LOCAL PUBLIC HEALTH AGENCY TUBERCULOSIS CASE MANAGEMENT GUIDE

IDPH TB CONTROL PROGRAM

Iowa Department of Public Health

Bureau of Immunization and TB

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CHAPTER 1: IOWA TB CONTROL PROGRAM

PURPOSE

This document provides a standardized framework of procedures for local public health agencies (LPHAs) with regard to case management of latent TB infection (LTBI) and suspected/confirmed cases of TB disease. The contents of this document are specific to the Iowa Department of Public Health (IDPH), Tuberculosis (TB) Control Program, hereafter referred to as "the Program."

AUTHORITY

Iowa Code Chapter 139A.6 and 641 Iowa Administrative Code Chapter 1 provides the local Boards of Health and IDPH with the legal authority to implement TB disease control measures. (Appendix 1)

DEFINITIONS

Infectious Tuberculosis

For the purpose of these rules *"Infectious tuberculosis"* means pulmonary or laryngeal tuberculosis as evidenced by:

- Isolation of *M. tuberculosis* complex (positive culture) from a clinical specimen or positive nucleic acid amplification test (NAA) such as MTD or GeneXpert, or
- Both radiographic evidence of TB, such as an abnormal chest X-ray, **and** clinical evidence, such as a positive skin test or interferon-gamma release assay (IGRA) test for tuberculosis infection, coughing, sputum production, fever, or other symptoms compatible with infectious TB that lead a physician to diagnose infectious TB according to currently acceptable standards of medical practice and to initiate treatment for tuberculosis.

Source: 641—1.1 (139A)

NATIONAL AND STATE PROGRAM GOALS AND OBJECTIVES

The goal of TB control in the United States, and subsequently Iowa, is to reduce TB morbidity and mortality by doing the following:

- Preventing transmission of *M. tuberculosis* from persons with contagious forms of the disease to uninfected persons
- Preventing progression from latent TB infection (LTBI) to active TB disease among persons who have contracted *M. tuberculosis* infection.

For detailed information on the transmission of *M. tuberculosis* and on how LTBI progresses to TB disease, see the Centers for Disease Control and Prevention's (CDC's) online course, Interactive Core Curriculum on Tuberculosis (2011).

The four fundamental strategies to reduce TB morbidity and mortality include the following:

1. Early and accurate detection, diagnosis, and reporting of TB cases, leading to initiation and completion of treatment
2. Identification of contacts of patients with infectious TB and treatment of those at risk with an effective drug regimen
3. Identification of persons with latent TB infection at risk for progression to TB disease and treatment of those persons with an effective drug regimen
4. Identification of settings in which a high risk exists for transmission of *M. tuberculosis* and application of effective infection control measures.

For detailed information on these strategies see "Controlling Tuberculosis in the United States: Recommendations from the American Thoracic Society, CDC, and the Infectious Diseases Society of America" (MMWR 2005: 54 [No. RR-12])

The general, national TB program objectives reflect the national priorities for TB control in the United States. The 15 high-priority TB program objective categories are:

- Completion of treatment
- Contact investigations
- Laboratory reporting
- Treatment initiation
- Sputum culture conversion
- Recommended initial therapy
- Universal genotyping
- TB case rates (in populations: U.S.-born persons, foreign-born persons, U.S.-born non-Hispanic blacks, and children younger than 5 years of age)
- Data reporting (Report of Verified Case of Tuberculosis [RVCT], the Aggregate Reports for Tuberculosis Program Evaluation [ARPEs], and the Electronic Disease Notification [EDN] system).
- Known HIV status
- Evaluation of immigrants and refugees
- Sputum culture reporting
- Program evaluation
- Human resource development plan
- TB training focal points

CHAPTER 2: REPORTING TUBERCULOSIS

LABORATORY AND HEALTHCARE PROVIDER REPORTING REQUIREMENTS

Iowa Administrative Code 641-1.3-1.4 (139) stipulates that laboratory and the healthcare provider must report suspected/confirmed *M. tuberculosis*. (Appendix 1)

WHAT TO REPORT

- Cases of suspected or lab confirmed pulmonary and extrapulmonary TB disease should be reported to IDPH within one working day.
- If extrapulmonary TB is suspected/confirmed the site of disease should also be reported.
- Latent tuberculosis infection (LTBI) is not reportable in Iowa.

HOW TO REPORT

The Program requests that TB cases be reported by phone to help ensure timely public health follow-up measures. Alternatively, faxed notification is acceptable. Laboratory specimens should be submitted directly to the SHL for rapid diagnosis of *M. tuberculosis* complex, culture speciation, drug susceptibility testing, and genotyping.

Phone:	Nurse Consultant: Bridget Konz, RN	515-281-8636
	TB Control Program Manager: Allan Lynch	515-281-7504
Fax:	TB Control Program Secure Fax	515-281-4570
SHL:	State Hygienic Lab information on how to submit samples	

TB DISEASE CASES

Cases that meet the current CDC surveillance case definition of verified TB are reported in IDSS. The Program Manager is the only official with the authority to report cases in IDSS and transmit to CDC. For detailed overview of the guidelines for counting TB Cases, see Recommendations for Counting Reported Tuberculosis Cases.

INTER-JURISDICTIONAL REFERRALS

TB Disease

The Program is responsible for transfer of TB disease case notifications between states and other LPHAs within Iowa. The LPHAs should notify the Program when a patient plans or requests to transfer to another jurisdiction. The Program will need the following information for transfer:

- Name and DOB
- Address where patient will be relocating
- Phone number where patient can be reached
- Treatment start date
- Amount of medication given to patient prior to transfer (see below for guidance)
- Amount of medication transferred to Iowa LPHA receiving patient (see below for guidance)
- If an interpreter is needed (specify language)

Patients with infectious TB are not allowed to move to another jurisdiction by commercial transportation. Generally, patients with infectious TB are discouraged from moving to another jurisdiction until they meet criteria for non-infectiousness. However, if infectious TB patients request permission to move to another jurisdiction, the Program is obligated to honor the request as long as appropriate precautions are taken to assure the general public is not exposed. LPHAs are to notify the Program as soon as it is known the patient is requesting transfer to another jurisdiction. The Program will notify the county or jurisdictional state health department of such intention. . The Program needs the same information listed in bullets above to complete the transfer paperwork.

Giving the patient two to four weeks of travel medications is standard. Each case should be discussed with the treating clinician in advance of the transfer of care. Infectious TB patients are free to travel by private transportation to their next arrival destination. All relevant treatment records to include any legal orders are to be sent to the Program for transfer to the new jurisdiction.

LTBI

Movement from one LPHA in Iowa to another can be accomplished at the local level with notification to the Program. If out of state notification is necessary, the LPHA should notify the Program to include:

- Name and DOB
- Address where patient will be relocating
- Phone number where patient can be reached
- Treatment start date
- Amount of medication given to patient prior to transfer (see below for guidance)
- Amount of medication transferred to Iowa LPHA receiving patient (see below for guidance)
- If an interpreter is needed (specify language)

The Program will contact the receiving jurisdiction to determine if they will follow-up on the LTBI case and report back to the LPHA. There are some jurisdictions in the US that do not routinely follow-up on LTBI cases. LPHAs should notify departing patients of this information and instruct them to seek the local, city, district or state health department where they are moving. Additionally, it may be helpful for patients if LPHA provides them documentation of treatment, including the LTBI Patient Information Sheet (Appendix 18), their chest x-ray interpretation, and notes as to the start date of medications.

