Ministry of Health and Long-Term Care

Infectious Diseases Protocol

Appendix A: Disease-Specific Chapters

Chapter: Tuberculosis

Effective: February 2019



Tuberculosis

Communicable

Virulent

Health Protection and Promotion Act: O. Reg. 135/18 (Designation of Diseases)

1.0 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. canetti, M. africanum, M. caprae, M. microti, M. pinnipedii, and M. bovis.*¹ *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.²

Other nontuberculous mycobacteria causing disease in humans are not communicable and not reportable in Ontario, with the exception of leprosy.³

2.0 Case Definition

2.1 Surveillance Case Definition

Refer to Appendix B for Case Definitions.

2.2 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.

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

3.0 Identification

3.1 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.³

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.³

Pulmonary symptoms may include:³

- Persistent cough (of more than 3 weeks);
- Sputum production, sometimes with hemoptysis;
- Chest pain; and
- Shortness of breath.

Systemic symptoms consistent with TB include:³

- 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.³

3.2 Diagnosis

See Appendix B for diagnostic criteria relevant to the Case Definitions.

For further information about human diagnostic testing, contact the Public Health Ontario Laboratories or refer to the Public Health Ontario Laboratory Services webpage: <u>http://www.publichealthontario.ca/en/ServicesAndTools/LaboratoryServices/Pages/default.aspx</u>

4.0 Epidemiology

4.1 Occurrence

Occurrence is worldwide. Tuberculosis cases in Ontario account for approximately 40% of the cases of TB reported in Canada each year.³

In Ontario, the highest incidence of TB is seen in the city of Toronto, followed by other densely populated urban areas including Peel Region, Ottawa and York Region. Provincially, nearly 90% of reported TB cases occur among the foreign born.³ Persons at greater risk of developing active TB after being infected include persons with immunosuppressive conditions (especially HIV), homeless individuals, Aboriginal persons and children under 5 years old.³

There were 45 cases of multidrug-resistant TB (MDR-TB) in the province between 2011 and 2015. Extensively drug-resistant TB (XDR-TB) is very rare in Canada. In Ontario, only three cases of XDR-TB were reported between 2011 and 2015.⁴

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

http://www.publichealthontario.ca/en/DataAndAnalytics/Pages/DataReports.aspx

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

4.2 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.

4.3 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.³

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.³

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.¹

Extrapulmonary TB is generally not communicable. Concurrent pulmonary involvement, however, should always be ruled out in any case of extrapulmonary TB.³

4.4 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.³

4.5 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.³

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.³

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).³

Children with primary pulmonary TB are generally not considered infectious.³

4.6 Host Susceptibility and Resistance

Susceptibility is essentially universal. The risk of infection with the tubercle bacillus is related to multiple host, pathogen, and environmental factors.³

The first 18 to 24 months after infection constitutes the most hazardous period for the development of clinical disease.³

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.³

5.0 Reporting Requirements

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:

- Ontario Regulation 569 (Reports) under the Health Protection and Promotion Act (HPPA);⁵
- The iPHIS User Guides published by PHO; and
- Bulletins and directives issued by PHO.

6.0 Prevention and Control Measures

6.1 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)⁶
- Guidelines to Reduce TB Transmission in Homeless Shelters and Drop-In Centres⁷
- Tuberculosis Program Guideline, 2018 (or as current)⁸

6.2 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 Standards³
- Tuberculosis Prevention and Control Protocol, 2018 (or as current)⁶
- Guidelines to Reduce TB Transmission in Homeless Shelters and Drop-In Centres⁷
- Tuberculosis Program Guideline, 2018 (or as current)⁸

Refer to PHO's website at <u>www.publichealthontario.ca</u> to search for the most up-to-date information on Infection Prevention and Control.

