TUBERCULOSIS (TB) Protocol

1. Cause/Epidemiology

Tuberculosis (TB) is an infectious disease caused by the bacteria, *Mycobacterium tuberculosis* (MTB). Worldwide, more people die of TB than of any other infectious disease, including malaria and acquired immune deficiency syndrome (AIDS). TB has increased incidence in developing countries. In Manitoba, the disease burden isn't distributed equally with disparities pronounced in certain population groups and geographic regions; foreign-born individuals and Indigenous peoples in particular are disproportionately affected by TB. While the greatest number of cases in Canada is reported among foreign-born individuals, the reported incidence rate has consistently been highest among Canadian-born Indigenous individuals over the past decade.

Groups at higher risk of developing active TB disease include:

- People living with individuals diagnosed with active tuberculosis
- People who previously had active tuberculosis
- People born or previously residing in countries with a high TB incidence in Asia, Eastern Europe, Africa and Latin America,
- Staff and residents of homeless shelters
- Urban poor
- Injection drug users
- Indigenous Canadians residing in communities with high TB rates
- Elderly persons
- People infected with HIV/AIDS
- People with:
  - transplantation (related to immune-suppressant therapy)
  - silicosis
  - chronic renal failure requiring hemodialysis
  - carcinoma of head and neck
  - recent TB disease (less than 2 years)
  - abnormal chest x-ray – fibronodular disease
- Immunocompromised patients, residents, clients (P/R/C) (e.g., HIV, diabetes, alcoholism, end stage renal disease, P/R/C on immunosuppressive therapy)
- Staff and inmates of correctional facilities and previously incarcerated people
- Healthcare workers serving at-risk groups.

Key Infection Prevention and Control strategies to prevent the transmission of TB within healthcare facilities include:

- Early identification of infectious cases
- Isolation of infectious cases and use of appropriate Infection Prevention and Control Precautions
- Prompt initiation of appropriate therapy
- Investigation of source case, including pediatrics, for possible undiagnosed cases of active TB disease or newly infected persons.

2. Clinical Presentation

TB may present as either an infection or as a disease. TB disease most commonly presents as a respiratory infection; it can also present in any system of the body. Signs and symptoms depend on the site of the disease. TB can also be multi-drug resistant (where there is resistance to Isoniazid [INH] and/or Rifampin), or extensive drug resistant (where there is resistance to INH, Rifampin, and at least one of the three injectable second-line drugs [e.g., Amikacin]).

The presence of any of the following signs/symptoms should prompt rapid consideration of active TB disease:

- Cough > 3 weeks
- Unexplained weight loss
- Night sweats
- Bloody sputum/hemoptysis
- Unexplained loss of appetite
- Hoarseness
- Fever
- Fatigue
- Chest pain.

2.1. **TB Infection** (TBI) *(formerly Latent TB Infection)*

People with TBI are asymptomatic, **cannot spread TB to other people** (i.e., are not infectious), and usually have a normal chest x-ray.

People who have TBI have been "infected" with TB and may have a positive tuberculin skin test. Approximately 10% of non-immunocompromised individuals with TBI will progress to active TB disease if untreated.

There are two tests for identification of TBI: the Tuberculin Skin Test (TST) and the Interferon gamma release assay (IGRA). Both tests evaluate cell-mediated immunity, and neither test can distinguish between TBI and active TB disease. The TST consists of the intradermal injection of a small amount of purified protein derivative (PPD) from *M. tuberculosis* bacteria. In a person who has cell-mediated immunity to these tuberculin antigens, a reaction will occur within 48 to 72 hours. The reaction will cause localized swelling and will be manifest as induration of the skin at the injection site.

Due to the decreasing utility of TST to diagnose TBI after age 65 and the increasing risk of adverse effects from TBI treatment in this age group, screening with only a posterior-anterior and lateral chest x-ray for active TB is preferred upon admission for residents born in Canada prior to 1955, Indigenous persons, and people born in or previously residing in countries with high TB incidence.

> The tuberculin skin test (TST) is performed to **diagnose latent TB infection (TBI)**. It is **not** a diagnostic tool for **active TB disease** in adults.

2.2. Active TB Disease

Active TB disease is most commonly seen as:

- Respiratory
- Laryngeal
- Non-respiratory
- Disseminated/Miliary
- Meningeal
- Peripheral TB Lymphadenitis.

Active TB disease is potentially infectious, depending on the site of disease (e.g., respiratory and laryngeal are more infectious), the amount of anti-tuberculosis treatment received (e.g., fewer doses and ineffective treatment).To ensure the right drugs are being given MTB sensitivities must be considered as soon as available. Resistant strains are no more transmissible than non-resistant strains provided the right drugs are being given.
There is a significantly greater risk of developing active TB disease when there is co-infection of HIV and MTB, as these P/R/Cs have impaired immunity.

3. Incubation Period and Period of Communicability

The incubation period for infection (TBI) is 3 to 8 weeks after exposure to develop cell mediated immunity. The risk of progression to active TB disease is greatest within the first two years after infection. TB infection may exist for an individual's lifetime as an asymptomatic infection (TBI).

Active infectious TB disease occurs when live tubercle bacilli are dispersed in sputum or aerosolized fluid. Untreated or inadequately treated persons may be infectious for a prolonged period of time. In general, non-respiratory active TB disease is not communicable, unless fluid from the site is aerosolized.

A number of variables influence the length of time an individual remains infectious:

- Initial level of infectivity
- Level of the P/R/C's immune response
- Duration and efficacy of, and adherence to, TB therapy.

4. Transmission

Mycobacterium tuberculosis (MTB) is carried in microscopic airborne particles that settle slowly and may remain suspended in the air for hours, particularly in locations without proper negative pressure ventilation. These particles are dispersed when a person with active infectious TB disease (respiratory/laryngeal) sneezes, coughs, speaks, shouts, or sings.

