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Preface

Tuberculosis (TB) continues to be a public health concern in Ontario in 2006. Although the TB rate has steadily declined, Ontario faces challenges in TB prevention and control. Over 90% of Ontario’s TB cases are in the foreign-born. There is also a large pool of latent TB found in persons with HIV, the elderly, immigrants and refugees who come from areas where TB is endemic. It will be increasingly difficult to maintain proficiency among those responsible for TB control as the frequency of TB continues to be less common. On March 24 2006, the Centers for Disease Control and Prevention (CDC) in the United States warned that there are now reports of multiple cases of TB with resistance to virtually all the drugs available to treat TB. This is called extensively drug resistant (XDR) TB. XDR TB has emerged worldwide as a threat to public health and TB control, raising the concerns of a future epidemic of virtually untreatable TB. There have been persons diagnosed with XDR TB in Ontario – these cases are costly to treat and involve complex treatment regimens, posing unique challenges to the public health management of the disease.

This interim protocol for the public health management of TB in Ontario is based on the recommendations of the TB Committee of the Canadian Thoracic Society 5th Edition (2000), “Canadian Tuberculosis Standards”, as well as the opinions of local and national experts in TB diagnosis, treatment and control. It is expected that the national standards will be revised in early 2007. Ontario’s protocol will be finalized after review of the revised national standards and with feedback received from this interim protocol.

An attempt has been made to develop a comprehensive protocol but it cannot substitute for clinical judgment. However, if adhered to, it will result in the control of TB in Ontario.

The writing team of this protocol deserves special attention and acknowledgement. There was only one face-to-face meeting of the team. All the work was done over many months by the Internet and by phone. Each person on the team functioned as a lead author for at least one chapter as well being a member of the writing team for other chapters. The protocol would not have been done without this team’s dogged determination and constant striving for relevant content and research based evidence.

The reviewers also deserve thanks for their valuable feedback and attention to detail.

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A final thank you to Dr. Barbara Kawa, Senior Medical Consultant of the Vaccine Preventable Disease Control and Immunization Unit. Dr. Kawa was head of the VPD/TB Control Unit when the first TB protocol was written in 1998 and she initiated the work on the revision of this protocol (prior to the unit’s reorganization in June 2006). Her commitment to public health and passion for TB control and management are the foundation of this protocol.

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1. Tuberculosis (TB): A Brief Background

The infectious agent of tuberculosis infection and disease in humans is the *Mycobacterium tuberculosis* complex which consists of *M. tuberculosis* (which is the primary concern of this protocol), *M. africanum*, *M. canetti* and *M. bovis*. *M. bovis* includes: *M. bovis* subsp. *caprae*, *M. bovis* subsp. *bovis* and the vaccine strain *M. bovis* BCG. The reservoir is primarily humans, but diseased cattle (*M. bovis*) and other mammals are implicated in some areas. Transmission usually occurs by inhalation of droplet nuclei produced by people with pulmonary or respiratory disease. Healthcare workers may be exposed during patient care or during procedures such as bronchoscopy, intubation or autopsy. Bovine tuberculosis, though rare, can be acquired by the ingestion of unpasteurized milk or dairy products from tuberculous cattle, and sometimes it is spread to farmers and animal handlers through airborne means.

Primary infection usually goes unnoticed. Early lung lesions heal, leaving no detectable changes except for occasional calcified pulmonary or tracheobronchial lymph nodes. About 10% of those with initial infection will develop active disease, 5% within the first two years. Another 5% will go on to develop active disease sometime in their lifetime. ² Seventy percent of active tuberculosis disease is pulmonary; but the disease can affect any organ or tissue. The risk of developing active TB may be 100 times greater in persons infected with HIV than in the general population.³

Tuberculin skin test sensitivity usually appears within 2-10 weeks of infection. Latent foci of infection may persist for a lifetime. Mass treatment for latent TB infection is unrealistic and inappropriate for most communities. However, a risk assessment can determine which infected persons would benefit most from treatment for latent disease.

The majority of cases of TB disease represent reactivation of latent infection. Virtually any clinical presentation of tuberculosis is possible and the illness should be considered whenever protracted febrile illness of unknown origin or undiagnosed coughing of more than three weeks is encountered. Drug treatment of TB must always include an appropriate combination of antimicrobials and never a single drug. For respiratory cases, sputum smears are utilized to determine communicability. Directly-observed, supervised treatment should be used, when possible.

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³ Ibid, p. 142
1.1 Tuberculosis in Ontario

There were 661 cases of tuberculosis (TB) reported in Ontario in 2004. The annual incidence rate of 5.3 per 100,000 population was lower than the rate of 5.9 per 100,000 population seen over the previous 3 years. However, in 1994 the TB rate in Ontario was 8.0 / 100,000 and the rate has been slowly decreasing annually. The incidence rate of TB in Ontario in 2004 was slightly higher than that of Canada as a whole, which in 2004 was 4.9 / 100,000. The highest rate of TB in 2004 was in Toronto (14 / 100,000 - 362 cases) followed by Peel (10.2 /100,000 - 119 cases), York (5.3 /100,000- 47 cases), Ottawa (4.8 /100,000 – 40 cases) and Hamilton (2.7 /100,000 –14 cases). These five urban health units accounted for 88% of TB cases seen in Ontario in 2004. Toronto alone had 55% of Ontario’s TB cases in 2004, averaging almost one case per day.

In 2004, just over 1% of TB patients were under 5 years of age. The vast majority of cases occurred in the 30-49 age group (35%) and those over 60 years of age (27%).

Origin was recorded for 639 of the 661 cases in 2004. Of these 639 cases, 576 (90.1%) were foreign-born, 45 (7%) were born in Canada and 18 (2.8%) were Aboriginal. Among the foreign-born cases in 2004, 50% came from four countries: India (19.9% of all foreign-born cases), Philippines (11.7%), Vietnam (9.8%), and China (8.9%).

In 2004, 647 cases listed a method of detection. The vast majority of TB cases, 525 (81%), were culture positive for TB and 122 (19%) showed no bacteriologic evidence and were considered clinical cases.

There were 705 ‘sites of TB’ identified for 640 of the 661 cases (some cases had multiple sites). Pulmonary and primary TB accounted for 55.7% of the sites reported (393 sites) while 44.3% (312 sites) were extra pulmonary.

Of the 525 culture positive cases, 78 showed resistance to at least one TB drug. The resistance pattern to any of the first line TB drugs was: isoniazid 45, rifampin 3, ethambutal 5, and pyrazinamide 4. There were 3 multi-drug resistant TB cases (resistant to at least INH and rifampin) in 2004, down from 14 in 2002 and 7 in 2003. However, 60 cases showed resistance to ‘any other’ TB drugs, indicating resistance to second line TB drugs.

It is not yet possible to determine the Canadian incidence of TB-HIV co-infection from our existing surveillance systems. Screenings for HIV in TB cases and the reporting of results have been identified as essential tasks for the future prevention and control of TB in Canada.
1.2 Tuberculosis Control Programs: A Definition

1. The first priority of a TB control program is the early identification and the curative treatment of all infectious cases. This reduces the bacillary burden and decreases the risk of infection being transmitted to others.

Rapid diagnosis of suspected cases depends on:

- the patient entering the health care system when the first signs of TB appear; and,
- the health care practitioner’s ability to recognize TB.

To ensure that both the public -- particularly populations at risk of TB -- and health care practitioners have the knowledge and awareness to act quickly to diagnose and treat TB, an effective control program must provide on-going public and health care provider education.

2. The next priority is evaluation and follow-up of close contacts of active cases in order to identify secondary cases and to provide therapy for latent tuberculosis infection (LTBI).4

Three basic strategies critical to the prevention and control of TB in order of priority are:

i) identifying and completely treating all persons with active TB.

ii) Carrying out contact investigations

iii) Screening populations at high risk for TB (infection and/or other diseases).5

1.2.1 Tuberculosis Control in Ontario: Current Mandatory Programs and Services Guidelines (MHPSG)

Under the Mandatory Health Programs and Services Guidelines (MHPSG), published by the Ontario Ministry of Health in January 1998, each Board of Health is required to provide a Tuberculosis Control Program. Revised program standard are expected in 2007 and it is anticipated that objectives will be updated. The current MHPSG are described below:

1.2.2 Goal

The goal of a TB Control Program is to reduce the incidence of tuberculosis.

1.2.3 Objectives

To achieve this goal, boards of health will strive to meet the following objectives:

(a) Reduce the annual incidence rate of active and reactivated TB to 3.5 per 100,000 population by the year 2005.
(b) Reduce the progression of latent TB infection to active TB.
(c) Reduce secondary drug-resistance by the year 2005.

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5 Ibid p. 189
(d) Achieve the following completion rates by the year 2005:

- 95% of active TB cases will complete treatment as prescribed.
- 90% of individuals on chemoprophylaxis will complete therapy.
- 90% of contacts of active cases of TB will be assessed.
1.3 Roles and Responsibilities in TB Control

1.3.1 The Board of Health

According to the Program Requirements and Standards (TB Control Program, MHPSG), each Board of Health:

1. Shall have in place an effective program for TB control outlined in a policy and procedure manual, consistent with the Ontario Ministry of Health Tuberculosis Control Protocol.

For people with active tuberculosis, the Board of Health program will include case finding, case holding, treatment and follow-up. Such programs will, at a minimum:

(a) Ensure that all cases/suspected cases are fully investigated, according to the Ontario Ministry of Health Tuberculosis Protocol.
(b) Ensure the provision of provincially-approved anti-tuberculosis drugs, as required, at no cost to the patient.
(c) Review drug regimens and sensitivity results for each case to ensure their appropriateness and adequacy.
(d) Monitor patient compliance with prescribed drug regimens, including the completion and outcome of therapy, according to the Ontario Ministry of Health Tuberculosis Protocol.
(e) Ensure that all persons with active (infectious) tuberculosis complete the prescribed course of chemotherapy through the provision of directly-observed therapy (DOT), or other appropriate intervention, according to the Ontario Ministry of Health Tuberculosis Protocol.
(f) Notify the Ontario Ministry of Health immediately in the event that a patient does not complete the above therapy.
(g) Provide, or ensure the provision of, annual updates to physicians and other health professionals in the form of written materials and/or presentations on signs and symptoms, risk factors and reporting requirements to achieve the early identification and early reporting of active cases.
(h) On an on-going basis and in collaboration with community organizations, local agencies and institutions, provide to the community written materials and educational sessions on the signs and symptoms, epidemiology, risk factors and the benefit of treatment to promote the early identification and treatment of persons with active tuberculosis.

