalers in accordance with manufacturer's instructions and with any additional requirements established by the department; and

(b) Designate an employee or agent who holds a certificate issued under this section to be responsible for the storage, maintenance, and general oversight of injectable epinephrine devices and bronchodilator rescue inhalers acquired by the authorized entity.

(6) Any individual or entity who administers or provides an injectable epinephrine device to a person who is experiencing a severe allergic reaction shall contact the local emergency medical services system as soon as possible.

(7) Any individual or entity who acquires and stocks a supply of injectable epinephrine devices in accordance with this section shall notify an agent of the local emergency medical services system and the local emergency communications or vehicle dispatch center of the existence, location, and type of the injectable epinephrine devices acquired if a severe allergic reaction has occurred.

- An "Authorized entity" means an entity that may at any time have allergens present that are capable of causing a severe allergic reaction and has an individual who holds a certificate issued under KRS 311.646 on the premises or officially associated with the entity.
- 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.
- The school nurse or designee shall check the expiration date monthly and obtain a new prescription for replacement medication prior to expiration date.
- Any school employee authorized to administer medications should be aware of and understand their protections and liabilities as established in applicable regulations, including KRS 158.836 and KRS 156.502.

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What is Anaphylaxis?

Anaphylaxis occurs when symptoms affect two or more body systems. It is caused by your immune system flooding your body with chemicals to fight off an allergen. These chemicals often work fast to trigger a cascade of allergy symptoms.

Anaphylaxis is a severe allergic reaction that can progress into a life-threatening condition and can cause death in less than 15 minutes. It is caused by exposure to something the person is allergic to. Symptoms involve multiple body systems including the skin, heart, stomach, and airways. The most common triggers are certain foods, certain medications, and insect stings.

Anaphylaxis is defined in three different ways:

1. Sudden onset of skin symptoms along with respiratory OR circulatory symptoms.
2. Sudden onset of a combination of two body system symptoms.
3. Exposure to allergens and a drop in blood pressure.

What are the most common triggers for anaphylaxis?

- Legumes (such as peanut)
- Animal proteins (such as cow's milk, egg, finned fish, and shellfish)
- Venom from stinging insects (such as bee stings, wasps, and yellow jackets)
- Venom from insect bites (such as fire ants)
- Pain medications (such as aspirin or ibuprofen)
- Tree nuts (such as almonds, walnuts, pecans, and hazelnut), soy, wheat and sesame are other common triggers. Food allergy research reveals more than 170 different foods can trigger allergic reactions.

What are anaphylaxis symptoms?

Symptoms can be different each time a person experiences an anaphylactic reaction. They may vary in severity each time. Once symptoms start, they usually progress quickly.

Signs and Symptoms of the Skin

- Swelling of the face, lips, tongue, neck, and/or hands.
    - Eyes can begin to look puffy and talking and annunciating may become difficult if the lips or tongue swell.
    - Hives are raised, red, and itchy bumps on the skin. The redness of hives is easier to see on lighter skin, but the raised bumps can be felt on anyone.

While skin symptoms such as an itchy rash or hives are common, they do not always occur. Ten to 20 percent of the time, symptoms will occur with no skin symptoms.

Signs and Symptoms of the Respiratory System

- Nasal congestion - stuffy and/or runny nose.
- Wheezing - can sound like a flute when breathing out!
- Coughing.
- Rapid, noisy, and/or difficulty breathing. Someone will struggle to take normal or deep breaths.
- Sudden change or loss of one's voice.

- Trouble swallowing.
  - A child may think they have a sore throat.
- Stridor.
  - High-pitched noise when breathing in.
  - Like a squeaking noise - at times it can sound like a seal-like bark.

Signs and Symptoms of the Neurological System

- Agitation.
  - Acting strangely & differently than normal.
- Confusion.
  - Confusion can also show up in a child getting quiet when they normally do not. Agitation can be a child getting frustrated or mad at activities that don't normally cause that reaction. Behavioral changes are a sign that not enough oxygen is getting to the brain!
- Headache.
- Fainting & Loss of Consciousness (passing out).
  - This can be a child collapsing and quickly becoming responsive and awake again to collapsing and not reacting to attempts to wake them up.

Signs and Symptoms of the Gastrointestinal System

- Nausea.
  - Can be described as a tummy ache in younger children.
- Vomiting (throwing up).
- Diarrhea (runny stools/poop).
- Stomach pain.
  - May be described as a tummy ache or a child may be holding their stomach area.

Signs and Symptoms of the Circulatory System

- Increased heart rate.
  - A child may think their heart is pounding in their chest along with a fast pulse.
- Decrease in blood pressure.
  - If blood vessels get bigger during anaphylaxis, it may be hard to feel a child's pulse.
- Cool, clammy skin.
  - While it is normal to sweat while exercising or in the heat, a child with what feels sweaty but also cool skin is a sign of anaphylaxis.

What is the difference between an allergic reaction and anaphylaxis?

- With an anaphylactic reaction, there will be symptoms involving two or more body systems at the same time.
- With an allergic reaction, you will have one type of symptom – either have a rash OR be itchy OR have an upset stomach.

How long does anaphylaxis last?

Symptoms normally peak within a half-hour of exposure, but they can last for several hours. About 20% of the time**,** symptoms can be controlled with treatment, but they may come back.

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Sometimes there can be a biphasic reaction which is defined as a rebound reaction. Biphasic means the symptoms come in two phases. There may be recovery from the first reaction, but symptoms come back. This can occur up to 12 hours after the first symptoms. The rebound may be mild, but there may still be a need for a second dose of epinephrine.

Epinephrine is a relatively quick-acting medication. It begins to work immediately and wears off quickly. The side effects don't last very long. Most of the side effects should start to resolve within about 30 minutes and fully disappear within a few hours.

What is Anaphylaxis? | Allergy & Asthma Network

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What is Epinephrine?

Epinephrine, also known as adrenaline, is both a hormone and a medication. A person's adrenal glands produce epinephrine, which helps to regulate organ functions. It is typically released when the body is under stress. It is part of the fight or flight response. When an epinephrine injection is given, it does all of this simultaneously. It also gives some people the feeling of being hyper or anxious.

Epinephrine should be administered promptly at the first sign of anaphylaxis. It is safer to administer epinephrine than to delay treatment for anaphylaxis. Epinephrine is the only medication that can reverse symptoms. It is crucial to
use epinephrine first and epinephrine fast. Then seek prompt treatment in your nearest emergency room.

Epinephrine should be stored at room temperature (between 59-86 degrees F) and should be protected from light. The epinephrine should be checked monthly to ensure proper storage, expiration date, and medication stability. Expired injectable epinephrine device or those with discolored solution or solid particles should not be used. Personnel should be familiar with the type of injectable epinephrine device maintained by the school and its use.

What does Epinephrine do?

Epinephrine has different effects on different parts of the body which are normal and expected including:

- Heart — it causes the heart to pump faster and harder. This raises your blood pressure and circulates blood more quickly throughout the body.
- Lungs and airways — your breathing becomes deeper and faster. It dilates the airways and may reduce swelling.
- Eyes — it causes the pupils in your eyes to dilate.
- Skin — it becomes pale, as blood is diverted to your major organs and muscles.
- Muscles — they have increased blood flow.

How to Use Epi-Pen YouTube

How to Use an Auvi-Q YouTube Video

How to use Neffy YouTube Video

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Responding to anaphylaxis

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 injectable epinephrine after exposure to a known allergen and before symptoms of anaphylaxis may be present.

For a student without specific orders on file: Based on symptoms observed, determine that an anaphylactic reaction is occurring.

Go to the student. Never send a student to the health room alone or leave a student alone. Do not move a student who is in severe distress.

1. Act quickly. Only a few symptoms may be present. The severity of symptoms can change rapidly.
2. Call 911 for emergency medical services (EMS)
3. Direct someone to call the school nurse or front office.
4. Direct someone to notify the child's parents.
5. Place student on his/her back, if possible, with feet elevated, unless upper airway obstruction is present, or the patient is vomiting.
6. Determine the proper dose of epinephrine.
   - **Epinephrine** (1 mg/ml aqueous solution [1:1000 dilution]) is the first-line treatment for anaphylaxis and should be administered immediately.
     - In adults, administer a 0.3 mg intramuscular dose using an injectable epinephrine device.
     - In children, administer a standard dosage using the Jr. injectable epinephrine device.
     - For children ≥33 lbs. to <65 lbs. administer the 0.15 mg injectable epinephrine device (FDA product insert). The 0.15mg injectable epinephrine device can also be used for children 7.5 kg (16.5 lbs.) to <15 kg (33 lbs.) when other alternatives are not available (American Academy of Pediatrics).
     - For children ≥66 lbs. administer the 0.30 mg injectable epinephrine device (FDA product insert).
       - Administer in the mid-outer thigh (through clothing if necessary).

Administer the injectable epinephrine:

1. Take off the cap.
2. Press the tip firmly on the thigh at a perpendicular (right) angle.
3. Swing and push the injectable epinephrine device firmly until you hear a click.
4. Hold firmly for 10 seconds.
5. Remove the injectable epinephrine device.
6. Massage area for 10 seconds.
7. Begin monitoring airway and breathing.
8. For a severe reaction consider keeping the student lying on his/her back with legs raised.
9. Remain with the student and reassure him or her as needed.
10. A second dose of epinephrine may be given 5 minutes or more after the first if symptoms persist or recur.

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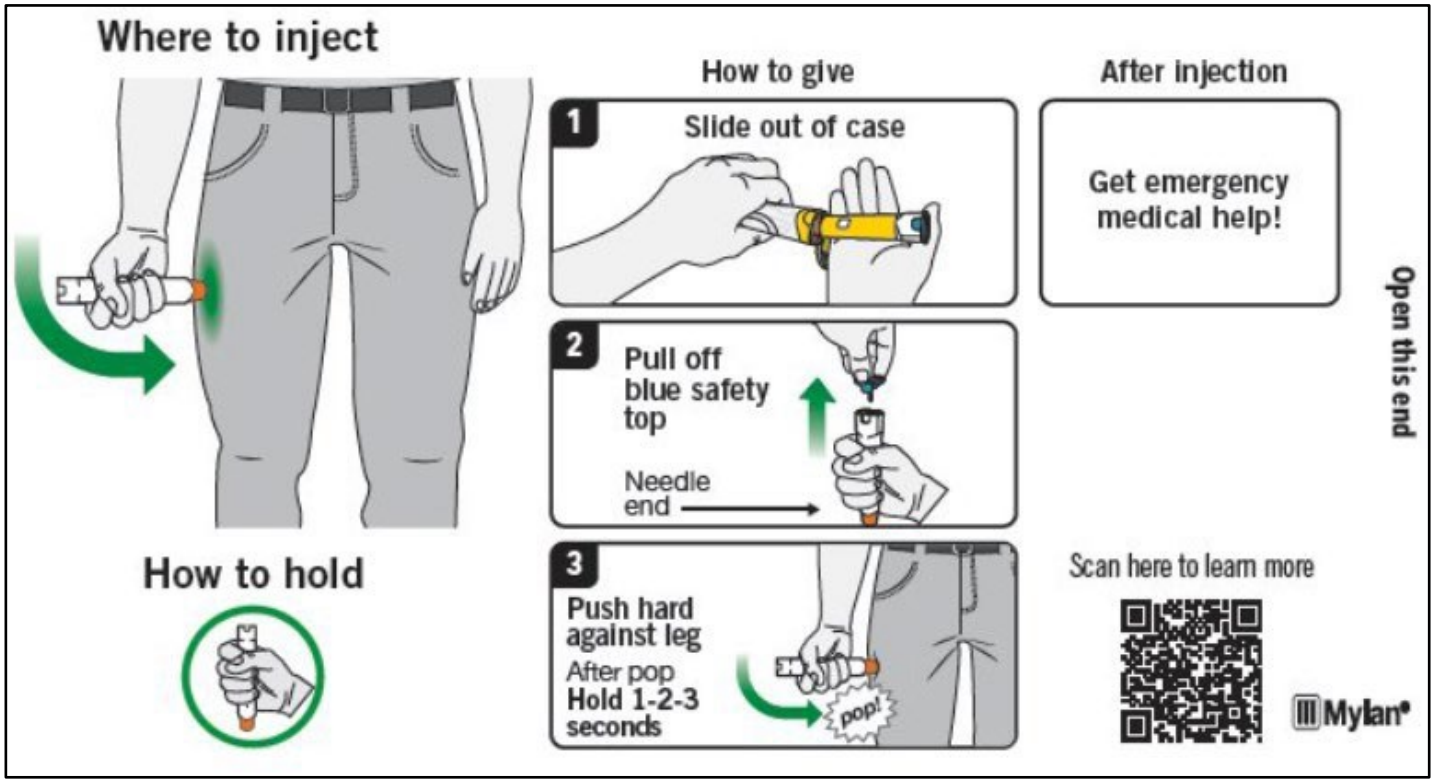
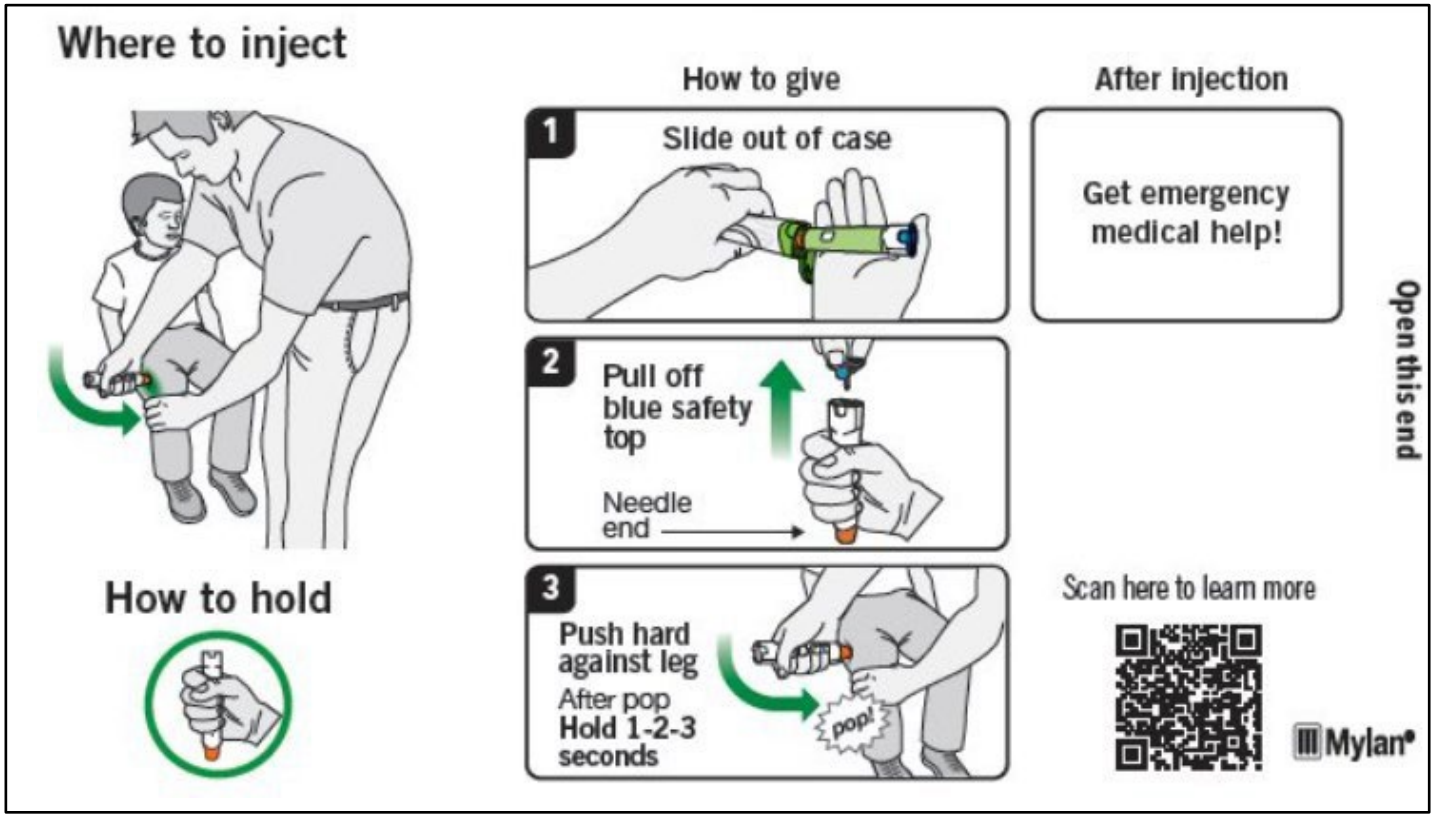
11. Document student's name, date and time epinephrine was administered on the used injectable epinephrine device and give to Emergency Medical Services (EMS), when EMS arrives, so that the information will accompany the student to the emergency department.
12. Even if symptoms subside or go away, EMS 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.
13. Document the incident and complete the school incident report.
14. Replace epinephrine stock medication as appropriate.





- How to Use an EpiPen Video:EpiPen Administration Video
- How to Use an Auvi-Q Video:Auvi-Q Administration Video

Note the time that the epinephrine is administered. For questions regarding dosage or timing of the injectable epinephrine device brand being used, please see product instructions developed by the manufacturer. Because anaphylaxis may recur after patients begin to recover, monitoring in a medical facility for at least four hours is advised, even after complete resolution of symptoms.

How long do side effects of epinephrine last?

Epinephrine is a relatively quick-acting medication. It begins to work immediately and wears off quickly. The side effects don't last very long. Most of the side effects should start to resolve within about 30 minutes and fully disappear within a few hours.

When to give a second dose of epinephrine?

A second dose of epinephrine should be given if symptoms persist 5-15 minutes after the first dose is administered. Sometimes symptoms reemerge between 8 and 72 hours after the first injection. These are called biphasic anaphylactic reactions.
You should call 911 or go to your nearest emergency room for medical assistance anytime you administer epinephrine.

Check expiration dates. Epinephrine auto-injectors should be replaced as soon as they expire. Check the date on devices monthly and document appropriately.