MTB is communicable mainly by the aerosol route. Droplet nuclei are created by forceful expiratory efforts, such as coughing, sneezing, singing, playing wind instruments and even speaking. The numbers of droplet nuclei can be greatly reduced by wearing a procedure or surgical mask, or covering the mouth and nose during coughing/sneezing.

Certain procedures, e.g., bronchoscopy, sputum induction, specimen processing, autopsy, and even irrigation or other manipulation of non-respiratory tuberculous abscesses, may also produce infectious aerosols.

Bacteria lodged on fomites (e.g., linen, furniture, books, floors) do not constitute a significant source of infection; most die quickly through the action of drying, heat or sunlight.

Because of the highly variable latency period of *M. tuberculosis* infection, it is difficult to precisely document transmission. People with positive TST and/or IGRA results found during contact investigation may have been infected in the past (remotely) rather than by the recent source case of concern.

Acquisition of *M. tuberculosis* is most likely to result from exposure to persons who have:

- Unsuspected/undiagnosed active infectious TB disease and are not receiving anti-TB therapy/are not appropriately isolated
- Diagnosed active infectious TB disease and are receiving inadequate therapy, or
- Diagnosed active infectious TB disease and are early in the course of effective therapy.

5. Infection Prevention & Control Practices

5.1. Assessment for Tuberculosis

5.1.1. P/R/Cs who have sputum that is Acid Fast Bacilli (AFB) smear positive and MTB culture positive have active infectious TB disease. A P/R/C, who has AFB smear positive sputum that is 3+ or 4+, with or without cavitating chest lesions, and is coughing, is the most infectious.

P/R/Cs with active TB disease whose sputum is AFB smear negative and MTB culture positive are also infectious, with increased risk if a cough is present.

5.1.2. The chest radiograph is one of the first steps in the evaluation of an individual with respiratory symptoms who is suspected of having active infectious TB disease. A P/R/C with highly suspicious clinical findings and chest radiograph results suggestive of active TB disease with negative AFB smear results bears careful consideration of their infectivity. These P/R/C must be assessed on a case-by-case basis. Approximately 10% of cases of active respiratory TB disease may have normal chest x-rays.

5.1.3. A clinically-confirmed case of TB is one in which there is absence of a positive culture or positive direct PCR, and a physician or TB

expert has indicated TB disease is likely present and decide to give the P/R/C a full course of TB treatment; based on one or more of the following:

- Common signs and symptoms of respiratory TB, which include cough of at least three weeks' duration. This cough is initially dry but after several weeks to months will become productive.
- Fever and night sweats are common but may be absent in the very young and elderly.
- Hemoptysis, anorexia, weight loss, chest pain (pleuritic pain) and other symptoms are generally manifestations of more advanced disease.
- Chest radiographic changes compatible with active TB disease (e.g., pulmonary infiltrates, volume loss due to destruction of the lung tissue and cavitation in the upper segments of the lung lobes). These are classic triad findings, mainly seen in non-immunocompromised adults.
- Favorable response to a therapeutic trial of anti-TB drugs [8.17]

Maintain a high index of suspicion for active TB disease and rapidly implement Airborne Precautions to minimize TB transmission

5.2. Implementation of Airborne Precautions

Place patients on Airborne Precautions until deemed non-infectious if:

- ✓ Low index of suspicion for active infectious TB disease
- ✓ Suspected/Confirmed active infectious TB disease
- ✓ Suspected/Confirmed active non-respiratory TB disease (until active infectious TB is ruled out)
- ✓ Clinically Confirmed Case

Implement Airborne Precautions immediately upon suspicion of active infectious TB disease. A high index of suspicion for active infectious TB disease and rapid implementation of Airborne Precautions are essential to minimizing transmission.
Refer to Airborne Precautions in the Additional Precautions from the IP&C Manual.
Refer to the Clinical Presentation/Microorganism/Infectious Disease Table for specific disease/microorganism information.

Notify **site/program infection control professional/designate** of:

- Any patient placed on Airborne Precautions for investigation of possible active infectious TB disease
- Any patient admitted for investigation of active infectious TB disease
- Any patient admitted for treatment of active infectious TB disease
- Possible discontinuation of Airborne Precautions related to MTB.

The site/area ICP reports cases where isolation is breeched to the Tuberculosis Infection Control Professional (TB ICP). The TB ICP will send notification of all new cases that requires contact investigation to Occupational and Environment Safety and Health and to Population Public Health Tuberculosis unit.

5.3. Discontinuation of Airborne Precautions

Airborne Precautions may only be discontinued by the Attending Physician and/or Infection Prevention and Control.

5.3.1. When there is a **Low Index of Suspicion**, Airborne Precautions may be discontinued when ALL of the following criteria are met:

- There are no findings on the patient's chest radiograph indicating active infectious TB disease
- There are three negative AFB sputum smear results, where the specimens were collected at least 1 hour apart, and
- An alternative diagnosis has been made by a physician with expertise in TB diagnosis AND has concluded it is unlikely the patient has active infectious TB disease.

5.3.2 When there is **Suspected or Confirmed Active smear-negative**, culture-pending, culture-positive drug-susceptible respiratory TB on admission to a facility. Airborne Precautions may be discontinued when ALL of the following criteria are met:

- Evidence of clinical improvement
- The patient had a minimum of 14 days of anti-tuberculosis treatment using 4 drugs
- The prescribed medication regimen was appropriate*
- There is evidence of adherence to the treatment regimen.

5.3.3 When there is **Suspected or Confirmed Active Infectious TB Disease**, with AFB sputum smear positive **(1+ or 2+)** on admission to facility, Airborne Precautions may be discontinued when ALL of the following criteria are met:

- Three AFB sputum smear negative specimens have been obtained in the early morning on Days12, 13 and 14 of anti-tuberculosis medication treatment. [8.7] Specimens can be collected within 1 hour of each other on the same day, with at least one of the specimens taken in the early morning.
- The patient has had a minimum of 14 days of anti-tuberculosis treatment using 4 drugs
- There is evidence of clinical improvement
- The prescribed medication regimen was appropriate*
- There is evidence of adherence to the treatment regimen.

