

PROTOCOL FOR TUBERCULOSIS

1. Each LHD shall have a designated employee responsible for Tuberculosis (TB) services in their county. This person must attend periodic TB updates or keep updated by having the latest ATS/ALA TB scientific materials.
2. A physician 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.**

Condition	Assessment		Education	Follow-up
<p><u>Classification 0</u></p> <p>No TB Exposure Not Infected</p>	<p><u>Groups that should be TB Tested</u></p> <p><u>Persons with Population Risk Factors</u> <i>Persons at higher risk for exposure to or infection with TB</i></p> <ul style="list-style-type: none"> • Close contacts of a person known or suspected to have TB • Foreign-born persons, including children who have immigrated within the last 5 years from areas where TB is prevalent • Residents and employees of high-risk congregate settings • Health care workers (HCWs) who serve high-risk clients • Medically underserved, low income populations, homeless • High-risk racial or ethnic minority populations • Children exposed high-risk adults • Persons who inject illicit drugs <p><u>Persons with Medical Risk Factors</u> <i>Persons at higher risk for developing TB disease once infected who need testing</i></p> <ul style="list-style-type: none"> • Persons with HIV infection • Persons recently infected with Mycobacterium Tuberculosis • Persons who inject illicit drugs • Persons with certain medical conditions • Persons with a history of inadequately treated TB <p>Examples of groups that are not included in the MMWR, June 19, 2000, Targeted Testing are: foster care parents, day care workers, firefighters, police, school employees/school children and food service workers.</p> <p>Members of these groups should receive individual TB risk assessments and TSTs administered to those at increased risk.</p>	<p>Tuberculin skin test (TST) with Purified Protein Derivative (PPD) using the Mantoux method (use Tubersol antigen)</p> <p>A two-step TST is usually recommended initially for:</p> <ul style="list-style-type: none"> • Anyone required to have regular TB testing, regardless of age <p>The TST must be given and read by a nurse per Kentucky Board of Nursing</p> <ul style="list-style-type: none"> • HIV positive • Silicosis • Chronic renal disease • Diabetes • Gastrectomy/Jejunioileal bypass • Organ transplants • Cancer of the head, neck, or lung • Certain hematologic disorders (leukemias and lymphomas) • TB-like symptoms • People receiving specialized treatment for rheumatoid arthritis or Crohn's disease • Low body weight <p>Develop a policy that the LHD will repeat TSTs given by other health care providers not trained by the LHD unless the skill is known and trusted by the LHD.</p>	<p>See procedure in this reference Review CDC TST Video, 2003</p> <p>Two-step TST:</p> <ul style="list-style-type: none"> • If first test positive, consider the persons infected. • If first step negative, give second test 1-3 weeks later. • If second test positive, consider person infected. • If second test negative, consider person uninfected. <p>See TST Recommendations for Infants, Children, and Adolescents in this reference</p>	<p>All testing activities should be accompanied by a plan for follow-up care. Return in 48-72 hours for interpretation and recording by nurse.</p> <p><u>Anergy Suspects</u> Do not rule out diagnosis based on negative skin test result; consider anergy if immunosuppressed; also see other diseases/conditions that can cause suppression of delayed-type hypersensitivity (DTH) response. DTH Antigen Tests no longer recommended for LHD's administration.</p>

* See Core Curriculum for Classification System for TB 2004

PROTOCOL FOR TUBERCULOSIS (continued)

