



Missouri Tuberculosis (TB) Protocol and Guidance for Higher Education Institutions

Missouri TB Elimination Program

Bureau of Communicable Disease Control and Prevention

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This document provides guidance for the collaboration of higher education and local and state public health institutions in Missouri to prevent the spread of tuberculosis among students, faculty, and staff of Missouri higher education institutions.

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Testing for Tuberculosis (TB) in a College Setting, Quick Reference:

1. All students complete a risk assessment on matriculation
2. Students with risk factors identified are referred for testing
3. Skin testing (TST)/IGRA are performed (recommend completing [Appendix A](#) at this visit)
4. Negative TST/IGRA: no additional follow up
5. Positive TST/IGRA: referral for medical evaluation and chest x-ray (CXR). If symptomatic, ensure patient wears a mask and the facility performing the CXR knows the purpose of the visit prior to the appointment.
6. CXR negative (normal): consider treatment for TB infection (see [Appendix C](#))
7. CXR abnormal (Cavitary, nodular infiltrates, pneumonia, densities are some examples but not a complete list): proceed to [Medical Guidance for Healthcare Providers](#)



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**Medical Evaluation Guidance for Healthcare Providers:
Patients Presumed to have or Diagnosed with Active Tuberculosis**

Definitions of frequently used terms:

Active TB case	Illness caused by <i>Mycobacterium tuberculosis</i> , in which TB bacteria are multiplying and attacking parts of the body, most commonly the lungs. Patients are capable of spreading disease to others.
Clinical case	All bacteriology is negative but patient improved on treatment. Patient has a positive TST/IGRA and one of the following: abnormal radiography or symptoms consistent with TB disease (cough, fever, night sweats, weight loss, hemoptysis, etc.)
Lab confirmed case	Laboratory confirmation of tuberculosis by nucleic acid amplification (NAA) test and/or isolated from culture.
Physician diagnosed case	Bacteriology is negative; no indication of TB (TST/IGRA negative) but, physician feels TB is likely and treats accordingly.
Presumed (suspected) Case	Clinical findings indicate tuberculosis is likely (abnormal radiography, symptomatic). This term is used while a person is under evaluation for TB disease.
Tuberculosis infection	Person is infected with TB bacteria, but TB disease has not developed. Patients are not considered infectious.

Assessment:

- Review CXR to ensure a 2 view CXR was completed. If the patient is less than 18 years of age, then obtain a PA/AP and lateral. If the CXR is abnormal per physician assessment (e.g. cavity/Cavitary lesion, cavitation, infiltrate(s), nodule(s), granuloma, etc) isolate the patient and notify the LPHA. If unsure if patient needs to be isolated, consult the LPHA.
- Assess for signs and symptoms of tuberculosis disease (fever, fatigue, night sweats, loss of appetite, unexplained weight loss, coughing lasting three (3) weeks or longer, chest pain). If symptoms are present, determine the duration and if there has been known exposure to a person with infectious TB. (refer to [Appendix A](#))

Note: not all persons with TB disease have symptoms.

If the patient is symptomatic:

- Isolate the patient in a location without a shared ventilation system. They should not return to a dormitory, or multi-person dwelling.

- Collect 3 sputum specimens with at least one early morning collection. All specimens should be collected a minimum of eight (8) hours apart, and tubes should be labeled with the patient’s name, date, and time of collection. One sputum specimen should be observed (preferably initial specimen) to ensure proper specimen collection. Subsequent specimen collection does not need to be observed by health care personnel unless there is a concern that the patient will not send subsequent specimens for testing.
- Send specimens to the State Public Health Laboratory (SPHL) by courier through the Local Public Health Agency (LPHA) the same day that they are received from the patient. Do not hold specimens past a courier pick up time to group them together. For example: George gives you a specimen on Monday. He is planning to collect a specimen again on Tuesday and Wednesday. Send the sample collected on Monday with the courier on Monday. Do not wait until all three samples are collected. (If George collected 2 samples in one day, then they could be sent together with the courier.)
- Refrigerate all specimens until courier pick up time to help decrease overgrowth of normal bacteria from the respiratory tract.

Notify the LPHA within **24 hours** when a patient is presumed to have active TB. If the LPHA is unavailable, please notify the Missouri Department of Health and Senior Services (MDHSS), TB Elimination Program, 573-751-6113.