5.3.4 When there is **Suspected or Confirmed Active Infectious TB Disease**, with AFB sputum smear positive **(3+ or 4+)** on admission

to facility, Airborne Precautions may be discontinued when ALL of the following criteria are met:

- Three AFB sputum smear negative specimens have been obtained in the early morning on Days 19, 20, 21 of anti-tuberculosis treatment. [8.7] Specimens can be collected within 1 hour of each other on the same day, with at least one of the specimens taken in the early morning.
- The patient has had a minimum of 21 days of anti-tuberculosis treatment using 4 drugs
- There is evidence of clinical improvement
- The prescribed medication regimen was appropriate*
- There is evidence of adherence to the treatment regimen.

***The prescribed medication regimen is considered appropriate when it includes at least 4 effective drugs (as recommended by the Canadian TB Standards) and the drug susceptibility tests have determined the treatment is the appropriate regimen, or in the event drug susceptibility tests are not yet available, the risk of drug resistance is considered to be very low.

5.3.5 When there is **Suspected or Confirmed Active Infectious TB Disease in Prepubertal Children,** smear-negative, culture-pending, culture-positive drug-susceptible respiratory TB on admission to a facility. Airborne Precautions may be discontinued when ALL of the following criteria are met:

- Evidence of clinical improvement
- The patient had a minimum of 5 days of anti-tuberculosis treatment using 4 drugs
- The prescribed medication regimen was appropriate*
- There is evidence of adherence to the treatment regimen.
- The patient can be transported home, no mask needed. [8.12]

5.3.6 When there is **Suspected or Confirmed Active Infectious TB Disease in Prepubertal Children** with AFB sputum smear positive **(1+ to 4+)** on admission to facility, Airborne Precautions may be discontinued when ALL of the following criteria are met:

- Three AFB sputum smear negative specimens have been obtained in the early morning on Days19, 20 and 21 of anti-tuberculosis medication treatment. [8.12] Specimens can be collected within 1 hour of each other on the same day, with at least one of the specimens taken in the early morning.
- The patient has had a minimum of 21 days of anti-tuberculosis treatment using 4 drugs
- There is evidence of clinical improvement
- The prescribed medication regimen was appropriate*
- There is evidence of adherence to the treatment regimen.

- The patient can be transported home without wearing a mask [8.12]

Note: If **ANY** of the follow up sputum specimens is AFB smear positive the patient is to remain on Airborne Precautions. Do not collect further specimens until the patient has received an additional seven days of anti-tuberculosis treatment. Following an additional seven days of anti-tuberculosis treatment, collect sputum specimens from the patient on Days 7, 8, and 9 of the additional week. This sequence is repeated until there are three consecutive AFB sputum smear negative specimens. In patients who are no longer able to spontaneously produce a sputum specimen, sputum induction is useful and appropriate.

Patients with MDR-TB or XDR-TB remain on Airborne Precautions through their entire hospitalization, or until three negative sputum CULTURES have been obtained.

5.3.7 When there is **Suspected or Confirmed Active Non-Respiratory TB Disease**, Airborne Precautions may be discontinued when:

- Active infectious TB disease has been excluded AND
- There are no open lesions/abscess within the oral cavity
- The affected site has no drains in situ
- There is no risk of aerosolization of drainage from lesions/abscess or affected site.

5.4. Cohorting

Cohorting of patients with or suspected of active infectious TB disease is not recommended in healthcare settings, and does not meet the Canadian standard of care expected in healthcare settings.

If in exceptional circumstances, hospitals choose to cohort patients with or suspected of active infectious TB disease, the potential for organism transmission between these patients should be minimized. Issues of infectivity and the consequences of possible transmission should be considered (as outlined below) in consultation with Infection Prevention and Control. Patients with drug resistant (e.g., MDR, XDR) strains of active infectious TB disease cannot be cohorted under any circumstances.

Consultation with the TB ICP/designate, and/or the Infectious Disease specialist on duty must occur whenever cohorting of patients with or suspected of active infectious TB disease is being considered.

The following patients must never be cohorted with patients with or suspected of active infectious TB disease, or with whom procedures are performed where irrigation of MTB is likely (e.g., wound irrigation)

- Patients with non-respiratory TB

- Patients without a clear diagnosis of active infectious TB disease, e.g., patients who are sputum AFB smear-positive with a high index of suspicion of having an atypical mycobacterial infection.

5.5. Code Blue

Unit staff to inform Code Team of patient's status and provide N95 respirators.

5.6. Suspect and Case Management for Procedures

5.6.1. Contact IP&C

- For further information on management of patients with Suspect TB please contact your site ICP
- Further information can be found in specific sections of this manual.

5.6.2. Communication

- Booking physician shall indicate patient TB status on booking form.

5.6.3. Additional Precautions & PPE

5.6.3.1. Additional Precautions

- Airborne Precautions required until deemed non-infectious
- Post sign on door/bed space.

5.6.3.2. Personal Protective Equipment

- All those entering the room are required to wear a N95 respirator.

5.6.4. Patient Accommodations

5.6.4.1. Patient Registration

- Instruct patient who self-identifies they are a TB suspect to wear a medical mask until appropriate room placement is established.

5.6.4.2. Pre-op

- Patient to wear a medical mask while in pre-op waiting area.

5.6.4.3. Intra-Operative

- Perfomr procedure under **Airborne Precautions**
- Keep doors to OR and/or bronchoscopy suite will be kept closed
- Keep doors closed for one hour post procedure (to allow for adequate air exchanges unless air exchanges are known and a shorter time period will allow for appropriate air exchanges).