2. For TB prevention, the Board of Health shall have in place an effective program, consistent with the Ontario Ministry of Health Tuberculosis Control Protocol. Such a program will, at a minimum:

(a) Trace and investigate contacts of cases according to the Ontario Ministry of Health Tuberculosis Protocol.
(b) Trace and monitor individuals placed on medical surveillance for inactive tuberculosis according to the Ontario Ministry of Health Tuberculosis Protocol.
(c) Promote, through education and selective group screening programs, the screening of all persons in high risk groups and assessment of those testing positive to rule out active tuberculosis.
(d) Encourage the prescribing of anti-tuberculosis chemoprophylaxis to those testing positive, unless medically contraindicated.
(e) Ensure the provision of provincially-approved anti-tuberculosis chemoprophylaxis drugs at no cost to the patient.
(f) Review the required drug regimens for each person on chemoprophylaxis to ensure their adequacy and appropriateness.
(g) Monitor patient compliance with prescribed drug regimens and completion of therapy according to the Ontario Ministry of Health Tuberculosis Protocol.
(h) Monitor the completion rate of the prescribed course of chemoprophylaxis for the purpose of achieving the above-stated objectives.
(i) Provide or ensure the provision of annual updates in the form of presentations and/or written materials to health professionals on risk factors for tuberculosis infection, administration and interpretation of skin tests, indications for and benefits of chemoprophylaxis and reporting of positive skin test results.
(j) On an on-going basis and in collaboration with community organizations, local agencies and institutions, provide to the community written materials and educational sessions on risk factors for tuberculosis infection and benefits of chemoprophylaxis.

1.3.2 The Ontario Ministry of Health and Long Term Care
To support boards of health in their efforts to control TB, the Ontario Ministry of Health will:

(a) Establish provincial standards for Tuberculosis Control Programs and review and update them, as required.
(b) Design, implement and evaluate provincial TB control strategies.
(c) Administer the TB drug program.
(d) Collect, analyze and disseminate provincial data.
(e) Assist in the interpretation and enforcement of legislation as it relates to TB control.
(f) Liaise with federal, provincial and territorial TB Control Programs to:
   ▪ develop and implement national policies
   ▪ facilitate the administration of TB Control Programs across boundaries (provide inter-provincial consultation and liaison for case and contact follow-up)
   ▪ consult with Citizenship and Immigration Canada on policies related to screening and follow-up of cases of inactive tuberculosis in immigrants, refugees, visitors, visa students and persons of undetermined immigration status.
(g) Provide consultation to other Ontario Ministry of Health branches (e.g., Residential Services Branch) and provincial Ministries (e.g., Ministry of Correctional Services, Ministry of Education).
(h) Report TB data to the Public Health Agency of Canada (PHAC).
(i) Provide and support educational updates to groups and individuals involved in TB control.
1.3.3 Private Physicians

For most people, physicians are usually the first point of contact with the health care system and the health care providers most likely to see people at risk and to diagnose TB.

As part of the TB Control Program, physicians will:

(a) Administer and interpret PPD skin tests.
(b) Assess and diagnose suspect cases of TB.
(c) Report to the local Medical Officer of Health, or designate, all cases of active and suspect cases of active TB within 24 hours of making the diagnosis and report positive skin tests within 7 days.
(d) Provide chemoprophylaxis as outlined in the current Canadian Tuberculosis Standards.
(e) Provide treatment to cases and chemoprophylaxis to contacts of drug-resistant cases in consultation with an expert in TB management.
(f) Provide treatment and medical follow-up of case until the person has completed therapy.
(g) Provide information requested by the local Medical Officer of Health as well as interim and final reports on all cases and contacts on chemoprophylaxis. This information should, at minimum, include X-ray, smear and culture results as well as medication changes throughout the duration of treatment.
(h) Monitor and report in a timely fashion to the local Medical Officer of Health any issues re: non-compliance with treatment, including missed appointments.

1.3.4 The Laboratory/Diagnostic Facility

To support the TB Control Program, the laboratory/diagnostic facility will:

(a) Provide instructions to physicians/patients on collecting and submitting specimens
(b) Adhere to Laboratory Proficiency Testing Program (LPTP) standards in the collection, transportation, processing and retention of specimens
(c) Report positive results promptly to the attending physician and the Medical Officer of Health of the jurisdiction where the laboratory is located and where the specimen was collected
(d) Refer all culture positive specimens to the Public Health Laboratory (See Chapter 3: Diagnostics for details in specific health unit jurisdictions)
(e) Interpret results to health professionals and health unit staff
(f) Consult with and educate health care providers.
1.4 Reporting Requirements

Ontario’s TB Control Program depends on maintaining accurate information about TB cases in the province and having the ability to transfer or share information when appropriate. The Health Protection and Promotion Act 1990 (HPPA) clearly outlines the requirements of physicians, practitioners and institutions to report TB. The newly amended Regulation 569 in the HPPA specifically lists the reportable information required for TB. In order to maintain the integrity of the reporting system, all parties involved must fulfill their roles and responsibilities.

1.4.1 Definitions

(a) Surveillance Case Definition for Active Tuberculosis

An Individual:

- with Mycobacterium tuberculosis complex (i.e. M. tuberculosis, M. bovis (excluding BCG strain), or M. africanum) demonstrated on culture from sputum, body fluids, or tissues, or,

- without bacteriological proof but with clinical symptoms or signs, radiological or pathological evidence of active pulmonary or non-pulmonary disease, preferably with:
  - a positive tuberculin skin test (as defined by these provincial guidelines), and/or
  - demonstration of acid-fast bacilli in smears from sputum, other body fluids or tissue, and/or
  - response to anti-tuberculosis treatment.

(b) ICD 10 Coding for Tuberculosis

The new Integrated Public Health Information System (iPHIS), initiated in Spring 2005 in Ontario, is an information system for public health reporting and surveillance in Ontario. iPHIS replaced the Reportable Disease Information System (RDIS). In iPHIS, ICD 10 codes are used for TB.

These codes are provided on the following tables:
## Table 1: Respiratory TB

<table>
<thead>
<tr>
<th></th>
<th>ICD 10 Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>A15.0</td>
<td>Tuberculosis of Lung</td>
</tr>
<tr>
<td>ii.</td>
<td>A15.4</td>
<td>Tuberculosis of Intrathoracic Lymph Nodes</td>
</tr>
<tr>
<td>iii.</td>
<td>A15.5</td>
<td>Tuberculosis of Larynx, Trachea and Bronchus</td>
</tr>
<tr>
<td>iv.</td>
<td>A15.6</td>
<td>Tuberculosis Pleurisy</td>
</tr>
<tr>
<td>v.</td>
<td>A15.7</td>
<td>Primary Respiratory Tuberculosis</td>
</tr>
<tr>
<td>vi.</td>
<td>A15.8</td>
<td>Other Respiratory Tuberculosis</td>
</tr>
<tr>
<td>vii.</td>
<td>15.9</td>
<td>Respiratory Tuberculosis Unspecific</td>
</tr>
</tbody>
</table>

## Table 2: Tuberculosis of Nervous System

<table>
<thead>
<tr>
<th></th>
<th>ICD 10 Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>A17.0</td>
<td>Tuberculosis Meningitis</td>
</tr>
<tr>
<td>ii.</td>
<td>A17.1</td>
<td>Meningeal Tuberculoma</td>
</tr>
<tr>
<td>iii.</td>
<td>A17.8</td>
<td>Other Tuberculosis of Nervous System</td>
</tr>
<tr>
<td>iv.</td>
<td>A17.9</td>
<td>Tuberculosis of Nervous System Unspecified</td>
</tr>
</tbody>
</table>

## Table 3: Tuberculosis of Other Organs

<table>
<thead>
<tr>
<th></th>
<th>ICD 10 Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>A18.0</td>
<td>Tuberculosis of Bones and Joints</td>
</tr>
<tr>
<td>ii.</td>
<td>A18.1</td>
<td>Tuberculosis of Genitourinary System</td>
</tr>
<tr>
<td>iii.</td>
<td>A18.2</td>
<td>Tuberculosis Peripheral Lymphadenopathy</td>
</tr>
<tr>
<td>iv.</td>
<td>A18.3</td>
<td>Tuberculosis of Intestines, Peritoneum and Mesenteric Lymph Nodes</td>
</tr>
<tr>
<td>v.</td>
<td>A18.4</td>
<td>Tuberculosis of Skin and Subcutaneous Tissue</td>
</tr>
<tr>
<td>vi.</td>
<td>A18.5</td>
<td>Tuberculosis of Eye</td>
</tr>
<tr>
<td>vii.</td>
<td>A18.6</td>
<td>Tuberculosis of Ear</td>
</tr>
<tr>
<td>viii.</td>
<td>A18.7</td>
<td>Tuberculosis of Adrenal Glands</td>
</tr>
<tr>
<td>ix.</td>
<td>A18.8</td>
<td>Tuberculosis of Other Specified Organs</td>
</tr>
<tr>
<td>x.</td>
<td>A19.0</td>
<td>Acute Miliary Tuberculosis of a Single Specified Site</td>
</tr>
</tbody>
</table>

## Table 4: Miliary Tuberculosis

<table>
<thead>
<tr>
<th></th>
<th>ICD 10 Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>A19.1</td>
<td>Acute Miliary Tuberculosis of Multiple Sites</td>
</tr>
<tr>
<td>ii.</td>
<td>A19.2</td>
<td>Acute Miliary Tuberculosis, Unspecified</td>
</tr>
<tr>
<td>iii.</td>
<td>A19.8</td>
<td>Other Miliary Tuberculosis</td>
</tr>
<tr>
<td>iv.</td>
<td>A19.9</td>
<td>Miliary Tuberculosis, Unspecified</td>
</tr>
</tbody>
</table>
1.4.2 Definitions Related to Staging of a TB Episode:

(a) New Active Case:
No documented evidence or history of previously active TB.

(b) Relapsed (Reactivated) Case:
Documented evidence or history of previously active TB which became inactive.

