

Ontario Public Health Standards:
Requirements for Programs, Services and Accountability

Infectious Disease Protocol

Appendix 1:

Case Definitions and Disease-Specific Information

Disease: Tuberculosis

Effective: May 2022

Tuberculosis

☒ Communicable

☒ Virulent

[Health Protection and Promotion Act \(HPPA\)](#)

[Ontario Regulation \(O. Reg.\) 135/18](#) (Designation of Diseases)

Provincial Reporting Requirements

☒ Confirmed case

☐ Probable case

As per Requirement #3 of the "Reporting of Infectious Diseases" section of the *Infectious Diseases Protocol, 2018* (or as current), the minimum data elements to be reported for each case are specified in the following:

- [O. Reg. 569](#) (Reports) under the HPPA;¹
- The [iPHIS User Guides](#) published by Public Health Ontario (PHO); and
- Bulletins and directives issued by PHO.

Type of Surveillance

Case-by-case.

Case Definition

Confirmed Case

- Laboratory confirmed case: cases with *Mycobacterium tuberculosis* complex (MTB complex) demonstrated on culture from an appropriate clinical specimen (e.g., sputum, body fluid or tissue) specifically *M. tuberculosis*, *M. africanum*, *M. canetti*, *M. caprae*, *M. microti*, *M. pinnipedii* or *M. bovis* (excluding *M. bovis* Bacillus Calmette Guérin [BCG] strain),

OR

- In the absence of positive culture, cases clinically compatible with active tuberculosis that have:
 - Chest radiological changes compatible with active tuberculosis;

OR

- Histopathologic or post-mortem evidence of active tuberculosis;

OR

- Response to anti-tuberculosis treatment;

OR

- Detection of MTB complex by nucleic acid amplification test (NAAT) with compatible clinical and epidemiological associated information;

OR

- Active non-respiratory tuberculosis (meningeal, bone, kidney, peripheral lymph nodes, etc.).

A case should not be counted twice within any consecutive 12-month period, unless a second genotype is detected.

Suspect Case

- Signs and symptoms compatible with active disease;

And at least one of the following:

- Radiological findings suggestive of active disease;

OR

- Demonstration of acid-fast bacillus (AFB) in clinical specimen.

Latent TB Infection

- The presence of latent infection with *Mycobacterium tuberculosis* as determined by a tuberculin skin test (TST) **or** an interferon gamma release assay (IGRA);^{*}

AND

- No evidence of clinically active disease;

AND

- No evidence of radiographic changes that suggest active disease;

AND

- Negative microbiologic tests, if performed.

Outbreak Case Definition

The outbreak case definition varies with the outbreak under investigation. Please refer to the *Infectious Diseases Protocol, 2018* (or as current) for guidance in developing an outbreak case definition as needed.

The outbreak case definitions are established to reflect the disease and circumstances of the outbreak under investigation. The outbreak case definitions should be developed for each individual outbreak based on its characteristics, reviewed during the course of the outbreak, and modified, if necessary, to ensure that the majority of cases are captured by the definition. The case definitions should be created in consideration of the outbreak definitions.

^{*} **Note:** If both TST and IGRA are performed and results are discordant, they should be interpreted in the context of other relevant clinical information (e.g., BCG vaccination history), and a decision made as to whether a diagnosis of latent TB infection is appropriate. Please see [Chapter 4 of the Canadian Tuberculosis Standards, 7th ed.](#) (or as current) for more example scenarios.

Outbreak cases may be classified by levels of probability (i.e., confirmed and/or probable).

Clinical Information

Clinical Evidence

- Clinically compatible signs and symptoms of active tuberculosis include but are not limited to cough, chest pain, fevers, night sweats, weight loss and haemoptysis. Active extrapulmonary tuberculosis (e.g., meningeal, bone, kidney, peripheral lymph nodes) consists of signs or symptoms referable to the extrapulmonary organ involved, and histopathologic or post-mortem evidence of active tuberculosis.
- MTB complex comprises *M. tuberculosis*, including *M. canetti*, *M. bovis* (including BCG strain, though this strain is not included in the case definition of tuberculosis), *M. africanum*, *M. caprae*, *M. microti*, and *M. pinnipedii*. New species may be added with the progress of scientific development in the field.

Clinical Presentation

Among those with newly developed latent TB infection (LTBI), approximately 90% will never develop active disease. The remaining 10% will develop active disease at some point in their lifetime, half of these within the first two years of infection. The risk of developing active TB is higher when other risk factors or comorbidities are involved, such as HIV co-infection. Those with HIV co-infection have an increased risk of 10% per year of developing active TB disease.²

Among those infected with TB, early lung lesions commonly heal, leaving no residual changes. However, in some cases pulmonary lesions do not heal, and as cellular infiltration continues, granulomata become caseous and necrotic. These may or may not become calcified or show scarring upon radiograph.²

Pulmonary symptoms may include:²

- Persistent cough (of more than 3 weeks);
- Sputum production, sometimes with hemoptysis;

- Chest pain; and
- Shortness of breath.