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Allergy and Asthma Network Epinephrine Treatment Options Chart

Epinephrine Treatments 2024

AllergyAsthmaNetwork.org • 800-878-4403

	Brand Devices			Generic Devices		
	Auvi-Q®	EpiPen®	neffy®	Auto-Injector (Amneal)	Auto-Injector (Teva)	Auto-Injector (Viatris)
Type	Auto-Injector	Auto-Injector	Nasal spray	Auto-Injector	Auto-Injector	Auto-Injector
Dosage	0.10 mg for **16.5 - 33 lbs.** 0.15 mg for **33 - 66 lbs.** 0.3 mg for **over 66 lbs.**	0.15 mg for 33 - **66 lbs.** 0.3 mg for **over 66 lbs.**	2 mg for **over 66 lbs.**	0.15 mg for **33 - 66 lbs.** 0.3 mg for **over 66 lbs.**	0.15 mg for **33 - 66 lbs.** 0.3 mg for **over 66 lbs.**	0.15 mg for **33 - 66 lbs.** 0.3 mg for **over 66 lbs.**
Storage Temperature	68 to 77 degrees F	68 to 77 degrees F	68 to 77 degrees F (with excursions up to 122 degrees F)	68 to 77 degrees F	68 to 77 degrees F	68 to 77 degrees F
Administration	Outer middle of thigh	Outer middle of thigh	Spray in nostril (use same nostril if second dose is needed)	Outer middle of thigh	Outer middle of thigh	Outer middle of thigh
Hold Time	2 seconds	3 seconds	None	10 seconds	3 seconds	3 seconds
Is a trainer available?	Yes	Yes	Yes	Yes	Yes	Yes
Twin-packs available?	Yes	Yes	Yes	Yes	Yes	Yes
Shelf life	12 to 18 months	12 to 18 months	30 months	12 to 18 months	12 to 18 months	12 to 18 months
Special feature	Voice prompt; needle fully covered after injection	Needle fully covered after injection	Needle-free	If needle is sticking out after injection, you received the dose	Needle fully covered after injection	Needle fully covered after injection
Manufacturer	Kaléo	Viatris	ARS Pharmaceuticals	Amneal Pharmaceuticals	Teva Pharmaceuticals	Viatris
Website	*auvi-q.com*	*epipen.com*	*neffy.com*	*epinephrineautoinject.com*	*tevaepinephrine.com*	*epipen.com*
Patient assistance	877-302-8847	800-395-3376	877-696-3339	800-934-6729	844-248-7949	800-395-3376

Reviewed by Dennis Williams, PharmD

Thank you to ARS PHARMA ars-pharma.com for supporting the 2024 update of this poster.

How should epinephrine auto-injector be stored?

- Store epinephrine auto-injectors as close to room temperature as possible. Leaving them in extremely hot or cold temperatures can make the epinephrine ineffective or cause the injector to malfunction. Do not store them in a car or in a refrigerator. Keep auto-injectors out of direct sunlight. This can cause the epinephrine to oxidize (combine with oxygen, changing the makeup of the drug) and become ineffective. Oxidized epinephrine will appear dark or have solid particles in it.
- Epinephrine can also oxidize on its own over time, so check your device regularly to be sure the liquid inside is clear.

Common Epinephrine Delivery Devices

- EPIPEN® (epinephrine injection, USP) Auto-Injector| Official Website
  - Instructions for use of the EpiPen® and EpiPen Jr® are found at How to use EpiPen
    - Epinephrine in Schools | EpiPen4Schools®
    - The EPIPEN4SCHOOLS program provides up to four free EPIPEN (epinephrine injection, USP) or EPIPEN JR (epinephrine injection, USP) Auto-Injectors in the form of two EPIPEN 2-PAK® cartons, two EPIPEN JR 2-PAK® cartons or one 2-Pak of each kind along with EPIPEN Trainers and a detailed training video, to qualifying public and private kindergarten, elementary, middle, and high schools in the US. Schools may receive the authorized generic versions of EPIPEN and EPIPEN JR.
- Generic EpiPen®
  - EPIPEN® (epinephrine injection, USP) Auto-Injectors| Authorized generics
  - Teva's Epinephrine Auto-Injector – Using the device (tevaepinephrine.com) Instructions for use of generic or Teva® epinephrine auto-injector.
- HIGHLIGHTS OF PRESCRIBING INFORMATION: These highlights do not include all the information needed to use EPIPEN® and EPIPEN Jr® safely and effectively. See full prescribing information for EPIPEN and EPIPEN Jr. EPIPEN® (epinephrine injection), for intramuscular or subcutaneous use EPIPEN Jr® (epinephrine injection), for intramuscular or subcutaneous use Initial U.S. Approval: 1939 (nih.gov)AUVI-Q® (epinephrine injection, USP)auto injector is pocket-sized device that can be used to self-administer epinephrine in response to symptoms of anaphylaxis. It has a voice prompt that gives step-by-step instructions on the administration of the medication.
  - Instructions on use found at How to Use AUVI-Q® (epinephrine injection, USP).
- SYMJEPI® (epinephrine) Injection, is a syringe with the correct dose of epinephrine already loaded. The needle must be inserted, and the plunger depressed to deliver the medication. It is also available in both 0.15 mg dose for children 33-65 lbs. and 0.3 mg for people over 66 lbs.
  - Instructions on how to use found at SYMJEPI® (epinephrine) Injection | How to Use SYMJEPI | Official Website.

- Neffy (epinephrine nasal spray) is the first FDA-approved needle-free way to administer epinephrine. Product information and administration instructions can be found at Epinephrine Nasal Spray for Type I Allergy Patients | Neffy.
  - How to Use Neffy Video- Adolescent Neffy Administration Video-Adolescent
  - How to Use Neffy Video- Adult Neffy Administration Video- Adult

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References and Resources

Allergy and Asthma Network

- Managing Allergies in Schools: A Guide for Parents - Allergy & Asthma Network
- Anaphylaxis = Epinephrine: Treating a Severe Allergic Reaction (allergyasthmanetwork.org)
- Anaphylaxis | Allergy & Asthma Network (allergyasthmanetwork.org)
- What is Epinephrine? | Allergy & Asthma Network (allergyasthmanetwork.org)

American Academy of Allergy Asthma & Immunology (AAAAI)

- Anaphylaxis Symptoms, Diagnosis, Treatment & Management | AAAAI
- Stock Epinephrine Toolkit for Schools (aaaai.org)

American Academy of Pediatrics

- Allergy and Anaphylaxis Management in Schools (aap.org)
- Epinephrine for First-aid Management of Anaphylaxis | Pediatrics | American Academy of Pediatrics (aap.org)
- Guidance on Completing a Written Allergy and Anaphylaxis Emergency Plan | Pediatrics | American Academy of Pediatrics (aap.org)
- AAP_Allergy_and_Anaphylaxis_Emergency_Plan.pdf

ARS Pharmaceuticals

- Epinephrine Nasal Spray for Type I Allergy Patients | Neffy
- Neffy Introduction and How to Use Presentation-ARS Pharma

Centers for Disease Control and Prevention

- Food Allergies in Schools
- Food Allergies in Schools Toolkit
- Voluntary Guidelines for Managing Food Allergies In Schools and Early Care and Education Programs

Food Allergy and Anaphylaxis Network (FAAN)

- Back-to-School Resource Hub | Food Allergy Research & Education
- Food Allergy & Anaphylaxis Emergency Care Plan - FoodAllergy.org

Food Allergy Research and Education

- Food Allergy and Anaphylaxis Emergency Care Plan
- Microsoft Word - Anaphylaxis Emergency Action plan updated 2020_AM.docx (aaaai.org)

Kentucky Department of Education

- Student Health Services - Kentucky Department of Education
- Health Services Reference Guide - Kentucky Department of Education
- Medication Administration Training Program - Kentucky Department of Education

National Association for School Nurses (NASN) Updated 2021

- Allergies and Anaphylaxis - National Association of School Nurses (nasn.org)
    - Sample Planning Checklists
    - Sample Policy
    - Sample Practice Forms
    - School Personnel Training Resources
    - Education Resources

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Kentucky Department for Public Health
Clinical Protocol for Stock Naloxone (OPIOID ANTAGONIST) Emergency Use in the School Setting
Medically Approved Guideline for Stock Over-the-Counter Naloxone Emergency Use in the School Setting

Background

KRS 217.186 Definition -- Provider prescribing or dispensing opioid antagonist -- states that the board of each local public school district and the governing body of each private and parochial school or school district may permit a school to keep naloxone on the premises and regulate the administration of naloxone to any individual suffering from an apparent opiate-related overdose. As used in this document, "opioid antagonist" means naloxone or any other United States Food and Drug Administration-approved drug designed to reverse the effects of an opioid overdose includes:

- The Kentucky Department for Public health (KDPH) shall develop clinical protocols (medically approved guidelines) to address supplies of naloxone including over-the-counter nasal spray kept by the schools.
- A person or agency, including a school employee authorized to administer medication under KRS 156.502 may:
  - Receive a prescription for the drug naloxone.
  - Possess naloxone pursuant to this subsection and any equipment needed for its administration; and
  - Administer naloxone to an individual suffering from an apparent opioid-related overdose.
- 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 an opioid antagonist, naloxone displaces opiates from receptor sites in the brain and reverses respiratory depression, which 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 overdose. 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. There are many formulations of naloxone. The FDA has approved over the counter (OTC), Naloxone ReVive 3 milligram (mg) and Naloxone Narcan generic 4 milligram (mg) single use nasal spray. Other formulations of naloxone will remain available as prescription products.
- Naloxone may be purchased with a prescription from a medical provider or pharmacist who has met the requirements and received certification from the Board of Pharmacy in accordance with 201 KAR 2:360 Opioid antagonist dispensing. This administrative regulation establishes the minimum requirements for the pharmacist to be able to dispense an opioid antagonist pursuant to a physician-approved protocol. Naloxone is not a substitute for emergency medical care. Repeating dosing may be necessary. Use as directed.
- 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.

KRS 314.021 Policy states that "all individuals licensed or privileged under provisions of this chapter and administrative regulations of the board shall be responsible and accountable for making decisions that are based upon the individuals' educational preparation and experience and shall practice with reasonable skill and safety".

- Over-the-Counter Naloxone Nasal Spray:

  The Kentucky Board of Nursing KBN AOS #16 Scope of Nursing Practice in the Recommendation and Administration of Over the Counter (OTC) Medications states:

  - When a nurse, as an employee or volunteer of a healthcare delivery system, provides non-prescription medication to an individual, the nurse should do so based on an order from a qualified healthcare provider or medically approved guidelines to supply the non- prescription medication.
  - An educationally prepared and clinically competent nurse, as an individual who is acting outside a health delivery system, **may choose to recommend or administer a non-prescription drug (in a pre-labeled, pre-packaged form) to a person whose condition warrants it based on nursing assessment.**
  - Nurses who make delegatory decisions regarding the performance of acts/tasks by others are governed by 201 KAR 20:400 Delegation of nursing tasks.

WHAT ARE OPIOIDS?

- Opioids are drugs that alter the body's perception of pain. These drugs are among our most important tools for treating chronic and acute pain. 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 can also trigger other systems of the body, such as those responsible for regulating mood, breathing, and blood pressure
- Opioids work in the same part of the brain that controls breathing. Overloading the brain with too many opioids can slow down or shut down breathing and lead to death.

Common opioids Include:

GENERIC	Brand Name
Buprenorphine	Suboxone, Subutex, Zubsolv, Bunavail,
Codeine	Tylenol with Codeine, TyCo, Tylenol #3
Diacetylmorphine	Herion
Fentanyl	Duragesic, Actiq
Hydrocodone	Vicodin, Lorcet, Lortab, Norco, Zohydro
Hydromorphone	Dilaudid
Meperidine	Demerol
Methadone	Dolophine, Methadose
Morphine	MSContin, Kadian, Embeda, Avinza
Oxycodone	Percocet, OxyContin, Roxicodone, Percodan
Oxymorphone	Opana

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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.

- Using again after taking a break, a person who has recently gone through opioid withdrawal has decreased opioid tolerance and can overdose very easily.
  - This applies especially to people who have recently been in treatment, recovery, or have been incarcerated.
- 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 unregulated drugs.
- Accidental exposure and unintentional opioid use
  - Includes members of a patient's household who may discover and use the prescribed opioid inappropriately.
  - Unregulated fentanyl may be found in drugs such as cocaine, meth, or in counterfeit pills.
- A morphine-equivalent dose (MED) ≥20 mg per day.
- Switching to another opioid.
- Chronic pulmonary disease.
- Sleep apnea.
- Asthma.
- Chronic kidney and/or liver impairment.
- Use of CNS depressants, including benzodiazepines and alcohol.
- Use of certain medications for depression, including monoamine oxidase inhibitors (MAOIs).

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SIGNS AND SYMPTOMS OF OPIOID OVERDOSE

All school staff, including those in extracurricular programs, should be trained in how to recognize the signs and symptoms of an opioid overdose requiring the use of naloxone.

Symptoms of an opioid **overdose** requiring the use of naloxone may include but are not limited to the following:

- Extreme sleepiness (inability to awaken verbally or upon tactile stimulation)
- Slow (less than 5 breaths per minute), 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 <u>all</u> signs and symptoms may be present during an opioid overdose. If the individual is not responsive to aggressive yelling, or tactical stimulation,

- **ACT PROMPTLY!!**
- **CALL FOR HELP**
- **CHECK FOR BREATHING**
- **HAVE SOMEONE CALL 911 IMMEDIATELY**
- **GET THE NALOXONE**

RESPONDING TO AN OPIOID OVERDOSE

ACT FAST!! Always go with 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.

Suspected opioid poisoning.

- Check for responsiveness.
- Shout for help nearby.
- Activate the emergency response system (call 911).
- Get naloxone and an AED if available.

If the person is breathing normally, you can **prevent deterioration** by:

- Tap and shout.
- Reposition.
- Consider naloxone.
- Continue until EMS arrives.

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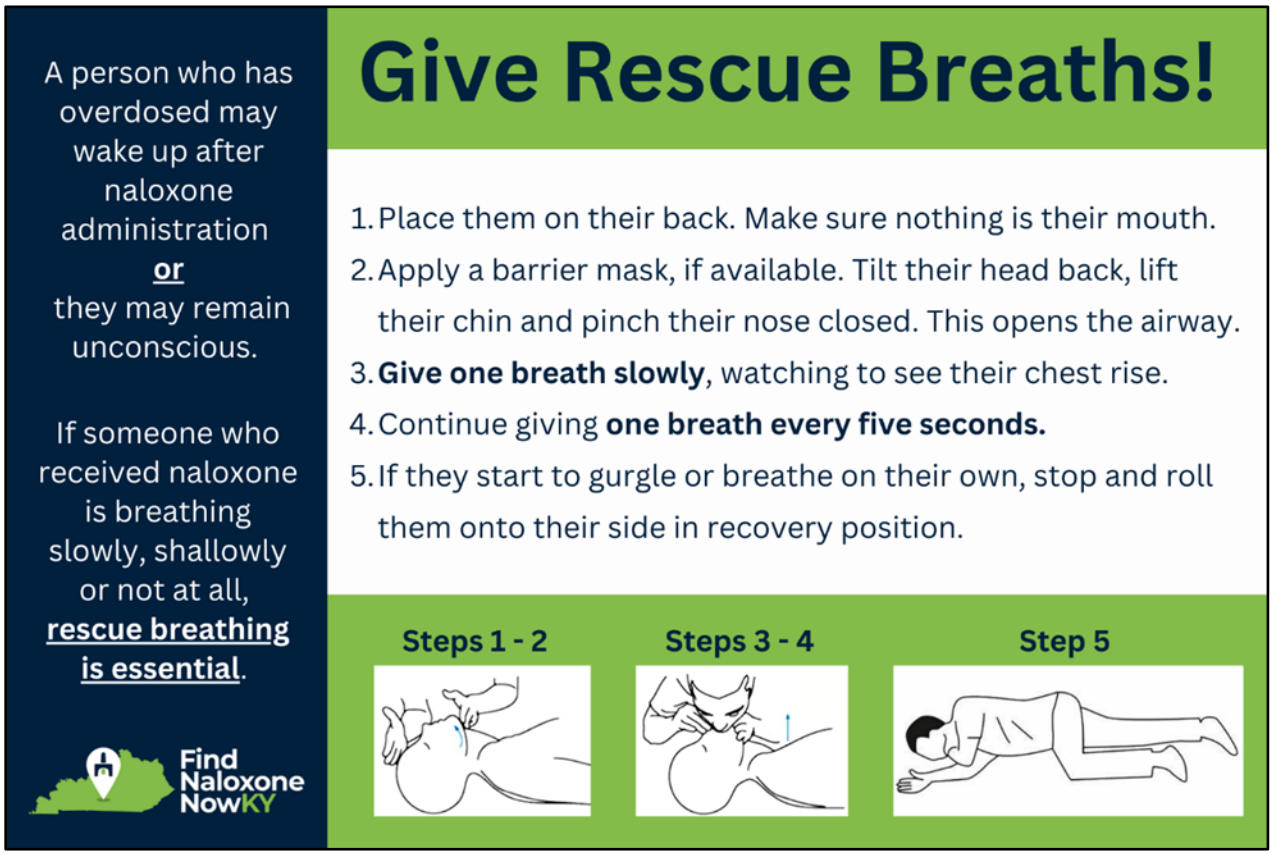
If the person is NOT breathing normally (gasping, or shallow, infrequent breathing) but has a pulse felt within 10 seconds:

- Provide rescue breathing, one breath every 6 seconds. Apply a rescue breathing barrier mask, if available.
- Check pulse every 2 minutes, **if there is no pulse, start CPR**.
- If possible opioid overdose, administer naloxone per protocol.

If no breathing or only gasping, and no pulse felt:

- **Start CPR**
- Perform cycles of 30 compressions and 2 breaths.
- Use an AED as soon as it is available.
- Resume CPR until prompted by AED to allow rhythm check and continue until EMS arrives or victim starts to move.

- Note: For adult and adolescent victims, responders should perform compressions and rescue breaths for opioid associated emergencies if they are trained and perform Hands-Only CPR if not trained to perform rescue breaths. For infants and children, CPR should include compressions with rescue breaths.