CHAPTER 3: CASE MANAGEMENT

Case management of TB disease describes the activities undertaken by the LPHA and the Program to ensure successful completion of TB treatment and cure of the patient. Case management, under the umbrella of IDPH, is a system in which a specific LPHA is assigned primary responsibility for the TB patient and IDPH Program staff (Nurse Consultant) are assigned systematic regular review of patient progress.

The LPHA is responsible for the majority of patient monitoring and ensuring the quality of TB case management. The Nurse Consultant will ensure that medical treatment is in compliance with current CDC/ATS and IDSA guidelines for the treatment of TB disease. The Program Manager will verify all reported cases meet the definition for public health surveillance, assign and evaluate contact investigations as appropriate, monitor progress, and implement corrective action as needed for stated program performance objectives.

The Program will provide the LPHA with guidance on TB case management of LTBI and TB disease to include:

- Testing and identification of LTBI and suspect/confirmed TB
- Monitoring adverse reactions to anti-tuberculosis medications
- Monitoring bacteriologic and clinical improvement

LOCAL PUBLIC HEALTH AGENCY

The Program contacts the local public health nurse (LPHN) or designee and/or treating clinician to determine treatment plans, document response to therapy, non-adherence issues, adverse drug reactions, and TB discharge planning. Effort should be made to have the LPHN or designee as the point of contact to the treating clinician. The purpose for this is to establish competence in TB control principles at the local level as well as provide the treating clinician direct access to their counterpart serving the patient.

The Nurse Consultant/Program Manager will provide relevant consultation and education to the LPHN or designee to enable them to be the point of contact.

LATENT INFECTION (LTBI)

LTBI is not a reportable condition in Iowa. However, the Program provides medication to treat LTBI, regardless of income status of the patient. Upon identification of LTBI the LPHN will:

- Complete the Patient Information for LTBI (Appendix 18)
- Gather chest x-ray interpretation (see Timeframes for CXR below)
- Request prescription (if separate from the Patient Information for LTBI form)
- Fax all information to: 515-281-4570

Once medications are received from the IDPH-contract pharmacy (NJL Pharmacy Services of Pleasant Hill) the LPHN should verify the script and received medications match (contact the Program if they do not). When the patient comes to the LPHA for the first month of medications, the LPHN should initiate the LTBI Monitoring Form (Appendix 19) (or a similar local form). The form allows for review of common side effects of LTBI meds monthly and document compliance. One month of medication should be given at a visit unless the prescribing clinician indicates differently in writing. Time Frames CXR/CT

LTBI medication orders require a medical evaluation including a current chest x-ray or CT that rules out pulmonary TB. The Program requires immigrants and refugees to present a U.S. chest x-ray or CT to obtain LTBI medications. Timeframes in which the chest x-ray or CT were completed until medications are ordered differ depending on the patient's risk factors.

Six months: No identified risk factors

3 months: Any identified risk factor including:

5mm TST Positives

- HIV infection (the virus that causes AIDS)
- Close contacts of a person with infectious TB disease (as identified in public health investigation)
- Person with changes to CXR consistent with prior TB
- Organ transplants or other immunosuppressed people
- Specialized treatment (i.e. meds that depress immune system) for rheumatoid arthritis or Crohn's disease

10mm TST Positives

- Persons who have immigrated (within the last 5 years) 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
- Substance abuse
- Silicosis (occupational exposure to stone dust: mining, sandblasting, quarry, ceramics and foundry workers, as well as grinders, stone cutters, refractory brick workers, tombstone workers, pottery workers)
- Diabetes mellitus
- Severe kidney disease
- Low body weight (less than 10% of Ideal)
- Head and neck cancer
- Medical treatments such as corticosteroids or organ transplant

EXTRAPULMONARY TB RULE OUT

Extrapulmonary TB must also be ruled out by the clinician upon exam (i.e., absence of cervical swelling etc) before LTBI treatment is initiated. For detailed information on extrapulmonary disease see section *Extrapulmonary TB Disease*.

TUBERCULOSIS DISEASE

INTAKE PROCEDURE FOR INFECTIOUS SUSPECTED/CONFIRMED TB:

Once a patient is identified as a suspect/confirmed TB case, all pertinent patient history and physical, lab, and X-ray/CT information is requested from the treating clinician or facility. If the Program is notified of the suspect patient first, the nurse clinician will request this information and forward to the appropriate LPHA and vice versa.

At IDPH, the nurse clinician initiates completion of the '*TB Suspect/Active Patient Intake Form'* (Appendix 2) for all suspected/confirmed cases of active TB disease. The LPHN assigned to case manage the patient should review this form and conduct follow up to respond to all questions.

The Program, in cooperation with LPHAs and private clinicians, determines if a person meets criteria for infectious TB. If the criteria for infectiousness are met, the Program will make recommendations to the LPHA to issue the appropriate isolation and/or treatment orders. See *Chapter 5 – Isolation* for guidance on isolation procedures including issuance of legal isolation orders.

INTAKE PROCEDURE FOR SUSPECTED/CONFIRMED EXTRAPULMONARY TB:

Intake procedures are the same for suspected/confirmed cases of extrapulmonary TB (EPTB) as pulmonary cases with the exception of isolation control measures and subsequent monitoring of sputa.

Documentation of a clinician's statement that pulmonary TB has been ruled out is required. No issuances of legal orders are necessary for extrapulmonary cases. Exception to this rule is extrapulmonary cases with co-morbidity of HIV/AIDS. This circumstance requires individual case review, and if deemed appropriate, issuance of a treatment completion order executed.

EXTRAPULMONARY TB DISEASE

Extrapulmonary tuberculosis (EPTB) refers to disease outside the lungs. It is sometimes confused with non-respiratory disease. Disease of the larynx for example, which is part of the respiratory system, is respiratory but defined as extra-pulmonary.

Extra-pulmonary TB may be characterized by swelling of the particular site infected (lymph node), mobility impairment (spine), or severe headache and neurological dysfunction (TB meningitis) etc. Extra-pulmonary TB is not accompanied by a cough because it does not occur in the lungs. It is

equally important that both the infectious and non-infectious forms of TB are diagnosed and treated as both can be fatal.

Development of extra-pulmonary disease

At the time of primary infection blood or lymphatic spread of tubercle bacilli to parts of the body outside the lung may occur. In the fully immunocompetent host these bacteria are probably destroyed. If some immune deficit is present some may concentrate at a particular site where they may lie dormant for months or years before causing disease.

Bacteria may be coughed from the lungs and swallowed. By this route they may enter the lymph nodes of the neck or parts of the gastro-intestinal (GI) tract. Before milk was routinely pasteurized cattle infected with *M. bovis*, the bovine variant of tuberculosis could pass disease to humans who drank infected milk. Transmission by this route would also give rise to GI diseases.

The most common sites of infection are:

- Lymph glands and abscesses particularly around the neck.
- Orthopedic sites such as bones and joints. The spine is affected in about half such cases.
- GU tract - In women uterine disease is probably the most common while in men the epididymis is the site most frequently affected. Both sexes are affected by renal, ureteric or bladder disease equally.
- Abdomen - This may affect the bowel and or peritoneum.
- Meningitis - which may be rapidly fatal if not, treated in time
- Pericardium- which causes constriction to the heart
- Skin - which can take a number of forms, most notably Lupus vulgaris where changes of the facial skin was supposed to give patients a wolf-like appearance

Clinical presentation

Clinical presentation is characteristically chronic with pain and swelling being the principal features. Lymph glands of the neck may develop singly or in chains. They become swollen painful and may have a rubbery texture. They may break down to give abscess formation. These may discharge onto the skin giving a combination of swelling and pus around the neck.