5.6.4.4. Post-Operative

- Recovery will be done under **Airborne Precautions**

- Place patient in an AIIR
- If AIIR not available, place patient in a single room or procedure room
- Door shall remain closed
- If patient can tolerate a procedure or surgical mask, they can be recovered in the recovery area.

5.6.4.5. Patient Transport

- Staff performs hand hygiene and wears a N95 respirator.

5.6.4.6. Housekeeping

- Door to room is to remain closed following patient discharge or Airborne Precautions are discontinued:
  - **When air exchanges are known** (recorded in the last year) the door will remain closed until (ideally) 99.9% or (minimally) 99% of airborne microorganisms are removed from the room. (This will be determined using Airborne Precautions - Appendix C: Air Exchanges Needed to Remove Airborne Microorganisms).
  - **When air exchanges are *not* known** door will remain closed until three hours after the patient is discharged or Airborne Precautions are discontinued.
- Staff should write on Additional Precautions sign posted "Airborne Precautions until XX:XX am/pm" to inform team when room is safe to enter without N95 respirator
- Staff entering room to perform isolation discharge cleaning (i.e., terminal clean) before time has elapsed may do so provided they wear a N95 respirator.

5.7. Discharge/Transfer between Facilities

- Unit informs receiving facility of patient's status in advance, and documents same on Transfer/Referral Form
- Unit notifies Transport Services Airborne Precautions are required
- Patient performs hand hygiene prior to transfer; wears procedure or surgical mask
- Staff wears an N95 respirator during transport.

5.8. Post Mortem/Autopsy

- Airborne Precautions required.

5.9. Transport within Facility

- Transport patient out of room for medically essential purposes only
- Healthcare worker performs hand hygiene and applies an N95 respirator

- Patient performs hand hygiene prior to transfer; wears procedure or surgical mask.

6. Specimen Collection

A variety of specimens may be submitted to assess for the presence of MTB, including spontaneous sputum, induced sputum, bronchoscopy, gastric aspirate, urine, blood/body fluids, and biopsy.

It is important to obtain the appropriate specimens as soon as possible, once appropriate precautions have been implemented. When collecting specimens for suspected or active TB, **specimens must be collected utilizing Airborne Precautions regardless of age**.

If possible, collect diagnostic specimens before anti-tuberculosis treatment has been initiated. If the P/R/C has already started treatment, indicate this on the Clinical Microbiology Requisition.

Collect specimens in sterile leak-proof containers. The requisition must accompany the specimen and indicate:

- Specimen number (e.g., sputum #1)
- Specimen type (e.g., spontaneous)
- Site of collection (e.g., sputum), and if
- The specimen is a diagnostic or follow-up specimen
- Additionally, all standard information must be indicated on the requisition: P/R/C name (first and last), P/R/C's PHIN, test(s) requested and any relevant clinical information.

Specimen results must be evaluated in conjunction with all available P/R/C **data.**

For **diagnostic purposes** a **minimum of three separate specimens** (any combination of: induced sputum, spontaneous sputum, bronchoscopy, post bronchoscopy sputum, or gastric aspirate) must be obtained **at least 1 hour apart.**

Sputum collection for all suspected or confirmed case of TB should be performed in an AIIR, regardless of risk level.

6.1. Spontaneous Sputum

- Should be collected in the early morning, when the patient first awakens
- Should contain a minimum of 5-10mL of material
- Is delivered to the lab immediately to prevent bacterial overgrowth. If this is not possible, place the specimen in the specimen fridge
- May be collected a minimum of **one hour apart for diagnostic purposes**, with one obtained in the early morning

6.2. Induced Sputum (usually performed by Respiratory Therapists)

- Maintain patients in Airborne Precautions until most of the coughing has ceased (usually 20 – 30 minutes post saline administration)
- Patients are not required to have 'nothing by mouth' (NPO) prior to this procedure. The principles are as follows:

The patient should be in an AIIR with the door closed.
Cover mouth with tissue when coughing, except to expectorate into the specimen container.

6.3. Bronchoscopy

Bronchoscopy may be used to obtain respiratory specimens when patients are unable to spontaneously produce reliable sputum or induced sputum is not possible.

When performing bronchoscopy, additional specimens must be collected.
A single negative AFB smear from a bronchoscopy does not definitively exclude active respiratory TB disease.
See principles applied before, during and after bronchoscopy in section 5.6.4.

6.4. Gastric Aspirate

This technique may be used to collect a specimen in patients who cannot expectorate sputum, but can swallow. Gastric aspirates are known to be low yielding specimens, and though widely used in children, should only be used in adults when there are no other viable options.

- Must be performed immediately upon the patient awakening from a long sleep, at least six hours after ingestion of food or liquid, and before the stomach has emptied
- Three early morning specimens on consecutive days are required
- The specimen cannot wait for processing for more than four hours
- The specimen must arrive at the lab within one hour of collection.

6.5. Urine

Three consecutive early morning (first voiding) specimens (40mL) are required.
Collect samples using the mid-stream urine technique. 24 hour urine collections are not suitable for culture due to overgrowth of organisms.

6.6. Body Fluids

Most normally sterile body fluids (e.g., cerebrospinal, pleural, peritoneal, pericardial) contain only small numbers of mycobacteria, even in patients with symptomatic disease. Collect as much fluid as possible to increase the likelihood of detection and decrease the possibility of having to recollect the specimens. Deliver specimens to the lab as soon as possible after collection.

6.7. Biopsies

Biopsy of infected tissue is often the most sensitive diagnostic procedure in non-respiratory TB disease.

Do not place specimens for MTB examination in formalin. Place biopsy tissue in a dry, sterile container without saline (or with less than 5mL of saline).