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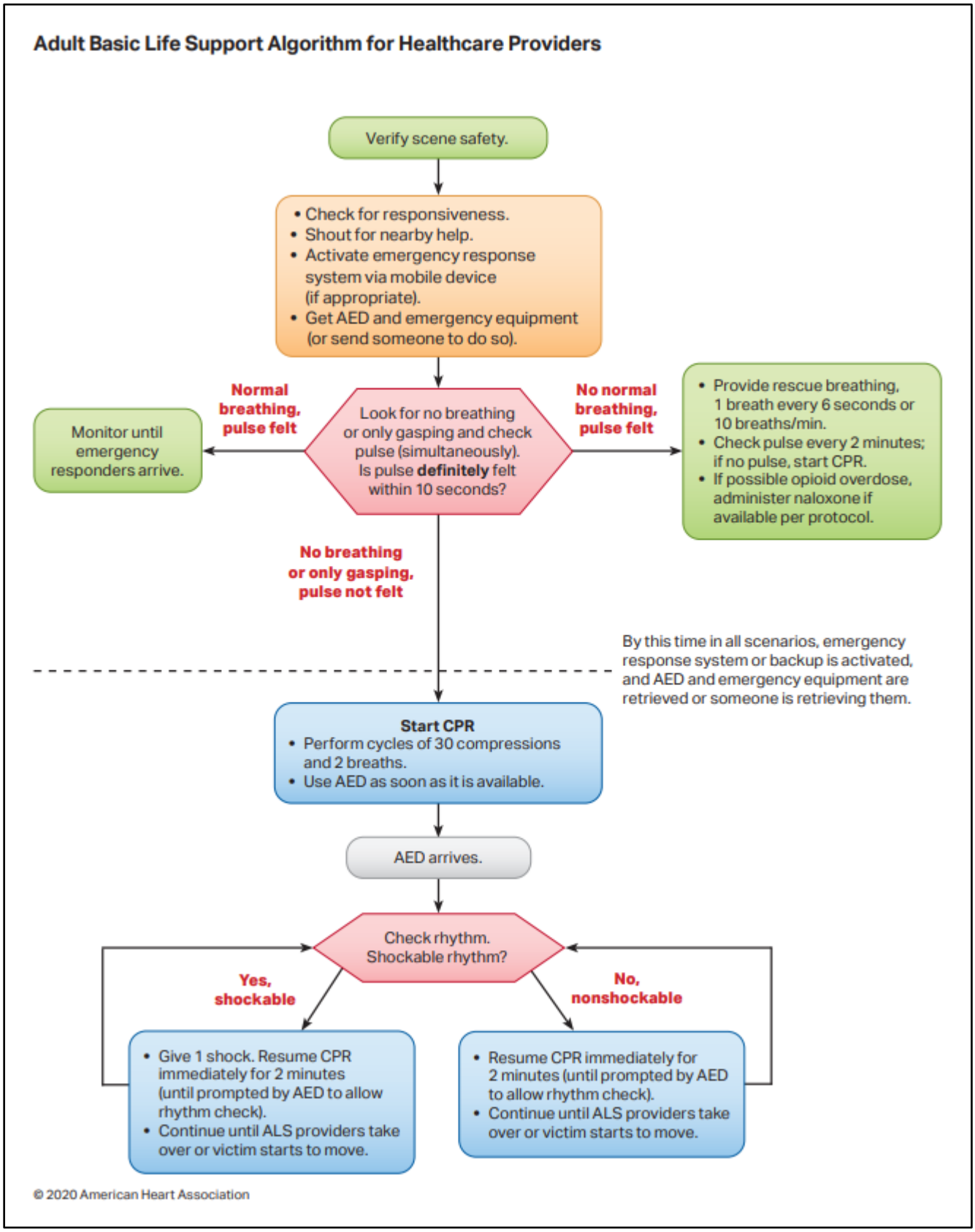
[Basic Adult Life Support Algorithm for Healthcare Providers2020 (heart.org)]



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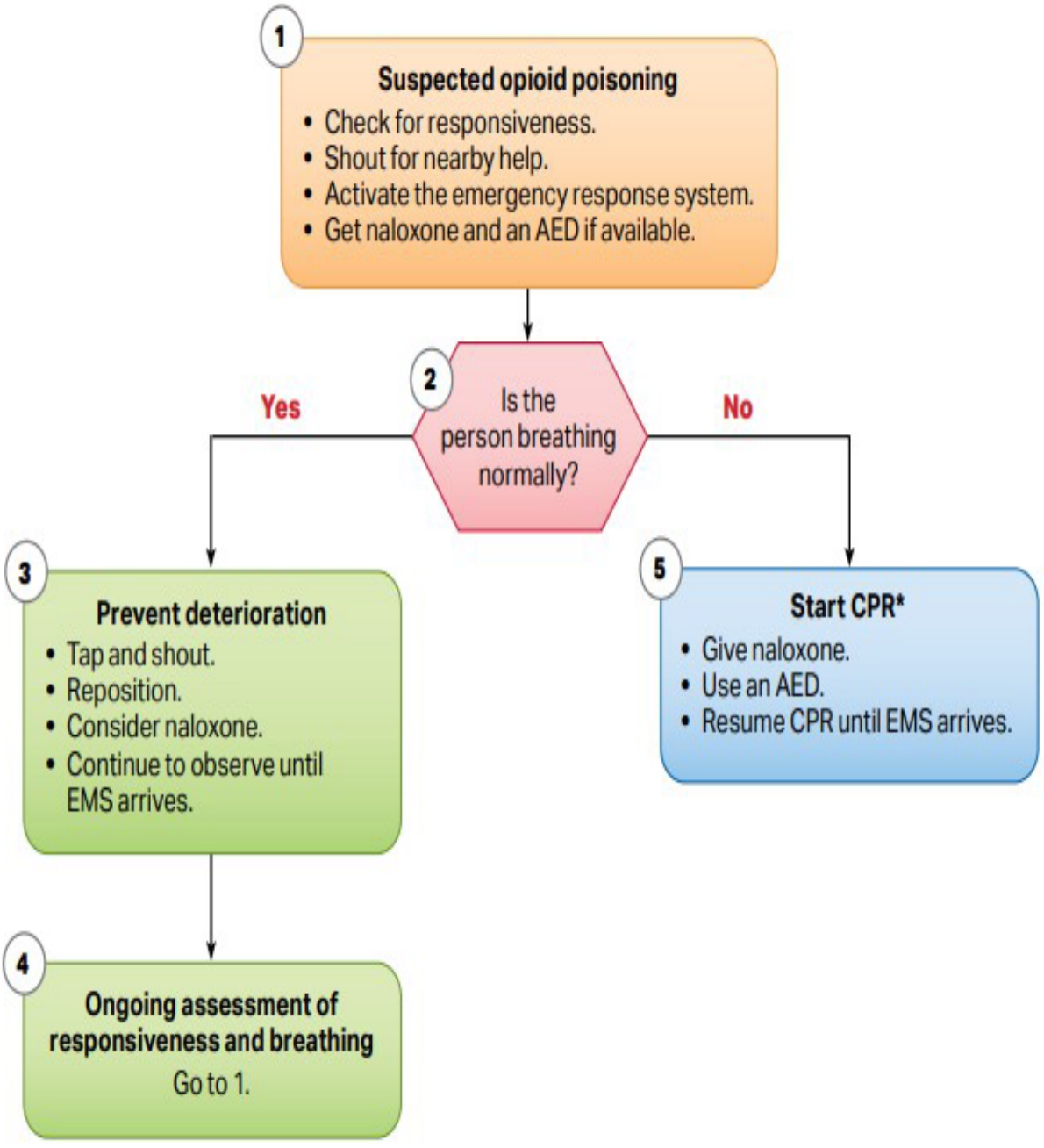
Algorithm Opioid Lay_Responder_2006 (heart.org)

Opioid-Associated Emergency for Lay Responders Algorithm-Written description of illustration (heart.org)

Opioid-Associated Emergency for Lay Responders Algorithm



*For adult and adolescent victims, responders should perform compressions and rescue breaths for opioid-associated emergencies if they are trained and perform Hands-Only CPR if not trained to perform rescue breaths. For infants and children, CPR should include compressions with rescue breaths.

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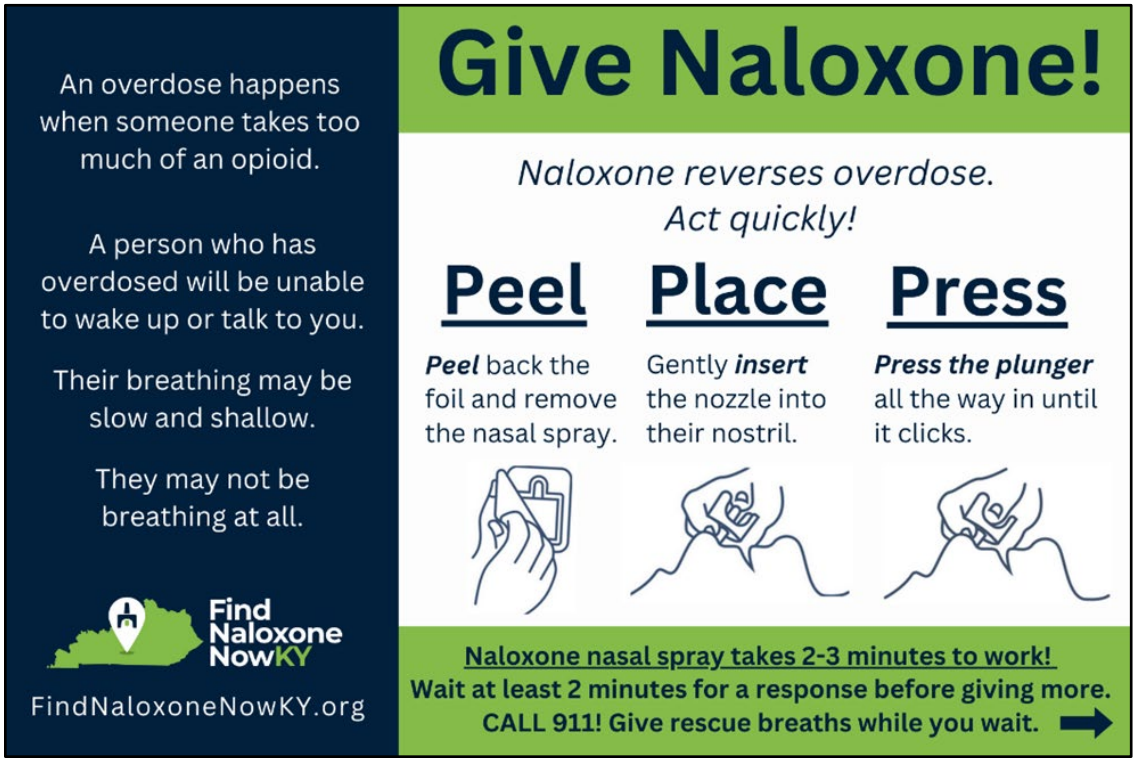
1. ADMINISTER NALOXONE

There are multiple routes of administration for FDA approved naloxone: intramuscular, subcutaneous, intranasal (most commonly available), and intravenous. Schools may choose to use administration methods that best suit their needs. Current drug products approved by the FDA may be found here: Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations (fda.gov)



1. Remove blister packs from carton.
2. Peel back the foil on one blister pack.
3. Remove the nasal spray device from the blister pack.
4. Hold the nasal spray device with index and middle finger on either side of the nozzle. Be careful not to press the plunger yet.
5. Insert the nasal spray device into a nostril. The index and middle fingers should be touching the bottom of the nostril.
6. Press the plunger all the way in until it clicks.
7. Remove the nasal spray device from the nostril.
8. Assure that 911 has been called.
9. Begin rescue breathing.
10. Repeat every 2-3 minutes until the person begins breathing effectively or EMS arrives. Follow each dose with rescue breathing. If the person begins to breathe effectively, wake up, or vomit, place the person on his/her side in the recovery position. Allow space between you and the individual to protect yourself.

DIRECT SOMEONE TO CALL AND NOTIFY THE FRONT OFFICE AND THE SCHOOL NURSE

Following naloxone administration, assure that 911 has been called and that EMS has been activated.

Stay with the person and monitor and intervene for respiratory distress.

If there is no breathing or breathing continues to be slow (less than 5 breaths/minute) or shallow, continue to administer doses of naloxone every 2-3 minutes. Between doses, continue to perform rescue breathing while waiting for the return of an effective breathing pattern or the arrival of EMS. If they are breathing effectively 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 overdose symptoms are present again.

The duration of action of most opioids may 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.

A person may remain unconscious if non-opioid drugs have been taken or if they have experienced another medical emergency such as:

- Traumatic brain Injury
- Stroke
- Diabetes
- Infection
- Heart attack
- Seizures

2. DOCUMENT

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 the school incident report.
- Replace naloxone in-stock medication as appropriate as soon as possible.

Following naloxone administration, assure that 911 has been called and that EMS has been activated.

Stay with the person and monitor and intervene for respiratory distress.

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NALOXONE

Naloxone Hydrochloride Nasal Spray: 4mg / 0.1mL in carton containing two blister packages each with a single 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. Follow each dose with rescue breathing.
- Infants, Children & Adolescents: 1 spray (4 mg) intranasally; repeat every 2-3 minutes alternating nostrils until desired response, breathing returns or EMS arrives. Each device contains a single dose.
  Follow each dose with rescue breathing.

Current drug products approved by the FDA may be found here:
Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations (fda.gov)

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

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. Prolonged respiratory depression may result in damage to the central nervous system or death. Do not delay life-saving interventions.
- Make sure someone calls 911 to activate EMS as soon as an emergency is identified. Assure 911 has been called immediately after administering the first dose of naloxone.

HOW NALOXONE IS SUPPLIED

- The intranasal formulation can be dispensed as a commercially available product or a kit that requires assembly.
- The commercially produced naloxone nasal spray may be preferred by patients and caregivers due to cost and ease of assembly/administration.
- Naloxone can be supplied as an intramuscular (IM) injection into a person's muscle, typically the butt, shoulder, or thigh, or as an intranasal (IN) spray, a device that sprays the medication into the person's nose. Both formulations are effective. There are two primary ways naloxone can be administered. Different FDA-approved naloxone products are available in different doses.
- There is also a commercially available prefilled syringe and needle

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STORAGE AND HANDLING OF NALOXONE

- 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 in a sharps container.
- School staff should be familiar with the type of naloxone maintained by their agency and its use.
- School 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 RESOURCES

KDPH:

- Harm Reduction Program - Cabinet for Health and Family Services (ky.gov)
  - Harm Reduction: Outreach Services
  - You Can Reverse Overdose: Naloxone and Rescue Breathing - YouTube 4:15
  - KDPH EHP From Crisis to Care: Overdose Interventions for First Responders ID: 1121200 - Kentucky TRAIN - an affiliate of the TRAIN Learning Network powered by the Public Health Foundation
  - Fentanyl and Xylazine Test Strips
- Find Naloxone Now Kentucky
  - What are Opioids? - FINDNALOXONE
  - What is Naloxone? - FINDNALOXONE
  - How Do I Use Naloxone? - FINDNALOXONE
    - Nasal Spray - Generic - Opioid Overdose Recognition and Response
      - KLOXXADO® (naloxone HCl) Nasal Spray
      - NARCAN® Nasal Spray
      - Rivive - Harm Reduction Therapeutics
    - IM - Generic - Opioid Overdose Recognition and Response
      - ZIMHI® for Opioid Overdose Emergency Rescue
  - Opioid Overdose Prevention - FINDNALOXONE

CDC:

- Lifesaving Naloxone | Stop Overdose | CDC
- Naloxone Toolkit | Overdose Prevention | CDC
- Reverse Opioid Overdose to Prevent Death | Overdose Prevention | CDC
- Naloxone Frequently Asked Questions | Stop Overdose | CDC

FDA:

- FDA Approves First Over-the-Counter Naloxone Nasal Spray | FDA
- OTC Naloxone.pdf (kphanet.org)
- Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations (fda.gov)

NIH:

- Naloxone Drug Facts | National Institute on Drug Abuse (NIDA) (nih.gov)

MedlinePlus:

- Naloxone Nasal Spray: MedlinePlus Drug Information

FREE Naloxone in Kentucky:

- Find Naloxone Now Kentucky (Naloxone locator and map)
- Next Distro: Free Naloxone Access for Impacted Communities — NEXT Distro
- Kentucky — NEXT Distro

Kentucky Public Health
Prevent. Promote. Protect.

REFERENCES AND RESOURCES

American Heart Association

- Part 3: Adult Basic and Advanced Life Support | American Heart Association CPR & First Aid
- Opioid Education | American Heart Association CPR & First Aid

American Red Cross

- How to Perform CPR | Red Cross

Center for Disease Control (CDC)

- Drug Overdose | Injury Center | CDC
- Fentanyl: Emergency Responders at Risk | Substance Use | CDC
- Fentanyl Safety Recommendations for First Responders

Kentucky Board of Nursing (KBN)

- Overview - KBN (ky.gov)
- Advisory Opinion Statements

Kentucky Department of Education (KDE)

- Medication Administration Training Program - Kentucky Department of Education

Kentucky Department for Public Health (KDPH)

- Kentucky Department for Public Health HARM REDUCTION PROGRAM
- Find Naloxone Now Kentucky - FINDNALOXONE

National Association of School Nurses

- Drugs of Abuse - National Association of School Nurses (nasn.org)
- Naloxone in the School Setting - National Association of School Nurses

National Harm Reduction Coalition

- Overdose Prevention Resources | National Harm Reduction Coalition

National Institute on Drug Abuse (NIDA)

- Commonly Used Drugs Charts | National Institute on Drug Abuse (NIDA) (nih.gov)
- Opioids | National Institute on Drug Abuse (NIDA)

Readiness and Emergency Management for Schools (REMS)

- Readiness and Emergency Management for Schools Technical Assistance Center (ed.gov)
- Fact Sheet Preparing for Opioid-Related Emergencies for K-12 Schools
- Naloxone Saves Lives in Opioid Overdose | National Institute on Drug Abuse (video 5:39 min)

Substance Abuse and Mental Health Services Administration (SAMHSA)

- SAMHSA Overdose Prevention and Response Toolkit (Revised 2024)
- Preventing, Recognizing, and Treating Opioid Overdose | SAMHSA
- Evidence-Based Resources About Opioid Overdose | SAMHSA
- Substance Misuse Prevention for Young Adults | SAMHSA Publications and Digital Products
- Talk. They Hear You: What Educators Can Do to Help Prevent Underage Drinking and Other Drug Use Fact Sheet | SAMHSA Publications and Digital Products

U.S. Department of Health and Human Services (HHS)

- National Opioids Crisis: Help and Resources | HHS.gov
- U.S. Surgeon General's Advisory on Naloxone and Opioid Overdose | HHS.gov

STD
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STD MATRIX

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Requirements of an STD Visit
Males and Females</th></tr>
<tr><td>REASON FOR VISIT</td><td>PRIMARY REASON:
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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)
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<tr><td>MEDICAL HISTORY</td><td>Significant illnesses; hospitalizations; chronic or acute medical conditions
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Current prescription medication and/or antibiotics w/in the last month
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<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
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</table>
Frequency of condom usage
FEMALES: Last menstrual period, obstetrical history, and gynecological conditions, and current contraceptive use.</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 assertive 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 a vaginal specimen for gonorrhea, Chlamydia and trichomoniasis utilizing an APTIMA test kit. A urine specimen should be obtained from females without a cervix. Optional: an endocervical specimen may be used.	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 urine specimen 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. Optional: an intraurethral specimen may be obtained. • 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). For specimens submitted to Kentucky's Division of Laboratory Services, a reflexive Nucleic Acid Amplification Test (NAAT) for Trichomoniasis will be obtained. 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
LABORATORY	• 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, or trichomoniasis. 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, gonorrhea and/or trichomoniasis 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, trichomoniasis, 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, trichomoniasis, NGU, or 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, chlamydia or trichomoniasis 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, chlamydia or trichomoniasis 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, chlamydial infections or trichomoniasis 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.