Bony disease causes pain and swelling of the affected part. Spinal disease may cause paraplegia if enough of the vertebrae are destroyed to cause instability of the spine.

Abdominal disease characteristically causes pain and constipation. If advanced it may cause complete obstruction of the bowel.

Tuberculous meningitis (TBM)

Tuberculous meningitis (TBM) may cause a wide variety of symptoms. A single cranial nerve may be affected resulting in double vision. There may be mental confusion developing over days or weeks. If not detected and treated coma may develop. If treated soon enough recovery may be complete but long term sequelae are likely if the treatment is delayed. TBM has the highest mortality of all complications of tuberculosis.

SPECIAL CIRCUMSTANCES

High Risk Contacts: children less than 5 years of age

Children younger than 5 years of age are more susceptible to TB disease and more vulnerable to invasive, fatal forms of TB disease, such as TB meningitis. Because of this, the Program deems them a high priority contact during investigations and recommends they receive a full diagnostic medical evaluation including a TB skin test and a chest x-ray, regardless of TB skin test result (negative or positive). If the parent/guardian refuses evaluation for the child, consideration should be given to issuing the template '*Order for Diagnostic Evaluation– Minor.'* (Appendix 4). See section: *Diagnostic Evaluation Order: Adults and Children* for more information.

If the LPHA determines that child/children younger than 5 years of age may have been exposed to infectious TB, the LPHA should issue the parent/guardian of said minor '*Recommendation for Window Period Prophylaxis (WPP)'.* (Appendix 3)

- ***Window Period*:** The period of time between which a person is exposed to an infectious organism (TB) and when that organism (TB) becomes detectable via a test (TB skin test). For children younger than 5 years of age who have been exposed to someone with infectious TB, the window period is the interval between the first and second round of testing (8 – 10 weeks).
- ***Prophylaxis*:** Taking medicine to prevent a disease. For children younger than 5 years of age who have been exposed to someone with infectious TB, it is recommended they take an antibiotic (INH) during the window period to prevent the development of TB disease.

The reasons for WPP should be clearly explained to the parent/guardian and signature of the parent/guardian obtained, regardless of acceptance/rejection of WPP. **If WPP is rejected, document the reasons for rejection specifically noting that the parent/guardian understand that fatal TB is a medical possibility if WPP is not used.**

High Risk Contacts: Children ages 5 – 17 years

Minors in this high-risk category include children who have not been properly evaluated for exposure to infectious TB. It is intended for children who do not fall into the 'Children less than 5 years of age' category, but may be used for any child considered a minor. If this situation occurs, consideration should be given to issuing the template '*Order for Diagnostic Evaluation– Minor.'* (Appendix 4).

Diagnostic Evaluation Order: Adults and Children

A person diagnosed with extrapulmonary TB or clinically suspected of having infectious TB who fails to comply with a physician's recommendation for diagnostic testing may be ordered to undergo diagnostic testing by the Program, LPHA or local board of health. The intent of this action is twofold:

- To keep patients with confirmed extrapulmonary TB who chooses to stop taking TB medication, from subsequently developing infectious pulmonary and or laryngeal TB.
- To complete the diagnostic evaluation of person's clinically suspected of having infectious TB.

The diagnostic evaluation may include, but is not limited to, a physical examination, a chest x-ray or CT, and bacteriologic examinations at intervals established by the treating clinician and the LPHA.

Untreated patients with extrapulmonary TB are at risk for developing infectious TB, especially those with weakened immune systems (e.g., HIV+, other medical conditions).

Other scenarios that warrant an order to undergo evaluation include a child whose parent(s)/guardians did not present the child for evaluation, despite written request to do so.

Templates to be used are the '*Order for Diagnostic Evaluation – Minor'* (Appendix 4) or '*Order for Diagnostic Evaluation – Adult'* (Appendix 5).

CHAPTER 4: TREATMENT OF TUBERCULOSIS

TREATMENT OF LTBI

Shipping: For LTBI medications, the entire course of treatment (6 or 9 months) is sent to the LPHA at initiation of treatment because of cost savings over multiple mailings of medications. The cost of shipping and staff time outweighs savings in medication if patient subsequently does not start/stops taking medication.

Processing of LTBI medication requests: Complete LTBI orders will be processed as soon as possible (not to exceed 5 business days). If LTBI orders are submitted to the Program and information is missing or incomplete, the Program will fax a request for missing/incomplete information back to the provider's office within a reasonable timeframe. Once complete orders have been entered into TB Meds program they will be submitted to the contractual pharmacy for distribution.

Monitoring: LPHA should distribute no more than 30 days of medication at a time to the patient. At monthly intervals, the LPHA assesses patients being treated for possible adverse reactions to the medication, especially those associated with drug-induced hepatotoxicity. LPHAs should utilize the '*LTBI Monitoring Flow Sheet'* or similar form to document any clinical concerns. Patients who have adverse reactions, especially those consistent with drug-induced hepatotoxicity should immediately stop taking medication and see their healthcare provider.

Private clinics/MD offices: The same recommendation for monthly monitoring for patients receiving treatment for LTBI applies to these settings. If the clinic releases the entire prescription to the patient, documentation should occur..

Patients temporarily leaving jurisdiction: Patients leaving the area for durations greater than 30 days may be given no more than 30 days of travel medications due to necessity of monitoring for adverse reactions to medication. LPHAs intending to give greater than 30 days should seek approval of the treating clinician.

Patients moving to another state: The Program will send an inter-jurisdictional referral (IJR) to the receiving state TB Control program. IJR should include chest x-ray report, prescription and medication record. Thirty days of travel medications are given to the patient for LTBI. For patients with TB disease (extrapulmonary or pulmonary) 2 weeks of travel meds is recommended.

For detailed information of the treatment of LTBI see the following CDC Fact Sheets:

- Treatment of LTBI
- LTBI treatment Options

TREATMENT OF TB DISEASE

GENERAL RECOMMENDATIONS

General CDC/ATS and IDSA recommendations include starting patients on a standard four-drug regimen of Isoniazid (INH), Rifampin (RIF), Ethambutol (EMB) and Pyrazinamide (PZA) if the patient's drug sensitivities are unknown or are pan-sensitive. If treatment variance to these recommendations occurs, the Program must resolve the variance with the treating clinician and if unable to do so, involve the TB Medical Consultant (Dr. Hornick), State Medical Director or designee, or Heartland National TB Center.