6.8. Microbiological Testing and Interpreting Results

Mycobacteria are referred to as acid fast bacilli. The term acid fast comes from the special staining techniques (fluorochrome and carbol fuchsin) used in laboratories. The specimen is stained and washed with an alcohol-acid solution. Due to the unique chemical properties of mycobacteria, the original stain is retained by the organism, hence the term acid fast.

Success of identifying mycobacteria in the laboratory depends on several factors:

- Quality of the specimen (deep cough versus saliva)
- Handling and transport of the specimen to the laboratory
- Laboratory experience working with mycobacteria.

6.8.1. Smear (Microscopic Examination)

A positive AFB smear indicates mycobacteria, but not necessarily *Mycobacteria tuberculosis (MTB)*,as other mycobacteria are also acid fast. Additional tests must be done to differentiate MTB from other non-tuberculosis mycobacteria. Microscopic examination may fail to identify between 20 – 80% of P/R/C s who have MTB disease.

The microbiology report reflects the number of AFB seen on examination of the stained smear. The more organisms seen the higher the number on the report and the more infectious the P/R/C. For instance, a specimen with 4+ is more infectious than 1+.

Depending on the presence or absence of AFB on microscopic examination, 2 additional tests may be performed.

6.8.2. Culture

Culturing mycobacteria is the most reliable method to identify P/R/Cs with MTB disease; all specimens are sent for culturing.

Detection of positive cultures can vary from 11 – 21 days or longer, depending on the organism load.

Respiratory specimen cultures (e.g., sputum, bronchoscopy) are observed for 7 weeks before reported as negative for mycobacteria. Fluid and tissue specimen cultures (e.g., lungs, pleural fluid) are observed for 8 weeks, skin specimens are held for 8 weeks unless *M. ulcerans* is suspected, in which case, cultures are held for 12 weeks.

Antimicrobial susceptibility testing is performed on all *M. tuberculosis* cultures.

6.8.3. Nucleic Acid Amplification Tests (NAAT)

If AFB is detected on microscopic examination of a respiratory specimen, NAAT, such as Polymerase Chain Reaction (PCR) is performed. These results are available in 24 – 48 hours. NAAT may be performed on other specimens (consultation with the TB laboratory is recommended).

At least one respiratory sample should be tested with a Health Canada approved or validated in-house NAAT in all new, smear-positive cases. In addition, NAA testing may be performed in smear-negative P/R/Cs upon request by the physician or the TB control program. NAAT results are not recommended for monitoring TB treatment response. [8.3] AFB smears and culture results remain the gold standard of testing; however, the organism may take weeks to grow. Positive NAAT results can be used to support treatment and isolation decisions.

6.8.4. Non-Tuberculosis Mycobacteria

Mycobacterium other than *M. tuberculosis* may produce disease in humans and is usually non-infectious from person to person; therefore these types do not require Airborne Precautions.

These organisms are acid-fast bacilli like *M tuberculosis* but are described as atypical, unclassified mycobacteria, non-tuberculosis mycobacteria (NTM) or mycobacteria other than tuberculosis (MOTT).

6.8.5. Clinical syndromes

Clinical syndromes associated with the pathogenic species of mycobacteria include the following:

- Disseminated disease in the presence of severe immunodeficiency such as AIDS: *M. avium complex, M. kansasii, M. haemophillum, M. chelonae*
- Pulmonary disease resembling tuberculosis: *M. kansasii, M. avium complex, M. abscessus, M. xenopi, M. simiae*
- Lymphadenitis (primarily cervical): *M. avium complex, M.scrofulaceum, M. kansasii*
- Skin ulcers: *M. ulcerans*
- Post traumatic wound infections: *M. fortuitum, M. chelonae, M. abscessus, M. marinum, M. avium* complex
- Nosocomial disease: surgical wound infections (following cardiac surgery, mammoplasty wounds), catheter-related infection bacteraemia, peritonitis, post-injection abscesses): *M. fortuitum, M. chelonae, M. abscessus*

- Crohn's Disease: *M. paratuberculosis*.

The epidemiology of these diseases has not been well defined but the organisms have been found in soil, milk and water. Other factors, such as host tissue damage and immunodeficiency predispose the individual to infection. There is no evidence of transmission through person-to-person contact.

The diagnosis of disease requiring treatment is based on repeated positive cultures from symptomatic individuals with illness. Human infections with non-tuberculous Mycobacterium avium complex (MAC) infection are a major problem in HIV-infected individuals.

7. Specific Populations/Settings

7.1. Maternal and Newborn

Notify the TB ICP/designate when perinatal mothers are admitted or scheduled to attend out-patient appointments, who have:

- Suspected or confirmed active infectious TB disease;
- Recent close contact to a case of active infectious TB disease.

Do not separate mother and newborn if the mother is not infectious.

In the event of fetal demise; the attending Physician will document the suspect/confirmed diagnosis of active TB disease in the mother and request evaluation for the presence of congenital TB post mortem.

Infants born to mothers:

- Under investigation as a contact to a case of active TB disease OR
- Under investigation for probable (suspect) TB disease OR
- Under investigation for active TB disease
- Must be managed according to one of the following four categories below (7.1.1 – 7.1.4).

7.1.1. Mother with low index of suspicion for active TB disease and no abnormality on chest x-ray:

- No special precautions for mother
- No special investigation or therapy for newborn
- Do not separate mother and newborn
- Offer mother TBI treatment if appropriate (e.g., recently infected; HIV co-infected).

7.1.2. Mother with abnormal chest x-ray consistent with active TB disease: Rule out active infectious TB disease prior to delivery:

- Obtain three sputum specimens for AFB
- Refer mother to Respirologist or Infectious Diseases specialist with expertise in Tuberculosis

- Refer newborn to Infectious Diseases prior to delivery
- If active infectious TB disease is ruled out, delivery can occur as per routine; follow-up of the newborn is not required.