Guidance for Delivering Expedited Partner Therapy

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)
- Sexual contact of a person diagnosed with trichomoniasis.

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

Trichomoniasis:

a. Female-Metronidazole 500 mg 2 times/day for 7 days or alternative Tinidazole 2 g orally in a single dose
b. Male-Metronidazole 2 g orally in a single dose or alternative Tinidazole 2 g orally in a single dose

Contraindications:

- Contraindications include allergy to metronidazole

Precautions: Pregnancy and Chest/Breastfeeding*

- Metronidazole may be used during the first trimester (first three months) of pregnancy only after discussing this with your healthcare provider, and during the second and third trimesters of pregnancy.

- Metronidazole may be used during chest/breastfeeding, depending on the dose prescribed. If you are prescribed a single 2-gram dose of metronidazole, pump and discard breastmilk for 12-24 hours after your dose to allow the medication to leave your body.

*Metronidazole passes into breastmilk. The amount of metronidazole that passes into breastmilk can depend on the dose and how the medication is taken (by mouth, by IV, vaginally, or topically). With oral or IV use, the amount of metronidazole in breast milk can be similar to the dose given to infants for treatment. Most babies exposed to metronidazole through breast milk have not had any side effects. If a chest/breastfeed baby shows symptoms like loose stools, diaper rash, or thrush, contact their healthcare provider. Some metronidazole product labels have suggested to not breastfeed during treatment and for two days after the last dose. But the benefit of using metronidazole may outweigh possible risks. Your healthcare providers can talk with you about using metronidazole and what treatment is best for you. Be sure to talk to your healthcare provider about all of your breastfeeding questions.

Partners in the 60 days prior to diagnosis should be treated with the same medication(s). Partners of partners are not candidates for EPT.

Partner Information

Written partner informational materials are printed in the partner's language and given to the patient to deliver to each partner. A referral for partner evaluation is included. Key partner counseling messages include:

- Partners should seek a complete STD evaluation as soon as possible.
- Partners should read the informational material very carefully before taking the medication.
- Partners who have allergies to antibiotics or who have serious health problems should not take the medication and should see a health care provider.
- Partners who have symptoms of a more serious infection (e.g., pelvic pain in women, testicular pain in men, or fever in men or women) should not take EPT and should seek care as soon as possible.
- Partners who are or who could be pregnant should seek care as soon as possible.
- Patients and partners should abstain from sex for at least seven days after treatment and for seven days after all partners have been treated, 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) Indurated chancre usually painless SECONDARY(2º) Rash-bilateral maculopapular, follicular, papulosquamous pustular lesions. alopecia, condyloma talata, mucous patches EARLYLATENT • No Symptoms (SX) at Exam PLUS, one of the following: • History of SX within last 12 months • Documented Negative test 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 using reverse syphilis testing: VDRL/RPR plus, confirmatory test such as: TPPA, FTA, TP Ab or MHA Stat RPR 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. *During times of PCN shortages, non-pregnant individuals should be given doxycycline as a first line of treatment	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 EPID200and 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) *During times of PCN shortages, non-pregnant individuals should be given doxycycline as a first line of treatment	For penicillin allergic non-pregnant adult patients: DOXYCYCLINE 100 mg orally 2 times a day for 28 days (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

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)**					
Children (aged > 1 month) Late Latent or Unknown Duration See CDC Treatment Guidelines for the 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. .	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 adult total dose of 7.2 million units)	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.
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 STD Program.

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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)**					
SYPHILIS WITH A CO-INFECTION OF HIV	See Appropriate Section Above	See Appropriate Section Above	See Appropriate Section Above Additional doses of Benzathine penicillin G* in early syphilis do not enhance efficacy, regardless of HIV status. *During times of PCN shortages, non-pregnant individuals should be given doxycycline as a first line of treatment	The use of nonpenicillin regimens should be used only in conjunction with close serologic and clinical follow-up.	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.
SYPHILIS AND 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 EPID200and fax to State STD Program within 24 hours. Indicate pregnancy status on EPID 200.

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 within12months 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 EPID200 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	SEE GC SX IN ADULTS	DLS 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						
child should 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 and LHDs shall assure adequate RX.	SEE GC SX IN ADULTS	DLS does not perform GC cultures. Because of the legal implications 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 Program within 14 days. Report suspected cases of sexual abuse to the Dept of Community Based Services
GC - PREGNANCY	SEE GC SX IN ADULTS	SEE GC 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.	Program within 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 Program within 14 days. EPID 200's that do not contain treatment at time of initial report shall be updated with treatment information and sent to state STD office 7 days after RX administration 85% and 90% of patients DX w/CT should be treated within 14 and 30 days, respectively, from the date of lab collection.

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 ethyl succinate 50mg/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 ADULTSABOVE	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 >12years 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 for1%–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 immersion field 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 NAAT testing 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 (For persons >/= 300 lb., 1 gm should be given) 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	1. Commonly asymptomatic 2. Frothy grey or yellow-green discharge (vaginal or penile) 3. Pruritus/Itching 4. Reddened genitalia 5. Discomfort/pain when urination or during intercourse 6. Cervical (if applicable) Petechiae ("strawberry-cervix") 7. Odor-foul, strong	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 reflex NAAT testing for trichomoniasis on any approved specimen type which includes female endocervical, vaginal, and female and male urine, will automatically have testing performed for Trichomonas from the same specimen tube as existing Chlamydia and Gonorrhea testing.)	Female: Metronidazole 500 mg orally 2 times a day for 7 days Male: Metronidazole 2g orally in a single dose The ERRN may implement treatment for patients with positive (NAAT) laboratory results. Refer to the Trichomoniasis standing order.	Tinidazole[7] 2 g orally in a single dose (not recommended in pregnancy)	Advise to have partners treated. Partners shall be screened for CT, GC, syphilis, and HIV. Female: Metronidazole 500 mg orally 2 times a day for 7 days Male: Metronidazole 2g 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 cheesy discharge in labial folds 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 bioadhesive product), 5 g intravaginally in a single application OR Fluconazole 150 mg PO for 1 dose (contraindicated in pregnancy) Please see 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, Indurated bleeding, etc.)	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	EXTERNAL ANOGENITAL 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

HPV (Genital Warts) and Pregnancy	SEE ABOVE Genital warts can proliferate and become friable during pregnancy. Although removal of warts during pregnancy can be considered, resolution might be incomplete or poor until pregnancy is complete. HPV types 6 and 11 rarely can cause respiratory papillomatosis in infants and children.	SEE ABOVE	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. 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.)	EXTERNAL ANOGENITAL WARTS N/A (Imiquimod, podophyllin, Sinecatechins and Podofilox should not be used during pregnancy.)	N/A	N/A

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 (cont.) **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) 564-6353 or (502) 564 6352

Downloads & Resources:

2021 STD Treatment Guidelines

2021STD TX Guide App

Download the 2021 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

Standing Order Name: Trichomoniasis (Trich)

Scope (condition and patient group): Patients (male and female) presenting with clinically suspicious symptoms, positive laboratory confirmation of trichomonas or a sexual contact with a person diagnosed with trichomonas.

Assessment:

- Symptoms
  - Commonly asymptomatic
  - Frothy grey or yellow-green vaginal/penile discharge
  - Pruritus/itching
  - Reddened genitalia
  - Discomfort/pain when urination or during intercourse
  - Cervical petechiae ("strawberry cervix") (if applicable)
  - Odor-foul, strong
- Tests
  - Traditional mode of assessment has been made by observation of motile trichomonas in saline wet mount, if available. This must be completed by APRN/MD.
  - DLS Nucleic Acid Amplification Test (NAAT) Reflex: Any approved specimen type, which includes female endocervical, vaginal, and female and male urine, will automatically have testing performed for Trichomonas from the same specimen tube as existing Chlamydia and Gonorrhea testing.

Interpretation of Laboratory Findings:

1. Positive - C. trachomatis RNA detected and/or N. gonorrhoeae RNA detected and/or Trichomonas Vaginalis RNA detected If Trichomonas is identified in urine, urethral or vaginal specimen, treatment should be provided.

2. Negative - C. trachomatis RNA not detected and/or N. gonorrhoeae RNA not detected and/or Trichomonas vaginalis RNA not detected

3. Equivocal - Indeterminate (specimen should be repeated)

Treatment*:

STD Enhanced Role RN may implement treatment for patients with **confirmed positive laboratory results.**

- Female-Metronidazole 500 mg 2 times/day for 7 days or alternative Tinidazole 2 g orally in a single dose
- Male-Metronidazole 2 g orally in a single dose or alternative Tinidazole 2 g orally in a single dose

Contraindications:

- Allergy to metronidazole then defer to tinidazole.
- Allergy to tinidazole then consult with healthcare provider.

Precautions: Pregnancy and Chest/Breastfeeding*

- Metronidazole may be used during the first trimester (first three months) of pregnancy only after discussing this with your healthcare provider, and during the second and third trimesters of pregnancy.
- Metronidazole may be used during chest/breastfeeding, depending on the dose prescribed. If you are prescribed a single 2-gram dose of metronidazole, pump and discard breastmilk for 12-24 hours after your dose to allow the medication to leave your body.

*Metronidazole passes into breastmilk. The amount of metronidazole that passes into breastmilk can depend on the dose and how the medication is taken (by mouth, by IV, vaginally, or topically). With oral or IV use, the amount

of metronidazole in breast milk can be similar to the dose given to infants for treatment. Most babies exposed to metronidazole through breast milk have not had any side effects. If a chest/breastfeeding baby shows symptoms like loose stools, diaper rash, or thrush, contact their healthcare provider. Some metronidazole product labels have suggested to not breastfeed during treatment and for two days after the last dose. But the benefit of using metronidazole may outweigh possible risks. Your healthcare provider can talk with you about using metronidazole and what treatment is best for your patient. Be sure to talk to your healthcare provider about all of your breastfeeding questions.

- Tinidazole should be avoided for pregnant women, and breastfeeding should be deferred for 72 hours after a single 2-g oral dose of tinidazole (

*If treatment failure occurs in a woman after completing a regimen of metronidazole 500 mg 2 times/day for 7 days and she has been re-exposed to an untreated partner, a repeat course of the same regimen is recommended. If no re-exposure has occurred, she should be treated with metronidazole or tinidazole 2 g once daily for 7 days. If a man has persistent T. vaginalis after a single 2-g dose of metronidazole and has been re-exposed to an untreated partner, he should be retreated with a single 2-g dose of metronidazole. If he has not been re-exposed, he should be administered a course of metronidazole 500 mg 2 times/day for 7 days.

Partner Services:

Refer to the Expedited Partner Therapy Standing Orders.

Additional Information: Provide medication information sheet to all patients.

Reporting: N/A

Competency and Training Requirements: All nurses working under this standing order must have completed required training and have demonstrated competency of the STD Enhanced Role RN.

Notify Medical Provider if there is any question about whether to carry out any provision of this standing order.

Follow up as per individual patient needs.

Metronidazole Information Sheet

Metronidazole is an antibiotic taken by mouth for the treatment of bacterial vaginosis (BV) or certain sexually transmitted infections (STI) e.g. trichomoniasis

Allergies

- Tell your healthcare provider if you have an allergy to metronidazole (Flagyl®).

Pregnancy and Chest/Breastfeeding*

- Metronidazole may be used during the first trimester (first three months) of pregnancy only after discussing this with your healthcare provider, and during the second and third trimesters of pregnancy.
- Metronidazole may be used during chest/breastfeeding, depending on the dose prescribed. If you are prescribed a single 2-gram dose of metronidazole, pump and discard breastmilk for 12-24 hours after your dose to allow the medication to leave your body.
- *Metronidazole passes into breastmilk. The amount of metronidazole that passes into breastmilk can depend on the dose and how the medication is taken (by mouth, by IV, vaginally, or topically). With oral or IV use, the amount of metronidazole in breast milk can be similar to the dose given to infants for treatment. Most babies exposed to metronidazole through breast milk have not had any side effects. If your baby shows symptoms like loose stools, diaper rash, or thrush, contact their healthcare provider. Some metronidazole product labels have suggested to not breastfeed during treatment and for two days after the last dose. But the benefit of using metronidazole may outweigh possible risks. Your healthcare providers can talk with you about using metronidazole and what treatment is best for you. Be sure to talk to your healthcare provider about all of your breastfeeding questions.

CAUTION

- **Tell your healthcare provider if you have any liver, blood, or neurological disorders.**
- **Do not take alcohol or alcohol-containing medications (e.g., Nyquil®) 12 hours before a dose, during treatment, and 24-48 hours after a dose to prevent adverse effects** (flushing, headache, nausea, vomiting, cramps, very fast or uneven heartbeat, fainting).
- **Please notify your healthcare provider if you have any pre-existing heart conditions or arrhythmias.**
- **Do not take the following medication while taking metronidazole:**
  - **Antiarrhythmic:** dronedarone (Multaq®)
  - **Antipsychotic:** pimozide (Orap®), ziprasidone (Zeldox®)
  - **Alcoholism treatment:** disulfiram (Antabuse®)
  - **HIV medication:** lopinavir/ritonavir (Kaletra®) oral solution; tipranavir (Aptivus®)
  - **Parasitic worm treatment**: mebendazole (Vermox®)
  - **Oral Typhoid vaccine** (Vivotif®)

- **Drug Interactions**: Please note that individual drug interactions are no longer listed in this document. If you are taking any prescription, non-prescription, herbal, or recreational products, please discuss with your healthcare provider.

Side Effects

- You may experience diarrhea, nausea, abdominal pain, vomiting, indigestion, unpleasant metallic taste in the mouth, and darkened urine.
- If you experience any neurological disorders such as seizures, confusion, dizziness, headache, weakness, numbness or pain in your extremities, or transient visual problems, contact your healthcare provider immediately and do not drive or operate machinery.
- If you experience any allergic or skin reactions such as rash or itchiness, contact your healthcare provider immediately.

Instructions for Taking

- Metronidazole may be taken with food to reduce stomach upset.
- If you miss a dose, take it as soon as you remember. However, if it is close to your next dose, skip the dose and resume your usual dosing time. Do not take a double dose.

Storage Instructions

- Store at room temperature between 15°C and 30°C.
- Protect from light, heat, and moisture.
- Do not use medications beyond the printed expiry date.
- Keep away from the reach of children.

Special Instructions: _____

_____

Treatment of bacterial vaginosis:

- If you are a female with female partners, it is recommended that your partner(s) be tested for bacterial vaginosis and treated if positive.

Treatment of trichomoniasis:

- Do not have sex until:
  - One week after your one-dose treatment, or until you have completed your 7-day treatment, and
  - Your sex partner(s) have also been treated, and one week has passed since the start of their treatment, even if their test results are negative.
- You will need retreatment if you have sex with an untreated partner, or you have sex before either you or your partner(s) treatment is complete. Please discuss with your healthcare provider.

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 LTBI or active 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 after the date the first step is read. . • 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 cannot 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-15a.	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 pg. 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 **≤ 7 business days** if LHD is initiating 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: • Because of the urgency of finding other infectious persons associated with the index patient, **the first interview should be conducted** i) **<1 business day of reporting for infectious persons** ii) **<3 business days for others.** • The interview should be conducted in person (i.e., face to face) in the hospital, the TB clinic, the patient's home, or a convenient location that accommodates the patient's right to privacy • 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

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)
        A. During the initial patient interview, discuss with the patient the need for continued isolation. Have patient sign the TB-8 (Isolation Agreement).
    2. Schedule a clinical examination (Performed by a contracted APRN or MD)
    3. Medication orders (RIPE therapy)
    4. Additional lab work (HIV, AST, ALT,CREAT, and PLT)
        A. If history of chronic liver disease, check a bilirubin level.
        B. If patient has a diagnoses of Diabetes Mellitus check A1C
    5. Additional radiology(Chest X-ray or CT)
    6. Initial vision acuity exam, with color assessment (if EMB 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 VII)

II. Initial Steps For Hospitalized Patients: 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)
- 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)

4.) 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 (TB-4)
- 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
        A. During the initial patient interview, discuss with the patient the need for continued isolation. Have patient sign the TB-8 (Isolation Agreement).
    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

12.) NEDSS Reporting (See NEDSS Reporting Section VIII)

III. Initial Steps for Incarcerated Patients: Upon notification of a suspected or confirmed incarcerated patient, The TB Nurse Case Manager (NCM) should immediately contact the jail or prison to assure coordination and collaboration of TB care.
During this call, the NCM should initiate the following:

1.) Assure isolation:

- Inquire regarding sputum collection, signs and symptoms. If patient is deemed infectious, ensure patient is in Airborne Infection Isolation (AII) or if unavailable, discuss transfer of patient to a hospital setting to place in Airborne Infection Isolation.

2.) 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)
    - Facility provider may request/write orders for PCR

3.) Reporting

- Discuss with the medical staff the need for patient's medical records faxed to the health department.
  - Medication Administrative Record
  - Radiology
  - Provider Notes

- If patient is a resident of another county, update the residential health department. Follow the Pending Transfer: Host County guidelines found in Section V. Interjurisdictional Reporting of this document

4.) Assure continuity of care and collaboration of partnership

- Jail or Prison medical staff must communicate with the local health department during the duration of the patient's TB treatment via medical records while incarcerated.

- Jail or Prison medical staff must communicate with the LHD the anticipated release date and when the patient is actually released. This assures continuity of care and prevent community transmission of an infectious disease.

5.) Documentation

- Add patient information to the TB-7 or facility case management reporting sheet.
- Document any contacts identified. Consult with the State TB Program for Contact Investigation guidance.

IV. 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.

It is highly recommended that you use the TB-16b Clinical Pathway Checklist for case management.

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 • Report patient in TBLISS
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-8 Isolation Agreement	✓		Use LHD letterhead
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	✓	✓	Submit all requests via: https://redcap.link/kentucky-tb-incentives-enablers
TB-32 LHD TB Monthly Report	✓	✓	Records all outreach activities via:https://redcap.link/kentucky-tuberculosis-monthly-reporting

V. Interjurisdictional (IJN) Reporting:

Procedures:
The following section details the protocols and procures on how TB patient information is transferred, and when follow-up is necessary.