Assess for medical conditions that could increase the patient’s risk for progression to disease if they are infected. See

Persons at Increased Risk
<ul style="list-style-type: none"> • Persons infected with HIV; • Children younger than 5 years of age; • Persons who were recently infected with <i>M. tuberculosis</i> (within the past 2 years); • Persons with a history of untreated or inadequately treated TB disease, including persons with fibrotic changes on chest radiograph consistent with prior TB disease; • Persons who are receiving immunosuppressive therapy such as tumor necrosis factor-alpha (TNF) antagonists, systemic corticosteroids equivalent to/greater than 15 mg of prednisone per day, or immunosuppressive drug therapy following organ transplantation; • Persons with silicosis, diabetes mellitus, chronic renal failure, leukemia, or cancer of the head, neck, or lung; • Persons who have had a gastrectomy or jejunioileal bypass; • Persons who weigh less than 90% of their ideal body weight; • Cigarette smokers and persons who abuse drugs and/or alcohol; and • Populations defined locally as having an increased incidence of disease due to <i>M. tuberculosis</i>, including medically underserved, low-income populations.

Figure 1

- Figure 1.**
- Review TB risk assessment, note risk factors, and provide a copy to the LPHA.
 - Review [Appendix A](#) and assess for previous treatment. Please send a copy of [Appendix A](#) to the LPHA.
 - Provide a copy of the CXR report to the LPHA.
 - Provide medical evaluation to LPHA if completed on campus. Please include weight.

Treatment:

- Start approved treatment regimen for active disease if the student is suspected of having or a laboratory has confirmed TB and maintain patient isolation (see below for regimen).
- Directly Observed Therapy (DOT) should be initiated. This is the method whereby a trained healthcare or other trained designated person (approved by the TB Elimination Program) watches a person swallow each dose of anti-TB medications and documents it. DOT increases adherence to therapy and decreases drug-resistance, treatment failure, or relapse after the end of treatment. DOT is the standard of care for all active TB cases.
- Standard drug regimens are given by weight in milligrams (mg)/kilogram (kg) unless drug resistance is suspected/known or the patient has had any previous known issues with the medications. See [Appendix A](#) to determine if patient has suspected drug –resistance. Please see [Multi-Drug Resistant TB Protocol for College Students](#). Otherwise, the standard four (4) drug regimen should be started. (Note: the following are adult dosages, if pediatric dosing is required, please call the LPHA for assistance)
 - Isoniazid (INH) 5 mg/kg daily
 - Rifampin (RIF) 10 mg/kg daily
 - Pyrazinamide (PZA) given by weight:
 - 40-55 kg: 1000 mg daily
 - 56-75 kg: 1500 mg daily
 - 76-90 kg: 2000 mg daily
 - Ethambutol (EMB) given by weight:
 - 40-55 kg: 800 mg daily
 - 56-75 kg: 1200 mg daily
 - 76-90 kg: 1600 mg daily

Centers for Disease Control and Prevention Core Curriculum on Tuberculosis, Sixth Edition 2013, Chapter 6, Treatment of TB Disease, page 155, Table 6.4 Dosage Recommendations for the Treatment of TB in Adults and Children. See also Table 6.3 Drug Regimens for Pulmonary TB in Adults Caused by Drug-Susceptible Organisms (No suspicion for drug resistance):

<http://www.cdc.gov/tb/education/corecurr/default.htm>

Release from Isolation:

- Patients are considered noninfectious and can leave isolation when they meet certain criteria.

See Figure 2.

Criteria
<p>Patients can be considered noninfectious when they meet all of the following three criteria:</p> <ol style="list-style-type: none">1. They have three consecutive negative AFB sputum smears collected in 8- to 24-hour intervals (at least one being an early morning specimen);2. Their symptoms have improved clinically (for example, they are coughing less and they no longer have a fever); and3. They are compliant with an adequate treatment regimen for 2 weeks or longer.