For detailed information on the current treatment recommendations for TB, use the following guideline: Treatment of Tuberculosis: American Thoracic Society, CDC, and Infectious Diseases Society of America

INTERMITTENT THERAPY

There are four generally accepted regimens for treating TB disease caused by drug-susceptible organisms. The most commonly used regimen is daily four-drug therapy for two weeks and then switching to twice weekly therapy for duration of treatment. This treatment regimen is a preferred 'A' rated option and causes the least interference in patients daily lives, and allows for significantly less public health intervention with the same treatment outcome of TB being treated until cure. **All intermittent (twice weekly on the regimen above) doses must be performed using DOT**[1]. Monitoring of TB Cases

The Program or the LPHA should obtain all relevant health/physical assessments, demographic, laboratory and discharge information as possible from the Infection Control Practitioner (ICP) or other designee. This information is used to complete the '*TB Suspect/Active Intake Form' (*Appendix 2) upon notification of TB case. Periodically throughout the course of treatment the Nurse Consultant will consult with the LPHA as follows:

- **Initial Phase of Treatment:** The Nurse Consultant will contact the LPHN or designee and/or provider at least one time weekly. After care is established, contact intervals may be lengthened as mutually agreed upon by both parties.
- **Continuation Phase:** The Nurse Consultant will contact the LPHN or designee and/or provider at least monthly.

At a minimum, monthly documentation includes basic narrative format noting any adverse reactions to TB medications and monitoring bacteriologic and clinical improvement.

[1] Treatment of Tuberculosis: American Thoracic Society, CDC, and Infectious Diseases Society of America, section 4.3

DIRECTLY OBSERVED THERAPY

Directly observed therapy (DOT) is the standard of care for all patients in TB control programs in the United States and should be provided by the LPHN or designee.

COUNTING DOT DOSES

There are two main citations from CDC/ATS/IDSA MMWR *Treatment of Tuberculosis* on this subject that seemingly contradict one another. Both citations are referenced below. In summation, the contention is how to count weekend dosing for those patients receiving daily therapy.

- One point advocates 5 days/week DOT dosing, adding missed doses to the end of treatment.
- The other point advocates 5 days/week DOT dosing but not adding missed doses to the end of treatment. Option is given to allow patients to self-administer weekend doses.

The Program accepts either position as effective treatment. However, the Program's preference is for patients receiving daily therapy to have 5 days/week DOT dosing, with patients self-administering weekend doses. This should be documented as 5 day/week DOT.

Source: MMWR; Treatment of TB June 20, 2003/vol. 52 section: 5.2.1.: "Based on substantial clinical experience 5 days-a-week drug administration by DOT is considered to be equivalent to 7 day-a-week administration, thus, either may be considered "daily." Although administration of anti-tuberculosis drugs by DOT at 5 days/week, rather than 7 days, has been reported in a large number of studies it has not been compared with 7-day administration in a clinical trial and therefore is rated 'AIII'." (Approved drug treatment regimes range from A(I), most preferred, to E(I),least preferred).

Source: *MMWR; Treatment of TB June 20, 2003/vol. 52 section: Completion of Treatment (page 8)*. "Clinical experience suggests that patients being managed by DOT administered 5 days/week have a rate of successful therapy equivalent to those being given drugs 7 days/week. Thus, "daily therapy" may be interpreted to mean DOT given 5 days/week and the required number of doses adjusted accordingly. For example, for the 6-month "daily" regimen given 5 days/week the planned total number of doses is 130. (Direct observation of treatment given 5 days/week has been used in a number of clinical trials, including USPHS Study 22, but has not been evaluated in a controlled trial; thus, this modification should be rated AIII.) As an option, patients might be given the medications to take without DOT on weekends."

FREQUENCY OF SPUTUM COLLECTION

Sputum's should be collected on pulmonary TB patient until sputum culture conversion is documented. Sputum culture conversion is reached when specimens no longer culture TB. Recommended interval of sputum collection is monthly. If sputum culture conversion is not documented by the end of the initial phase of treatment, it is imperative to collect sputum's by the 60 day treatment mark or risk extension of treatment for the patient.

- **For patients with positive sputum smears -** after treatment is initiated sputum collection is at approximately days 13, 14 and 15 of treatment and then at least every two weeks until the patient meets criteria for non-infectiousness. After criteria for non-infectiousness has been met, follow-up collections should continue every 2 weeks until the patient is presumed to be close to the point of smear conversion. The frequency of collections should then be increased to at least weekly to "catch" the point of conversion as precisely possible, so the patient can be released from ordered isolation and return to normal activity.
- **Patients whose sputum specimens are initially negative on smear-** should have monthly specimen collection until cultures have converted to negative. After culture conversion has been documented, no further sputum collection is necessary unless there is a clinical indication (e.g., recurrence or persistence of TB-like symptoms or treatment interruption). Individuals with MDRTB or HIV-TB may require additional sputum testing to monitor their clinical course.
- **Patients whose sputum smears convert to negative during treatment -**. No further sputum collection is necessary beyond the point of culture conversion unless there is a clinical indication (e.g., recurrence or persistence of TB-like symptoms or treatment interruption). Individuals with MDRTB or HIV-TB may require additional sputum testing to monitor their clinical course.

RECOMMENDATIONS FOR SPUTUM COLLECTION TABLE

Purpose	Frequency	Number of specimens
Initial Monitoring for smear conversion	Every 2 weeks after week 2 of therapy	1 sample - Collection observed by HCW
Monitoring for imminent smear conversion	Every few days to weekly	3 samples on three different days - At least one should be observed by HCW
Monitoring for culture conversion	Monthly	3 samples on three different days - At least one should be observed by HCW
Monitoring after culture conversion	Only if clinically indicated	3 samples on three different days - At least one should be observed by HCW

HOSPITALIZATION VERSUS OUTPATIENT CARE

Need for Hospitalization

Hospitalization is not necessary for TB to be diagnosed or treated, unless clinically indicated.

Airborne Precautions in Hospital Setting

Hospitalized patients in whom infectious (i.e., pulmonary or laryngeal) TB is suspected should be placed in an airborne-infection isolation (AII) room and should wear a surgical mask during transport and in waiting areas.

Health care workers and visitors entering the isolation room should wear at least N95 disposable respirators, as should health care workers performing procedures such as sputum induction, bronchoscopy, jet irrigation of abscesses, and autopsies.

Airborne Precautions for Outpatient Care

Patients who have not met criteria for non-infectiousness should wear a general surgical mask to all appointments for required health care. Arrangements should be made in advance of healthcare appointments to ensure patients with infectious TB do not sit in general waiting area with other patients and instead are immediately escorted into an AII room.

Routine appointments for medical care should be delayed until the patient has met criteria for non-infectiousness.

CRITERIA FOR NON-INFECTIOUSNESS IN THE HOSPITAL SETTING

Smear negative and culture pending or positive pulmonary specimens

Hospitalized patients for whom the suspicion of TB disease remains after the collection of three negative AFB sputum smear results should not be released from airborne precautions until they are on standard multidrug anti-tuberculosis treatment (minimum of 7 days) and are clinically improving. http://www.cdc.gov/mmwr/pdf/rr/rr5417.pdf

Smear positive and culture pending or positive pulmonary specimens

In addition to meeting standard criteria for non-infectiousness, stringent criteria 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 more than 8 hours apart (with one specimen collected during the early morning) before being considered noninfectious (*42*). Page 7 http://www.cdc.gov/mmwr/pdf/rr/rr5415.pdf

HIV AND TB

All patients with TB should have counseling and testing for HIV infection. People infected with HIV are more likely than uninfected people to get sick with TB disease.

- Among people with latent TB infection, HIV infection is the strongest known risk factor for progressing to active TB disease
- A person who has both HIV infection and active TB disease has an AIDS-defining condition

For current guidelines on the treatment of TB disease in a HIV co-infected person click here.