- ***Interstate Transfers:***
    1. When a local health department (primary) who is overseeing the treatment or evaluation of a TB patient becomes aware that they are re-locating to another jurisdiction (secondary) within Kentucky, they should notify:
        a. The KY State TB Program.
        b. The Local TB Coordinator who oversees the secondary jurisdiction to discuss coordination of care before patients move.
    2. The primary jurisdiction should send all patient information and records to the secondary jurisdiction as appropriate.
    3. The primary jurisdiction should send 1 week of medications with the patient and continue providing VDOT until secondary jurisdiction establishes care.
    4. **Follow-up**: The secondary jurisdiction is **not required** to follow-up with the primary jurisdiction in this situation.
        a. The State TB Program will ensure that all information and surveillance records are submitted as appropriate.

- **Pending Transfer: Host County**
    1. When a local health department (primary) becomes aware of a TB patient who is a resident of another local jurisdiction (secondary), but the patient has settlement in the primary jurisdiction for ≥ 1 month, that primary jurisdiction becomes a “host county” until discharge or release of the TB patient from the place of settlement back to their original residential county.

    2. The host county is responsible for TB Case Management of the case until discharge or release of the TB patient from the place of settlement back to their original residential county.

    3. Notifications should be sent to:
        a. The KY State TB Program
        b. The Local TB Coordinator who oversees the secondary jurisdiction to notify details of the case and to discuss future coordination of care.

    4. For Contact Investigations coordinate with the KY State TB Program.

- ***State-to-State Transfers:***
  Outgoing:
  1. When a Kentucky local health department (primary) who is overseeing the treatment or evaluation of a TB patient becomes aware that they are re-locating to a jurisdiction in another state (secondary) they should notify:
     a. The KY State TB Program.

  2. The Primary LHD will then complete the IJN form and submit it to the KY TB Program who will forward it to the secondary jurisdiction to inform them that that a TB patient will be transferring to their area.

     a. The primary local health department will need to send patient information and records with the completed IJN.
     b. The primary jurisdiction should send 1 week of medications with the patient and continue providing VDOT until secondary jurisdiction establishes care.

  3. **Follow-up**: A follow-up by the secondary jurisdiction to Kentucky ***may be required*** depending on the type of referral submitted. The primary care jurisdiction is responsible for knowing when follow up is required and the appropriate time frame.

     a. Active/Suspect TB
        i. For patients who have been diagnosed with active TB disease and have been counted as a case in Kentucky – follow-up **will be required**. Follow up should include:
           1. Last date of treatment with the secondary jurisdiction
           2. Outcome information (i.e. complete treatment, lost, etc.)
           3. Medical Records
        ii. For patients who still under evaluation as they are suspected to have active TB disease, the secondary jurisdiction is **not required** to follow-up.
     b. TB Contact
        i. Close contact(s) to an active case of TB in Kentucky who reside in a jurisdiction in another state.
        ii. An IJN will be sent to that jurisdiction requesting that they evaluate and test this patient for TB as appropriate.
        iii. Follow-up **will be required:**
           1. Testing/evaluation outcomes
           2. Diagnosis (i.e. active TB or LTBI)
           3. Treatment initiation/completion

     c. TB Infection
        i. For patients who have been diagnosed with LTBI who started on treatment with a local health department in Kentucky and counted, follow-up **will be required**:
           1. Last date of treatment
           2. Outcome information (i.e. complete treatment, lost, etc.)

     d. Class A/B
        ii. Contact the State TB Program

- **State-to-Sate Transfers:**

  Incoming

  1. When a TB patient is re-locating from a jurisdiction in another state (primary) to a jurisdiction in Kentucky (secondary) they will notify the KY State TB Program.

  2. The KY State TB Program will then forward the incoming IJN form and all appropriate patient information and records to the local health department in Kentucky to begin follow-up with the patient, as appropriate.

  3. If VDOT was conducted by primary jurisdiction, the receiving KY LHD will be required to conduct DOT for 1 week until adherence and rapport can be established.
     - Once adherence is established, have patient sign the TB-14 VDOT agreement.

  4. **Follow-up**: Kentucky follow-up with the primary jurisdiction ***may be required*** depending on the type of referral submitted. The request for follow-up will be indicated on the IJN form.

     a. Active/Suspect TB
        i. For patients who have been diagnosed with active TB disease and have been counted as a case in the primary jurisdiction – Kentucky follow-up **will be required**:
           1. Last date of treatment with the secondary jurisdiction
           2. Outcome information (i.e. complete treatment, lost, etc.)
           3. Medical Records
        ii. For patients who still under evaluation as they are suspected to have active TB disease, Kentucky is **not required** to follow-up.

     b. TB Contact
        i. If the primary jurisdiction identifies a close contact – to an active TB case in their region – who resides in Kentucky, follow-up **will be required:**
           1. Testing/evaluation outcomes
           2. Diagnosis (i.e. active TB, LTBI, or neither)
           3. If diagnosed, treatment information:
              a. Last date of treatment with the secondary jurisdiction
              b. Outcome information (i.e. complete treatment, lost, etc.)

     c. TB Infection
        i. For patients who have been diagnosed with LTBI in their primary jurisdiction, but need to continue treatment with a local health department in Kentucky, follow-up ***may be required****:*
           1. Last date of treatment
           2. Outcome information (i.e. complete treatment, lost, etc.)

     d. Class A/B
        i. Contact State TB Program

- **Out-of-Country Transfers:**
  1. Contact the State TB Program

VI. Case Completion Final Steps:

Final closeout of a case includes the following documentation:

1. Final DOT note in patient's medical record
2. Enter nursing notes in patients' medical record indicating that the patient has completed treatment and any additional required testing has been completed.
    a. Final CXR is recommended to be completed 2 weeks before last DOT dose.
    b. Document education on risks for reactivation during the next two years. Advise to notify LHD if any s/s and need for evaluation.
3. Provide patient a completion of treatment card
    a. Some LHDs also provide a letter stating patient completed treatment. Include letterhead and healthcare representative signature (MD, APRN, or RN)
4. Complete any outstanding data in NEDSS
    a. It is recommended to print a final copy of the RVCT and place in chart
5. Assure a copy of all ID Crowd narratives are added to the patient's chart
    a) See below details in Medical Record Documentation
6. Follow up in six months with the patient via telephone call to assess if no further complications or signs/symptoms of reactivation of disease

VII. Medical Record Documentation:

1. Review MR section of the LHD Administrative Reference (LHDAdminRef.pdf)

2. For Medical Consultation with the TB Center of Excellence
    a. Print final consultation note from IDCrowd and include in patient's medical record under "Incoming Records"
    b. Sign off/date consult note added to MR
    c. Enter Nursing or Provider note (Example: "See incoming record for SNTC Medical Consultation <date of consult>"

VIII. NEDSS Reporting:

Contact the state TB Program to request TB-NEDSS access, training, and guidelines at: 502-564-4276

- Data Reporting Time Frames:
    a. Open case/suspect investigation within ≤ 7 business days.
    b. Update investigation every 2 weeks
    c. Closeout case within ≤1 week of meeting treatment completion criteria

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, (i.e., positive TST or IGRA, signs and symptoms and abnormal chest x-ray) 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 afore mentioned 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

Timeline Sputum Collection and Therapy Chart

							If extended treatment is needed		
Months Of Treatment	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**
Drug Therapy (6-month regimen)	**ISONIAZID (INH)**						**INH**		
	RIFAMPIN (RIF)						**RIF**		
	PYRAZINAMIDE (PZA)								
	ETHAMBUTOL (EMB)								
	B6 (25 mg) *{B6 should always accompany INH}*								
Sputum Specimen Collection Time Frame	**3 samples collected every 2 weeks** until 3 consecutive negative smears & 2 negative cultures**		**Monthly**						
Chest X-Ray Timeframe		**X**				**X***			**X***
Medication Administration	**DOT**		**VDOT** *{If patient is compliant}*						
Visual Acuity and Color Vision	**X**	**X**	***Required monthly when patient is on EMB***						
HIV, LFTs, CREAT, PLT	**X**	***As needed during the duration of treatment***							
Clinic Evaluations	**Monthly**								

Sputum samples are collected 8 – 24 hours apart. Early morning samples are best. Recommended that initial sample collection be observed by health care worker.* ***Obtain an initial sputum sample BEFORE initiating tuberculosis therapy.

- Once **3 consecutively negative sputum** are obtained, consider releasing patient from home isolation. (*Note: 3 negative smears are required per MMWR 2005 vol 52)*

** CXR if end of treatment*

- 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.

Source: (*MMWR 2009; 58(01):7-10)*

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: *(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,

- For TDM information, contact the State TB Prevention and Control Program for collection instructions, shipping and handling instructions.

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.

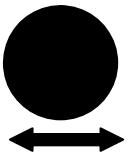
2. The second contact should be a regular mailed letter with directions for the patient to contact the LHD for follow-up.

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) and IGRA RECOMMENDATIONS FOR INFANTS, CHILDREN, AND ADOLESCENTS[a]

Children for whom immediate TST or IGRA is indicated[b]:

- 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 history of significiant[C] travel to countries with endemic infection who have substantial contact with the resident population[d].

Children who should have annual TST or IGRA:

- Children infected with HIV infection (TST only)

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 immunodeficiencies, and children receiving tumor necrosis factor (TNF) antagonist 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 systemic corticosteroid administration, organ transplantation, use of tumor necrosis factor (TNF) -alpha antagonists or blockers, 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.).

Children ≤5 years of age, SNTC should be consulted, particularly for infants ≤ 4 months of age, for appropriate testing methods.

IGRA indicates interferon-gamma release assay; HIV indicates human immunodeficiency virus; LTBI, latent tuberculosis infection.

[a] Bacille Calmette-Guérin (BCG) immunization is not a contraindication to a TST; IGRA is generally preferred for BCG-vaccinated children

[b] Beginning as early as 3 months of age for TST & ≥ 5 years old for IGRA, for LTBI and active disease

[c] Some experts define significant travel as birth, travel or residence in a country with elevated tuberculosis rate for at least 1 month.

[d] If the child is well, and has no history of exposure, the TST or IGRA should be delayed for up to 10 weeks after return

Reference: Red Book 2021-2024

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

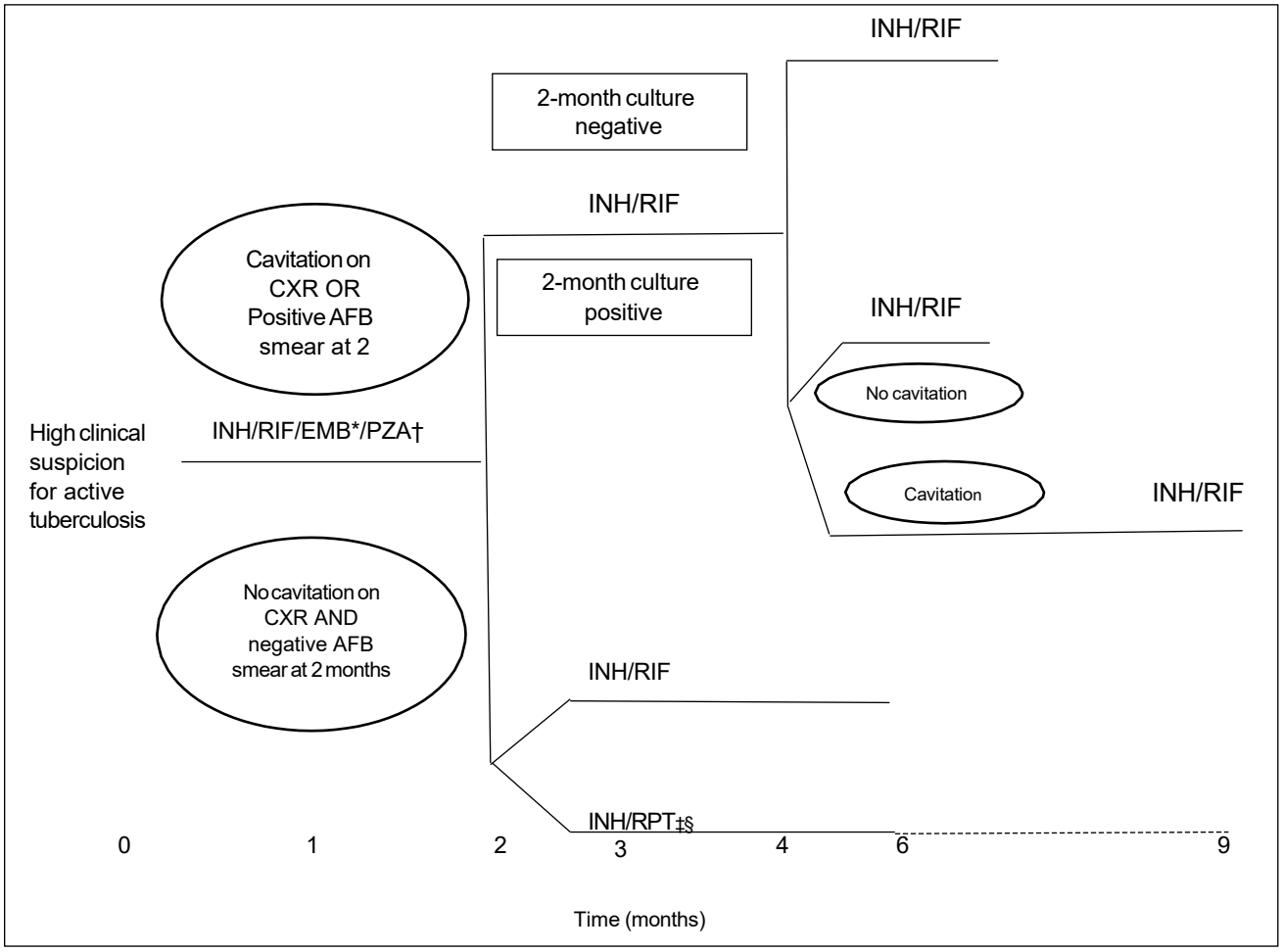
- persons with human immunodeficiency virus (HIV) infection;†
- infants and children aged <5 years;†
- persons who are receiving immunosuppressive therapy such as tumor necrosis factor--alpha (TNF-
  mg of prednisone per day, or immune suppressive drug therapy following organ transplantation;†
- persons 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 /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

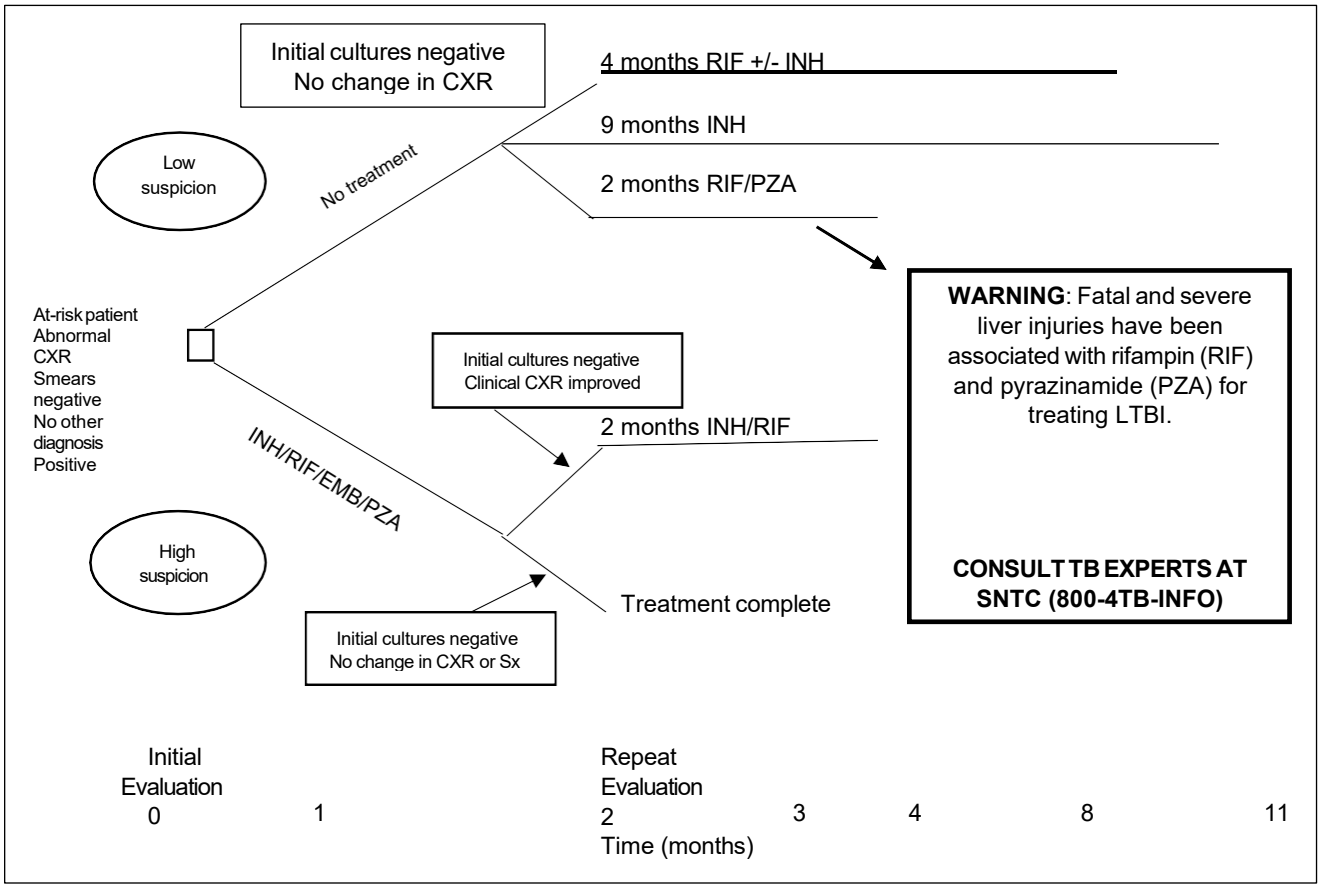
If a patient is slow to convert smears or culture by 40 doses (two months) it is highly recommended by TB experts to continue administration of EMB and PZA until culture conversion.

When two or more drugs are used simultaneously, each helps prevent the emergence of tubercle bacilli resistant to the others. Even with susceptible organisms, sputum conversion is accomplished more rapidly from positive to negative with a four-drug regimen than with a three-drug regimen of INH, RIF, and PZA. Finally, a patient who is treated with the four-drug regimen, but who defaults therapy is more likely to be cured and not relapse when compared with a patient treated for the same length of time with the three-drug regimen.

Sources: MMWR May 21st, 1993, vol 42 (RR-7);001 &

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-ray and / or clinical improvement on anti-TB therapy.

The initial phase of treatment requires DOT. Travel during this phase of treatment is not recommended in order to ensure patient adherence.

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 time that a patient is able to spread the disease in the community.

Directly Observed Therapy (DOT) Vs Self Administration (SAT):

The following excerpt was taken from the Center of Disease Control and Prevention (CDC), Clinical Infectious Disease 2016, IDSA guidelines. This quote enforces the importance of DOT therapy five days a week for the management of active disease.