If unable to rule out active infectious TB disease prior to delivery, consider mother infectious. Manage care as outlined below (section 7.1.4).

If chest radiograph indicates abnormality that is considered related to previous healed TB and mother was not previously treated, refer P/R/C for assessment to a Respirologist or Infectious Disease Specialist with expertise in Tuberculosis.

7.1.3. Mother with abnormal chest x-ray but no evidence of active TB disease: Rule out active infectious respiratory TB disease prior to delivery:

- Obtain three sputum specimens for AFB
- Refer mother to Respirologist or Infectious Diseases Specialist with expertise in Tuberculosis
- Refer newborn to Infectious Diseases prior to and upon delivery
- If active infectious respiratory TB disease is ruled out, delivery can occur as per routine.

If unable to rule out active infectious TB disease prior to delivery, consider and treat mother as infectious. Manage care as outlined below in 7.1.4, 'Mother with confirmed or suspected active TB disease at or close to the time of delivery'.

7.1.4. Mother with Confirmed or Suspected Active Infectious TB Disease at, **or close to the time of delivery:**
If the mother is considered infectious/potentially infectious:

- Place the mother on Airborne Precautions
- Immediately separate mother and infant upon delivery
- Newborn may go to nursery; there is no requirement for Airborne Precautions for newborn.

If mother has suspected or confirmed active TB disease (infectious or non-infectious) at the time of delivery, evaluate the newborn for congenital TB.

The care of the newborn should include:

- Notifying Infectious Diseases of impending delivery
- Notifying Neonatology of impending delivery
- Sending placenta for physical examination and AFB
- Sending amniotic fluid (if available) for AFB
- Collecting gastric aspirates for AFB X 3 (one upon delivery)
- Collecting a chest radiograph (PA/LAT)

- Collecting blood specimens [CBC, Sed rate (ESR)]
- Collecting urine and stool for AFB
- Considering a lumbar puncture
- Considering an abdominal ultrasound.

7.1.5. Other Considerations

Consider priority screening of household members for active TB disease prior to delivery, or as close to delivery as possible. Contact TB ICP/designate for assistance as required.

7.2. Breastfeeding

- Mothers to use a breast pump until she is non-infectious; consider referral to a Post Natal Nurse with lactation training; expressed breast milk is safe to feed the newborn.
- Breastfeeding is not contraindicated once the mother is deemed no longer infectious; mother should be encouraged to breastfeed
- Women receiving first-line TB drugs, including INH and Rifampin, may continue to breastfeed (note: concentrations of drugs in breast milk are insufficient to protect the infant).
- INH may cause peripheral neuropathy in both infant and mother, administration of supplemental Vitamin B6 (pyridoxine) to both mother and baby will prevent this.

7.3. Children

TB in children differs from that in adults in several ways:

- Diagnosis in young children may be difficult since signs and symptoms are often non-specific and disease is often paucibacillary (few bacilli present)
- TB disease in a very young child is often a sentinel event indicating recent transmission
- In young children, especially infants, there is a high risk of progression from latent TB infection (TBI) to active and sometimes severe TB disease, especially in the absence of a BCG vaccination.

Children of any age who show signs and symptoms of active TB disease; whose respiratory secretions (e.g., sputum or bronchial alveolar lavage) have yielded AFB or are MTB culture positive; or who have a chest radiograph indicative of active TB should be immediately isolated using Airborne Precautions.

Rooming in is evaluated by the TB ICP/designate on an individual case by case basis**.**

Children most often acquire TB disease from close adult contacts. This should be considered when Airborne Precautions are necessary for children, especially those under 5, for suspected or confirmed active infectious respiratory TB disease. These same adults may pose a risk to healthcare workers and other patients while visiting.

To ensure a safe environment, considerations should include potentially infectious close adult contacts. Visitors (limited to immediate adult family, guardians, Designated Caregivers [DC]) should be screened by symptomology

and radiography for active infectious TB disease. Those visitors/DC having clinical symptoms suggestive of active infectious TB disease should be discouraged from visiting. Those who are required to visit should wear a procedure mask (both inside and outside of the isolation room) until active infectious TB disease is ruled out. Visitation by children is evaluated on a case-by-case basis by the TB Infection Control Professional/designate.

7.4. Renal Insufficiency and End-Stage Renal Disease (ESRD)

In P/R/Cs with renal insufficiency and end-stage renal failure special consideration should be given to the following areas:

- Dosing of medications
- Drug interactions
- Drug side effects
- Difficulty with medication absorption
- Dialysis – timing of dosing.

P/R/Cs with renal insufficiency and end-stage renal failure diagnosed with infectious respiratory TB disease will be placed on a medication regime which coincides with their hemodialysis/peritoneal dialysis schedule. Both Rifampin and INH are metabolized by the liver and are not dialyzed, dose adjustments are not necessary for either of these medications. The other two first-line medications, Ethambutol and Pyrazinamide (PZA) are dialyzed out so must be given following hemodialysis treatment. P/R/Cs on this anti-tuberculosis regime are to follow the criteria for discontinuation for Airborne Precautions.
There is no data on the pharmacokinetic characteristics of first line anti-tuberculosis medication in P/R/Cs receiving peritoneal dialysis. The standard dosing and schedule used for hemodialysis is recommended but P/R/Cs should be monitored closely and therapeutic drug monitoring (i.e., measurement of serum drug concentrations) should be considered.

7.5. Persons with HIV Infection

P/R/C care should be provided in collaboration with an Infectious Diseases specialist with expertise in management of both tuberculosis and HIV to assist in determining possible TB risk. Include the following information:

- Document anti-retrovirals, if any, he/she is presently taking in the P/R/C's health record.
- Document clinical history – clinicians involved in care, current medications, recent blood work (e.g., CD4 cell count and viral load)
- A Drug Program Information Network (DPIN) printout in the patient's health record.