Condition	Assessment	Treatment	Education	Follow-up
<p><u>Classification 1</u></p> <p>TB Exposure (contact), no evidence of infection</p>	<p>Identify contacts within 3 workdays of suspect/case report, using Concentric Circle Approach found in this reference</p> <p>Give TST/Examine high-risk contacts within 7 workdays of identification</p> <p>Give TST for medium and low-risk contacts based on findings from the Concentric Circle</p> <p>Do the following:</p> <ol style="list-style-type: none"> 1. Medical History 2. TST (unless there is previously documented positive reaction) 3. Chest x-ray, at the same time those who: <ul style="list-style-type: none"> • Have TB symptoms • Are HIV infected or have other immunosuppressed conditions • Are < 4 years of age <p>Posterior–Anterior (PA) chest x-ray is the standard view used to detect abnormalities</p> <p>PA <u>and</u> lateral view should be done on those < 5 years of age <i>Targeted Testing, page 25</i></p> <p>If symptomatic, see sputum collection recommendations in this reference</p>	<p>If newborn, children and adolescents, HIV or immunosuppressed, place on treatment for LTBI by DOT until retested</p> <p><u>If repeat test is positive</u>, continue medicines by DOT</p> <p><u><i>If repeat TST is negative, stop medicine unless contact with infectious case has not or cannot be broken or immunosuppression is suspected</i></u></p> <p>See Medications to Treat Latent Tuberculosis Infection in the reference</p>	<p>Discuss:</p> <ul style="list-style-type: none"> • How TB is transmitted • Infection versus disease • Importance and significance of repeat skin test in 3 months • Treatment of disease or Latent TB Infection (LTBI) • Importance of taking medicine on a regular basis if indicated <p>Steps for patient producing a sputum specimen at home:</p> <ul style="list-style-type: none"> • Clean & thoroughly rinse mouth with water • Breathe deeply 3 times (a tickling sensation at end of breath) • After 3rd breath, cough hard & try to bring up sputum from deep in lungs • Expectorate sputum into a sterile container collecting at least one teaspoonful • Perform this in a properly ventilated room, booth, or outdoors <p>Provide patient information for an informed consent (also cover HIV testing—see PHPR)</p>	<p>If TST is negative, must return 8–12 weeks after contact has been broken, for repeat TST</p>

*Self-Study Modules on Tuberculosis, Contact Investigation for Tuberculosis
CDC Core Curriculum
MMWR, Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection, June 9, 2000*

PROTOCOL FOR TUBERCULOSIS (continued)

Condition	Assessment	Treatment	Education	Follow-up
<p><u>Classification 2</u></p> <p>Infection without disease</p> <ul style="list-style-type: none"> • Positive TST (mm induration) • Negative bacteriological studies (if done) • No clinical bacteriological or radiographic evidence of active disease. 	<p>Candidates for treatment of Latent TB Infection</p> <ul style="list-style-type: none"> • See TST reaction classification, this reference • Careful assessment to rule out TB disease is necessary before treatment for LTBI is started • Immediately get a chest x-ray for positive TST patients with symptoms • Others should be given a chest x-ray as soon as possible. When TB disease is ruled out, treat for TB infection if indicated. • Determine history of prior treatment for LTBI or TB disease • Determine if there are any medical conditions that are contraindications to treatment or would increase risk of adverse reactions <p>Baseline hepatic measurements recommended for:</p> <ul style="list-style-type: none"> • Patients whose initial evaluation suggests a liver disorder or regular use of alcohol • Patient with HIV infection • Pregnant women and those in immediate post-partum period (3 months, especially Black and Hispanic women) • Patients with history of chronic liver disease (Hep B/Hep C) 	<p>See LTBI regimens in this reference</p> <p>Directly Observed Therapy (DOT) for latent TB infection should be strongly recommended if:</p> <ul style="list-style-type: none"> • Non-adherent • Children and adolescents • HIV-positive patient <p>DOT is a <u>must</u> if intermittent dosing is ordered</p>	<p>Establish rapport with patient and emphasize:</p> <ul style="list-style-type: none"> • Benefits of treatment • Importance of adherence to treatment regimen • Possible adverse side effects of medicine(s) • When to stop medication and call the local health department (LHD) • HIV testing with pre and post counseling <p>Directly observed therapy (DOT) for LTBI recommended for at risk adults and children who cannot or will not reliably self-administer drugs</p>	<p>Baseline laboratory testing</p> <ul style="list-style-type: none"> • Not routinely indicated <p>During the course of therapy:</p> <p>At least monthly, a LHD licensed medical or nursing professional must evaluate for:</p> <ul style="list-style-type: none"> • Adherence to prescribed regimen • Signs/symptoms of active TB <p>Chest x-ray not recommended at the completion of routine LTBI treatment</p>

*Centers for Disease Control and Prevention, Core Curriculum, 2004
Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection, MMWR, June 9, 2000*