(c) Inactive TB:
Negative cultures of mycobacterium tuberculosis negative for at least 6 months OR, in the absence of a culture, chest (or other) x-rays that have been stable for a minimum of 6 months.
1.5 Duty to Report

Under the *Health Protection and Promotion Act* (HPPA) Revised Statutes of Ontario, 1990 Chapter H.7, the following sections apply:

1.5.1 Physicians and Practitioners

Section 25 requires a physician or a practitioner to report as soon as possible to the Medical Officer of Health in the health unit in which the professional services are provided if a person, who is not a patient in or an out-patient of a hospital, has, or may have, a reportable disease. TB is a reportable disease under the HPPA.

Practitioners include:

- Chiropractors,
- Dentists,
- Nurses,
- Pharmacists,
- Optometrists, and
- Registered drugless practitioners.

The person’s name, address, date of birth, gender and date of onset of symptoms and additional information as the Medical Officer of Health (MOH) considers necessary must be provided.

1.5.2 Carriers of Disease

Section 26 requires a physician to report as soon as possible to the Medical Officer of Health in the health unit in which the professional services are provided if a person is, or may be, infected with an agent of a communicable disease. This would include carriers of TB; i.e., persons who have a positive Mantoux skin test or who have an abnormal chest x-ray.

The person’s name, address, date of birth, gender and date of onset of symptoms and additional information as the MOH considers necessary must be provided.

1.5.3 Hospital Administrators and Superintendents of Institutions

Section 27 requires hospital administrators and superintendents of institutions to report to the Medical Officer of Health in the health unit in which the hospital or institution is located, if an entry in hospital or institution records indicates that a patient or an out-patient:

- Has, or may have, a reportable disease; or,
- Is infected, or may be infected, with an agent of a communicable disease (i.e., TB cases and carriers).

The report should be made as soon as possible after the entry is made in the records of the hospital or institution.

The person’s name, address, date of birth, gender and date of onset of symptoms and additional information as the MOH considers necessary must be provided.
1.5.4 **School Principals**  
Section 28 requires the principal of a school to report if a student in the school has, or may have, a communicable disease (i.e., TB), as soon as possible, to the Medical Officer of Health in the health unit in which the school is located.

The student’s name, address, date of birth, and gender, as well as the name and address of the school that the student attends, must be provided.

1.5.5 **Operator of a Laboratory**  
Section 29 requires the operator of a laboratory to report each case of a positive laboratory finding in respect of a reportable disease (i.e., TB) *within 24 hours* to the Medical Officer of Health in the health unit in which the laboratory is located.

The person’s name, address, date of birth, gender, and the name and address of the physician or dentist attending the person, must be provided.

1.5.6 **Reporting Death due to a Communicable Disease**  
Section 30 requires that a physician who signs a medical certificate of death to report if a reportable disease was the cause or a contributing cause of death, as soon as possible to the Medical Officer of Health in the health unit in which death occurred.

The deceased person’s name, address, gender, date of birth, and date of death as well as the name and address of the physician who attended the deceased, must be reported.

1.5.7 **Medical Officer of Health Reporting**  
Section 31 requires that every Medical Officer of Health (MOH) reports to the Ministry after receiving a report of reportable diseases or deaths from such diseases that occur in the health unit served by the MOH.

1.5.8 **Physician Reporting Refusal or Neglect of Treatment**  
Section 34 requires physicians to report the name and residence address of any person who, while under the care and treatment of a physician in respect of a communicable disease, refuses or neglects to continue the treatment the physician has prescribed, to the Medical Officer of Health serving the health unit in which the physician provided the care and treatment.

If the person does not reside in the health unit served by the MOH where the physician provided the care and treatment, the MOH shall transmit the report to the MOH serving the health unit where the person resides.
1.6 Information Collected for Reporting TB:

1.6.1 Regulation 569 of the HPPA
This regulation was amended in 2005 to ensure that the necessary information is obtained for reporting communicable diseases. There is a separate section for TB.

Section 6 Tuberculosis:
1. The date of the diagnosis.
2. The agent of disease.
3. The name and address of the physician attending the person.
4. Medical condition and status of the person including signs, symptoms and site, if any, of the infection.
5. The clinical history of the person, including:
   (a) The name of the hospital, date of admission and the date of discharge from the hospital if the person is admitted to hospital; or, the name of the hospital if the person is seen as an out-patient of the hospital.
   (b) The date and duration of isolation, if isolated.
   (c) Vaccination history.
   (d) Reactivation of old disease and years of previous treatment setting out the drugs and dosages used and the dates treatment commenced and ended.
6. The case classification of the person.
7. Laboratory findings and investigative tests including, without being limited to:
   • culture and antimicrobial sensitivity,
   • serological tests,
   • X-ray examination,
   • microscopic examination, and
   • cerebrospinal fluid examination, together with the results of the tests.
8. Current treatment, if any, of the infection, setting out the drugs and dosage used and the date treatment commenced and ended.
9. Completion of the course of treatment including the major mode of therapy (Directly-Observed Therapy - daily or intermittent or Daily, self-administered) and the treatment compliance estimate (80%, 50-79%, less than 50% or unknown).
10. Place where infection is believed to have been acquired.
11. The source of infection including history of exposures.
12. Risk factors for the disease.
13. The immigration status and origin of the person, including:
   (a) Country of birth.
   (b) Country of last residence.
   (c) Immigration Medical Surveillance serial number or Inland Processing Number.
   (d) Date of arrival in Canada.
   (e) Reported for medical surveillance (has made contact with health unit or equivalent agency in other jurisdiction.)
   (f) Has had medical assessment in Canada for immigration surveillance.
   (g) Immigration status at time of arrival in Canada.
   (h) Country of birth of parents, if person is under 20 years of age and Canadian-born but non-Aboriginal.
14. The registered Indian status of the person.
15. The travel history of the person, including:
   (a) Date and place of entry into country where disease acquired.
   (b) Date of departure from country where disease acquired.
1.6 Information Collected for Reporting TB

(c) Date and time of entry into Canada and carrier and flight number, if applicable.
(d) Travel within country where disease acquired by date, place and length of stay.
(e) Any other places visited en route to and from Canada.

16. List places and method of travel within Canada prior to and since the onset of illness.
17. The employment details of the person including job title and place of employment.
18. The name and address of the school the person attends, if applicable, including the classroom.
19. Health unit responsible for identifying contacts.
20. Names of health units with contacts.
21. Number of contacts identified.
22. Number of contacts traced.
23. Number of contacts tested and number of contacts treated.
24. Results of testing of contacts.
25. Outcome:
   (a) If the person is deceased: date of death and cause of death.
   (b) Complications.
   (c) Absconded - lost to follow-up before treatment completion.
   (d) Other.
1.7 Roles and Responsibilities

1.7.1 The Board of Health TB Staff

The Board of Health TB Staff will:

(a) Ensure that information collected on a reported case of tuberculosis or infection meets the requirements of the HPPA Ontario Regulation 569 (Amended to O. Reg. 1/05).

(b) Establish whether the case of disease/infection meets the surveillance definition.

(c) Report cases within 7 days to the Disease Control Service (DCS), Infectious Diseases Branch (IDB), Ontario Ministry of Health and Long-Term Care (MOHLTC) via the provincial reportable disease information system (iPHIS).

(d) Report to the senior medical consultant or designate, immediately upon notification, TB cases that are lost to follow-up, including people who have moved out of province, and cases on whom Section 35 orders have been written.

(e) Report to the senior medical consultant or designate immediately any TB cases that involve:

- Infants or children
- Media releases or have evoked media attention
- Outbreaks
- Contacts of cases who become active cases
- Schools, teachers, health care professionals
- Ambulance workers, firefighters or police
- TB in the jail or correctional system
- A person who has used bus, train or plane transportation for a journey in excess of eight hours during the infectious period (See Chapter 6: Contact Management for special forms for notification of TB on an aircraft.)
- Any other situation that you consider important that the MOHLTC should be made aware.

(f) Ensure that the information reported through iPHIS is complete, accurate, and updated, as appropriate, including the provision of the final case disposition.

1.7.2 Retention of TB Records By Health Units

There are two documents that provide guidance for the length of time a health unit should retain TB records. They are, as follows:

(i) Ministry of Health Records Management


This document was sent to Medical Officers of Health on September 26, 1986 to complete the Records Management Project which was initiated by the Public Health Resource Service in response to health unit requests for assistance in issues related
to record retention and filing systems. It provides recommendations for the retention of records in local public health units; however, local bylaws should also be considered in the retention schedules used by each Board of Health.

It was recommended that TB records be retained in the health unit office for five years after the date of the last activity in the file then sent to off-site storage for 35 years (total 40 years), after which the files can then be destroyed.

The Chest Disease patient records that were provided by the Ministry of Health for skin tests and chest x-rays (3 ½ ” x 6” cards) were discontinued after the closure of the Provincial Chest Clinics in 1982. They should be retained for two years then destroyed.

(ii) aIPHa Records Retention Guidelines for Ontario Health Units November 2000
This document describes and classifies most types of records that are maintained by each health unit in Ontario and specifies when such records can be transferred offsite and when they should be destroyed.

TB records are recommended to be kept in the office for two years after discharge then kept off-site for 18 years.

1.7.3 The Disease Control Service, Infectious Diseases Branch
The Disease Control Service, Public Health Division, Ontario Ministry of Health will:

(a) Report agreed upon data to the Public Health Agency of Canada.
(b) Analyze and summarize provincial TB data and make it available to the health units in the form of an annual report as well as providing a detailed epidemiologic review annually in PHERO.
(c) Provide feedback to each health unit on the quality of iPHIS data.
(d) Inform the health units of changes in TB policies and procedures.
(e) Act as liaison in transferring information between federal/provincial/territorial TB authorities and the health units.
(f) Provide guidance and assistance as required with complex cases or outbreak management.
(g) Search for old TB records for patients who were in sanatoriums in Canada.
(h) Request the services of a field epidemiologist from the Public Health Agency of Canada on an as-needed basis.
1.8 Transferring Information between Public Health Jurisdictions

People with TB and their contacts will often travel from one public health jurisdiction to another and their case information must follow them. Case information may be sent to the TB Control Unit by standard mail or by fax. When cases have not received treatment before leaving the health unit’s jurisdiction, then notification should be considered urgent and made by telephone or fax, rather than standard mail. The following describes responsibilities in transferring case information.