Systemic symptoms consistent with TB include:²

- Fever and night sweats;
- Loss of appetite and weight loss; and
- Fatigue.

Extrapulmonary symptoms are dependent on the site affected, for example, TB of the spine might produce back pain; TB of the kidney may cause flank pain, frequency and dysuria; and TB involving lymph nodes presents with swelling in the affected lymph nodes. Extrapulmonary TB should be suspected in anyone with systemic symptoms who is at high risk for TB.²

Laboratory Evidence

Laboratory Confirmation

Any of the following will constitute a confirmed case of Tuberculosis:

- Positive culture of MTB complex (*M. tuberculosis*, *M. canetti*, *M. africanum*, *M. caprae*, *M. microti*, *M. pinnipedii*, or *M. bovis*, excluding BCG strain).

Approved/Validated Tests

- Standard culture for MTB complex;
- Biochemical tests to differentiate between *M. bovis* and *M. bovis* BCG;
- AFB smear; and
- NAAT for MTB complex.

Indications and Limitations

- Direct NAAT is used for smear positive and smear negative respiratory specimens. However, a negative NAAT result does not rule out MTB complex.
- Direct NAAT for MTB may be useful in extrapulmonary TB but current Health Canada approved assays are not approved for extrapulmonary specimens.

- Direct NAAT for MTB has the potential for false positive results; therefore, direct NAAT positive results should be confirmed by culture when possible.

For further information about human diagnostic testing, contact the [Public Health Ontario Laboratories](#).

Case Management

In addition to the requirements set out in the Requirement #2 of the "Management of Infectious Diseases – Sporadic Cases" and "Investigation and Management of Infectious Diseases Outbreaks" sections of the *Infectious Diseases Protocol, 2018* (or as current), the board of health shall investigate cases to determine the source of infection. Refer to Provincial Reporting Requirements above for relevant data to be collected during case investigation.

Refer to the following documents and the other references listed below for information on prevention and education:

- [Tuberculosis Prevention and Control Protocol, 2018](#) (or as current)³
- [Guidelines to Reduce TB Transmission in Homeless Shelters and Drop-In Centres](#)⁴
- [Tuberculosis Program Guideline, 2018](#) (or as current)⁵
- Use of Rifapentine and isoniazid combination therapy for the treatment of latent tuberculosis infection: Interim guide for Ontario³

Contact Management

Refer to the following documents and the other references listed below for information on prevention and education:

- *Tuberculosis Prevention and Control Protocol, 2018* (or as current)³
- Guidelines to Reduce TB Transmission in Homeless Shelters and Drop-In Centres⁴
- *Tuberculosis Program Guideline, 2018* (or as current)⁵

Outbreak Management

Please see the *Infectious Diseases Protocol, 2018* (or as current) for the public health management of outbreaks or clusters in order to identify the source of illness, manage the outbreak and limit secondary spread.

Refer to the following documents and the other references listed below for information on prevention, education and outbreak management:

- Canadian Tuberculosis Standards²
- *Tuberculosis Prevention and Control Protocol, 2018* (or as current)³
- Guidelines to Reduce TB Transmission in Homeless Shelters and Drop-In Centres⁴

Publicly funded rifapentine is only available to manage outbreaks and other exceptional circumstances. It has been included on Health Canada's [Access to Drugs in Exceptional Circumstances](#) pathway and is not available through the Special Access Programme (SAP). Any use of rifapentine requires approval from the Office of the Chief Medical Officer of Health, in consultation with the infectious diseases policy and programs section of the Ministry of Health. Further information about the use of rifapentine can be found by referring to the following document:

- [Use of Rifapentine and isoniazid combination therapy for the treatment of latent tuberculosis infection: Interim guide for Ontario](#) (2018, or as current)⁶

Prevention and Control Measures

Personal Prevention Measures

Refer to the following documents and the other references listed below for information on prevention and education:

- *Tuberculosis Prevention and Control Protocol, 2018* (or as current)³
- Guidelines to Reduce TB Transmission in Homeless Shelters and Drop-In Centres⁴
- *Tuberculosis Program Guideline, 2018* (or as current)⁵

Infection Prevention and Control Strategies

Refer to the following documents and the other references listed below for information on infection prevention and control strategies:

- Canadian Tuberculosis Standards²
- *Tuberculosis Prevention and Control Protocol, 2018* (or as current)³
- Guidelines to Reduce TB Transmission in Homeless Shelters and Drop-In Centres⁴
- *Tuberculosis Program Guideline, 2018* (or as current)⁵

Refer to [PHO's website](#) to search for the most up-to-date information on Infection Prevention and Control (IPAC).