The systematic review conducted to obtain evidence in support of this practice guideline did not find any significant differences between self-administered therapy (SAT) and DOT when assessing several outcomes of interest, including mortality, treatment completion, and relapse. However, DOT was significantly associated with improved treatment success (the sum of patients cured and patients completing treatment) and with increased sputum smear conversion during treatment, as compared to SAT. Because DOT is a multifaceted public health intervention that is not amenable to the conventional clinical trial approaches to assessing benefits, and because participation in DOT can be advantageous for early recognition of adverse drug reactions and treatment irregularities, for allowing providers to establish rapport with the patient and for addressing treatment complications expeditiously, DOT remains the standard of practice in the majority of tuberculosis programs in the United States and Europe. To be consistent with the principles of patient-centered care noted previously, decisions regarding the use of DOT must be made in concert with the patient. For example, DOT can be provided in the office, clinic, or in the "field" (patient's home, place of employment, school, or any other site that is mutually agreeable) by appropriately trained personnel.

The CDC MMWR publication suggest using DOT rather than SAT for routine treatment of patients with all forms of tuberculosis (conditional recommendation; low certainty in the evidence)

With respect to administration schedule, the preferred frequency is once daily for both the intensive and continuation phases (see PICO Questions 3 and 4). Although administration of antituberculosis drugs using DOT 5 days a week has been reported in a large number of studies, it has not been compared with 7-day administration in a clinical trial. Nonetheless, on the basis of substantial clinical experience, **experts believe that 5-days-a-week drug administration by DOT is an acceptable alternative to 7-days-a-week administration**, and either approach.

PICO Question 3: Does intermittent dosing in the intensive phase have similar outcomes compared to daily dosing in the intensive phase for treatment of drug-susceptible pulmonary tuberculosis? Recommendation 3a: We recommend the use of daily rather than intermittent dosing in the intensive phase of therapy for drug susceptible pulmonary tuberculosis (strong recommendation; moderate certainty in the evidence

PICO Question 4: Does intermittent dosing in the continuation phase have similar outcomes compared to daily dosing in the continuation phase in patients with drug-susceptible pulmonary tuberculosis patients? Recommendation 4a: We recommend the use of daily or thrice weekly dosing in the continuation phase of therapy for drug susceptible pulmonary tuberculosis (strong recommendation; moderate certainty in the evidence)

Sources:

Nahid P, Dorman SE, Alipanah N, et al (2016) Official American Thoracic Society/Centers for Disease Control and Prevention/Infectious Diseases Society of America Clinical Practice Guidelines: Treatment of drug-susceptible tuberculosis. Clinical Infectious Diseases. doi: 10.1093/cid/ciw376

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.

Steps to take for initiation of Video DOT:

- 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.

Special Instances in the Initial Phase:

- Video DOT in the initial phase may occur during national and/or culturally overserved holidays.

- Local health department personnel must have patient sign a Video DOT agreement with the specific holiday dates listed and when DOT will resume.

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
- Less than 90% compliance with the treatment regimen or scheduled Video DOT appointments
- Patient has received one (1) or more Health Orders due to noncompliance.
- 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
    - BPaL is **NOT** eligible for Video DOT unless special circumstances. Consult the State TB Prevention and Control Program for further recommendations and evaluation.

Interim Guidance: 4-Month Rifapentine-Moxifloxacin Regimen for the Treatment of Drug-Susceptible Pulmonary Tuberculosis

The 4-month RPT-MOX regimen is a treatment option for patients aged ≥12 years with drug-susceptible pulmonary TB. Additional studies are needed to understand the pharmacokinetics and efficacy of the 4-month daily treatment regimen in patients for whom this regimen is not currently recommended, including young children, persons who are pregnant, patients with extrapulmonary TB, and patients with an HIV infection who are taking non-efavirenz–based antiretroviral therapy. Clinicians should carefully review a patient's clinical history, concurrent medications, social determinants of health, and risk factors for adverse drug reactions when making the decision to use this regimen.

This regimen consist of:

- high-dose daily rifapentine (RPT) with
- moxifloxacin (MOX),
- isoniazid (INH), and
- pyrazinamide (PZA)

The 4-month daily treatment regimen consists of an intensive phase composed of 8 weeks of daily treatment with RPT, MOX, INH, and PZA, followed by a continuation phase of 9 weeks of daily treatment with RPT, MOX, and INH.

Anti-TB drugs should be administered once daily with food, **7 days per week**, for a total of 119 treatment doses (17 weeks); similar to the standard 6-month regimen, at least 5 of 7 weekly doses should be administered under direct observation.
The 4-month daily treatment regimen is considered complete based on the total number of doses taken (119).

Note:

- ***Weekend doses should not be omitted. Please consider this difference in DOT/VDOT protocol prior to decision to initiate treatment.***

- ***If you have further questions regarding this novel regimen, or in the event an acute care facility initiates this novel regimen and your local health department does not have the resources to implement, then seek clinical consultation by contacting the KY State TB Program, or TB Center of Excellence (at SNTC 1-800-4TB-INFO) for further guidance.***

Resources:

CDC. (2025, April 17). Treatment for Drug-Susceptible Tuberculosis Disease. Tuberculosis (TB). https://www.cdc.gov/tb/hcp/treatment/tuberculosis-disease.html?CDC_AAref_Val=https://www.cdc.gov/tb/topic/treatment/tbdisease.htm

MMWR. Morbidity and Mortality Weekly Report, *71*(8), 285–289. https://doi.org/10.15585/mmwr.mm7108a1

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 OF ANTITUBERCULOSIS DRUGS FOR ADULTS AND CHILDREN

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 OF ANTITUBERCULOSIS DRUGS FOR ADULTS AND CHILDREN

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.[i]
		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.

Rifabutin 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 OF ANTITUBERCULOSIS DRUGS FOR ADULTS AND CHILDREN

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 exclusively breastfed
- 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.

ATS/CDC/IDSA Clinical Practice Guidelines for Drug-Susceptible TB * CID 2016:63 (1 October)

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

I. 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.

II. HIV

Treatment of tuberculosis in patients with HIV infection follows the same principles as treatment of HIV-uninfected patients. However, there are several important differences between patients with and without HIV infection. These differences include the potential for drug interactions, especially between the rifamycins and antiretroviral agents, paradoxical reactions that may be interpreted as clinical worsening, and the potential for the development of acquired resistance to rifamycins when treated with highly intermittent therapy.

- Expert consultation, (i.e.. SNTC) should always be made before initiation of treatment therapy.
- Rifabutin is highly active against M. tuberculosis but has less of an effect in inducing hepatic microsomal enzymes than RIF. Data from clinical trials suggest that rifabutin and RIF-based regimens are equally efficacious.
- The use of ART during tuberculosis treatment in persons with HIV infection also reduces mortality rates significantly and decreases the risk of developing AIDS-related conditions.
- ART should ideally be started within 2 weeks for those patients with a CD4 count <50 cells/μL and by 8–12 weeks for those with a CD4 count ≥50 cells/μL (see PICO Question 6 and Supplementary Appendix B, Evidence Profile 13). An exception is HIV-infected patients with tuberculous meningitis, in whom ART is not initiated in the first 8 weeks of antituberculosis therapy
- We recommend initiating ART during tuberculosis treatment. ART should ideally be initiated within the first 2 weeks of tuberculosis treatment for patients with CD4 counts <50 cells/μL and by 8–12 weeks of tuberculosis treatment initiation for patients with CD4 counts ≥50 cells/μL (strong recommendation; high certainty in the evidence). Note: an exception is patients with HIV infection and tuberculous meningitis (see Immune Reconstitution Inflammatory Syndrome)
- Patients with HIV infection and tuberculosis are at increased risk of developing paradoxical worsening of symptoms, signs, or clinical manifestations of tuberculosis after beginning antituberculosis and antiretroviral treatments. These reactions presumably develop as a consequence of reconstitution of immune responsiveness brought about by ART, and are designated as the **immune reconstitution inflammatory syndrome (IRIS).** Tuberculosis IRIS has been noted to be more common in participants with earlier ART initiation and CD4+ cell counts <50 cells/μL.

- Signs of IRIS may include high fevers, worsening respiratory symptoms, increase in size and inflammation of involved lymph nodes, new lymphadenopathy, expanding central nervous system lesions, worsening of pulmonary parenchymal infiltrations, new or increasing pleural effusions, and development of intra-abdominal or retroperitoneal abscesses. Such findings are attributed to IRIS only after excluding other possible causes, especially tuberculosis treatment failure from drug-resistant tuberculosis or another opportunistic disease, such as no-Hodgkin lymphoma or infection.

III. Pregnancy

- Thus, treatment of a pregnant woman with suspected tuberculosis should be started if the probability of tuberculosis is moderate to high. The initial treatment regimen should consist of INH, RIF, and EMB.
- Although PZA is recommended for routine use in pregnant women by the WHO (4) and the IUATLD (5), the drug has not been recommended for general use in pregnant women in the United States because of insufficient data to determine safety
- INH, RIF, and EMB cross the placenta, but none has been shown to have teratogenic effects (6).
- SM, the only antituberculosis drug documented to have harmful effects on the human fetus, interferes with development of the ear and may cause congenital deafness
- The administration of the fluoroquinolones during breastfeeding is not recommended
- However, in women who are being treated for drug-resistant tuberculosis, counseling concerning the risk to the fetus should be provided because of the known and unknown risks of the second-line agents
- Expert consultation (i.e.. SNTC) should be sought when first-line drugs cannot be used due to adverse effects or antibiotic resistance, when there is extensive disease and/or a risk of noncompliance.
- Changes in contraceptive effectiveness associated with co-administration of other products:
    - If a woman on hormonal contraceptives takes a drug or herbal product that induces enzymes, including CYP3A4, that metabolize contraceptive hormones, counsel her to use additional contraception or a different method of contraception. Rifampin may decrease the effectiveness of hormonal contraceptives.
- Breastfeeding is encouraged for women who are deemed noninfectious and are being treated with first-line agents.
- Conversely, drugs in breast milk should not be considered to serve as effective treatment for active tuberculosis or latent tuberculosis infection in a nursing infant.
- Supplementary pyridoxine is recommended for the nursing mother receiving INH

IV. 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**. For all extra-pulmonary suspected or known cases, measures need to be taken to rule out pulmonary.**

For Epidermal TB. SNTC recommends the following:

- For dressing changes and irrigation of the affected site. Use of PPE and N95 mask are to be used as secretions become airborne during wound care.
- Contact investigations may be warranted if family has performed dressing changes or irrigation.

For V-DOT recommendations, consult the State TB Program.

V. Treatment Failures

Treatment failure is defined as continued or recurrently positive cultures in a patient receiving appropriate chemotherapy. Thus, patients with persistently positive cultures after 3 months of chemotherapy, with or without on-going symptoms, should be evaluated carefully to attempt to identify the cause of the delayed response. Patients whose sputum cultures remain positive after 4 months of treatment are considered to have failed treatment.

Potential reasons for treatment failure may include:

1. If the patient is not receiving DOT, the most likely explanation for persistently positive cultures is nonadherence to the drug regimen. Among patients receiving DOT, cryptic nonadherence (spitting out or deliberately regurgitating pills) or failure of the health care system to reliably deliver the drugs may be the cause.

2. Unrecognized drug resistance (Was initial drug-susceptibility testing done? Was it reported accurately?)

3. Malabsorption (prior re-sectional surgery of the stomach or small intestine, taking tuberculosis medication with antacids or other drugs/substances that might bind or interfere with drug absorption.)

4. Transient clinical or radiographic worsening (paradoxical reactions), despite appropriate therapy that would eventually result in cure. Examples of this include ongoing inflammation at sites of lymphadenitis, worsened abnormalities on chest radiographs after several months of treatment, or the new appearance of pleural effusions during therapy for pulmonary tuberculosis.

For patients who meet criteria for treatment failure, the possible reasons listed above should be addressed promptly. If clinicians are not familiar with the management of drug-resistant tuberculosis, prompt referral to, or consultation with a specialty center (SNTC) is indicated.

A fundamental principle in managing patients who have failed treatment is that a single new drug should never be added to a failing regimen; doing so may lead to acquired resistance to the added drug. In such cases, it is generally prudent to add at least three new drugs to which susceptibility could logically be inferred to lessen the probability of further acquired resistance.

Treatment of tuberculosis caused by drug-resistant organisms should be done by or in close consultation with an expert (SNTC) in the management of these difficult situations. Second-line regimens often represent the patient's last best hope for being cured. Inappropriate management can, thus, have life-threatening consequences.

VI: Multi Drug Resistance Tuberculosis (MDR) or Extremely Drug-Resistant Tuberculosis

For any MDR or drug-resistant Tuberculosis, please consult the State TB Program for recommendations for treatment management.

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.

CDC. Treatment of Tuberculosis. MMWR 2003; 52 (No. RR-11). https://www.cdc.gov/mmwr/pdf/rr/rr5211.pdf

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.

**After 14–21 days of treatment, infectiousness averages <1% of the pre-treatment level.

Health Recommendations and Procedures for the use of Therapeutic Drug Monitoring (TDM)

Slow response to TB treatment can be caused by several factors: non adherence, drug resistance, inadequately prescribed regimens, intolerance to TB medications and poor absorption often due to co-morbidities. Poor clinical response to TB therapy may lead to prolonged infectiousness or acquired drug resistance and further burden public health systems by extending treatment duration. Measurement of serum drug levels at the time of estimated peak concentration (Cmax), termed therapeutic drug monitoring (TDM), has been performed for clients with poor clinical response to tuberculosis (TB).

Table 1: Groups considered for TDM

Group	Definition	Drugs to check	Follow-up
1 - Slow responder (failure to clinically improve as expected)	Clients with smear positive pulmonary TB for a prolonged period of time without improvement (defined as a steady decrease from 4+ to 2+; 3+ to 1+; 2+/1+ to smear negative)	Isoniazid and Rifampin **ONLY**:	Dose increases in consultation with DTBNH staff and medical consultants. **Follow-up drug levels can be checked.**
2 - All diabetics (HbA1c ≥ 6.5)	Ideally test **2 weeks** after treatment begins. If a recent HbA1c (<3mo) result is not available, perform HbA1c to avoid delaying TDM upon intake. After 8 weeks the window of opportunity is lost so we do not perform TDM (unless slow response or another reason is identified)	Isoniazid and Rifampin **ONLY**:	Automatic dose adjustment for low level (See Table 2). **No follow-up drug levels checked.**
3 - All HIV positive (regardless of CD4 count or viral load)	Ideally test within **1- 2 weeks** after a stable regimen begins.	Isoniazid and Rifampin/Rifabutin **ONLY**:	Dose increase in consultation with DTBNH staff. **Follow-up drug levels can be checked.**
4 - Others	Other scenarios in discussion with TB consultants (e.g., new clinical deterioration, receiving second-line TB medications, sudden relapse, severe illness, other co-morbidities)	Case-by-case	Case-by-case

Sources:

Source: Virginia Department for Public Health, TB Program https://www.vdh.virginia.gov/tuberculosis/forms-for-local-health-departments/

Therapeutic Drug monitoring in Tuberculosis: Practical application for physicians. Clinical Infectious Diseases, 64(1), 104–105.

SLOW RESPONDERS:

Explore the likelihood of non-adherence to treatment or drug/drug or food/drug interactions before considering TDM. Ensure directly observed therapy is being adhered to. When evidence of non-adherence is found explore solutions to non-adherence before performing TDM. TDM is not to be used as a marker for non-adherence.

- Suspicion of possible drug resistance should be raised when there is a history of prior inadequate treatment or if the country of origin reports high levels of drug-resistant TB. (See High MDR-TB Burden Country list)
- When non-adherence and drug resistance is addressed and response remains slow, perform TDM. Low drug levels are often not the sole cause but are viewed as one element in the evaluation of poor clinical response.

Procedure:
• Draw a 2-hour level for isoniazid and rifampin only. Additional medications must be approved by a medical consultant (i.e.. SNTC).

Intervention:
Follow-up drug level monitoring is recommended after dose adjustment for those tested for slow response. **Follow-up levels can be checked 24 hours after a dose adjustment is made**. The first follow-up level will be at the two-hour mark. If this follow-up level remains low, discussion with a TB clinical consultant is recommended and a 2-hour and 6-hour level (for delayed absorption) may be recommended.

DIABETIC PATIENTS:

The goal for obtaining serum drug level testing in diabetics is to make early changes in treatment regimens to reduce the time from start of treatment to sputum conversion and diminish the rates of slow response.

Procedure:
• All confirmed and presumptive TB cases should have a Hemoglobin A1C drawn at the start of treatment unless there is a documented result within the past 3 months. Clients with a hemoglobin A1C ≥ 6.5 should be considered diabetic and have TDM performed.
• **IMPORTANT:** Do not discontinue PZA and EMB before Serum Drug Levels testing is performed.
• For diabetic patients, a single 2-hour level for isoniazid and rifampin is recommended as soon as feasible after treatment initiation, **ideally at 2 weeks** after treatment start. (*Table 1*)

Intervention:
- For those found to have low levels, a daily or thrice weekly regimen should be used in the continuation phase. Do not use biweekly treatment unless recommended by a TB clinical consultant.

• Dose counting for determination of treatment duration is not generally altered by the TDM result. Decisions to restart a dose count will be individually made based on the unique characteristics of the index case with the assistance of the medical consultants.

HIV/AIDS PATIENTS:

An association exists between HIV infected TB clients and slow response to TB treatment. The goal for obtaining serum drug level testing in HIV infected clients is to make early changes in treatment regimens that may reduce the time from start of treatment to sputum conversion, diminish the rates of slow response, prevent acquired drug resistance, and improve treatment outcomes.
Treatment regimens for this population often require substituting rifabutin for rifampin due to the many drug-drug related interactions between rifamycins and commonly used antiretrovirals. Scheduling TDM must consider the anticipated adjustments in treatment. Testing absorption of rifampin is not a surrogate for rifabutin and requires a different schedule for testing. If the rifamycin is changed during treatment it may be necessary to repeat SDL testing.

Procedure:
• **IMPORTANT:** Do not discontinue PZA and EMB before SDL testing is performed
• A single 2-hour level for isoniazid and rifampin (or a 3 hour level for rifabutin) is recommended **1 - 2 weeks, after a stable regimen** is initiated or as soon as feasible. (*Table 1*).

Intervention:
• Thrice weekly regimens may be acceptable with approval from a TB medical consultant. Do not use biweekly regimens in this population.
• Dose counting for determination of treatment duration could be, but may not be, altered by the TDM result. Decisions to restart a dose count will be individually made based on the unique characteristics of the index case with the assistance of the medical consultants.