1.8.1 Transferring Information within Ontario

Under the HPPA (S.32), the Medical Officer of Health can provide case details, including names, to the Medical Officer of Health, or designate, of other (Ontario) health units for the purpose of administering the tuberculosis control program. Information on cases or contacts that live in Ontario but outside the health unit should be sent to the appropriate health unit (where the case/contact resides).

The receiving health unit must notify the referring health unit if the patient is lost to follow-up in the transfer process. The receiving health unit is responsible for giving the referring health unit details about the case disposition as soon as they are available.

The referring health unit is responsible for recording the final case disposition through iPHIS.

1.8.2 Transferring Information outside Ontario

Information on cases or contacts outside of Ontario or Canada should be forwarded to the Disease Control Service, Infectious Diseases Branch, Ontario Ministry of Health, who will be responsible for notifying the appropriate jurisdiction.

The receiving health unit must notify the referring health unit if a patient is lost to follow-up in the transfer process. The referring health unit is responsible for providing the final case disposition in iPHIS.
1.9 Legislation

Both the federal and provincial governments have legislation to guide TB management and control, as follows:

- Federal legislation attempts to prevent people with active TB from coming into the country until they have been treated, and to control the spread of TB in federally managed, controlled settings, such as correctional institutions.

- Provincial legislation guides the ongoing prevention, control and management of TB in Ontario.

Tables 5 and 6 outline the Federal and Provincial legislation in place containing sections pertaining to TB control or communicable diseases in Ontario. These documents outline the current statutory requirements but may not reflect the current standards of practice.

Current information for the legislation under the above jurisdictions may be obtained at the following web sites:

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Ontario:</td>
<td><a href="http://www.e-laws.gov.on.ca">www.e-laws.gov.on.ca</a></td>
</tr>
</tbody>
</table>
### Table 5: Federal Legislation

<table>
<thead>
<tr>
<th>FEDERAL STATUTE</th>
<th>IMPLICATIONS FOR TB</th>
</tr>
</thead>
</table>
| **QUARANTINE ACT** R.S., c. 33(1st Supp.), s.1.     | • TB is designated as a ‘dangerous disease’: note that it is not considered an infectious or contagious disease under this Act.  
  • Please see Chapter 14 “Quarantining Persons with TB Under the Federal Quarantine Act” for the roles and responsibilities of local public health units and the MOHLTC if a person is quarantined for TB under the Federal Quarantine Act.  
  Relevant sections of the act are:  
  **Medical Examination for a Dangerous Disease (TB):**  
  • Section 11 states how a person arriving in Canada from a place outside Canada with a reasonable suspicion of having a suspected dangerous disease can be requested to undergo a medical examination immediately; if the person refuses they can be detained for a period not exceeding 14 days.  
  **Detention Longer than 48 hours:**  
  • Section 12 states that if a person is to be detained for longer than 48 hours, the federal Minister of Health applies for an order to a judge of the superior court of the province in which the person is detained, that the person has a dangerous disease.  
  **Detention of Persons with Dangerous Disease:**  
  • Section 14 says that if the quarantine officer determines the person has a dangerous disease, the person can be detained, subject to the Minister, until the quarantine officer is satisfied that the person is not capable of infecting other persons with that disease. |
| **IMMIGRATION AND REFUGEE PROTECTION ACT** Immigration and Refugee Protection Regulations SOR/2002-227 | The Immigration and Refugee Protection Act requires that all applicants for permanent residence and some visitors who apply to enter Canada have a medical examination. Based on this examination, applicants might be refused entry into Canada if they have a health condition that is likely to be a danger to public health or safety, or that could be very demanding on health or social services. The Act also requires that people with certain medical conditions be placed under medical surveillance to encourage appropriate treatment and follow-up.  
  • All potential immigrants, including sponsored refugees (people who immigrate from refugee camps outside of Canada) and people who are planning to stay in Canada for a period of six or more months and who have resided or sojourned, at any time during the one year period immediately preceding the date of seeking entry, for six consecutive months, in an area that, in the opinion of the National ... |
### 1.9 Legislation

#### FEDERAL STATUTE

<table>
<thead>
<tr>
<th><strong>IMPLICATIONS FOR TB</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Minister of Health, has a higher incidence of serious communicable disease (i.e., TB) than Canada, must have a medical examination before entering Canada.</td>
</tr>
<tr>
<td>• See Chapter 9: Immigration Medical Surveillance for details of the examination, assessment, process and forms.</td>
</tr>
</tbody>
</table>

#### Table 6: Province of Ontario Legislation

<table>
<thead>
<tr>
<th>ONTARIO STATUTE</th>
<th><strong>IMPLICATIONS FOR TB</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ambulance Act O. Reg. 257/100 Amended to O. Reg.317/04</strong></td>
<td>6(g) An emergency medical attendant and paramedic employed, or engaged as a volunteer, in a land ambulance service shall, be free from all communicable diseases set out in table 1 of the document “Ambulance Services Communicable Disease Standards” published by the Ministry, as that document may be amended from time to time.</td>
</tr>
</tbody>
</table>
| **Animals for Research Act (Reg.24)** | **Section 23:**  
(2) Every non-human primate shall, forthwith upon arrival at a research facility and at such further intervals as may be appropriate, having regard to all of the circumstances, be tested for tuberculosis in a manner adequate to disclose the presence of tuberculosis in the primate. R.R.O. 1990, Reg. 24, s. 23 (2).  

(3) Every non-human primate found to have tuberculosis by a test under subsection (2) shall be isolated from other non-human primates that have not been found to have tuberculosis or shall be humanely destroyed except only that such steps need not be taken to the extent that the spread of tuberculosis forms a necessary element in research. R.R.O. 1990, Reg. 24, s. 23 (3).  

(4) No person who is known to have active tuberculosis shall be employed in the care of non-human primates. R.R.O. 1990, Reg. 24, s. 23 (4). |
<p>| <strong>Cemeteries Act (Revised) R.S.O. 1990, c.C.4</strong> | 53 (2) If a Medical Officer of Health determines that remains are those of a person who died of a communicable disease within the meaning of the Health Protection and Promotion Act, the remains shall not be dealt with in any way except as prescribed by the regulations made under that Act. R.S.O. 1990, c. C.4, s. 53 (2). |</p>
<table>
<thead>
<tr>
<th>ONTARIO STATUTE</th>
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</thead>
<tbody>
<tr>
<td><strong>Charitable Institutions Act R.R.O. 1990 Reg. 69 s. 11,18</strong></td>
<td>11. (1) No board shall appoint an administrator or person to act temporarily as an administrator or employ a person on the staff of the charitable institution maintained and operated by it until the person so appointed or employed has obtained from a physician a certificate certifying that he or she is, (a) free from active tuberculosis or other communicable or contagious disease; (2) At least once a year the administrator and each staff member of the institution shall obtain the certificate prescribed in subsection (1). R.R.O. 1990, Reg. 69, s. 11 (2). (3) This section does not apply to a charitable institution that is an approved charitable home for the aged. O. Reg. 371/94, s. 4. (1) An approved corporation maintaining and operating a charitable institution other than an approved charitable home for the aged shall ensure that each person who is admitted to the institution as a resident is given a skin test for tuberculosis unless the test is medically contra-indicated. O. Reg. 371/94, s. 7. (2) An approved corporation maintaining and operating an approved charitable home for the aged shall ensure that each person who is admitted to the home as a resident is given a skin test for tuberculosis unless, (a) the person was given the skin test in an approved charitable home for the aged, a home under the Homes for the Aged and Rest Homes Act or a nursing home under the Nursing Homes Act less than one year before the date of admission; or (b) the test is medically contra-indicated. O. Reg. 371/94, s. 7. (3) The approved corporation shall ensure that the test required under subsection (1) or (2) is given, (a) within 14 days after the person's admission, if the person is admitted for a period of at least 14 days; or (b) within the period for which the person is admitted, if the person is admitted for a period of less than 14 days. O. Reg. 371/94, s. 7.</td>
</tr>
</tbody>
</table>

18.2 If the Ministry of Health gives an approved corporation maintaining and operating an approved charitable home for the aged a surveillance protocol for a particular communicable disease, the approved corporation shall implement the protocol. O. Reg. 371/94, s. 7.
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<tr>
<td><strong>Child and Family Services Act R.R.O. Reg.70</strong></td>
<td>93. Every licensee shall ensure that each person in a residence operated by the licensee who suffers from a communicable disease and for whom isolation is considered necessary by a physician is isolated from other persons in the residence who have not been infected. <em>R.R.O. 1990, Reg. 70, s. 93.</em></td>
</tr>
<tr>
<td><strong>Health Insurance Act R.R.O. 1990 Reg. 552</strong></td>
<td>This is a lengthy regulation that clearly outlines who is considered a resident of Ontario and who is eligible for a health card. The application for health insurance is outlined.</td>
</tr>
</tbody>
</table>
| **Health Protection and Promotion Act R.S.O. 1990, Chapter H.7** | The Health Protection and Promotion Act (HPPA), the main legislation for tuberculosis control, *provides the legal basis for controlling communicable diseases, including TB.*  

Under this Act, diseases are designated as reportable (*O. Reg. 559/91*), communicable (*O. Reg. 558/91*) or virulent (*HPPA, Section 1*). Communicable diseases are a subset of reportable diseases, and virulent diseases are a subset of communicable diseases.

In the HPPA, tuberculosis is a *Reportable, Communicable and Virulent disease*, and both tuberculosis infection (identified by a positive skin test) and tuberculosis disease are reportable to the Medical Officer of Health (*HPPA, Sections 25 and 26*).

The HPPA lists the reporting requirements for communicable diseases. It also gives the Medical Officer of Health the authority to issue orders against anyone who has a communicable disease, such as TB, and who is putting others at risk. It also provides:

a) the Medical Officer of Health the authority to access personal information that will assist in contact tracing

b) people with a communicable disease the right to appeal an order issued by a Medical Officer of Health.