Disease Characteristics

Aetiologic Agent - The infectious agent of tuberculosis (TB) infection and disease in humans is the *Mycobacterium tuberculosis* complex, which consists of *M. tuberculosis*, and includes *M. canettii*, *M. africanum*, *M. caprae*, *M. microti*, *M. pinnipedii*, and *M. bovis*.⁷ *M. bovis* includes the vaccine strain *M. bovis* Bacillus Calmette Guérin (BCG) however, *M. bovis* BCG is not in the Canadian case definition of TB.

Mycobacteria are aerobic, non-spore forming and non-motile bacteria.⁸

Other nontuberculous mycobacteria causing disease in humans are not communicable and not reportable in Ontario, with the exception of leprosy.²

Modes of Transmission - Transmission of tubercle bacilli in airborne droplet nuclei (1 to 5 microns in diameter) occurs via respiratory efforts such as coughing, sneezing, singing or speaking. Several patient, pathogen and environmental factors determine whether transmission occurs, largely by affecting the number of infectious droplet nuclei per volume of air. In most instances only one such droplet nucleus is believed to be responsible for establishing infection in the host. The droplets have an extremely slow settling rate (0.5 mm per second or less), which permits their transport by air currents, duct systems or elevator shafts for significant distances from the source case. Bacteria that are lodged on fomites (linen, furniture,

books, floors) do not constitute a significant source of infection: most die quickly through the action of drying, heat or sunlight.²

This generally requires prolonged or repeated exposure to an infectious case. Laryngeal tuberculosis, although rare, is highly infectious. Healthcare workers may potentially be exposed during bronchoscopy, intubation and autopsy.²

Bovine tuberculosis results from exposure to cattle infected with *M. bovis*, usually through ingestion of unpasteurized milk or dairy products, and sometimes through airborne droplet nuclei that can be spread to farmers and animal handlers.⁷

Extrapulmonary TB is generally not communicable. Concurrent pulmonary involvement, however, should always be ruled out in any case of extrapulmonary TB.²

Incubation Period - Variable. Five percent of infected individuals develop primary or progressive primary active disease within 18 to 24 months after infection, and 5% develop post primary disease over the remainder of their lifetime. While the subsequent risk of active pulmonary or extrapulmonary TB is greatest within the first 2 years after infection, without treatment, LTBI will persist for a lifetime. HIV co-infection and other immunocompromising conditions as well as age under 5 years increase the risk for the development of active TB disease following infection.²

Period of Communicability - Period of communicability is variable amongst infectious cases of TB; in theory it lasts as long as viable tubercle bacilli are discharged in the sputum. Some untreated or inadequately treated patients may be intermittently sputum-positive for years. The degree of communicability depends on the number of bacilli discharged, virulence of the bacilli, ventilation, exposure of bacilli to sun or UV light, and opportunities for aerosolization through coughing, sneezing, talking, singing or during procedures such as intubation, bronchoscopy and autopsy.²

For smear positive or symptomatic infections, the period of communicability may start up to 3 months before respiratory symptom onset; smear negative, asymptomatic cases with no evidence of cavities may be considered infectious up to 4 weeks prior to date of diagnosis.²

To determine if treatment is effective in reducing infectiousness, one should consider objective clinical, radiographic and/or microbiologic improvement. For guidance on when to determine a case is no longer infectious, or for details on when to discontinue airborne precautions, please refer to the Canadian Tuberculosis Standards (2014, or as current).²

Children with primary pulmonary TB are generally not considered infectious.²

Reservoir - The reservoir for *M. tuberculosis* is humans. Animals may be infected but are rarely a source of infection.³ Sporadic cases may result from inadvertent exposure of abattoir workers, veterinarians, and wild game handlers to infected animals.

Host Susceptibility and Resistance - Susceptibility is essentially universal. The risk of infection with the tubercle bacillus is related to multiple hosts, pathogen, and environmental factors.²

The first 18 to 24 months after infection constitutes the most hazardous period for the development of clinical disease.²

Once infected, the risk of developing active TB disease is influenced by the time since infection, age, and medical conditions or therapies that affect the immune system of the infected person. The risk is highest in the persons recently infected (i.e., the first 1 to 2 years), very young children (under 5 years of age), and in persons who are immunosuppressed, particularly those who have HIV/AIDS, diabetes, and certain types of cancer.²

Please refer to [PHO's Reportable Disease Trends in Ontario reporting tool](#) and other reports for the most up-to-date information on infectious disease trends in Ontario.

For additional national and international epidemiological information, please refer to the Public Health Agency of Canada and the World Health Organization.