Source: *Therapeutic Drug monitoring in Tuberculosis: Practical application for physicians. Clinical Infectious Diseases, 64(1), 104–105.*

MANAGEMENT OF TREATMENT INTERRUPTIONS

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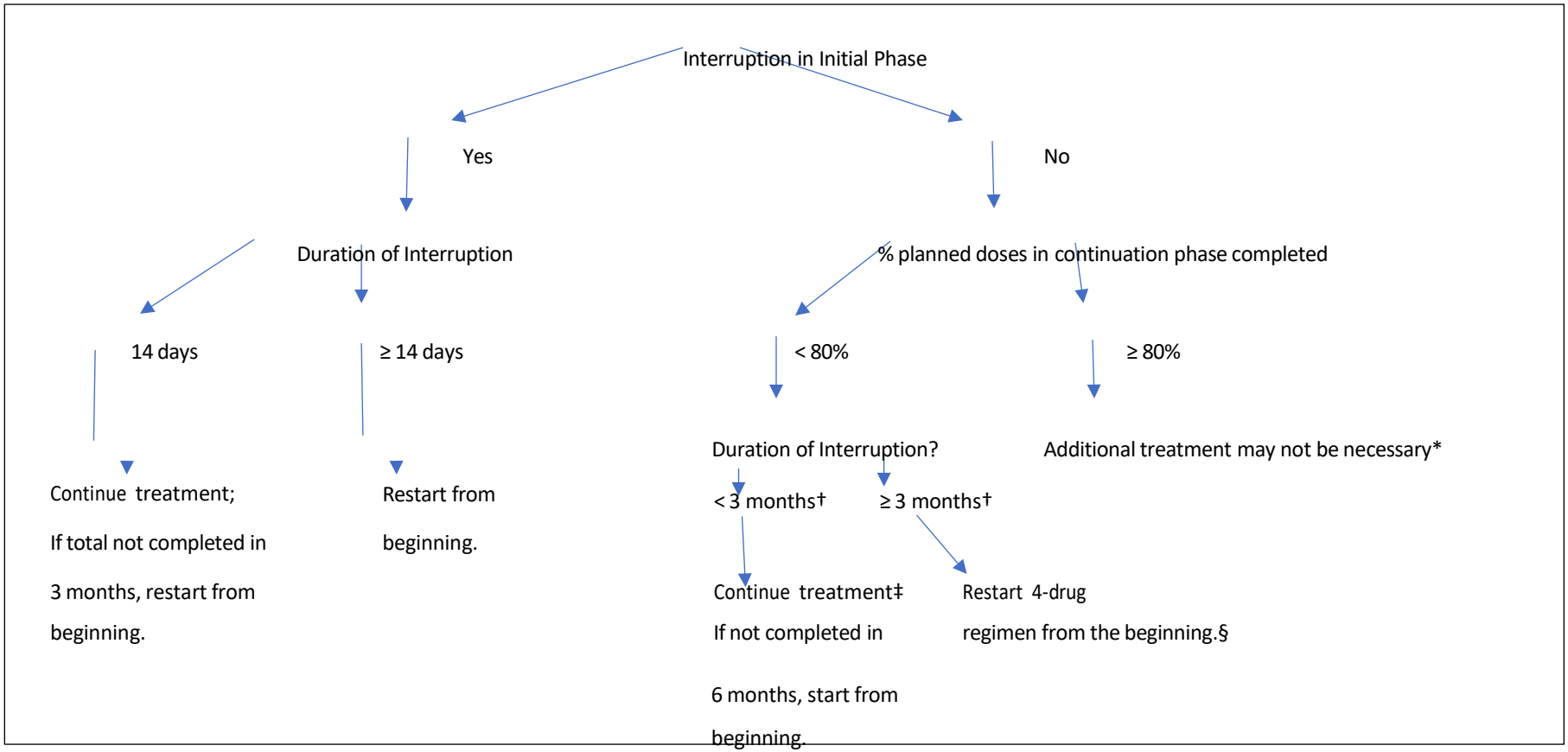


*Patients who were initially AFB smear-positive should receive additional therapy.

† 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

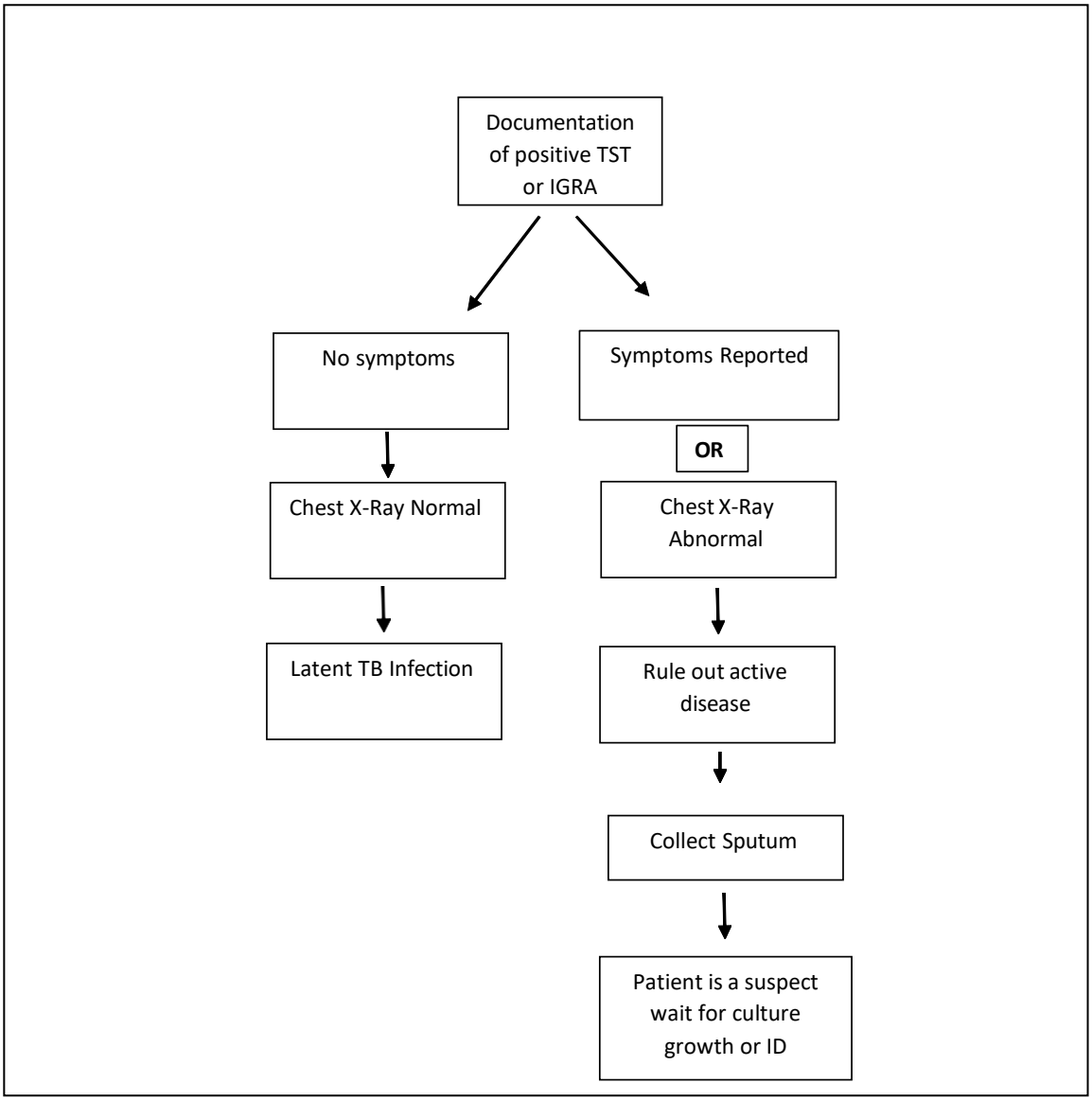
Persons at increased risk* for *M.tuberculosis* infection:

- 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.

Steps to Rule Out Active Disease with Reports of Positive IGRA or TST



Sources: CDC. Self-Study Modules on Tuberculosis (Modules 1–5), 2016. CDC. Self-Study Modules on Tuberculosis (Modules 6-9), 2018. http://www.cdc.gov/tb/education/ssmodules/default.htm

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 4-5.

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:

1. Children age <5 years
2. Contacts to a case with active TB disease

while members of these groups *should* be placed on DOPT:

3. Homeless individuals
4. Persons who abuse substances
5. Persons with a history of treatment non-adherence
6. Immunocompromised patients, especially HIV-infected

Sources:

Menu of Suggested Provisions for State Tuberculosis Prevention and Control Laws; Treatment | Case Management | State TB Prevention & Control Laws | TB Laws & Policies | Resources & Tools | TB | CDC

Improving Tuberculosis Medication Adherence: The Potential of Integrating Digital Technology and Health Belief Model https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10073608/

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.**

Characteristics of the Index Patient and Behaviors Associated with Increased Risk for Tuberculosis (TB) Transmission

TABLE 1. Characteristics of the index patient and behaviors associated with increased risk for tuberculosis (TB) transmission

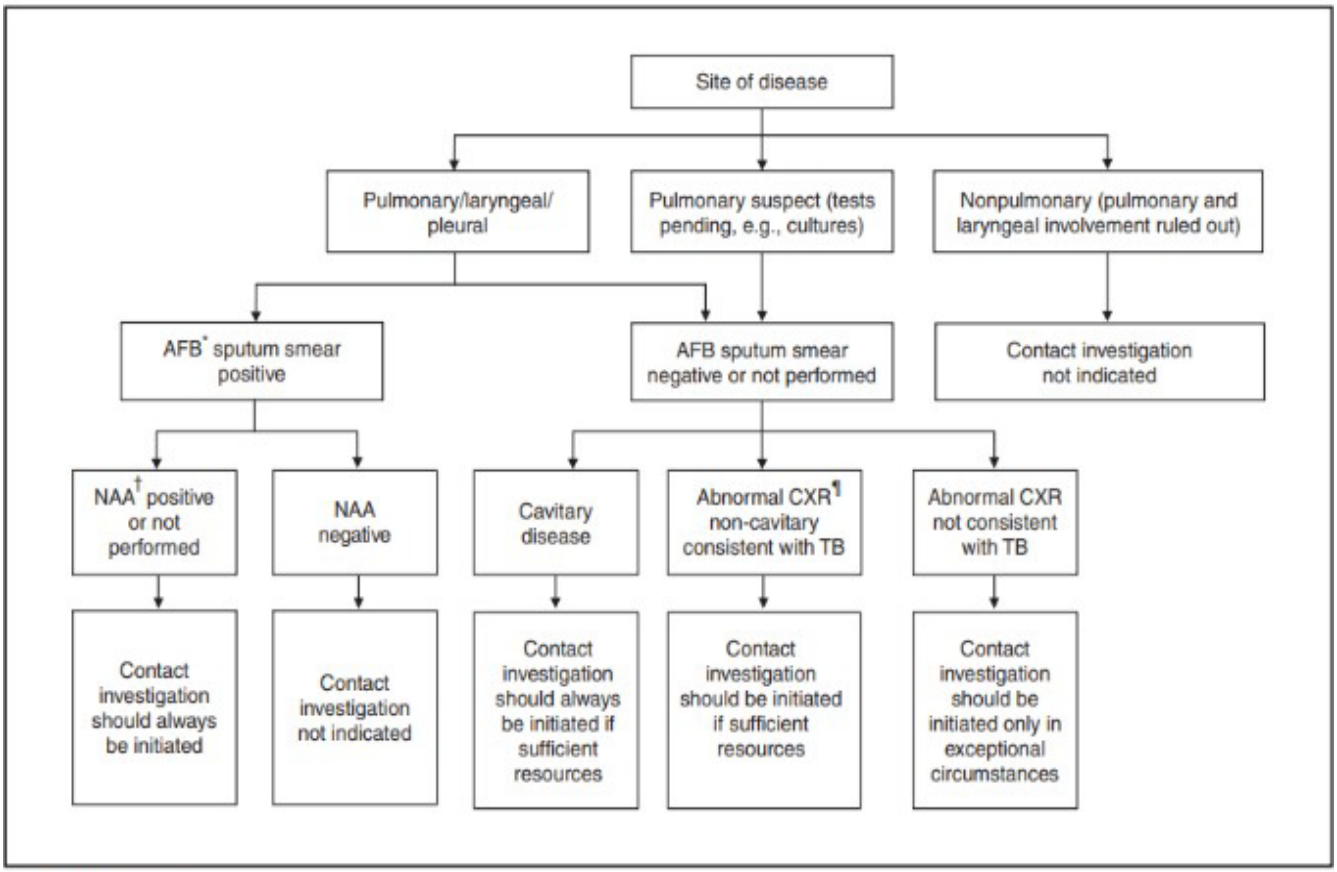
Characteristic	Behavior
Pulmonary, laryngeal, or pleural TB	Frequent coughing
AFB* positive sputum smear	Sneezing
Cavitation on chest radiograph	Singing
Adolescent or adult patient	Close social network
No or ineffective treatment of TB disease	

* 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 4.

Decision to Initiate a Tuberculosis (TB) Contact Investigation

FIGURE 1. Decision to initiate a tuberculosis (TB) contact investigation



* Acid-fast bacilli.
† Nucleic acid assay.
§ According to CDC guidelines.
¶ Chest radiograph.

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 5.

Calculation of the Window Period

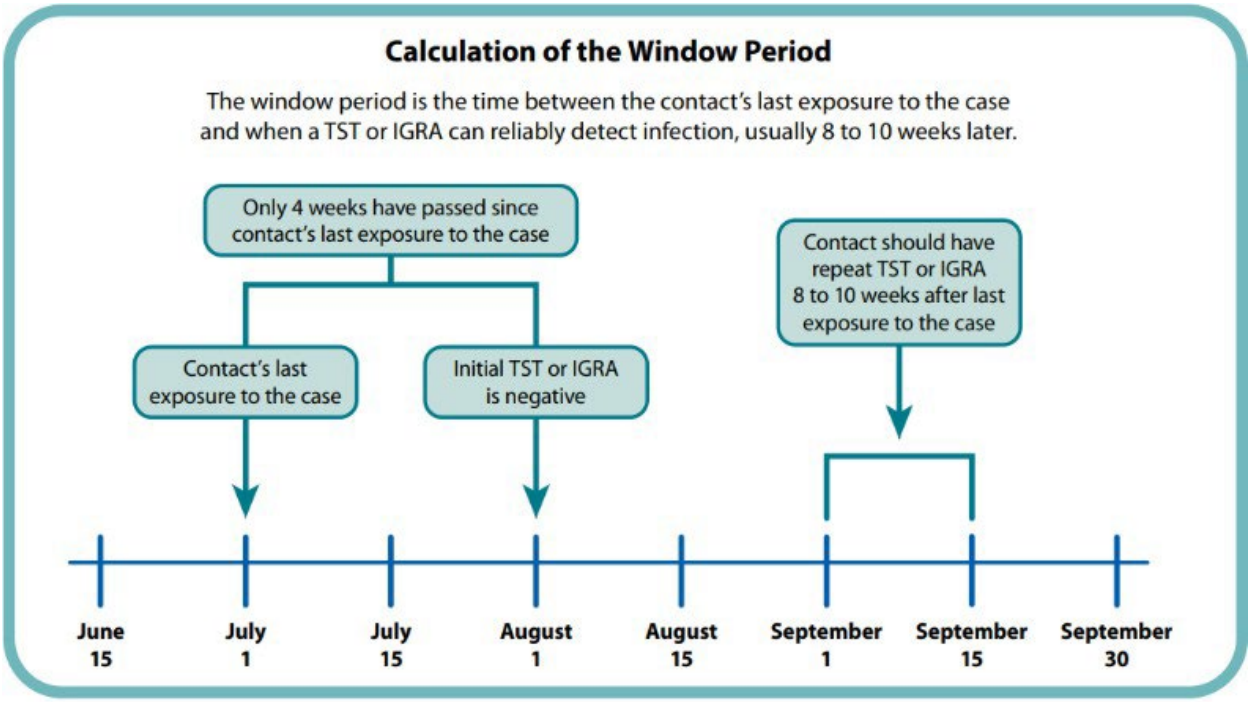


Figure 8.8—Example of calculating the window period. If a contact's last exposure to a TB case was July 1st, and he or she had a negative TST or IGRA on August 1st, a second TST or IGRA should be done between September 1st and September 15th (8 to 10 weeks after July 1st).

Source: CDC. Self-Study Modules on Tuberculosis (Modules 8 pg. 61), 2018. http://www.cdc.gov/tb/education/ssmodules/default.htm

Determining the Infectious Period for a Patient with Active TB Disease

Determining the infectious period for a case with active TB disease focuses the investigation on those contacts most likely to be at risk for infection and sets the timeframe for testing contacts. Because the start of the infectious period cannot be determined with precision by available methods, a practical estimation is necessary. Per CDC guidelines, an assigned start date, that is **3 months before** symptom onset or first positive finding consistent with active TB disease, is recommended (Table, p. 50). In certain circumstances, an even earlier start date should be used.

For example, a patient (or the patient's associates) might have been aware of protracted illness (in extreme cases, >1 year). Information from the patient interview and from other sources should be assembled to assist in estimating the infectious period. Helpful details are the approximate dates that TB symptoms were noticed, mycobacteriologic results, and extent of disease (especially the presence of large lung cavities, which imply prolonged illness).