Figure 2



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Protocol for Multi-Drug Resistant TB Case Management

Multi-drug resistant TB (MDR-TB) is defined as resistance to isoniazid and Rifampin. MDR TB is a complex disease that requires expert consultation and intervention. Many adjustments may be made over the course of treatment, which can last from 18-24 months depending on the patient's response to treatment. Management of MDR-TB cases is extremely challenging and certain treatment elements/recommendations can vary among national experts. These variances include but are not limited to:

- Duration of daily aminoglycoside/capreomycin therapy
- Dosing of aminoglycoside/capreomycin
- Total duration of injectable drug therapy
- Number of drugs included in the regimen
- Use of therapeutic drug monitoring
- Duration of therapy
- Treatment of MDR TB infection and the use of window prophylaxis for MDR-TB contacts

Please note: Consultation with Missouri's national MDR experts (Heartland National TB Center) may yield different recommendations than those published in *Drug-Resistant Tuberculosis: A Survival Guide for Clinicians, 2nd Edition*. Care of MDR patients is individualized based on the patient's response to treatment and their unique resistance patterns. While each patient's treatment plan is tailored to fit his or her illness, certain actions are taken for each patient and will be addressed in this protocol.

Please see [Appendix A](#) for questions to ask your patient to help determine risk for drug resistance when the patient is initially diagnosed with TB.

Diagnosis:

- Refer to the [MDDR/Pyrosequencing Protocol](#) for information on when samples will be tested. If any of the following occurs, notify Local Public Health Agency (LPHA) for assistance:
 - MDDR testing indicates a mutation to any medication.
 - Pyrosequencing indicates resistance to any medication.
 - Phenotypic drug susceptibility testing (DST) indicates resistance to any medications.

- Second line medications will be requested in collaboration with the LPHA, Missouri TB Elimination Program, and the Missouri State Public Health Laboratory (SPHL)

Isolation: Isolation protocol may vary once consultation is sought with Heartland National TB Center and/or the Centers for Disease Control and Prevention based upon the individual's risk of infectiousness.

([See Multi-Drug Resistant TB Flow Chart for Isolation and Medication: Appendix B](#))

- A patient that is smear positive is still considered infectious and is not permitted to relocate outside of the state until they have been released from isolation by the LPHA and the Missouri Department of Health and Senior Services (MODHSS).
- Refer to the protocol for isolation of drug-susceptible TB for initial recommendations. Please note: patients with MDR TB are usually in isolation for long periods (2 months or longer). If the patient is:
 - Still in isolation, then they should remain in isolation until 3 consecutive negative CULTURES are obtained.
 - Out of isolation, then they should be returned to isolation until 3 consecutive negative CULTURES are obtained.

Treatment: ([See Appendix B](#))

- Treatment is individualized based on the patient's medical conditions, resistance patterns, tolerance of medications, and MDR-TB experts' medical judgement. If the patient is:
 - On the standard 4 drug regimen, hold all medications until expert medical consultation can be obtained
 - Not on any medications, obtain expert medical consultation BEFORE starting a medication regimen

Additional notes:

- Directly Observed Therapy (DOT) is the standard of care for all patients with active TB and is especially important in patients with MDR TB. DOT helps prevent further resistance by ensuring that the patient takes all of the medications as prescribed. Patients with MDR TB require

frequent monitoring for medication side effects. DOT visits allow for opportunity to monitor for side effects. The local public health nurse or state TB nurse can assist with monitoring tools.

- Patients with MDR TB are often isolated for long periods of time. Assistance with activities of daily living is needed, such as arrangements for food delivery and laundry services.
- The mental health status of all MDR patients should be observed and documented. Medications and isolation can lead to depression.



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Protocol for Contact Investigation in a College Setting

In the event that a TB contact investigation involves college students, staff, or faculty, this protocol is meant to guide collaboration between the college and local public health agency (LPHA). Different resources exist at colleges/universities throughout the state and at each LPHA, so the protocol is not meant to include all possible scenarios that may be encountered. The Missouri Department of Health and Senior Services (MDHSS) encourages LPHAs in jurisdictions with colleges or universities to create a TB response plan designating the responsibility of each entity prior to cases being identified. Please contact MDHSS, TB Elimination Program for more information (573-751-6113).