Comments

Confirmed cases must fall into one of the following staging categories:

1) New Active Case

A confirmed case that has no documented evidence (e.g., clinical findings, radiological findings, lab results, etc.) either from within or outside of Ontario or no known history of previously active tuberculosis.

2) Re-treatment Case

Scenario 1

- Documented evidence or adequate history of previously active TB that was declared cured or treatment completed by current standards;

AND

- At least a 6-month interval since the last day of previous treatment;[†]

AND

- Diagnosis of a subsequent episode of TB that meets the active TB case definition.

OR

Scenario 2

- Documented evidence or adequate history of previously active TB that cannot be declared cured or treatment completed by current standards;

[†] If less than 6 months have passed since the last day of previous treatment and the case was not previously reported in Canada, report as a re-treatment case. If less than 6 months have passed since the last day of previous treatment and the case was previously reported in Canada, do not report as a re-treatment case.

AND

- Inactive[‡] disease for 6 months or longer after the last day of previous treatment;

AND

- Diagnosis of a subsequent episode of TB that meets the active TB case definition.

3) Inactive tuberculosis

- Inactivity for a respiratory tuberculosis case is defined as three negative tuberculosis smears and cultures plus a 3-month duration of stability in serial chest radiographs or a 6-month duration of stability in serial chest radiographs without laboratory testing. Inactivity for a non-respiratory TB case is to be documented bacteriologically, radiologically and/or clinically as appropriate to the site of disease

AND

- Does not meet re-treatment case staging category definition above.

References

1. Health Protection and Promotion Act, R.S.O. 1990, Reg. 569, Reports, (2018). Available from: <https://www.ontario.ca/laws/regulation/900569>
2. Canadian Lung Association, Canadian Thoracic Society, Public Health Agency of Canada. Canadian Tuberculosis Standards. Ottawa, ON: Her Majesty the Queen in Right of Canada; 2014. Available from: <https://www.canada.ca/en/public-health/services/infectious-diseases/canadian-tuberculosis-standards-7th-edition.html>

[‡] As defined in section 3) Inactive Tuberculosis.

3. Ontario, Ministry of Health and Long-Term Care. Tuberculosis Prevention and Control Protocol, 2018. Toronto, ON: Queen's Printer for Ontario; 2018.
Available from:
http://www.health.gov.on.ca/en/pro/programs/publichealth/oph_standards/protocolsguidelines.aspx
4. Toronto Public Health. Environmental Control Best Practices: Guidelines to Reduce TB Transmission in Homeless Shelters and Drop-In Centres. Toronto, ON: City of Toronto; 2007. Available from:
<https://www.toronto.ca/community-people/health-wellness-care/health-programs-advice/tuberculosis-tb/tuberculosis-tb-and-homeless-service-settings/>
5. Ontario, Ministry of Health and Long-Term Care. Tuberculosis Program Guideline, 2018. Toronto, ON: Queen's Printer for Ontario; 2018. Available from:
https://www.health.gov.on.ca/en/pro/programs/publichealth/oph_standards/docs/protocols_guidelines/Tuberculosis_Program_Guideline_2018.pdf
6. Ontario Agency for Health Protection and Promotion (Public Health Ontario). Use of rifapentine and isoniazid combination therapy for the treatment of latent tuberculosis infection: interim guide for Ontario. Toronto, ON: Queen's Printer for Ontario; 2018. Available from:
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7. Heymann DL, editor. Control of Communicable Diseases Manual. 20 ed. Washington, D.C: American Public Health Association; 2015.
8. Government of Canada. Pathogen Safety Data Sheets: Infectious Substances – Mycobacterium tuberculosis and Mycobacterium tuberculosis complex [Internet]. Ottawa, ON: Her Majesty the Queen in Right of Canada; 2012 [updated September 13, 2012; cited August 20, 2018]. Available from:
<https://www.canada.ca/en/public-health/services/laboratory-biosafety-biosecurity/pathogen-safety-data-sheets-risk-assessment/mycobacterium-tuberculosis-complex.html>

Case Definition Sources

Canadian Lung Association, Canadian Thoracic Society, Public Health Agency of Canada. Canadian Tuberculosis Standards. Ottawa, ON: Her Majesty the Queen in Right of Canada; 2014. Available from: <https://www.canada.ca/en/public-health/services/infectious-diseases/canadian-tuberculosis-standards-7th-edition.html>

Public Health Agency of Canada. Tuberculosis. In: Case Definitions for Communicable Diseases under National Surveillance. Canada Communicable Disease Report. 2009;35S2.

Document History

Revision Date	Document Section	Description of Revisions
April 2022	Entire Document	New template. Appendix A and B merged. No material content changes.
April 2022	Epidemiology: Occurrence section	Removed.
April 2022	ICD Codes	Removed.