**Sections in HPPA:**
See Chapter 12 for specific information on use of Orders s.22 and 35 under the HPPA:

s.22 Order by MOH re communicable disease  
s.23 Order by MOH re persons under 16 years of age  
s.24 Directions by MOH  
s.25 Duty to Report Disease
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<tr>
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<tbody>
<tr>
<td>s.26 Carrier of Disease</td>
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<tr>
<td>s.27 Duty of hospital administrator and superintendent of institution to report disease</td>
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<td>s.28 Duty of School principal to report disease</td>
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<td>s.29 Duty of Laboratory operator to report disease</td>
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<td>s.30 Duty to report death</td>
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<td>s.31 Reports by MOH’s re diseases</td>
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<tr>
<td>s.32 Communication between MOH’s</td>
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<td>s.34 Physician to report refusal or neglect of treatment</td>
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<tr>
<td>s.35 Order by Ontario Court of Justice</td>
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<td>s.36 Where person withdraws from care and treatment</td>
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<td>s.37 Examination of persons under detention</td>
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<td>s.38 Confidentiality</td>
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<td>s.43 Notice of right to hearing</td>
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<td>s.45 Appeal to court</td>
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<tr>
<td>Reg. 544 #4. Camps in unorganized territory – every operator shall forthwith notify the medical officer of health for public health inspector of an outbreak or suspected outbreak of any communicable disease in a camp operated by the operator.</td>
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</tbody>
</table>

**Homes for the Aged and Rest Homes Act R.R.O. 1990 Reg. 637**

25.1 (1) The municipality, municipalities or board maintaining and operating a home shall report to the Director in full detail each of the following occurrences in the home:

4. A communicable disease outbreak.

28.1 (1) The municipality, municipalities or board maintaining and operating a home shall ensure that each person who is admitted to the home as a resident is given a skin test for tuberculosis unless,

(a) the person was given the skin test in a home, a nursing home under the Nursing Homes Act or an approved charitable home for the aged under the Charitable Institutions Act less than one year before the date of admission; or

(b) the test is medically contra-indicated. O. Reg. 372/94, s. 14.

(2) The municipality, municipalities or board shall ensure that the test required under subsection (1) is given,

(a) within 14 days after the person’s admission, if the person is admitted for a period of at least 14 days; or

(b) within the period for which the person is admitted, if the person is admitted for a period of less than 14 days. O. Reg. 372/94, s. 14.

28.2 If the Ministry of Health gives the municipality, municipalities or board maintaining and operating a home a surveillance protocol for a particular communicable disease, the municipality, municipalities or board, as the case may be, shall implement the protocol. O. Reg. 372/94, s. 14.
<table>
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<tr>
<th>ONTARIO STATUTE</th>
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<tbody>
<tr>
<td><strong>Laboratory and Specimen Collection Centre Licensing Act R.R.O. Reg. 682</strong></td>
<td>9(1) The owner and the operator of a laboratory shall ensure that the staff of the laboratory,</td>
</tr>
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<td>(b) report the results of a test directly to the person who requested it and include in the report the name of the laboratory that received the specimen and the name and address of the laboratory in which the test was performed;</td>
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<td>(c) report all positive laboratory findings;</td>
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<td>(i) that indicate the presumptive presence of any communicable disease within the meaning of the Health Protection and Promotion Act to the Medical Officer of Health in the area from which the specimen originated within twenty-four hours after the test is conducted, and</td>
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<td>(ii) in respect of a reportable disease within the meaning of the Health Protection and Promotion Act to the Medical Officer of Health in the area in which the laboratory is located within twenty-four hours after the test is conducted.</td>
</tr>
<tr>
<td><strong>Livestock and Livestock Products R.R.O. Reg. 726</strong></td>
<td>23. Every person employed in the station is free from communicable disease and for that purpose shall, if so required by an inspector, be medically examined.</td>
</tr>
<tr>
<td><strong>Milk Act R.R.O. Reg. 761</strong></td>
<td>13. (7) No person shall milk an animal or handle milking equipment or utensils that come into contact with milk or cream except a person who is,</td>
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<td>(b) free from any communicable disease as defined in the Health Protection and Promotion Act and the regulations thereunder.</td>
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<td></td>
<td>Regulations with respect to the operation of plants:</td>
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<td>19. (1) The Commission may make regulations,</td>
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<td>23. providing for the pasteurizing of milk or cream used for the manufacture of a milk product;</td>
</tr>
<tr>
<td><strong>Mental Health Hospitals Act R.R.O. 1990 Reg. 744</strong></td>
<td>17. No employee found to be suffering from active tuberculosis shall be permitted to work in the institution and the officer-in-charge shall report the case within twenty-four hours to the Medical Officer of Health of the municipality in which the employee resides and to the Medical Officer of Health in the municipality in which he or she is employed. <em>R.R.O. 1990, Reg. 744, s. 17.</em></td>
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<tr>
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<td>19. The institution is responsible for all examinations for tuberculosis of an employee and none of the expenses thereby incurred are payable by the employee. <em>R.R.O. 1990, Reg. 744, s. 19.</em></td>
</tr>
<tr>
<td></td>
<td>20. No employee shall be detailed to care for a patient believed or suspected to be suffering from tuberculosis until the employee has received instructions</td>
</tr>
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</table>
### ONTARIO STATUTE

**IMPPLICATIONS FOR TB**

as to the necessary technique to protect himself or herself and others against infection and, where possible, the employee so detailed shall be a positive reactor to the tuberculin test. *R.R.O. 1990, Reg. 744, s. 20.*

21. Upon ceasing to be employed, every employee who has been employed for four or more months shall receive an x-ray film of the lungs and a nonreactor shall also receive a tuberculin test. *R.R.O. 1990, Reg. 744, s. 21.*

22. Nothing contained in sections 13 to 21 shall prevent any person from being employed in an institution when his or her tuberculosis is inactive. *R.R.O. 1990, Reg. 744, s. 22.*

23. A medical practitioner who believes or suspects that a person admitted to an institution is suffering from tuberculosis shall notify the officer-in-charge forthwith. *R.R.O. 1990, Reg. 744, s. 23.*

### Ministry of Health Act

**Regulations:**

12. Subject to the approval of the Lieutenant Governor in Council, the Minister may make regulations,

   (h) governing the establishment, maintenance, operation and use of and the treatment provided in facilities for the diagnosis, surveillance and treatment of tuberculosis, and governing the establishment, maintenance, operation and use of facilities for the diagnosis and surveillance of other respiratory diseases.

### Nursing Homes Act

**87.1 (1)** A licensee of a nursing home shall ensure that each person who is admitted to the home as a resident is given a skin test for tuberculosis unless,

(a) the person was given the skin test in a nursing home, an approved charitable home for the aged under the Charitable Institutions Act or a home under the Homes for the Aged and Rest Homes Act less than one year before the date of admission; or

(b) the test is medically contra-indicated. *O. Reg. 373/94, s. 16.*

(2) The licensee shall ensure that the test required under subsection (1) is given,

(a) within 14 days after the person’s admission, if the person is admitted for a period of at least 14 days; or

(b) within the period for which the person is admitted, if the person is admitted for a period of less than 14 days. *O. Reg. 373/94, s. 16.*

77.2 If the Ministry of Health gives the licensee of a nursing home a surveillance protocol for a particular communicable disease, the licensee shall implement the protocol. *O. Reg. 373/94, s. 16.*

### Personal Health Information

**Purposes**

1. The purposes of this Act are,
### ONTARIO STATUTE

<table>
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<tr>
<th><strong>Protection Act 2004</strong></th>
<th><strong>IMPLICATIONS FOR TB</strong></th>
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</thead>
<tbody>
<tr>
<td>(a) to establish rules for the collection, use and disclosure of personal health information about individuals that protect the confidentiality of that information and the privacy of individuals with respect to that information, while facilitating the effective provision of health care;</td>
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</tr>
<tr>
<td>(b) to provide individuals with a right of access to personal health information about themselves, subject to limited and specific exceptions set out in this Act;</td>
<td></td>
</tr>
<tr>
<td>(c) to provide individuals with a right to require the correction or amendment of personal health information about themselves, subject to limited and specific exceptions set out in this Act;</td>
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<tr>
<td>(d) to provide for independent review and resolution of complaints with respect to personal health information; and</td>
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<tr>
<td>(e) to provide effective remedies for contraventions of this Act. 2004, c. 3, Sched. A, s. 1.</td>
<td></td>
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</table>

Disclosures for health or other programs

2. A health information custodian may disclose personal health information about an individual,

(a) to the Chief Medical Officer of Health or a medical officer of health within the meaning of the Health Protection and Promotion Act if the disclosure is made for a purpose of that Act; or

(b) to a public health authority that is similar to the persons described in clause (a) and that is established under the laws of Canada, another province or a territory of Canada or other jurisdiction, if the disclosure is made for a purpose that is substantially similar to a purpose of the Health Protection and Promotion Act. 2004, c. 3, Sched. A, s. 39 (2).

<table>
<thead>
<tr>
<th><strong>Private Hospitals Act R.R.O. 937</strong></th>
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<tbody>
<tr>
<td>24. For the purpose of this Regulation, hospital employees are divided into Group 1 and Group 2. R.R.O. 1990, Reg. 937, s. 24 (1).</td>
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</tbody>
</table>

(2) Group 1 is composed of,

(a) graduate nurses;

(b) interns;

(c) graduate physiotherapists;

(d) graduate occupational therapists;

(e) nursing assistants, nurses' assistants, ward maids and ward orderlies;

(f) laboratory technicians; and

(g) X-ray technicians. R.R.O. 1990, Reg. 937, s. 24 (2).

(3) Group 2 is composed of all hospital employees not listed in subsection (2). R.R.O. 1990, Reg. 937, s. 24 (3).

25. (1) Every Group 1 employee shall receive a tuberculin test and an X-ray film of the lungs within thirty days of employment. R.R.O. 1990, Reg. 937, s. 25 (1).

(2) Every Group 1 employee who has a negative tuberculin reaction shall receive an additional tuberculin test within six months of the date of the first test and shall receive an additional test within six months after the date of each test, where the result of the test is negative. R.R.O. 1990, Reg. 937, s. 25 (2).