1. College notifies local public health agency (LPHA) about presumed or active tuberculosis (TB) case, or vice versa. LPHA notifies Missouri Department of Health and Senior Services (MDHSS) about presumed or active TB case.
2. A contact investigation should be initiated for any presumed or lab-confirmed pulmonary, laryngeal, or pleural TB case. Refer to CDC's 2005 MMWR, vol. 54, no. RR-15: [*Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis: Recommendations from the National Tuberculosis Controllers Association and CDC*](#) for detailed guidance regarding initiating and conducting a contact investigation. An online copy can be found at: <http://www.cdc.gov/mmwr/volumes/65/wr/pdfs/mm6501.pdf>.
 - The need for a contact investigation should be discussed with all involved partners including the LPHA, college health services, college administration, and MDHSS. This can be done via conference call. MDHSS can assist in setting this up.
 - The LPHA is the lead agency in a contact investigation and will ensure that the contacts are identified, tested and when necessary treated, and the test results are sent to MDHSS. The LPHA, in consultation with MDHSS, will provide guidance to the college on how to identify close contacts that need to be tested.
 - The college, in collaboration with the LPHA and MDHSS, is responsible for identifying individual students, staff, and faculty at their college that meet the description of a close contact, as determined by the LPHA and MDHSS, and may assist in contacting those identified and evaluating/testing these contacts. If the college completes testing as part of the contact investigation, results must be submitted to the LPHA in a timely manner.

- **Open communication between the college, LPHA, and MDHSS is key to ensuring that all contacts are identified and properly evaluated according to CDC guidelines.**
3. Common contacts in a college setting may include, but are not limited to, friends, significant others, roommates, classmates, study group members, extracurricular activity group members, advisors, instructors, etc.
 4. Before contacts are notified, the college, in collaboration with the LPHA and MDHSS, should identify a space to perform testing. This can usually be done at the student health center and may provide the best access for students. However, large scale testing may require a larger space. The college, LPHA, and/or MDHSS should also assign responsibility to nursing and/or administrative staff to record contact attempts, testing, and follow-up. Contacts should be tracked using the [MDHSS TBC-13](#) form or other form that captures the same information. The form must include which of the tested contacts are high, medium, or low priority contacts as defined by the investigation.
 5. Contacts can be notified in several ways: phone call, letter, or in-person meeting. A minimum of three failed contact attempts is recommended before listing the contact as “lost to follow-up”.
 - **Notification by e-mail is not recommended due to confidentiality concerns.** However, the college can e-mail a contact to notify them that they have an important and confidential message. The contact should be directed to the student health center to pick up a letter outlining that they have been identified as part of a TB contact investigation.
 - With all forms of contact notification, confidentiality of the index case must be maintained.
 - Nursing staff should be available to answer any questions the contact may have. Nursing staff should discuss TB transmission, signs and symptoms, initial and follow-up testing, latent tuberculosis infection (LTBI) versus active TB, and treatment.
 6. Contacts should be evaluated according to CDC guidelines.
 - If there is a recent (within 1 to 2 weeks of initial evaluation) tuberculin skin test (TST) or Interferon Gamma Release Assay (IGRA) result on record for a contact, it can be used as the initial baseline TB test. The contact will still need to be evaluated 8 to 10 weeks after their last exposure to the index case. Most individuals will have a detectable immune response by 8 weeks, but some may take up to 10 weeks.
 - MDHSS may be able to provide TST for medium and high priority contacts. Contact MDHSS to discuss if this is a possibility.

- T-SPOT[®], a type of IGRA test, may be available from the manufacturer at a reduced fee for a large-scale contact investigation (~100 or more contacts). Contact MDHSS to discuss if this is a possibility.
 - The college should notify the LPHA of all contact testing results both negative and positive as soon as they are available. If any contacts have a positive TB test, the LPHA will contact the college to instruct them on additional testing or next steps required for those individuals and discuss any assistance needed by the college.
 - The LPHA in conjunction with MDHSS will determine if the contact investigation needs to be expanded. If the contact investigation does need to be expanded, the LPHA will notify the college with guidance on who should be identified for the next round of contact testing and discuss any assistance needed by the college.
 - If contact testing is conducted by the college, the college should send the TBC-13 form containing the results of the initial testing and the plan for 8 to 10 week follow-up testing to the LPHA. The LPHA should forward this on to MDHSS.
7. If contact testing is conducted by the college, the college should conduct 8 to 10 week post-exposure follow-up evaluations according to CDC guidelines. The college should notify LPHA of all contact testing results both negative and positive should be sent to the LPHA as soon as they are available. If any contacts have a positive TB test the LPHA will contact the college to instruct them on additional testing or next steps required for those individuals.
- The college should send an updated [TBC-13](#) form containing the final testing results to the LPHA. The LPHA should forward this on to MDHSS.
8. In some instances, a public information release may be necessary to help identify contacts or to notify a large group of people of the need for testing. An example of this would be an instance in which a large group of people have an exposure of concern, but not all members of the group can be identified by available information sources. Information released to the public regarding a contact investigation should:
- protect the health information of the TB case. Even if the case is not identified by name, some characteristics, locators, or aspects of personal history may make the case identifiable to the public.
 - be coordinated between the local and/or state public health agencies and the college to ensure consistent messaging.