6.3 Management of cases of active TB, individuals with LTBI, and individuals placed on medical surveillance

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 Section 5: 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)⁶
- Guidelines to Reduce TB Transmission in Homeless Shelters and Drop-In Centres⁷
- Tuberculosis Program Guideline, 2018 (or as current)⁸
- Use of Rifapentine and isoniazid combination therapy for the treatment of latent tuberculosis infection: Interim guide for Ontario (2018, or as current)⁹

6.4 Management of Contacts

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)⁶
- Guidelines to Reduce TB Transmission in Homeless Shelters and Drop-In Centres⁷
- Tuberculosis Program Guideline, 2018 (or as current)⁸

6.5 Management of Outbreaks

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 Standards³
- Tuberculosis Prevention and Control Protocol, 2018 (or as current)⁶
- Guidelines to Reduce TB Transmission in Homeless Shelters and Drop-In Centres⁷

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 and Long-Term Care. 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)⁹

7.0 References

- 1. Heymann DL, editor. Control of Communicable Diseases Manual. 20 ed. Washington, D.C: American Public Health Association; 2015.
- 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: <u>https://www.canada.ca/en/public-health/services/laboratory-biosafetybiosecurity/pathogen-safety-data-sheets-risk-assessment/mycobacteriumtuberculosis-complex.html
 </u>
- 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: <u>https://www.canada.ca/en/publichealth/services/infectious-diseases/canadian-tuberculosis-standards-7thedition.html</u>

- 4. Public Health Agency of Canada. Tuberculosis: Drug resistance in Canada 2015 Ottawa, ON: Her Majesty the Queen in Right of Canada; 2017. Available from: <u>https://www.canada.ca/en/public-health/services/publications/diseases-</u> <u>conditions/tuberculosis-drug-resistance-canada-2015.html</u>
- 5. Health Protection and Promotion Act, R.S.O. 1990, Reg. 569, Reports, (2018). Available from: <u>https://www.ontario.ca/laws/regulation/900569</u>
- Ontario, Ministry of Health and Long-Term Care. Tuberculosis Prevention and Control Protocol, 2018. Toronto, ON: Queen's Printer for Ontario; 2018. Available from: <u>http://www.health.gov.on.ca/en/pro/programs/publichealth/oph_standards/protoc</u>

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- 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: <u>https://www.toronto.ca/communitypeople/health-wellness-care/health-programs-advice/tuberculosis-tb/tuberculosistb-and-homeless-service-settings/</u>
- 8. Ontario, Ministry of Health and Long-Term Care. Tuberculosis Program Guideline, 2018. Toronto, ON: Queen's Printer for Ontario; 2018. Available from: <u>http://www.health.gov.on.ca/en/pro/programs/publichealth/oph_standards/protoc_olsguidelines.aspx</u>
- 9. 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:

https://www.publichealthontario.ca/en/BrowseByTopic/InfectiousDiseases/Pages/ IDLandingPages/Tuberculosis.aspx

8.0 Document History

Revision Date	Document Section	Description of Revisions
April 2015	General	New template.
		Section 9.0 Document History added
April 2015	2.2 Outbreak Case Definition	Removed: "Cases should also be classified by levels of probability (i.e. confirmed, probable or suspect)."
April 2015	3.1 Clinical Presentation	Entire section revised.

Table 1: History of Revisions

Revision Date	Document Section	Description of Revisions
April 2015	3.2 Diagnosis	Added: For further information about human diagnostic testing, contact the Public Health Ontario Laboratories or refer to the Public Health Ontario Laboratory Services webpage: <u>http://www.publichealthontario.ca/en/Services</u> <u>AndTools/LaboratoryServices/Pages/default.a</u> <u>spx</u>
April 2015	4.1 Occurrence	First paragraph: Revised "approximately half" to read "approximately 40%".
		Second paragraph: Added "followed by other densely populated urban areas including Peel Region, Ottawa and Hamilton".
		Revised "upwards of 90%" to read "nearly 90%".
		Revised "(such as HIV)" to read "(especially HIV)".
		Third paragraph: Revised "around approximately 10 cases per year" to read "from 6 to 11 laboratory confirmed cases per year".
		Removed "To date, Ontario and Alberta are the only provinces in Canada that have had cases of extensively drug resistant TB (XDR- TB)." Replaced with "Extensively drug- resistant TB (XDR-TB) is very rare in Canada. In Ontario, only three cases of XDR-TB were reported between 2007 and 2012."
		Added: Please refer to the Public Health Ontario (PHO) Monthly Infectious Diseases Surveillance Reports and other infectious diseases reports for more information on disease trends in Ontario.
April 2015	4.3 Modes of Transmission	Second paragraph: Revised "is rare however" to read "although rare".