(3) Employees referred to in subsection (2) shall receive an X-ray film of the
## Tuberculosis Protocol

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### IMPlications FOR TB

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<tr>
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<tbody>
<tr>
<td>R.R.O. 1990, Reg. 937, s. 25 (3).</td>
<td>Lungs annually.</td>
</tr>
<tr>
<td>R.R.O. 1990, Reg. 937, s. 25 (4).</td>
<td>Every Group 1 employee who is found to have a positive tuberculin reaction shall not be required to take another tuberculin test but shall receive an X-ray film of the lungs forthwith and every six months thereafter.</td>
</tr>
<tr>
<td>R.R.O. 1990, Reg. 937, s. 25 (5).</td>
<td>Every Group 1 employee whose X-ray film shows evidence of abnormal shadowing shall forthwith receive further examination to determine the nature of the disease.</td>
</tr>
<tr>
<td>R.R.O. 1990, Reg. 937, s. 25 (6).</td>
<td>No tests other than the intradermal (Mantoux) test, using one-twentieth of a milligram of Old Tuberculin, or the patch test shall be used in the test given under this section.</td>
</tr>
<tr>
<td>R.R.O. 1990, Reg. 937, s. 25 (7).</td>
<td>Where an employee has received a tuberculin test and an X-ray film of the lungs within four months before the date of employment, the record of the result of the test and film may be accepted in lieu of the test and film required by subsection (1).</td>
</tr>
<tr>
<td>R.R.O. 1990, Reg. 937, s. 26 (1).</td>
<td>Every Group 2 employee shall receive an X-ray film of the lungs within thirty days of employment and annually thereafter.</td>
</tr>
<tr>
<td>R.R.O. 1990, Reg. 937, s. 26 (2).</td>
<td>Where an employee has received a tuberculin test and an X-ray film of the lungs within four months before the date of employment, the record of the result of the test and film may be accepted in lieu of the X-ray film required by subsection (1).</td>
</tr>
<tr>
<td>R.R.O. 1990, Reg. 937, s. 26 (3).</td>
<td>Every Group 2 employee whose X-ray film shows evidence of abnormal shadowing shall receive forthwith further examination to determine the nature of the disease.</td>
</tr>
<tr>
<td>R.R.O. 1990, Reg. 937, s. 27.</td>
<td>No employee found to be suffering from active tuberculosis shall be permitted to work in the hospital, and the superintendent shall report the case within twenty-four hours to the Medical Officer of Health of the municipality in which the employee resides.</td>
</tr>
<tr>
<td>R.R.O. 1990, Reg. 937, s. 28.</td>
<td>Where any legally qualified medical practitioner believes or suspects that any person admitted to the hospital is suffering from tuberculosis, he or she shall notify the superintendent forthwith.</td>
</tr>
<tr>
<td>R.R.O. 1990, Reg. 937, s. 29.</td>
<td>No employee shall be detailed to care for a patient believed or suspected to be suffering from tuberculosis until the employee has received instruction as to the necessary technique to protect himself or herself and others against infection and, where possible, the employee so detailed shall be a reactor to tuberculin.</td>
</tr>
<tr>
<td>R.R.O. 1990, Reg. 937, s. 30.</td>
<td>Upon ceasing to be employed, every employee who has been employed for four months or more shall receive an X-ray film of the lungs.</td>
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<td>ONTARIO STATUTE</td>
<td>IMPLICATIONS FOR TB</td>
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<tr>
<td>31. (1) The superintendent shall keep a permanent record of all examinations and tests of every employee of the hospital and if requested shall send a copy of every record, including the X-ray films, to the Workers’ Compensation Board or to the Minister. <em>R.R.O. 1990, Reg. 937, s. 31 (1).</em></td>
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<tr>
<td>32. The hospital is responsible for the examination of the employees and any expenses thereby incurred. <em>R.R.O. 1990, Reg. 937, s. 32.</em></td>
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<tr>
<td>33. Where an employee shows evidence of tuberculosis, the superintendent shall give written notice thereof and a complete report of the medical findings within seven days after the time of diagnosis to the Workers’ Compensation Board. <em>R.R.O. 1990, Reg. 937, s. 33.</em></td>
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<tr>
<td>34. Nothing contained in sections 24 and 33 prevents an employee from being employed in a hospital when his or her disease is inactive. <em>R.R.O. 1990, Reg. 937, s. 34.</em></td>
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<tr>
<td><strong>Public Hospitals Act</strong></td>
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<td><strong>R.R.O. 1990 Reg. 965</strong></td>
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<td>4. (1) Every board shall pass by-laws that,</td>
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<td>e) establish and provide for the operation of a health surveillance program including a communicable disease surveillance program in respect of all persons carrying on activities in the hospital;</td>
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<tr>
<td>2) The program referred to in clause (1) (e) shall, with respect to a particular communicable disease, include the tests and examinations set out in any applicable communicable disease surveillance protocol published jointly by the Ontario Hospital Association and the Ontario Medical Association for that disease and approved by the Minister. <em>R.R.O. 1990, Reg. 965, s. 4 (2).</em></td>
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<tr>
<td><strong>Workplace Safety and Insurance Act 1997 175/98</strong></td>
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<td><strong>SCHEDULE 3: OCCUPATIONAL DISEASES</strong></td>
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<tr>
<td>17. <strong>Tuberculosis</strong></td>
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</table>
| Any employment in a health care facility, a laboratory as defined in the Laboratory and Specimen Collection Centre Licensing Act or a reform institution, any employment in providing health care services or health care support services or any other employment in which there is a known risk of exposure to tuberculosis or to the tubercle bacillus.
2. Surveillance and Screening

2.1 Definitions

2.1.1 Surveillance

Epidemiologic surveillance of tuberculosis is the timely collection, analysis, interpretation and dissemination of data in order to:

(a) Identify TB trends in the community and
(b) Monitor and improve tuberculosis control activities.

2.1.2 Screening

Screening is the early identification of individuals who may have TB infection or disease.

An individual may be infected by *Mycobacterium tuberculosis* yet remain symptom free for many years or for their lifetime. The major screening test for tuberculosis infection is the tuberculin skin test.

Disease occurs when an infected person develops signs and symptoms of tuberculosis. Screening for active disease is often referred to as active case finding. Screening tests include sputum smear (this may include DNA fingerprinting if the patient is culture positive), chest radiograph or examination of tissue (biopsy) in a non-pulmonary site.

A TB screening program consists of testing, medical assessment and completion of recommended prophylaxis or treatment.

Testing is discouraged unless a plan has been developed to complete a course of treatment in persons found to have LTBI or active TB. Such planning should include arrangements for medical evaluation (e.g., chest radiographs) of persons with positive skin tests and for the medical supervision of the course of treatment.
2.2 Screening

2.2.1 Purpose of Screening

The purpose of screening is to:

(1) Identify undiagnosed active cases of infectious pulmonary TB in order to ensure adequate treatment and to prevent transmission to others.

(2) Identify infected people who are at high risk of developing TB in order to provide prophylaxis.

TB screening should be targeted at groups known to be at high risk for TB. With the exception of initial testing of persons at low risk whose future activity will place them at increased risk of exposure (e.g., employment in a setting where TB transmission may occur), screening of low-risk persons is discouraged because it diverts resources from activities of higher priority.

Each year, health units should review the TB epidemiology within their area, identify populations at risk of tuberculosis and target screening activities accordingly. Health units should evaluate their screening programs periodically to determine if they are effective and modify them as required. 6

2.2.2 Components of Screening

Tests used for screening are determined by the epidemiology, situation and purpose of screening. All screening for TB should include a symptom assessment. Any person with a history of symptoms should be investigated for TB disease.

- **For TB Infection:**
  Tuberculin Skin Testing (TST) (5TU PPD) is the recommended method of screening for TB infection. Other methods such as the Tine test should not be used. Further discussion about Mantoux skin testing may be found in Section 2.3. QuantiFERON® is a new blood test for TB infection which is under evaluation but has not been licensed in Canada. See Chapter 3: Diagnostics, Section 3.2.2. It is not yet approved by Health Canada and is not available at any labs in Canada except on a trial basis.

- **For TB Disease:**
  Screening for active case finding is rarely done. Focus should be on specific populations. (See: Section 2.2.3). Active case finding can include direct questioning for the presence of symptoms associated with active disease, sputum smears, chest radiographs or tissue examination for non-pulmonary TB. The presumptive diagnosis of active pulmonary TB is often made on the basis of microscopic examination of a stained sputum smear for acid-fast bacilli (AFB). Confirmation of the diagnosis usually requires identification of M. tuberculosis in culture.

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If a large number of sputum specimens are to be collected, prior arrangement needs to be made with the public health laboratory to ensure sufficient capacity for processing samples. If chest radiographs are planned, access to radiographic services and timely reading of chest x-rays need to be arranged.

- All screening programs should include:
  - (a) Clear rationale why a group is being screened
  - (b) Defined criteria of who is included or excluded (e.g., previous tuberculin skin test positive) from screening
  - (c) Written protocol stating how a person who tests positive will be managed (i.e., medical referral, further investigation, follow-up regarding prophylaxis or treatment).
  - (d) Data collection and compilation to track:
    - the number of eligibles,
    - the number of tests administered,
    - the number of positive tests,
    - the number who completed medical referral, and
    - the number who completed prophylaxis or treatment.
  - (e) Adequate resources to support the screening program.
  - (f) Evaluation of the effectiveness of the screening program.

- Operational issues to consider when screening is planned include:
  - (a) Education of group targeted for screening
  - (b) Training of staff who will be conducting the screening.
  - (c) Arrangements with laboratory if specimens e.g., sputum, are to be collected
  - (d) Written information about TB, translated into other languages as needed.
  - (e) Informed consent
  - (f) Relevant history taking. Ask clients about:
    - their history of BCG,
    - contact with active TB,
    - results of previous TB skin tests,
    - signs and symptoms of TB,
    - any previous treatment for LTBI or active TB, and,
    - their general health/current medical conditions.
  - (g) Referral for clinical evaluation of clients who have a positive test or are immune-compromised (e.g., HIV-positive) or are ≤5 years of age.
  - (h) Complete and accurate record keeping. Record TB skin test results, in millimeters of induration, for each person, preferably on the person’s immunization record (yellow card) and medical chart.