Protocol for MDDR Testing in College Populations:

A sample will be sent automatically to the CDC for Molecular Detection of Drug Resistance (MDDR) when all of the following criteria are met:

- Student has an acid-fast bacilli (AFB) positive smear
- Student has a positive Nucleic Acid Amplification (NAA) test for *M. Tuberculosis* complex
- Student is from an high burden multi-drug resistant TB (MDR TB) country as defined by the World Health Organization (WHO)**

http://www.who.int/tb/publications/global_report/high_tb_burden_country_lists_2016-2020_summary.pdf?ua=1

Testing may be performed under the following circumstances when the patient does not meet the above criteria and with consultation from the Missouri TB Elimination Program:

- Student previously received inadequate treatment for TB disease
- Student has multiple treatment attempts for TB disease
- Student is a contact to an MDR-TB case
- Student is significantly immunocompromised (e. g. HIV positive, cancer treatment)

DNA Pyrosequencing at the State Public Health Laboratory (SPHL):

Pyrosequencing will be performed on all TB isolates (cultures) unless drug susceptibility testing has been completed by a private reference laboratory. If any mutation is detected, the sample will be forwarded to the CDC for confirmation testing and second-line drug susceptibilities.

The SPHL Pyrosequencing will sequence specific DNA segments of the entire TB genome to identify common mutations associated with drug resistance to the following four drug classes: isoniazid (*katG*, *inhA*, and *ahpC*), rifampin (*rpoB*), fluoroquinolones (*gyrA*), and second-line injectable drugs (Amikacin, Kanamycin, and Capreomycin) (*rrs*). The CDC MDDR testing provides an expanded service to detect mutations conferring phenotypic drug resistance to first and second line medications commonly used to treat TB. The segments of DNA sequenced by the CDC include the SPHL targeted sections of DNA and additional drug classes such as ethambutol (*embB*) and pyrazinamide (*pncA*). Two additional targeted

sections of DNA for second-line injectable drugs (*eis* and *tlyA*) are sequenced by the CDC to increase the tests sensitivity.

The SPHL does not have the ability at this time to run the pyrosequencing directly on sputum samples; only TB isolates (cultures). The SPHL is working to complete validation to directly test sputum samples in the near future which will change the guidance located above.

**The WHO updates the countries that are considered high burden with MDR-TB. We will automatically test samples from the top thirty countries on their list. Note: this list may change.



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Available Resources

Department of Health and Senior Services (DHSS), Tuberculosis (TB) Elimination Program

Medications are available through the Missouri TB Elimination Program for treating tuberculosis infection (TBI) and TB disease. They are provided free of charge to patients whose insurance will not cover the cost through their local public health agency (LPHA), dependent on the availability of funds.

Diagnostic Services Program (DSP) – this program is to provide tuberculosis evaluation services for those economically disadvantaged patients who have been identified as infected with or suspected of having tuberculosis. The LPHA chooses a physician from among the list of DSP providers.

The patient is identified by the LPHA as eligible if:

- Patient's tuberculin skin test or IGRA positive.
- Patient is not covered by health care insurance.
- Patient is without financial capability of accessing diagnostic medical evaluation for tuberculosis.

The eligibility of a client to participate in the DSP Program is determined by the LPHA and DHSS and must be determined prior to client accessing services. Availability of DSP services is dependent upon the availability of funds.

Incentives – these are small rewards given to patients to encourage them to keep their clinic or field Directly Observed Therapy (DOT) appointments in order to facilitate successful treatment for TB disease. Reimbursement for incentives is dependent upon the availability of funds.