The infectious period is closed when the following criteria are satisfied:
1) Effective treatment (as demonstrated by *M. tuberculosis* susceptibility results) for ≥2 weeks;
2) Diminished symptoms;
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

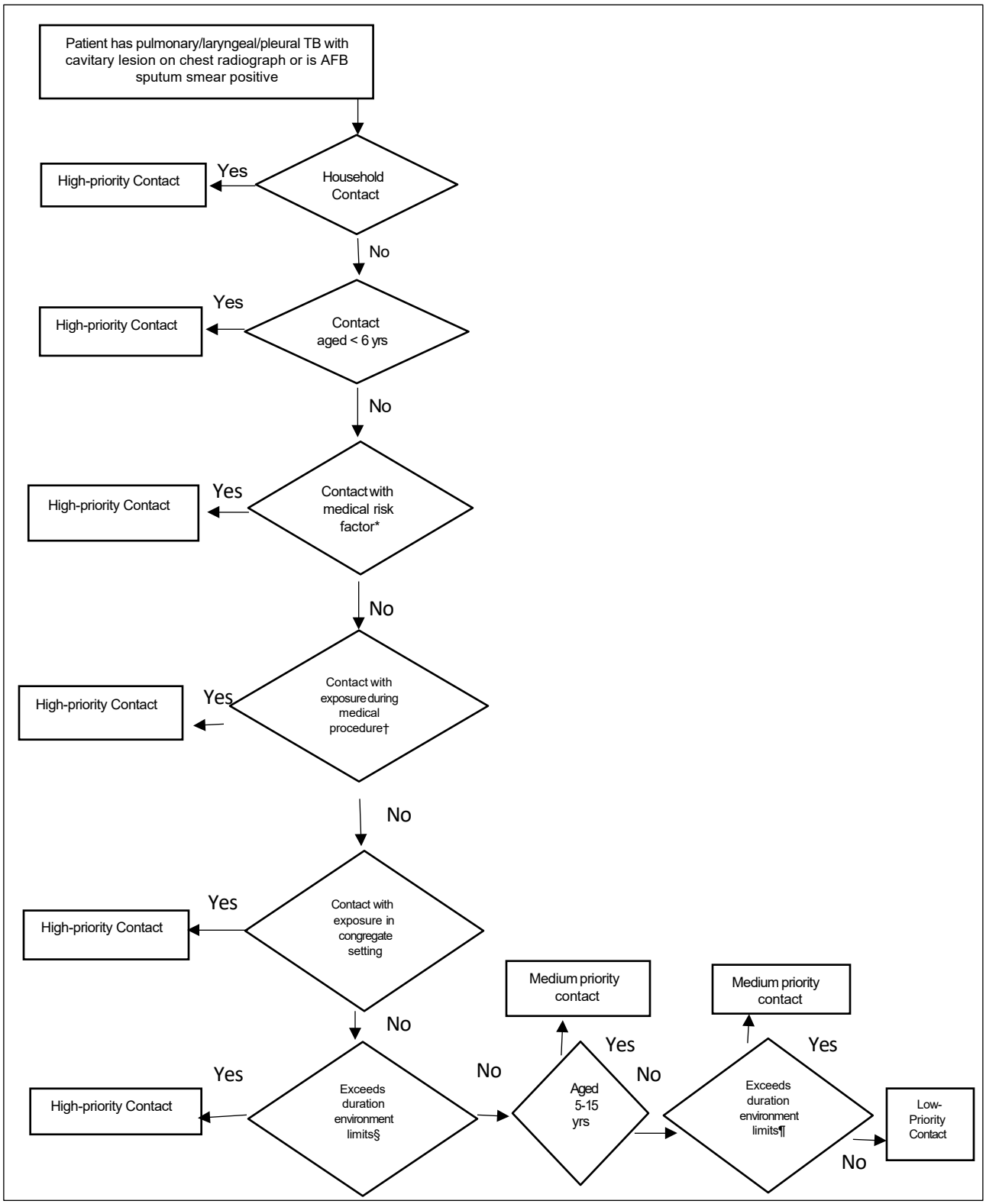
During the initial contact encounter, which should be accomplished within **3 working days** of the contact having been listed in the investigation, the investigator gathers background health information and makes a face-to-face assessment of the person's health. Performing a TB Risk Assessment and administering 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 TB disease;
    - Persons with silicosis, diabetes mellitus, chronic renal failure, leukemia, lymphoma, cancer of the head, neck, or lung;
    - Persons who have had a gastrectomy, or jejunoileal bypass;
    - Persons with low body weight (BMI < 19);
    - Cigarette smokers and persons who abuse drugs or alcohol.
- Mental health disorders (e.g., psychiatric illnesses and substance abuse disorders)
- Type, duration, and intensity of TB exposure; and
- Sociodemographic factors (e.g., age, race or ethnicity, residence, and country of birth) (see Data Management and Evaluation of Contact Investigations).

*HIV testing should be offered to all contacts

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:

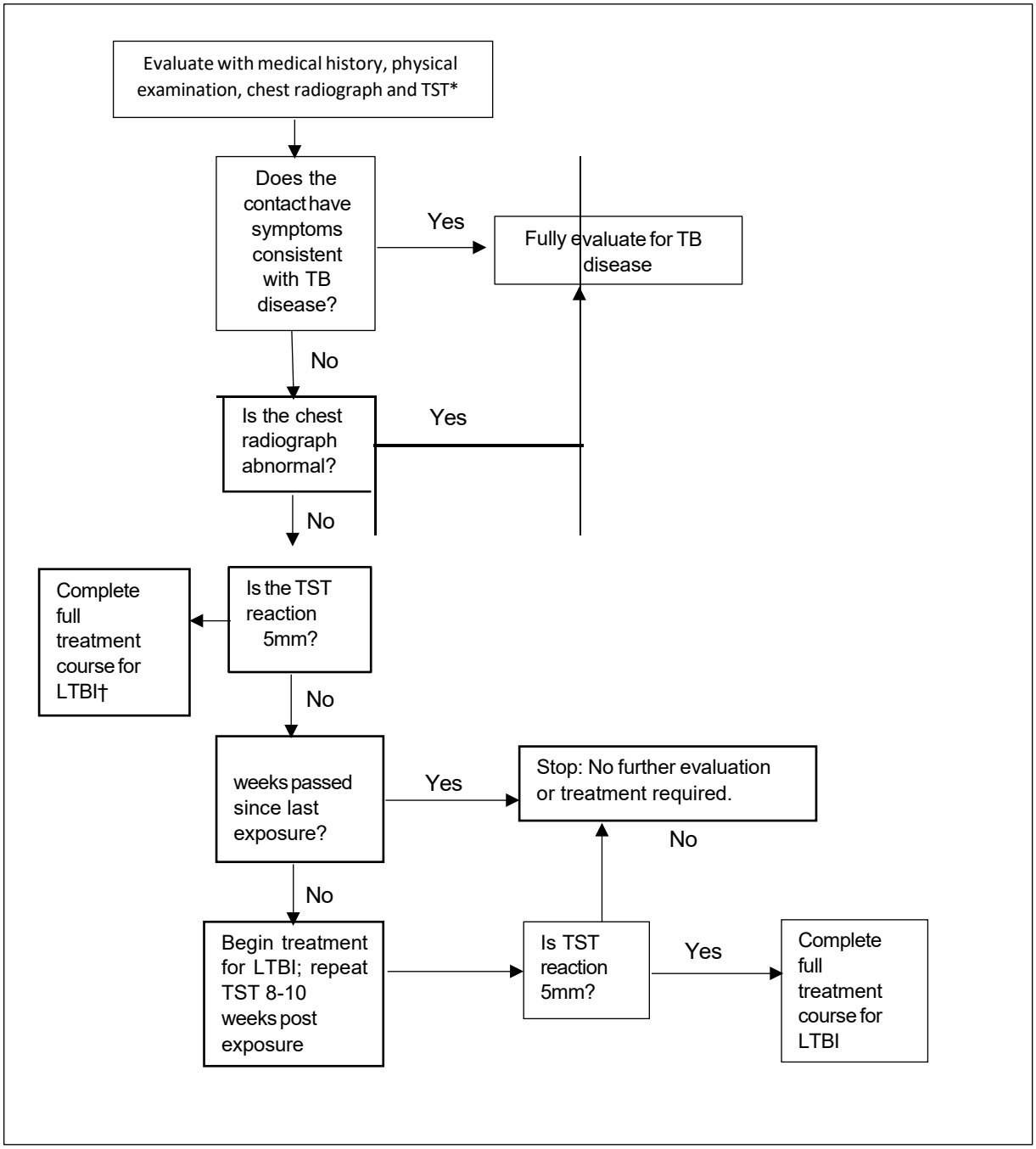
- Aged <5 years;
- Aged 5 through 15 years, at the clinician's discretion; or
- HIV-infected or otherwise immunocompromised.

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

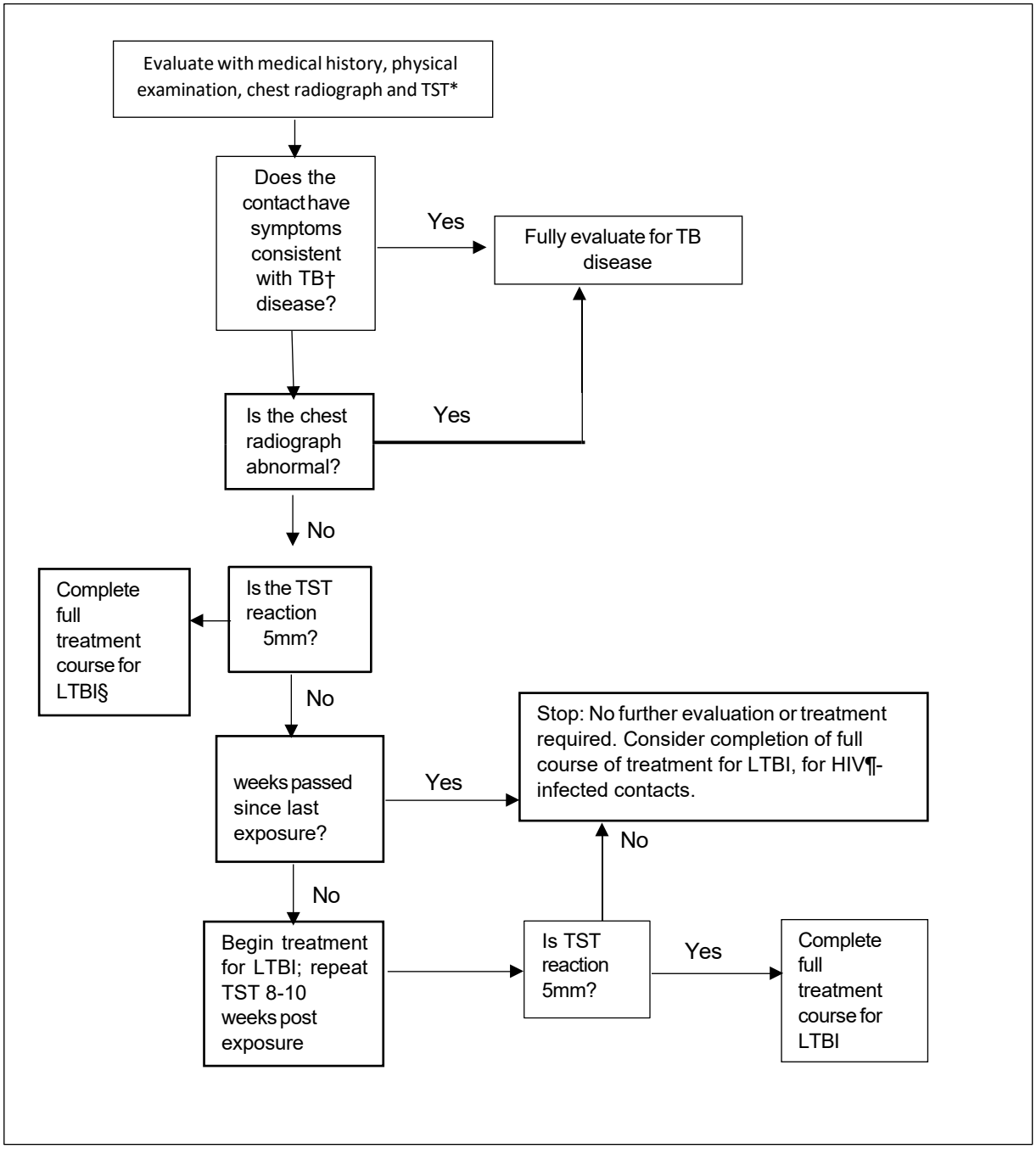


***Tuberculin skin test.**

†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

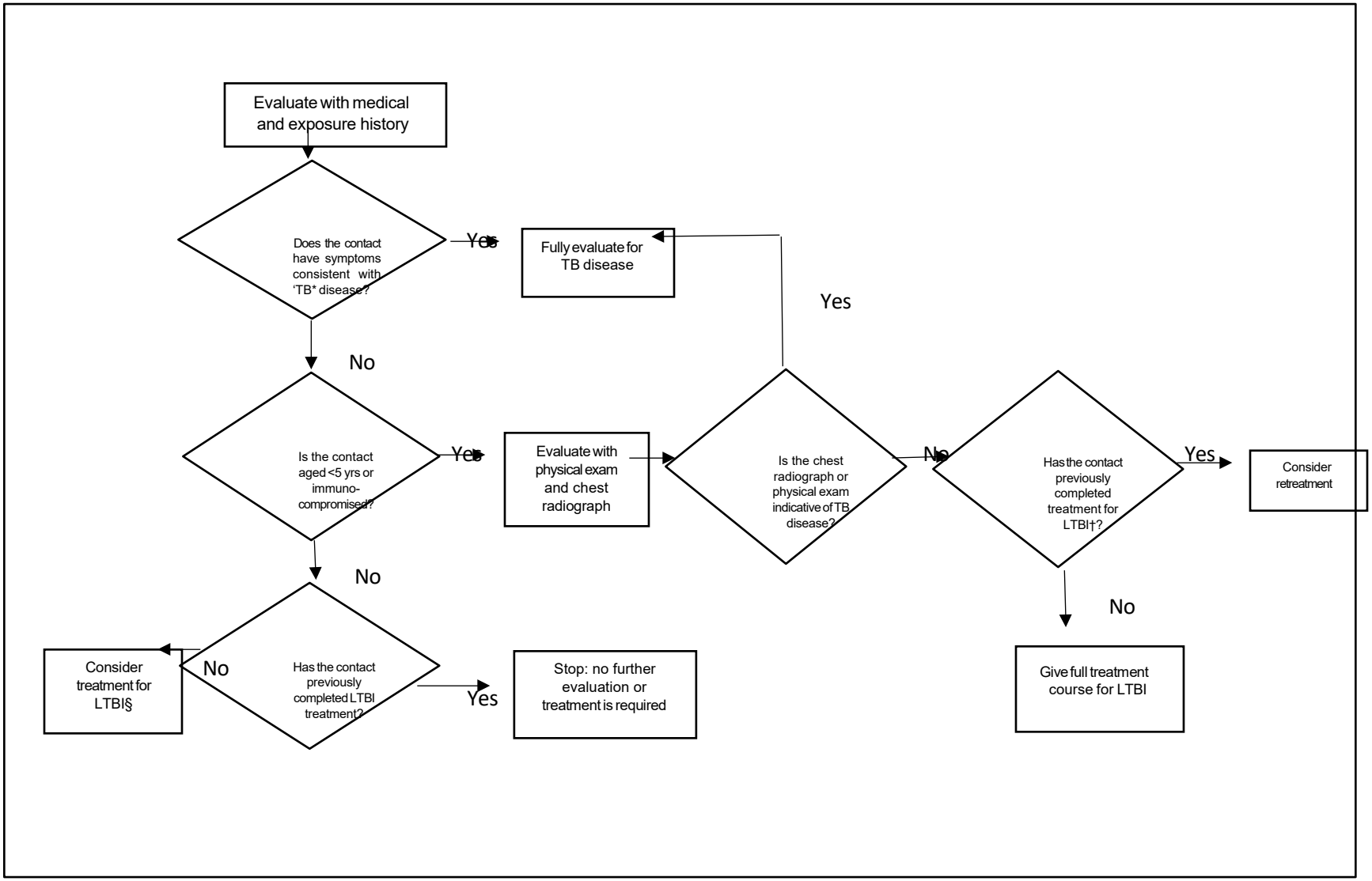
§Latent TB Infection

¶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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SECTION V

BLOOD ASSAYS and IGRAs

Table of Contents

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 to benefit from treatment, including persons who are or will be at increased risk for *M. tuberculosis* infection (Box 1, below) or for progression to active tuberculosis if infected (Box 2, below).
- IGRAs should be performed and interpreted according to established protocols using FDA-approved test formats. They should be performed in compliance with Clinical Laboratory Improvement Amendment (CLIA) standards.
- Both the standard qualitative test interpretation and the quantitative assay measurements should be reported together with the criteria used for test interpretation. This will permit more refined assessment of results and promote understanding of the tests.
- Arrangement for IGRA testing should be made prior to blood collection to ensure that the blood specimen is collected in the proper tubes, and that testing can be performed within the required timeframe.
- Prior to implementing IGRAs, each institution and tuberculosis-control program should evaluate the availability, overall cost, and benefits of IGRAs for their own setting. In addition, programs should consider the characteristics of the population to be tested.
- As with the TST, IGRAs generally should not be used for testing persons who have a low risk for both infection and progression to active tuberculosis if infected (except for those likely to be at increased risk in the future). Screening such persons diverts resources from higher priority activities and increases the number of false-positive results. Even with a test specificity approaching 99%, when the prevalence of *M. tuberculosis* infection
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 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

Table of Contents

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 active TB disease that may have developed since their overseas exam. ❑ Repeat TST or BAMT to confirm or rule-out an overseas diagnosis of LTBI. ❑ 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 a confirmed 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 overseas exam. ❑ Administer a TST or BAMT, regardless of BCG history. ❑ Obtain a chest x-ray (CXR) for individuals with a positive TST or positive BAMT, and anyone with symptoms compatible with TB disease, regardless of the TST or BAMT result. ❑ If more information is needed about the source case, call the Kentucky TB Program 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 cancer therapy).
- A TST is preferred for testing children aged less than 5 years.
- A TST administered prior to 6 months of age may yield a false negative result.
- Complete the TB Class Follow-up Worksheet for ALL TB Class B1 arrivals, and Immigrant arrivals with TB Class B2 and Class B3.

Return form by mail or fax to:

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 is recommended. ◦ If unable to complete or initiate the evaluation, indicate the reason. • Indicate diagnosis as described on the form. *Leave D4 blank – for KY TB Program use only.*
Section E **U.S. Treatment**	• Check appropriate box for treatment and document start date. • Use CDC treatment recommendations: ◦ No treatment indicated for Classes 0 and 1. ◦ Strongly consider treatment of Class 2 (LTBI) and Class 4 (old, healed TB) unless previously treated. ◦ Class 3 (active TB disease) patients should be treated using directly observed therapy (DOT); arranged through the local health department. *Leave E3-E4 blank – for KY TB Program use only.* *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
3772 275 East Main Street, HS2E-B
Frankfort, KY 40621

Fax# 502-564-

Phone# 502-564-4276

Technical Instructions for Civil Surgeons

Civil Surgeons will refer to the local public health jurisdiction in the following instances for follow up evaluation and/or testing if needed:

1. Individual with active signs/symptoms consistent with active TB and/or has an abnormal CXR
    a) These patients will have a need to rule out pulmonary TB with a clinical evaluation and collection of sputum (x3)
    b) If active TB is identified, then the LHD will assume care of the patient until TB treatment completion
    c) If TB ruled out, refer back to the Civil Surgeon for further eval or additional referrals as needed

2. Individuals who are HIV positive (previously or newly identified)
    a) The Civil Surgeon will still be responsible for the initial CXR.
    b) The LHD will provide a clinical evaluation, collect sputum (x3) to rule out infectiousness and monitor until final cultures

Tuberculosis | Technical Instructions for Civil Surgeons | Immigrant and Refugee Health | CDC

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/