2.2.3 Indications for Screening

High risk individuals who should be considered for screening for LTBI include:

- (a) Contacts with recent exposure to a known or suspected TB case (see Chapter 6 - Contact Management)
- (b) Persons with HIV (Human Immunodeficiency Virus) infection
- (c) Persons born in countries with a high prevalence of tuberculosis
- (d) The poor, especially the urban homeless.
- (e) Alcoholics and Injection drug users
- (f) Staff and inmates in correctional facilities
(g) Staff and residents of long-term care homes
(h) Persons with a history of active TB or a chest X-ray suggestive of past TB and inadequate therapy
(i) Persons with high-risk medical conditions such as chronic renal failure, diabetes mellitus, immunosuppressive therapy and silicosis as well as persons who have been prescribed tumor-necrosis factor-alpha antagonists (i.e., Remicade® or Infliximab®)
(j) Aboriginal communities with high rates of tuberculosis
(k) Persons working in settings in which they may be exposed to TB (e.g., healthcare workers, homeless shelter workers, correctional institutions). These workers should have a two-step TB skin test PRIOR to starting their training/employment (See: Chapter 5 Case Management: Interim Guidance for the Prevention and Control of TB in Homeless Shelters and Drop In Centres) and, annually, depending upon their exposure risk.
(l) Children who are household contacts of HIV-infected persons, adopted from TB endemic countries, or who have spent more than one month in a TB endemic country
(m) Travelers who are visiting a high-endemic area and who have one of the following risks:
   - A medical condition that increases the risk of active disease following infection
   - Prolonged travel (greater than 1 month)
   - Intention to work in healthcare, refugee or other high-risk settings

There is NO COST associated with the testing of an individual who has been identified as a contact of an active case of infectious TB. If you are aware of a physician charging for this service, please have the individual call:

PROVIDERS SERVICES BRANCH, MONITORING AND CONTROL (extra billing section)
COLLECT at (613) 536-3103
2.2.4 Screening in High Risk Environments:

This section discusses screening according to risk settings but persons infected with TB can move from one setting to another; e.g., a person in a shelter enters a correctional facility. Therefore, timely communication is essential between facilities so individuals identified through TB screening receive adequate care and follow-up.

(a) Hospitals

The current Tuberculosis Surveillance Protocol for Ontario Hospitals is applicable to all persons who carry on activities in the hospital, including employees, students, volunteers, medical house staff, physicians, and contract workers. It does not apply to patients of these facilities or to visitors.\(^7\)

Pre-placement or pre-appointment assessment should include tuberculin skin test status to determine an accurate baseline. Persons with positive skin tests require further assessment by the Occupational Health Service, or an appropriate physician. The frequency of routine surveillance is dependent on the risk for TB transmission. High risk health care facilities are those with > 6 active TB cases per year or > 1 active case and the ratio of health care workers to the number of cases of TB annually is ≤100.\(^8\) High-risk activities include cough-inducing procedures such as bronchoscopy, autopsy, pathology examinations, and designated mycobacterium laboratory procedures. Frequency varies from post-exposure only to every six months.\(^9\)

The protocol requires active investigation for anyone who has had contact with a potential TB transmitter in hospital.

(b) Long-Term Care Homes (LTCH)

Long term care homes include:

- homes for the aged
- retirement homes
- nursing homes
- chronic care facilities
- any other collective living settings for the elderly or infirm.

TB skin testing is required for all residents, staff and volunteers in long-term care homes. Two-step skin testing is recommended for residents and staff within 14 days of admission or hire. Routine repeat screening is not recommended unless prevalence on employment screening exceeds 5% or annual conversion rate among staff exceeds 0.5%.\(^10\) All residents who show symptoms or signs of active tuberculosis should be placed in respiratory isolation and receive immediate medical assessment.

Instruct employees known to be TST positive to promptly report any symptoms suggestive of TB; e.g., cough, fever, anorexia or weight loss. Retest individuals who

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\(^7\) OHA/OMA Communicable Disease Surveillance Protocol, December 2002, p. 4
\(^8\) Ibid, pp. 9-10
\(^9\) Health Canada. Guidelines for Preventing the Transmission of Tuberculosis in Canadian Health Care Facilities and Other Institutional Settings. CCDR April 1996: 22S1
were initially skin test negative and were subsequently exposed to an infectious case of TB as part of a contact investigation. Always investigate residents who are symptomatic for TB.\(^\text{11}\)

(c) Correctional Facilities
The type of screening program should be influenced by the local epidemiologic data and whether facilities are short-term or long-term detention settings. All inmates who show symptoms or signs of active tuberculosis should be placed in respiratory isolation and receive an immediate medical assessment.

Correctional Service Canada has a protocol for tuberculosis control in penitentiaries.\(^\text{12}\) Generally speaking, employees and inmates should receive Two-step tuberculin skin testing within one month of employment or incarceration. Routine serial skin testing is recommended until conversion rates are established for each facility. All facilities require a mechanism for the transfer of screening information when inmates are transferred or discharged.

(d) Shelters and Drop-In Centres for the Homeless
Tuberculosis screening in urban homeless populations is generally focused on the detection of persons with active disease (case-finding). All shelter or drop-in centre users who show symptoms or signs of active tuberculosis should be placed in respiratory isolation and receive immediate medical assessment. Incentives such as food and transit vouchers are likely to increase compliance with screening interventions.

Staff and volunteers working in homeless shelters and drop-in centres should be screened with a Two-step tuberculin skin test initially, for an accurate baseline. The need for routine or annual screening should be determined by the local public health unit. See Chapter 5 Appendix A.

(e) Specialized Care Facilities
TB screening in specialized facilities, such as residential drug treatment centres, hospices, group homes etc., should be determined by the local public health agency and should be based on local epidemiology, and risk of TB transmission.

(f) Day Care Centres and Schools
A number of factors conspire against the effectiveness of school-based screening programs to prevent future cases of tuberculosis. These include:

- When applying the tuberculin skin test, which has limited specificity in a population at low risk for tuberculosis, some of the positive skin tests are likely to be false-positive reactions
- Limited rates of utilization of treatment of LTBI result in minimal impact on future cases of tuberculosis
- Such programs have a very low yield of detection of active cases of tuberculosis.\(^\text{13}\)

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\(^{11}\) Ibid
Well-conducted contact tracing of infectious cases and refugee or immigrant testing are more efficient than non-selective school-based testing for children who have TB infection.\textsuperscript{14}

Screening of employees working in day care settings should be restricted to those individuals who are at risk of active tuberculosis and where local epidemiology and resources allow.\textsuperscript{15} As an example, the rate of TB in Toronto is almost 3 times the provincial rate. Toronto Public Health recommends TB testing prior to employment for all staff and volunteers in daycares and nursery schools. They recommend that a skin test be done within 6 months prior to employment.\textsuperscript{16}

\textsuperscript{14} MMWR, 1995; 44 (No. RR-11), p. 11
2.3 Tuberculin Skin Testing

2.3.1 Mantoux

The major tool to diagnose tuberculosis infection is the tuberculin skin test. The standard Mantoux skin test is done using 5TU (5 tuberculin units) preparation. Tubersol®, manufactured by Sanofi Pasteur, is the skin testing preparation used in Canada. This test consists of the intradermal injection of a small amount of purified protein derived from M. tuberculosis bacilli. It is the most accurate, consistent and reliable of the skin tests. Purified protein derivative (PPD) does not have any live organisms. It is both safe and reliable throughout the course of pregnancy and during breastfeeding.

Tuberculin skin testing will identify those persons who have developed cell-mediated immunity to the tuberculin antigens. A reaction consisting of local swelling, or induration, indicates the presence of delayed hypersensitivity, which peaks in 24 – 72 hours. Newly infected persons will develop delayed cell-mediated immunity between 2 – 10 weeks after encountering the mycobacteria.

Conversion occurs when someone who has had previous negative skin test responds to a tuberculin test with induration and swelling which meets the criteria for a “positive” result (See: Section 2.4.2: Reading and Interpreting the Mantoux Skin test). Conversion is an indicator of recent infection.

Since a single tuberculin test can stimulate an anamnestic response, yet appear negative, a second test repeated at least one week after a negative response will differentiate between a true positive and what is known as a “booster effect”. This phenomenon has been described in various populations and must be distinguished from a sero-conversion. For more information, see Two-Step Testing in Subsection 2.4.2, following.

Multiple puncture tests (MPTs), such as the Tine test, should not be used. The MPTs are not reliable because the amount of tuberculin injected intradermally cannot be precisely controlled. As a result, these tests may have significant false-negative rates and readings are very difficult to standardize.

The tuberculin skin test reaction is not specific to M. tuberculosis complex (the mycobacterium causing tuberculosis in humans). Infection with a variety of non-tuberculosis mycobacteria or with BCG vaccine (a live, attenuated vaccine derived from M. bovis) may also cause the person to react to the tuberculin skin test. It is also not possible for the tuberculin skin test to differentiate between past and ongoing infection.

2.3.2 Storage and Handling of the Tuberculin Preparation

Correct storage and handling of the tuberculin preparation is critical. Failure to do so will result in a loss of potency and inaccurate test results or false-negative results. (Tubersol product monograph).

2.3 Tuberculin Skin Testing

(a) Store the tuberculin preparation between +2ºC and +8ºC. Store it in the dark except when the doses are actually being withdrawn from the vial. Do not leave it exposed to heat or light.

(b) Do not inject air into the vial prior to the withdrawal of PPD solution into the syringe.

(c) Date the vial of tuberculin when first opened if it is anticipated that all doses will not be used. Discard a vial of tuberculin preparation that has been opened after one month as the potency may be reduced due to oxidation and degradation.

(d) Return to Ontario Government Pharmaceutical and Medical Supplies Services (OGPMSS) any vial of tuberculin preparation that is beyond the expiry date (the last day of the month that is identified on the box), even if it is unopened.

For mass TB screening clinics, store a syringe filled with tubersol in the dark and use within one hour of being filled.

2.3.3 Indications for Tuberculin Testing

Refer to Section 2.2.3 Indications for Screening for the list of populations that should be screened using the TST test. The tuberculin skin testing should be performed to diagnose TB infection in persons at increased risk of developing the disease. 21

Tuberculin screening of low risk populations is generally discouraged, although testing may be performed for individuals. 22

2.3.4 Contraindications to Tuberculin Skin Testing 23

(1) When to defer skin testing:

Do not conduct skin testing in:

(a) Any one with a previous severe reaction (e.g., blistering, necrosis, or ulceration) to a TB skin test.
(b) Anyone with documented active TB or treatment in the past. (The test does not distinguish between prior and recent infection, and will not provide any useful information in this case.)
(c) People with extensive burns or eczema.
(d) People with viral infections which may temporarily depress the reactivity to the TST. Defer TST for 4-6 weeks after the infection.
(e) Anyone immunized with a live viral vaccine, (e.g., MMR, varicella), which may temporarily depress the reactivity to the TST. Refer to the Canadian Immunization Guide for the complete list of live vaccines. Either administer the Mantoux test before or simultaneously with the live, viral vaccine or defer TST for 4 to 6 weeks after immunization with a live viral vaccine.