CHAPTER 5: ISOLATION

TREATMENT RESPONSIBILITIES FOR PATIENTS

The Program requests the LPHA (where the patient is residing at time of diagnosis) issue *a 'Notification of Treatment Responsibilities for Infectious Tuberculosis'* (Appendix 7). The document is issued at the same time the *'Notification of Isolation for Infectious Tuberculosis' (*Appendix 8) is issued.

LPHAs have the responsibility to educate patients that treatment must continue until they are cured and that there is a distinct difference between having infectious TB, non-infectious TB, and being cured of TB. The *'Notification of Treatment Responsibilities for Infectious Tuberculosis'* details that persons diagnosed with or clinically suspected of having infectious TB shall complete voluntary treatment until, in the opinion of the attending physician or the state public health medical director and/or epidemiologist, the person's TB is cured or such person is no longer a threat to public health. A signed copy of this order should be given to the treating clinician and the Program.

COLLABORATION WITH CLINICIANS

It is the responsibility of the LPHA to notify the treating clinician when patients are placed in isolation and when patients are released from isolation. At a minimum, a copy of the *'Notification of Isolation for Infectious Tuberculosis' (*Appendix 8) should be sent to the treating clinician.

The Program is responsible for assuring all TB patients in Iowa are managed in accordance with published guidelines from CDC/ATS and IDSA including following recommended treatment regimens. These recommendations are broadly applicable and modifications are expected to be made for specific circumstances, including, but not limited to: site of disease, immune status, clinical response to therapy, and other complicating medical factors.

EXAMINATION, TESTING, AND TREATMENT OF QUARANTINABLE DISEASES

TREATMENT

A person diagnosed with or clinically suspected of having **infectious TB** shall complete voluntary treatment until, in the opinion of the attending physician or the state public health medical director and epidemiologist, the person's TB is cured or such person is no longer a threat to public health.

If such person refuses to complete the course of voluntary treatment, the LPHA or local board of health may issue an order compelling mandatory treatment. Such order shall include the identity of the person subject to the mandatory treatment order, a description of the treatment ordered, the medical basis upon which the treatment is ordered, and a description of the potential medical and legal consequences of violating such order.

A person who violates a mandatory treatment order may be subject to the penalties provided in Iowa Code section 135.38 or 137.21 (Appendix 17) and may be placed under mandatory quarantine or isolation in accordance with the provisions of this chapter.

DIAGNOSTIC TESTING

A person diagnosed with extrapulmonary TB or clinically suspected of having infectious tuberculosis who fails to comply with a physician's recommendation for diagnostic testing may be ordered to undergo diagnostic testing by the department or local board of health. Such order shall include the identity of the person subject to mandatory diagnostic testing, a description of the diagnostic testing ordered, the medical basis upon which the diagnostic testing is ordered, and a description of the potential medical and legal consequences of violating such order.

A person who violates a mandatory diagnostic testing order may be subject to the penalties provided in Iowa Code section 135.38 or 137.21 and may be placed under mandatory quarantine or isolation in accordance with the provisions of this chapter. Source 641—1.9 (135,139A) (Appendix 1)

ISOLATION OF INFECTIOUS PATIENTS

ISOLATION AND ISOLATION STEPS

In general, patients are considered infectiousness when they have:

- Untreated pulmonary and/or laryngeal TB (suspected or confirmed),
- Have not been on effective treatment for at least 2 weeks (at TX initiation), and
- Acid Fast Bacillus (AFB) is demonstrated on initial pulmonary specimens "smear +".

The Program, in cooperation with LPHAs and private clinicians, determine if a person meets criteria of an infectious TB patient.

Persons with infectious TB are required to be isolated to their home or another dwelling as designated by the LPHA. Persons with infectious TB remain isolated until they meet criteria for non-infectiousness.

Determining Isolation Location

The least restrictive form of isolation shall be used when isolating persons diagnosed with, or clinically suspected, of having infectious TB. The steps for isolation in order of least to most restrictive are voluntary self-isolation, home isolation order and facility isolation order.

Isolation to the person's permanent dwelling represents the least restrictive isolation available and is appropriate if the person with infectious TB complies with the written isolation guidelines. Persons already living and/or frequently visiting said dwelling may continue to reside/visit as normal, since transmission of LTBI, if it has occurred at all, has likely already occurred. Patients are most infectious the day before treatment begins and the ability to transmit TB rapidly decreases with effective TB treatment as monitored by DOT.

PROCESS TO ISSUE ISOLATION ORDERS

Voluntary Self-Isolation

In the absence of lab confirmation of infectious TB, the LPHA request persons clinically suspected of having infectious TB to voluntarily self-isolate within their home and not attend school or work. No formal issuance of a legal document is executed in this situation unless the person refuses the request for voluntary self-isolation. If clinical suspicion is high for infectious TB, consideration is given to issuing a *'Notification of Isolation for Infectious Tuberculosis' (*Appendix 8) **even in the absence of lab confirmation.**

Home Isolation Order

For patients who have been diagnosed with or are clinically suspected of having infectious tuberculosis, the Program request the LPHA (where the patient is residing at time of diagnosis) issue a *'Notification of Isolation for Infectious Tuberculosis'* (Appendix 8). The LPHA issuing the notification should ensure the patient understands the scope and purpose of this isolation order. In the event the person receiving the notification does not understand English, a qualified interpreter should be obtained. A signature of the person receiving the notification constitutes agreement/understanding of the voluntary isolation.

Facility Isolation Order

If the LPHA has documented the person's refusal of cooperation with prescribed treatment/isolation for infectious TB, the Program requests the LPHA (where the patient is residing at time of diagnosis) issue a '*Facility Isolation Order'* (Appendix 9). Facility isolation may occur at anytime during treatment. The key variable is the patient's ability to transmit TB and refusal to follow prescribed treatment/isolation requirements.

EMERGENCY ACTION TRIGGERS

LPHAs are to notify the Program immediately if any of the following occur:

- An infectious patient (lab confirmed or clinically suspected) attempts to board commercial transportation or is attempting access to public accommodation (i.e., shelters)
- A person under a *'Facility Isolation Order'* (issued by IDPH or local board of health) attempts or has left the facility
- A person with infectious TB displays flagrant attempt to expose the public to TB
- An infectious person under home isolation order violates the conditions of their order and the recourse is facility isolation

NON-COMPLIANT PATIENTS

The Program requests the LPHA issue a written warning letter documenting factual non-compliance of the patient with the prescribed treatment regimen including missed DOT doses and efforts made by the LPHA to treat the patient. See *'TB warning letter template"* (Appendix 16). Generally speaking, a *'TB warning letter template'* should be issued to the patient before the issuance of a '*Notification of Isolation for Infectious Tuberculosis' (*Appendix 8). However, extenuating circumstances may warrant bypassing this step.

Non-compliance or refusal of treatment while patients are infectious constitutes an immediate public health action to isolate the patient from the public. This may or may not warrant isolation to a facility (jail, hospital, or other designated facility) determined by the LPHA.

Non-compliance or refusal of treatment **after** patients have been deemed to meet criteria for non-infectiousness necessitates a careful overview of the treatment interruption relative to the phase of treatment the interruption occurred (initial vs. continuation). However, patients remain obligated to continue treatment until in the opinion of the attending physician or the state public health medical director and/or epidemiologist, the person's TB is cured or such person is no longer a threat to public health.