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(continued)

Condition	Assessment	Treatment	Education	Follow-up
<p><u>Classification 3</u> TB, clinically active</p> <p>Tuberculosis Case Definition:</p> <p><u>Positive Culture</u> Mycobacterium Tuberculosis culture -or- <u>Clinical Case:</u></p> <ul style="list-style-type: none"> • Positive PPD • Abnormal changing chest x-ray or clinical evidence of disease • Placed on 2 or more antitubercular antibiotic drugs • Completed diagnostic evaluation <p>See RVCT form in this reference (copy as needed)</p> <p>Kentucky endorses the 4 drug TB antibiotic therapy initially</p>	<p>See <u>Contact Investigation</u> and the Concentric Circle approach in this reference</p> <p>Should be seen by local health department (LHD) physician as soon as possible if LHD is supplying TB medications</p> <p><u>Case Management</u></p> <ul style="list-style-type: none"> • Assignment of responsibility • Systematic regular review • Plans to address barriers to adherence • Counseling regarding HIV status <p><u>Adherence</u></p> <ul style="list-style-type: none"> • Non adherence is a major problem in TB control • Use case management and directly observed therapy (DOT) to ensure patients complete treatment • Initially order AST, ALT, Bilirubin, Alkaline phosphatase, serum creatinine, and platelets for adults • Visual acuity and color vision as baseline if on EMB, question vision status monthly <p>Client's clinical condition be determined:</p> <ul style="list-style-type: none"> • Immediately if not hospitalized • Within 3 days of notification if hospitalized (best to visit in hospital) • Basic physical exam done within 7 days of notification 	<p>Basic Principles of Treatment:</p> <ul style="list-style-type: none"> • 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 <p>Management of HIV related TB is complex; care should be provided by a consultant expert in both HIV and TB</p> <p><u>Pregnant Women</u></p> <ul style="list-style-type: none"> • 9 month regimen on INH, RIF, and EMB • PZA and SM are contraindicated • PZA <u>not</u> contraindicated in HIV-positive pregnant women <p><u>Infants</u></p> <p>Treat as soon as tuberculosis is suspected</p> <p>See regimens in this reference for treatment of adults, children, and those with extrapulmonary tuberculosis</p> <p><u>Tuberculosis caused by Drug Resistant Organisms</u></p> <p>Treatment should be done by, or in close consultation, with an expert in the management of these difficult situations</p> <p>Vitamin B6 10-25mg for those with certain conditions</p>	<p>Instruct patient about:</p> <ul style="list-style-type: none"> • TB disease and how it is spread • Importance of taking medications on a regular basis • The side effects of medication 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 <p>Confinement and/or restriction of activities must be addressed (TB Control Law, KRS 215.540)</p> <p>KRS 215.531 states drug susceptibility test on initial isolates from patient with active TB must be ordered by the physician</p> <p>Ensure that all initial cultures from independent labs have drug susceptibility studies ordered by private physicians</p>	<ul style="list-style-type: none"> • Monitor for Adverse Reactions • See Recommendations in Sputum Collection in this reference • Chest x-rays initially and at end of treatment at a minimum • 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 <u>must</u> be done • Monitor weight <p><i>See Kentucky TB Control Law KRS 215</i></p> <p><u>Directly Observed Therapy (DOT)</u></p> <ul style="list-style-type: none"> • Health care worker watches patient swallow each dose of medication • Strongly advocate for DOT for all patients • 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 <p>See DOT in this reference</p>

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(continued)

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<u>Classification 4</u>	TB no longer clinically active		Teach patient signs and symptoms of possible recurrence of TB	

Condition	Assessment	Treatment	Education	Follow-up
<u>Classification 5</u>	<p>TB suspected. Diagnosis pending. Should not have this classification for more than three (3) months</p> <p>Results of a positive GenProbe can help determine active mycobacterium tuberculosis (Mtb)</p>	If GenProbe is positive, treatment should begin with a 4-drug regimen until TB is ruled out	Teach patient signs and symptoms of possible recurrence of TB	As indicated

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M.D. Signature
(review and sign annually)

Date