Note: P/R/Cs with HIV may present atypically (e.g., normal chest radiograph, no cough). Active non-respiratory TB disease is more common in those with HIV.

7.6. Operating Room- Adult and Pediatric Patients

Only perform medically necessary surgery on patients with suspected or confirmed active infectious TB disease. This would include both E1 – immediately and E2 - within 4-6 hours. All other surgery and procedures should be delayed on patients with active infectious TB disease until the patient is deemed no longer infectious. Maintain Airborne Precautions for patients with suspected or confirmed active infectious TB disease; proceed as follows:

- If at all possible, patients with infectious tuberculosis should be scheduled at the end of the day to limit risk to other patients and healthcare workers.
- Perform the procedure with a minimal number of personnel.
- N95 respirators are indicated for all persons entering the OR room for respiratory protection.
- The patient should be intubated in an airborne isolation room, if intubation could not be done ensure the patient is wearing a surgical mask during transport[8.1]
- An Airborne Precautions sign should be posted on each door to the theatre[8.1]
- The doors to the OR -shall be kept closed
- If possible surgery should be done in an OR theatre with an attached anteroom[8.1]
- Patients should then be transported to a negative pressure ventilation room as soon as possible. The patient will have both nose and mouth covered with a regular surgical mask during transport
- Personnel performing environmental cleaning and disinfection in the room of a patient who has an infectious airborne disease must use a properly fit tested N95 respirator until complete air exchange has been achieved
- The period of time required for the ventilation system to achieve a (ideally) 99.9% or (minimally) 99% air exchange should be noted. the door will remain closed until (ideally) 99.9% or (minimally) 99% of airborne microorganisms are removed from the room. This will be determined using Airborne Precautions - Appendix C: Air Exchanges Needed to Remove Airborne Microorganisms).
- To minimize the risk of contamination to anesthesia equipment by installing a disposable anesthesia circuit, if one is not available; the entire system should be cleaned and disinfected according to manufacture instructions post procedure [8.1]
- Tuberculosis patients must be extubated and recovered in a negative pressure ventilation room and personnel will follow Airborne Precautions Protocol and wear N95 respirators. [8.1]

7.7. Persons in Long Term Care Facilities (LTCF)

7.7.1. TBI

Residents of long-term care facilities (LTCF) are considered to be at the same risk for having latent TB infection as other populations in the community, and have the same risk of developing active TB as persons

of the same age in the general population, with the exception of those belonging to identified at-risk groups. Because of the concern for transmission of TB in LTCF and the anticipated need for contact tracing should there be an exposure, many guidelines recommend screening newly admitted residents. LTCF admission criteria is as follows:

- A posteroanterior and lateral chest x-ray should be performed if a resident is symptomatic and the resident should be referred for medical assessment if indicated.
- Routine tuberculin skin testing on (or prior to) admission and periodic tuberculin skin tests (such as annually) are not recommended for residents.
- If a resident has had exposure to respiratory TB, the need for testing should be individualized as part of contact tracing.

7.7.2. Active TB

- Residents with active TB disease should be transferred to acute care for diagnostics and to be accommodated under Airborne Precautions. In the unusual event that a resident cannot be transferred to acute care, treatment may be implemented while the resident resides in the PCH/LTCF. In this circumstance, the attending physician or prescriber shall not initiate treatment without consultation with either an Infectious Diseases Specialist or Respirologist with expertise in TB diagnosis.
- Any active pulmonary or laryngeal TB is suspected, the resident should be transferred to acute care for accommodation under Airborne Precautions, unless the LTCF is able to implement Airborne Precautions.
- Contact Adult Chest Medicine or Pediatric Respiratory Services, as appropriate, at Health Sciences Centre to discuss the need for transfer.
- Immediately implement Airborne Precautions. Due to the lack of AIIRs in the LTCF, this usually means placing the resident in a private room with the door closed and having the resident wear a medical mask when outside of the room (e.g., during transport). Staff entering the room to provide care shall wear a fit-tested N95 respirator.
- The LTCF site Infection Control Professional or designate should be immediately informed of a suspected case however frontline staff should not wait for Infection Prevention and Control to implement precautions.

7.8. Ambulatory Care/Clinic Setting

- Unit/clinic/site booking the appointment must notify receiving Ambulatory Care clinic of the Airborne Precautions required in advance.
- Place P/R/C directly in examination room
- P/R/C performs hand hygiene on arrival; continues to wear procedure or surgical mask
- Keep door closed after appointment until air deemed cleared, if P/R/C removed their procedure mask (for unknown air exchanges wait 3 hours).

7.9. Diagnostic Imaging (DI)

- Bedside testing preferred.
- Unit/clinic booking appointment must notify DI department of the Airborne Precautions required in advance.
- P/R/C performs hand hygiene prior to transfer; wears procedure or surgical mask.

7.10. Visitors/Accompanying Individuals (AI)/Designated Caregivers (DC)

- Visitors check with staff on the unit before entering the patient's room.
- Staff assist visitors/AI/DC with performing a seal check to make sure the N95 respirator is fitted as best as possible.
- Staff should inform visitor/AI/DC that although this is a N95 respirator the protection afforded by this respirator is at a reduced level, as it has not been fit tested.
- Visitor/AI/DC performs hand hygiene and don an N95 respirator.

7.11. Occupational and Environmental Safety & Health Occupational (OESH)

Contact Occupational and Environmental Safety and Health (OESH) for staff assessment and / or concerns.

7.12. Public Health – Tuberculosis Services: See the TB Hospital admission/discharge process and the PH- TB webpage – Resource for Health Professionals for more information.