DO NOT BOARD ORDERS

A public health 'Do Not Board' (DNB) listing prevents a person with infectious TB from traveling via commercial aircraft. The DNB list, which is enforced through the Department of Homeland Security Transportation Security Administration (TSA), applies to all domestic commercial flights and international commercial flights that are departing from or arriving into the United States. The DNB applies to both U.S. citizens and foreign nationals. Detailed guidance for DNB list is available in Appendix 10. Criteria for DNB lists:

Contagiousness. Public health officials must reasonably believe that the individual is contagious, or likely to become contagious by the time of travel, with a communicable disease of that could constitute a public health threat should the individual be permitted to travel on a public conveyance or travel internationally.

Nonadherent or unaware. Public health officials must reasonably believe that the individual is unaware of, or will be noncompliant with, public health recommendations against travel. Typical evidence to support nonadherence includes disregard of an isolation recommendation or order, noncompliance with treatment, or evidence that the individual has compelling reasons to travel before receiving clearance by public health authorities.

Intent to travel: Public health officials must reasonably believe that the individual will attempt to fly on a commercial aircraft and/or travel across an international land border, as supported by a history of frequent travel, record of ticket purchase, new ticket reservation, or stated intent to travel by commercial aircraft by the individual, a relative, or other credible source.

STEPS FOR IDPH PLACING INDIVIDUAL ON DNB LIST

- LPHAs should direct request for DNB orders to the Program.
- The Program Manager will determine if the individual meets criteria for inclusion in the DNB lists.
- The Program Manager contacts the Bureau Chief and informs of the intent to place an individual on the DNB list.
- The Program Manager notifies the Medical Director of the situation to gain consensus on the decision to place an individual on the DNB list.
- If consensus is reached to place an individual on the DNB list, the Program Manager follows the procedure for requesting a conference call with CDC Chicago Quarantine Station at 773-894-2960 (24-hour access). Alternate number is the CDC Emergency Operations Center at 770-488-7100.

CDC estimates that it takes 9 hours from official request until a person is placed on a DNB.

RELEASE FROM QUARANTINE OR ISOLATION

Patients who are deemed infectious at intake and who have been placed on isolation, require frequent monitoring by sputum collection to determine when they meet criteria for non-infectiousness (see frequency of sputum collection in Chapter 4).

When patients meet criteria for non-infectiousness, the LPHA notifies the patient in writing that the isolation request has been discontinued. This is accomplished by the local health department signature/notation with the date patient met criteria for non-infectiousness on the original '*Notification of Isolation for Patients with Infectious Tuberculosis (TB).'* (Appendix 8*)* Consensus on releasing from isolation/quarantine should be obtained between the Program, LPHA and the treating clinician. If consensus is not reached – see 'Non-Infectiousness Difference of Opinion' section below.

CRITERIA FOR NON-INFECTIOUSNESS

In order to be released from isolation, patients must no longer have infectious TB. This is accomplished by the clinician ruling out TB or the patient meeting criteria for non-infectiousness. Generally, the infectious period is closed when the following criteria are satisfied:

1. **Effective treatment** (as demonstrated by *M. tuberculosis* susceptibility results) for at least 2 weeks using approved 3-4 drug regimen, administered via DOT by health department)
2. **Diminished symptoms** (e.g., improved CXR, cough, fever, fatigue, night sweats); **and**
3. **Mycobacteriologic response** (e.g., decrease in grade of sputum smear positivity detected on sputum-smear microscopy).

The earliest sputa specimens should be collected is at approximately days 13, 14 and 15 of treatment and at least one specimen collected upon waking. To meet criteria for non-infectiousness results do not have to be negative, but must demonstrate improvement. Generally speaking, a series of 1+AFB seen/2+AFB seen or better are needed for release from isolation. Specimens' with 3+ AFB seen and 4+ AFB seen demonstrate high bacterial burden and are not sufficient to demonstrate Mycobacteriologic response and should not be released from isolation.

Hospitals/Nursing Homes/other congregate settings: More stringent criteria are applied to determine the end of the infectious period if particularly susceptible contacts are involved.

Before returning to a congregate living setting (nursing home/hospital/assisted living center etc.) or to any setting in which susceptible persons might be exposed, a patient should be non-infectious by having **at least three** consecutive negative sputum AFB smear results from sputum collected at least 8 hours apart (with one specimen collected during the early morning or upon waking) before being considered noninfectious. Page 7 http://www.cdc.gov/mmwr/pdf/rr/rr5415.pdf

Smear negative and culture pending or positive pulmonary specimens

Patients on isolation (either voluntary or public health order) for whom the suspicion of TB disease remains after the collection of three negative AFB sputum smear results should not be released from isolation until the following criteria are satisfied:

1. On standard multidrug anti-tuberculosis treatment (minimum of 7 days) **and**
2. Are clinically improving.

http://www.cdc.gov/mmwr/pdf/rr/rr5417.pdf

NON-INFECTIOUSNESS DIFFERENCE OF OPINION

At times, the treating clinician will not agree with the Programs assessment that a patient is infectious or has/has not met criteria for non-infectiousness. In these situations the Program/LPHA should consult with the clinician outlining the position from a public health standpoint - citing published CDC/ATS guidelines, review of lab results, and overall clinical picture.

The Program follows these published guidelines and is responsible for ensuring infectious patients do not expose the public. Likewise, this necessitates release from isolation when the patient is no longer infectious. The LPHA and clinician should make every effort to gain consensus on the infectious status of patients. If consensus is not reached, the Program or LPHA's obligation to isolate and subsequently release from isolation supersedes a clinician's determination on a patient's degree of infectiousness. A key component to communicate to the clinician is the distinction between a legal order from the LPHA/IDPH –the Program vs. a medical decision by a clinician.

CHAPTER 6: CONTACT INVESTIGATIONS

GOALS

A contact investigation is the process of identifying, examining, evaluating, and treating all persons who are at risk for infection with TB due to recent exposure to a newly diagnosed case of infectious TB. LPHAs are responsible for identifying persons in need of evaluation. For detailed overview of contact investigations, including testing guidelines, assigning contact priority, evaluation, treatment options, and follow up of specific groups of contacts, refer to: Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis Recommendations from the National Tuberculosis Controllers Association and CDC.

A contact investigation is recommended for the following forms of confirmed TB because they are likely to be infectious:

- Pulmonary, laryngeal, or pleural disease with either pulmonary cavities, or respiratory specimens that have acid-fast bacilli (AFB) on microscopy, or (especially) both.
- Persons with AFB sputum smear negative results are less likely to be infectious but are still capable of infecting others.

The primary goal of a contact investigation is to identify persons who were exposed to an infectious case of TB and ensure that contacts receive these evaluation services:

- Testing for *M. tuberculosis* infection
- Screening for TB disease
- Medical evaluation, if indicated
- Prompt initiation of treatment for latent tuberculosis infection (LTBI) if at high risk for developing TB disease (younger than five years of age or immunocompromised)
- A complete, standard course of treatment, unless medically contraindicated

In addition, the following are secondary goals of a contact investigation:

- Stop transmission of *M. tuberculosis* by identifying persons with previously undetected infectious TB.
- Determine whether a TB outbreak has occurred (in which case, an expanded outbreak investigation should ensue).