Examples of Incentives

- Food vouchers for snacks or meals
- Groceries
- Restaurant coupons
- Clothing or personal products (i.e. soap, toothpaste)
- Books

Enablers - those things that make it possible or easier for the patients to receive treatment by overcoming barriers such as transportation difficulties. Reimbursement for enablers is dependent upon the availability of funds.

Examples of Enablers

- Transportation vouchers – cab fare
- Child Care – so patient can attend a doctor appointment
- Adjusted clinic hours and locations
- A person who speaks the languages of the populations served – Provider service

Training –onsite training is available for tuberculosis infection (TBI) and TB disease upon request. There must be a minimum of 6 attendees to justify travel costs. To request training, please call the LPHA.

Examples of Trainings

Tuberculosis Orientation - The target audience is public health staff and other medical providers who are actively engaged in the identification, diagnosis, management and treatment of patients with tuberculosis infection and disease. (One 6-hour day)

TB Contact Investigation Training - The Tuberculosis Contact Investigation Training is a skill-building two day training intended to improve the abilities of staff that are responsible for conducting TB contact investigation interviews. The training will provide an overview of the contact investigation process, basic communication and interviewing skills. (Two 8-hour days)

TB Skin testing (TST) – this is a hands on in-person training using dummy arms to teach new staff or staff that need a refresher on how to administer, read, and interpret the results of TST. The training time varies depending on how many attendees there are, questions asked, and how much time is spent practicing. (30 minutes to 2 hours)

Consultative Services

Onsite consultation for Colleges and Universities is available as needed and upon request. Please notify the LPHA, which will notify the TB Elimination Program.

Contact Investigation assistance as needed for 50 + contacts to an active disease case. DHSS staff member(s) will come and assist with the contact investigation depending on the need. Please notify the LPHA, who will notify the TB Elimination Program.



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Appendix A: Questions to Ask Your Patient

Questions to ask your patient to determine if previous treatment has been initiated:

- | | | |
|----------------------------------------------------------------------------|-----|----|
| 1. Have you been told you have TB before? | Yes | No |
| 2. Have you been treated for TB before? | Yes | No |
| 3. Have you received injections for a lung problem? | Yes | No |
| 4. Have you purchased and used medicated cough syrup in a foreign country? | Yes | No |

If your patient answered "Yes" to any question(s) above that indicate he or she may have been previously treated for TB, please ask the following:

1. Where were you treated? _____
2. What drugs did you receive? _____
3. How many different drugs? _____ How many pills each day? _____ What size and colors were the pills/capsules? _____
4. Did you receive injections? _____
5. How long were you on treatment? _____
6. When did you start? _____
7. When did you stop? _____
8. Why did you stop (completed treatment, adverse reaction)? _____
9. It's hard to remember to take medicine every day. How often did you take medications? daily, twice weekly, thrice weekly? _____ Did you take every pill?

10. TB medicine can be expensive. Were you ever without your medications? _____
11. Did you miss your medications sometimes? _____ How often? _____
12. Did healthcare workers observe you taking your medicine? _____
13. Did you urine change color? _____ What color was it? _____
14. Did you feel better? _____
15. Did you ever have sputum examined? _____ What was the result? _____
16. If positive, did your subsequent sputum test negative?

17. Did your doctor ever tell you: That you had to be treated longer for TB? _____ That your TB returned? _____ That you had drug resistance? _____

18. Did your TB symptoms return after finishing treatment? _____

If your patient answers “No” to the questions above that indicate he or she may have been previously treated for TB, please ask the following:

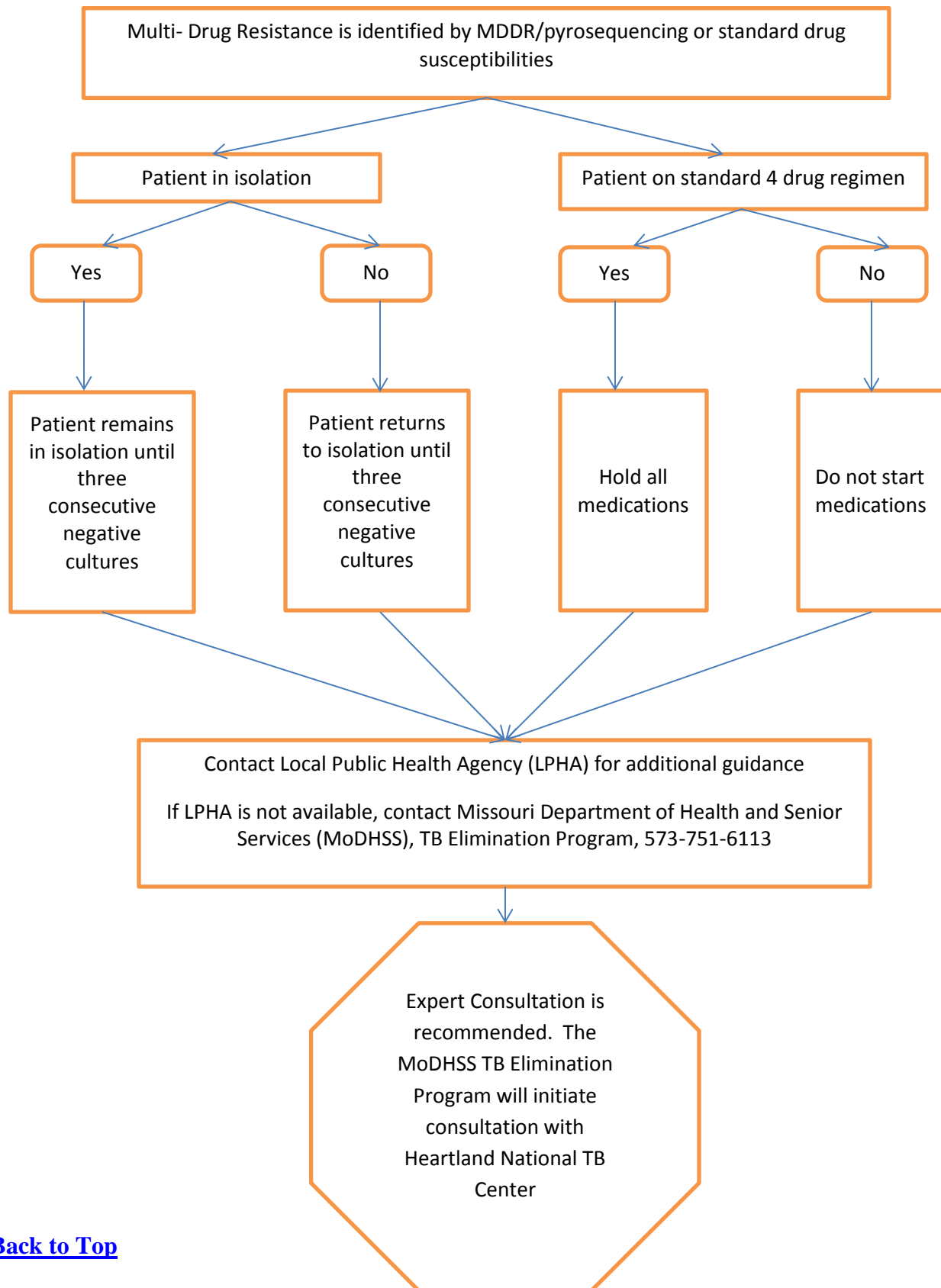
1. Have you been exposed to or had contact with anyone with TB? _____ If yes, when? _____
2. What is that patient’s name and birthdate? _____ Where was he/she treated? _____ How long was he/she treated? _____ Was he/she cured? _____
3. Did you have a skin TB test? _____ What were the results? _____
4. Did you have a blood test for TB? _____ What were the results? _____
5. Did you have a chest X-ray? _____ What were the results? _____
6. Did you receive medications to prevent TB? _____ If so, what drugs and for how long? _____ Did you come to a clinic for the medications where a healthcare worker observed you take the pills, or did a healthcare worker meet you and provide medications? _____ If so, where (name of clinic or location)? _____
7. Did you have cough, fever, weight loss, or other symptoms? _____ If yes, when did those symptoms start? _____
8. Are you having any symptoms now? _____ If so, what symptoms are you currently experiencing? _____
9. Have you ever given a sputum specimen to check for TB? _____ If so, what were the results? _____

Please provide this form to the LPHA and the MoDHSS to assist in determining risk factors for drug resistance.