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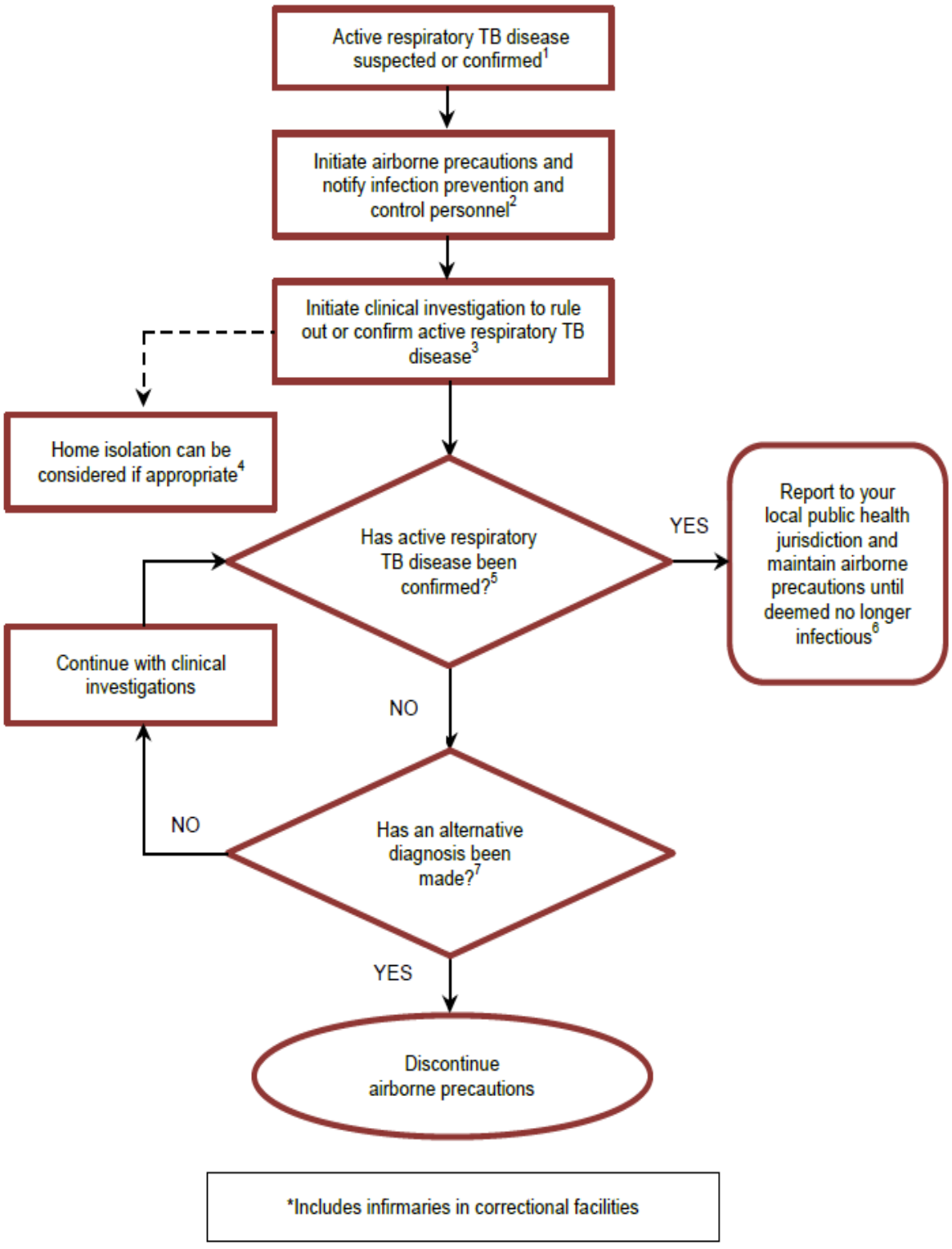
APPENDIX A

Recommended Steps for Isolation for Suspected or Confirmed Active Respiratory TB Disease in Hospital*



APPENDIX B

Definitions

1. **Aerosol**
   Solid or liquid particles suspended in the air, whose motion is governed principally by particle size, which ranges from 10µm-100µm.[8.13] Aerosol-generating medical procedures may produce particles less than 10 µm (i.e., droplet nuclei); however in a P/R/C with respiratory TB these may contain MTB bacteria that are suspended in the air and lead to the spread of infection.[8.3]

2. **Meningeal Tuberculosis**
   TB of the meninges is best diagnosed through MRI. The clinical course characterized by a prodromal headache, malaise, fever and personality changes, followed by meningismus, cranial nerve palsies and confusion, left untreated, can lead to seizures, coma and death within weeks. TB meningitis should be treated as a medical emergency; time is of the essence in achieving a good outcome, as the condition is frequently associated with devastating consequences: 25% morbidity (i.e., permanent neurologic deficit) and 15% to 40% mortality despite available treatment. [8.3]

3. **Peripheral TB Lymphadenitis**
   Presentation can be at a single nodal site or in multiple sites. A study of TB lymphadenitis in Manitoba found that 18% of cases also had a concurrent diagnosis of TB elsewhere in the body. In general, the disease is most often indolent, and the P/R/C usually presents with an isolated, unilateral, non-tender neck mass. Peripheral lymphadenitis is particularly common among immigrants to Canada from Asian countries such as China, Viet Nam and the Philippines. High rates of tuberculous lymphadenitis in the foreign-born are well documented in high-income countries. In Manitoba, the highest incidence of peripheral lymphadenitis has been reported among older Indigenous women. [8.3]

4. **Smear Positive**
   A specimen that is positive for acid-fast bacilli. [8.14] The mycobacterium species is identified within 48 hours by PCR with results and sensitivities confirmed within a 2 – 8 week period depending on the type of specimen.[8.14]

5. **Tuberculin Skin Test (TST)**
   Skin test to identify whether a person has delayed-type hypersensitivity reaction to tuberculin antigens. [8.3] This test is **NOT** helpful in diagnosis of active TB, in advanced active disease and/or immunocompromised P/R/Cs there is a high probability of a false negative result.