DECISION TO INITIATE CONTACT INVESTIGATION

The Program determines if a case meets criteria for investigation. Due to the availability of NAA rapid testing (e.g., MTD, GeneXpert, Accuprobe), investigations are not initiated without a NAA or culture positive test result. Exceptions are possible if rapid testing results are expected to be delayed and high priority contacts including children under the age of five, HIV+, or other high-risk contacts live in the household. In these circumstances, testing should be limited to the immediate household until confirmation of infectious TB has occurred. In the event TB has been ruled out, the results of the investigation are not reportable for purposes of CDC Aggregate Report.

If the case requires an investigation, the Program notifies the LPHA and together they determine individuals who should be evaluated. The Program will assign the case for investigation into IDSS under the 'TB Contacts' tab. The Program is the only entity with the authority to assign cases in IDSS for contact investigation. IDSS automatically notifies the LPHA of the assigned case for investigation when the Program designates the LPHAs responsible for investigation.

ASSIGNED RESPONSIBILITIES FOR CONTACT INVESTIGATIONS

LOCAL PUBLIC HEALTH AGENCIES

LPHAs are responsible for conducting contact investigations in all settings with the exception of health care facilities (HCFs). LPHAs should contact the director of nursing or other appropriate staff of HCFs to inform them of the exposure and provide guidance on conducting the contact investigation.

COVERED PUBLIC HEALTH CHARGES

PPD and /or QFT-GIT/T-spot for designated contacts. Arrangements for these testing materials must be authorized by the Program. In extenuating circumstances, medical evaluation charges for exposed contacts to include medical appointments, lab charges and chest – x-ray. CT scans are not covered. Public health provides medication for the treatment of LTBI and TB disease.

HEALTH CARE FACILITIES (HCFS)

HCFs are responsible for conducting contact investigations in their settings. HCFs are responsible for identifying HCWs, residents and or visitors in need of evaluation.

Covered Public Health Charges

HCFs are responsible for the cost of testing and follow up medical evaluation to include cost of PPD and/or QFT-GIT/T-spot. Use of the state hygienic lab for QFT-GIT and T-Spot is appropriate; however, the cost is not a public health charge.

HCFs typically provide for any follow up medical evaluations related to a positive TB test to include cost of medical evaluation, CXR and subsequent lab monitoring. Public health provides medication for the treatment of LTBI and TB disease.

Important Differences Between LPHAs Contact Investigations vs. HCFs Contact Investigations:

HCFs often test more potentially exposed persons then LPHAS based upon existing (internal) HCF policy. For instance, HCFs may choose to evaluate all HCWs (including all shifts) who worked on the same floor where an infectious TB patient was roomed. Many of these contacts would appropriately be classified as low priority contacts by the LPHAs. However, due to the fact they are HCWs, they are automatically designated as high priority contacts, even if exposure levels are deemed low.

In contrast, LPHAs will evaluate **only** high or medium priority contacts to determine if there is evidence of transmission. If evidence of transmission exits, then LPHAs continues to evaluate contacts until the data (test results) demonstrate no evidence of transmission. As a result, LPHAs typically evaluate far less contacts then HCFs.

COLLEGES/UNIVERSITIES OR SIMILAR INSTITUTIONS

TB Screening: Some institutions, especially those with established student health centers, conduct screening of students for TB risk factors. Students with identified risk factors are tested for LTBI.

Contact Investigations: If the Program determines a TB case meets criteria for a contact investigation, it is the responsibility of the LPHA to conduct contact investigations for exposure to infectious TB. In practice, the LPHA and the college/university will work closely together on the investigation in identifying students and staff in need of evaluation. LPHA determines the direction and extent of the contact investigation.

TIMELINES

Consultation with the LPHN or designee investigating the case is initiated within one business day of determination that a patient has infectious TB. Classification of contacts into High, Medium, or Low Priority is determined in accordance with current guidelines. See Classification of Contacts: Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis Recommendations from the National Tuberculosis Controllers Association and CDC.

Type of Contact	Business days from listing of a contact to initial encounter	Business days from listing of a contact to completion of medical evaluation
High-priority contacts	7	5
Medium-priority contacts	7	10
Low-priority contacts	14	10

CONTACT INVESTIGATIONS REPORTING REQUIREMENTS

The Iowa Administrative Code requires (641—1.7(135,139A)) (Appendix 1) LPHAs to report the results of public health investigations to the Department, however, it does not designate by which means this should be accomplished. Department preference is for LPHAs to manage and report results of investigations into IDSS TB Contacts. In cases where the LPHAs choose not to use IDSS for reporting purposes, the LPHA submits complete test results for those individuals determined to have exposure to infectious TB. The Program enters this data into IDSS for purpose of aggregate reporting to CDC.

RELEVANT ASPECTS OF CONTACT INVESTIGATIONS

COMPONENTS OF MEDICAL EVALUATION FOR EXPOSED CONTACTS

All identified contacts should be evaluated with TB skin test or Interferon Gama Release Assay (IGRA). The Programs recommendation is for LPHAs to use IGRAs to avoid the high rate of false positive test results associated with the TB skin test. There is no charge to the LPHA or the patient for this testing; it is paid for by the Program through an agreement with the State Hygienic Lab (SHL). LPHAs must contact SHL directly to arrange for blood collection kits, incubation procedures and courier transport of specimens.

The LPHAs should give priority to evaluating and testing all identified contacts during the first, and if necessary, second rounds of investigation. Contacts with a positive TST or IGRA require a medical evaluation including a chest X-ray to rule out active TB disease. Contacts requiring medical evaluation with no or limited ability to pay are eligible for medical evaluation funding. The Program will initiate a memorandum of understanding (MOU) with the LPHA to provide this funding. Details of the MOU are as follows:

Reimbursement for Medical Evaluations

- Cap Rate: $300 per case
- Provide funds for barrier free TB medical services to high-risk groups who meet the Medicaid Title 19 criteria with no means of payment
- Services include payment for office visits, chest x-rays, and lab work-up
- Reimbursements rates for specific services should be at the local T19 rate and negotiated by the LPHA and the service provider.

TREATMENT OF INFECTED CONTACTS

Identification and subsequent treatment of contacts with LTBI is a national objective for TB programs. As such, the Program strongly recommends the use of twice weekly DOT for all identified contacts with LTBI discovered as a result of the contact investigation. The Program is required to report on treatment initiation and treatment completion for this sub-set of contacts in the annual CDC Aggregate Report.

SITE VISITS

Failure to visit potential sites of transmission, such as patient's home, school, workplace, and frequent social sites (church, bar, etc.) has contributed to previous TB outbreaks. It is important that the LPHN or designee visit the relevant potential sites of transmission to make informed decisions regarding contact management.

It is imperative that public health officials, working closely with appropriate personnel of entities where possible exposure to infectious TB occurred, determines those in need of evaluation, **not** personnel

of said entities. Exposure to infectious TB in certain situations (schools, daycare, corrections, etc.) often results in officials of those entities demanding LPHAs test all/other selected persons for testing. LPHAs should consult with the Program on each investigation, especially those involving work and/or school site investigations.

Contact investigations in work site investigations may result in media attention. Companies often request the Program develop a news release for distribution to employees and/or the media. See SOP folder (Attachment 15). No identifying information may be released concerning the patient or the facility where suspected exposure has occurred.