Revision Date	Document Section	Description of Revisions
April 2015	4.5 Period of Communicability	First paragraph: Revised "Is variable; in theory as long as viable tubercle bacilli are discharged in the sputum" to read "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."
		Removed "adequacy of" in second sentence.
		Second paragraph: Added "respiratory" before symptom onset, and changed "asymptomatic smear negative" to "smear negative, asymptomatic", and changed "are infectious" to "may be considered infectious up to…"
		All of paragraph 3 revised.
		Paragraph 4: Revised "not infectious" to read "not considered infectious."
April 2015	4.6 Host Susceptibility and Resistance	Added "Host" to section title, "Host Susceptibility and Resistance".
		First paragraph: Removed "The risk of acquiring progressive disease due to infection with the tubercle bacillus is related to multiple factors including degree of exposure, nutritional and immune status of the host, and other factors including genetic factors." Replaced with current language.
		Second paragraph: Replaced "12 to 24 months" with "18 to 24 months".
		All of paragraph 3 revised.
April 2015	5.1 To local Board of Health	First paragraph: Removed "Clinical and or laboratory confirmed cases shall be reported to the medical officer of health by persons required to do so under the <i>Health Protection</i> <i>and Promotion Act</i> , R.S.O. 1990." Replaced with current language.

Revision Date	Document Section	Description of Revisions
April 2015	5.2 To the Ministry of Health and Long-Term Care (the ministry) or Public Health Ontario (PHO), as specified by the ministry	 Paragraph 1: Removed "to PHD". Paragraph 2: Revised the second bullet from "The disease-specific user guides published by the Ministry" to "The iPHIS user guides published by PHO". Revised the third bullet from "Bulletins and directives issued by the ministry" to "Bulletins and directives issued by PHO."
April 2015	6.1 Personal Prevention Measures	Third Reference: Revised <i>Tuberculosis</i> <i>Prevention and Control Best Practices</i> (formerly called Tuberculosis Protocol 2006) (6)" to " <i>Tuberculosis Prevention and Control</i> <i>Guidance Document, 2011</i> [Draft] ⁹ ".
April 2015	6.2 Infection Prevention and Control Strategies	Added: "Canadian Tuberculosis Standards". Fourth Reference: Revised Tuberculosis Prevention and Control Best Practices (formerly called Tuberculosis Protocol 2006) (6)" to "Tuberculosis Prevention and Control Guidance Document, 2011 [Draft] ⁹ ".
		Added: Refer to PHO's website at <u>www.publichealthontario.ca</u> to search for the most up-to-date Provincial Infectious Diseases Advisory Committee (PIDAC) best practices on IPAC. PIDAC best practice documents can be found at: <u>https://www.publichealthontario.ca/en/Browse</u> <u>ByTopic/InfectiousDiseases/PIDAC/Pages/PI</u> <u>DAC_Documents.aspx</u> .
April 2015	6.3 Management of cases of active TB, individuals with LTBI, and individuals placed on medical surveillance	Revised title from "Management of Cases" to current title. Revised <i>"Tuberculosis Prevention and Control Best Practices</i> (formerly called Tuberculosis Protocol 2006)" to <i>"Tuberculosis Prevention and Control Guidance Document, 2011</i> [Draft]".

Revision Date	Document Section	Description of Revisions
April 2015	6.4 Management of Contacts	Revised <i>"Tuberculosis Prevention and Control Best Practices</i> (formerly called Tuberculosis Protocol 2006)" to <i>"Tuberculosis Prevention and Control Guidance Document, 2011</i> [Draft]".
April 2015	7.0 References	Updated.
April 2015	8.0 Additional Resources	Updated.
February 2019	General	Minor revisions were made to support the regulation change to Diseases of Public Health Significance. Common text included in all Disease Specific chapters: Surveillance Case Definition, Outbreak Case Definition, Diagnosis, Reporting Requirements, Management of Cases, and Management of Outbreaks. The epidemiology section and references were updated and Section 8.0 Additional Resources was deleted.
February 2019	4.1 Occurrence	Minor revisions to entire section.
February 2019	4.3 Modes of Transmission	Paragraph one revised.
February 2019	6.3 Management of cases of active TB, individuals with LTBI, and individuals placed on medical surveillance	Resource document "Use of Rifapentine and isoniazid combination therapy for the treatment of latent tuberculosis infection: Interim guide for Ontario" added.
February 2019	6.5 Management of Outbreaks	Paragraph added: "Publicly-funded rifapentine is only available to manage outbreaks and other exceptional circumstances" Resource document "Use of Rifapentine and isoniazid combination therapy for the treatment of latent tuberculosis infection: Interim guide for Ontario" added.