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Appendix B: Multi-Drug Resistant TB (MDR) Flow Chart for Isolation and Medication



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Appendix C: Treatment Regimens

INH Regimens

When INH alone is given to persons with TB disease, resistance may develop. For this reason, persons suspected of having TB disease should receive the recommended multidrug regimen for treatment of TB disease rather than INH monotherapy until the diagnosis is confirmed or excluded.

There are two options for treatment with INH:

- 9-month regimen

- 6-month regimen

INH is normally used alone for treatment of LTBI in a single daily dose of 300 mg in adults and 10– 20 mg/kg body weight in children, not to exceed 300 mg per dose. INH can be given two times a week at a dosage of 20– 40 mg/kg by DOT for LTBI for children, or 900 mg for adults.

The 9-month regimen is the preferred because it is more efficacious. Treatment for LTBI for 6 months rather than 9 months may be more cost-effective and result in greater adherence by patients; therefore, local programs may prefer to implement the 6-month regimen rather than the 9-month regimen. Every effort should be made to ensure that patients adhere to treatment for LTBI infection for at least 6 months.

9-Month INH Regimen

A 9-month INH regimen is considered optimal treatment. In order to be considered adequate treatment, the patient must receive a minimum of 270 doses administered within 12 months. The preferred regimen for children 2 to 11 years of age is 9 months of daily INH. Patients may be treated with a twice-weekly regimen as an alternative as long as they are undergoing DOT. In a twice-weekly regimen, 76 doses administered within 12 months is considered adequate therapy.

6-Month INH Regimen

A 6-month INH regimen also provides substantial protection against developing TB disease, but it is less protective than the 9-month regimen. In order to be considered adequate treatment, the patient must receive a minimum of 180 doses administered within 9 months. Patients may be treated with a twice-weekly regimen given as DOT as an alternative. In a twice-weekly regimen, 52 doses administered within 9 months is considered adequate therapy. This regimen is not recommended for children, or immunosuppressed persons, or those with evidence of previous TB on chest radiograph.

3-Month INH-RPT Regimen (12-Dose Regimen)

The 12-dose regimen is a combination of INH and RPT given in 12 once-weekly doses under DOT. Because missed doses, altered dosing intervals or amounts, or incomplete treatment could jeopardize the 12-dose regimen efficacy or safety, DOT is strongly recommended for this regimen. Patients using the 12-dose regimen should undergo monthly clinical monitoring, including inquiries about side effects and a physical assessment for signs of adverse effects.

The 12-dose regimen does **not** replace other recommended treatment options for LTBI, but can be considered an equal option to the standard INH 9-month daily regimen for treating LTBI in otherwise healthy people, 12 years of age or older, who were recently in contact with infectious TB, or who had tuberculin skin test or blood test for TB infection conversions.

The dosage for a combination 12-dose regimen of INH and RPT is:

Isoniazid (INH)

15 mg/kg rounded up to the nearest 50 or 100 mg, with a 900 mg maximum.

Rifapentine (RPT)

10.0– 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.

INH is formulated as 100 mg and 300 mg tablets. RPT is formulated as 150 mg tablets packaged in blister packs that should be kept sealed until usage. New formulations with larger dosage per tablet and fixed-dose INH-RPT combinations are in development.

For persons who are at especially high risk for TB disease and are either suspected of nonadherence or given an intermittent dosing regimen, DOT for LTBI should be considered. This method of treatment is especially appropriate if the person in need of LTBI treatment lives with a household member who is on DOT for TB disease, or lives in an institution or facility where treatment for TB infection can be observed by a staff member. It is necessary to exclude TB disease before starting LTBI treatment.

Baseline laboratory testing is **not** routinely indicated for all patients at the start of treatment for LTBI. Baseline hepatic measurements of serum AST (SGOT) or ALT (SGPT) and bilirubin are indicated for patients whose initial evaluation suggests a liver disorder. Baseline testing is also indicated for:

Patients with HIV infection;

Women who are pregnant or in the immediate postpartum period (within 3 months of delivery);

or

Persons with a history of chronic liver disease (e.g., hepatitis B or C, alcoholic hepatitis or cirrhosis), persons who use alcohol regularly, and others who are at risk of chronic liver disease.¹



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¹ From: Centers for Disease Control (CDC). Core Curriculum on Tuberculosis: What the Clinician Should Know. 135-136.
<http://www.cdc.gov/tb/education/corecurr/pdf/chapter5.pdf>