TIMELINES

The Program Manager will assign cases into IDSS within two business days of determination that a case meets criteria for investigation. The Program Manager will monitor each investigation for the evaluation, treatment, and follow-up of identified contacts and will contact LPHAs that have not completed necessary fields to facilitate proper documentation of the contact investigation. Additional timelines for Program Manager to contact LPHN or designee for common identified issues:

- No contacts entered: 14 business days after interview
- No 1st round test results entered/incomplete information: 14 business days after testing
- No 2nd round test results entered/incomplete information: 14 business days after testing
- Treatment completion not recorded for contacts who started treatment: 30 business days after scheduled treatment completion

CHAPTER 7: DISCHARGE PROCEDURE

LTBI

Treatment for LTBI is not reportable or mandatory. As such, after the prescription is sent out to the LPHA, the Program does not actively monitor the treatment for the patient. The LPHA should distribute medication one month at a time and monitor for adherence and adverse reactions to medication on a monthly basis using the LTBI Monitoring Form (Appendix 19) (or a similar local form). The LPHA may inform the Program of patient adherence/complications, of which the Program documents in TB Meds program.

Once a patient has completed LTBI treatment or is determined to be lost to follow-up or non-compliant. The LPHA should notify the nurse clinician with the following information:

- Patient's name
- DOB
- Patient ID# (at the top left of the Patient Report)
- Date completed meds, or
- Reason medications not completed.

SUSPECTED/CONFIRMED TB DISEASE

If suspected TB disease cases are ruled out there is no formal discharge procedure; however, the Program Manager determines if the case should be reported to CDC for purposes of establishing program burden. In general, if a drug regimen was initiated or a MTD/GeneXpert or Accuprobe was ordered, consideration should be given to reporting as a suspected/ruled out case of TB.

Reported cases are discharged from the Program when treatment is completed to cure. Cases with incomplete treatment are evaluated individually as to why therapy was stopped and the appropriate-defined variable '*Reason Therapy Stopped'* is documented in IDSS. If warranted, possible legal intervention by the LPHA and/or the Program should be considered for pulmonary/laryngeal TB cases that do not complete treatment. Patients with untreated or incomplete treatment for extrapulmonary TB are at risk for developing infectious TB, especially those with weakened immune systems (e.g., HIV+, other medical conditions).

CHAPTER 8: COHORT REVIEWS

Cohort reviews are a systematic review of the management of patients with TB disease and their contacts. A 'cohort' is a group of cases counted over a specific period of time. Emphasis is placed on the patient's clinical status, adequacy of treatment regimen, treatment adherence or completion, and the results of contact investigation.

Frequency: Cohort cases are reviewed approximately six to nine months after treatment initiation, thus, many of the cohort cases have completed or are near treatment completion. The Program will select cases for review and arrange for systemic review twice a year.

Personnel: Involved personnel shall include the Program Manager and Nurse Consultant , TB Medical Consultant (Dr. Hornick), State Medical Director or designee, the LPHN or designee handling the case, and if possible, the treating clinician.

Reporting Requirements: Includes a summation of the date cohort review occurred, the number/type of cases reviewed, and aggregate report of selected performance objectives for the cohort will be submitted to CDC following the review.

CHAPTER 9: REFUGEE HEALTH

The Refugee Health Program is a separate and distinct program from the TB Control Program. However, a significant proportion of refugees receive a Class A or B TB designation, thus, there is significant overlap between the two programs. The Refugee Health Specialist has been assigned the duty to monitor and track all refugees and immigrants who receive a Class A or B TB designation. Immigrants and refugees are both political classifications and assigned by the U.S. Department of State. The Refugee Health Program does not track immigrants unless they have received a Class A or B designation. In doing so, the Refugee Health Specialist is performing these duties in cooperation with the TB Control Program and with oversight by the TB Program Manager.

CLASS A OR B NOTIFICATIONS

Domestic follow-up evaluation of immigrants and refugees with Class A, B1 and B2 TB page 21 of Technical Instructions for Tuberculosis Screening. Notification status is deemed a high priority by the Program. The Refugee Health Specialist is responsible for daily monitoring and receiving of notifications from the Electronic Disease Notification system (EDN). Newly arrived refugees and immigrants with Class A or B TB will receive thorough and timely TB evaluations and appropriate treatment to ensure prompt detection of TB disease and prevention of future cases.

All Class B designees are to receive an evaluation within 90 days of arrival to Iowa. The Refugee Health Specialist works directly with the Program, resettlement agencies and LPHAs to accomplish this goal.

Click here for detailed overview of the domestic refugee health screening programs, differences between political designations of immigrants and refugees and current medical screening recommendations. See 'Technical Instructions for Tuberculosis Screening and Treatment' for detailed overview of CDC overseas TB screening program for refugees and immigrants.

CLASS A OR B PROCEDURE

Review EDN daily for new notifications.

- Class A or B: Print/fax all medical records including '*TB Follow-Up Worksheet'* (Appendix 11) *and* '*TB Follow-Up Recommendations'* (Appendix 12) to LPHA.
- Record data into the Class B TB Tracking System.
- LPHAs return follow-up information to the Program. Relevant information is recorded in the EDN system and submitted to Division of Global Migration and Quarantine (DGMQ).
- Dual entry in the 'Class B TB Tracking System' completes the data entry.
- Follow-up on incomplete or non-returned TB Follow-up Worksheets is done by the Refugee Health Specialist.

REFUGEE HEALTH INTAKE PROCEDURE

- Review EDN daily for new notifications.
- All refugees, with or without a Class B designation, are tracked in the Refugee Health System.
- The resettlement agency assigned to a particular refugee is notified of EDN notification. Verification of EDN records with resettlement agency records occurs monthly to ensure accounting of all refugees in Iowa.
- Working in cooperation with the appropriate resettlement agency, all refugees should receive a domestic health screening utilizing the '*Iowa Refugee Health Assessment*' form (Appendix 13).
- No electronic re-submission of completed Iowa refugee health assessments are requested by DGMQ; however, aggregate analysis of this objective is reportable in the annual progress report.
- Clinics currently are not required to return health assessments, however it is recommended. The Refugee Health Specialist makes contact with clinics that do not return assessments to ascertain if assessments can be submitted to the Program for data collection purposes.

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Appendix 1: *TB Citations in Iowa Administrative Code 641*

Appendix 2: *TB Suspect/Active Patient Intake Form*

Appendix 3: *Available on the Health Alert Network (HAN) in the TB Folder*

Appendix 4: *Available on the Health Alert Network (HAN) in the TB Folder*

Appendix 5: *Available on the Health Alert Network (HAN) in the TB Folder*

Appendix 6: *DOT Tracking Log*

Appendix 7: *Available on the Health Alert Network (HAN) in the TB Folder*

Appendix 8: *Available on the Health Alert Network (HAN) in the TB Folder*

Appendix 9: *Available on the Health Alert Network (HAN) in the TB Folder*

Appendix 10: *Available on the Health Alert Network (HAN) in the TB Folder*

Appendix 11: *Refugee Health Program TB Follow-Up Worksheet*

Appendix 12: *Refugee Health Program TB Follow-Up Recommendations*

Appendix 13: *Refugee Health Program Assessment Form*

Appendix 15: *Available on the Health Alert Network (HAN) in the TB Folder*

Appendix 16: *Available on the Health Alert Network (HAN) in the TB Folder*

Appendix 17 *Iowa Code 135.38 and 137.21*

Appendix 18 *Patient Information Sheet for LTBI*

Appendix 19 *LTBI Monitoring Form*