(2) When not to defer skin testing:

Do not defer skin testing for:

---

22 Ibid, p. 46
23 Ibid
(a) People who have been immunized with a non-live vaccine, which does not suppress the reaction.
(b) Pregnant women.
(c) Anyone who had a previous BCG vaccination.
(d) Anyone who had a history of a positive TST in the past (without a severe reaction/blistering/ulceration/necrosis at the site) but the reaction was not documented in millimetres.
(e) Persons with a common cold.
2.4 Tuberculin Skin Testing (TST)

2.4.1 Mantoux Test Technique

(a) Use universal precautions during this procedure.

(b) Avoid the use of Emla cream or any other product that might, in and of itself, provoke a local reaction and interfere with the interpretation of the tuberculin.

Have Epinephrine Hydrochloride 1:1000 readily available for administration. Refer to the current Canadian Immunization Guide, Anaphylaxis: Initial Management in Non-Hospital Settings. The current recommendations of the National Advisory Committee on Immunization (NACI) say the patient who has had a Mantoux skin test should be monitored for immediate reactions for a period of at least 15 minutes after the test and for the initial management of anaphylaxis in non-hospital settings.

(c) Obtain an informed consent for the TST from the client.

(d) Use the Tuberculin Purified Protein Derivative (Mantoux) Tubersol preparation 5 TU for the test. Check expiry date on the vial.

(e) Assess the skin on the volar (flexor) surface of the forearm, about 4 inches below the bend of the elbow, in an area free of superficial blood vessels and free of skin lesions.

(f) Use a disposable, single-use sterile syringe and needle. The syringe should be a 1 ml syringe, calibrated in tenths fitted with a short (½inch) 26 or 27 gauge needle.

(g) Wipe the rubber cap of the vial of the tuberculin preparation with an alcohol swab. Do not inject air into the vial. Insert the needle gently through the cap and draw 0.1ml of the PPD

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tuberculin preparation into the syringe. Tap the syringe gently and remove any air until fluid can be expelled from the needle. **Ensure that exactly 0.1 ml. still remains in the syringe.**

(h) Clean the skin of the forearm with alcohol and allow to dry.

(i) With the bevel of the needle pointing upward, insert the point of the needle into the superficial layers of the skin (intradermally). If the tuberculin is injected correctly, a definite white bleb or “wheal” about 10mm in diameter will rise at the needlepoint. This bleb should disappear in 10 to 15 minutes.
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2.4 Tuberculin Skin Testing (TST)

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Figure 4: Wheal – Front View

Figure 5: Wheal – Side View

(j) If the tuberculin preparation is not injected correctly, repeat on the other arm following the
same procedure and document this clearly.


(k) If a drop of blood is present at the injection site, dab it (do not press with cotton ball). Do not cover with a Band-Aid.

(l) Dispose of needles in puncture resistant hazard container.

(m) Record the time, date, lot number and dose of tuberculin preparation injected and site(s) (including right or left arm) of injection. **Instruct the person to return at a specific date with 48-72 hours of the test to have the TST read.** Remind them that if the test is not read within the specified time frame, the test will have to be repeated.

(n) Although rare, vesiculation, ulceration or necrosis may appear at the test site in someone who is highly sensitive. If this occurs, advise the client to see a physician. Some people may also experience pain, itching, and redness at the site. **If the reaction is severe, it must be**
2.4.2 The Two-Step TST

(1) The Booster Effect:
A single TST may elicit little response but may stimulate an anamnestic immune response, so that a second TST given at any time from one week to one year later will elicit a much greater response. The booster effect was first described in older populations in whom it was felt to represent remote tuberculosis infection when immunity had waned. It has also been seen in persons with prior BCG vaccination or with non-tuberculosis mycobacteria. 25

*Note: Repeat skin testing will not induce a positive skin test reaction unless the individual has been exposed to the tubercle bacilli.*

The two-step testing is recommended for:

- Establishing a reliable base line for persons who have not been tested within the past year and who are going to be re-tested periodically.
- Resident of long term care home who may be tested subsequently
- Health care professional, staff in correctional facilities, workers in homeless shelters and drop-in centres
- For travellers to high prevalence area for prolonged visit.

The two-step test is NOT recommended for use as a baseline test for people who are contacts of an infectious case. In contacts, any change from negative to positive must be considered a conversion and treated appropriately.

(2) Method
The same method and techniques of administration and reading should be used. The second test should be performed one to four weeks after the first test. Less than one week does not allow enough time for the “booster ” effect to occur. More than four weeks, the second results may be a true tuberculin conversion, rather than the “booster “effect.

If the first test is positive (10 mm or more), do not perform the second test.

(3) Interpretation of the Two-Step TST
Consider anyone with a 10mm or greater reaction on the second TST for medical evaluation for their risk for tuberculosis. The reaction may indicate prior infection and/or disease with M. Tuberculosis and does not necessarily indicate the presence of active tuberculosis.

A chest x-ray should be done to determine the presence or absence of active pulmonary tuberculosis.

Microbiological examination of the sputum is recommended when the individual is symptomatic.

(4) Reading and Interpreting the TST

A person who is newly infected with tuberculosis will develop a positive skin test between 2 to 12 weeks after acquiring the infection. Induration is the result of a delayed hypersensitivity reaction. T-cells sensitized by prior infection are recruited to the skin site where they release lymphokines. Induration is induced through local vasodilatation, edema, fibrin deposition and recruitment of other inflammatory cells into the area.

(a) Reading the TST

1. Reading the TST should be done by a trained health care professional (never by the client).

2. Read the TST 48 to 72 hours after administration. Reactions may persist for up to one week or longer.

3. Measure induration (do not measure redness). Note any blistering, which may occur in 3% to 4% of cases.
4. To determine the size of the reaction, put the tip of a ball-point pen, at a 45 degree angle, towards the site of the injection. The tip of the pen will stop at the edge of the induration. Mark this point and repeat this process 3 times to determine the size of induration on both the transverse and long axis of the arm. (The four marks will form a rectangle.)

![Figure 10: Marking the Site](image)

5. Measure, in millimetres, the length of the transverse diameter (the line that is at right angles to the long axis of the forearm. This is the size of the reaction. **Always record the size of the reaction in millimetres (even if 0 mm). Do not use terms such as positive, or negative.**

![Figure 11: Reading the Test](image)
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<table>
<thead>
<tr>
<th>2.4 Tuberculin Skin Testing (TST)</th>
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</table>

6. **Do not measure the area of redness.** Approximately 2% to 3% of people test will have localized redness or rash (without induration), which occurs in the first 12 hours. These are allergic reactions. They are not serious, and do not represent tuberculosis infection.

7. **Document blistering or more serious reactions** (e.g. necrosis at the injection site) if they occur.
8. Record the date and size (in millimetres) of the TST result (induration) on the
immunization record as well as the physician/health unit chart.

(b) Interpreting the TST
When interpreting the TST, consider the following factors:
- Size of the tuberculin reaction.
- Purpose for which the test was given.
- Possible cause for false-negative and false positive reactions.
- Person’s risk factors for the development of tuberculosis.
- Local epidemiology of TB and prevalence of atypical mycobacterial infections.

<table>
<thead>
<tr>
<th>Tuberculin Reaction Size in MM Induration</th>
<th>Setting in Which the Reaction Is Considered Significant 26</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 – 4</td>
<td>HIV infection AND expected risk of tuberculosis infection is high (e.g., patient is an immigrant from a country where TB is endemic, is a household contact, or has an abnormal chest X-ray). This reaction size is not normally considered significant but in the presence of immune suppression may be important.</td>
</tr>
<tr>
<td>5 – 9</td>
<td>HIV infection Contact of active, contagious infection Abnormal chest X-ray with fibronodular disease.</td>
</tr>
<tr>
<td>&gt;10</td>
<td>All others (including routine screening).</td>
</tr>
</tbody>
</table>

(c) **Causes of a False Negative TST**

False negatives may be caused by the following factors:

(a) Incorrect storage/handling of the Tuberculin (i.e., exposure to heat/light, delayed injection after filling syringe, use of tuberculin that is outdated, or from vial first opened over one month ago).

(b) Poor injection technique.

(c) Lack of experience in interpretation, bias in interpretation.

(d) Severe illness, which can include TB.

(e) Immune suppression due to either advanced age or disease (e.g., HIV, lymphoma) or the effects of treatment (e.g., corticosteroids, oncologic chemotherapeutic agents).

(f) Malnutrition especially if there has been recent weight loss.

(g) Viral infection within the past 4 to 6 weeks.

(h) Recent immunization of a live viral vaccine, in the past 4 to 6 weeks. 27

(d) **Anergy Testing in People with HIV Infection**

People infected with HIV are at risk for active TB disease. Active TB may also speed the progression of HIV-related disease. All people with HIV who have clinical symptoms compatible with tuberculosis should be evaluated diagnostically for TB, regardless of the results of the tuberculin skin test.

Anergy testing is a diagnostic procedure used to obtain information about the competence of a person’s cellular immune system. However, anergy testing is no longer recommended as a routine component of TB screening among HIV-infected persons because of:

(a) problems standardizing, reproducing and interpreting results with the currently-available anergy testing methods; and,

(b) the lack of apparent benefit of preventive therapy for groups of anergic HIV-infected persons. 28

(e) **Causes of a False Positive TST**

(a) Cross-reactions between the PPD and mycobacteria other than M. tuberculosis.

(b) BCG vaccination. 29

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3. Diagnostics

3.1 Overview

Diagnostic tests can assist in determining:

- The identity of the infecting mycobacteria,
- The risk status of an infected person,
- Whether TB is latent or active,
- The site of TB disease,
- The infectiousness of a person with active disease,
- Appropriate treatment, and
- The extent and nature of a TB outbreak.

The presentation of TB varies according to the host, the environment, the site of infection and the clinical stage. Before turning to diagnostic studies, it is imperative to undertake a thorough history, regardless of whether one is investigating a positive skin test, an active case, or a contact.

Table 1 on the following page outlines the essential components of a diagnostic work-up for TB. The first two components, the history and the examination, should assist in determining whether the person of interest has latent or active disease, is at greater risk for TB disease, has a prior history of disease, and whether treatment was adequate.
Table 1. Components of a Tuberculosis Diagnostic Work-up

| Medical History                | TB history: history of TB exposure, prior tuberculin skin tests, prior TB infection or disease, risk factors for drug resistant TB (history of incomplete treatment, foreign birth, incarceration).
|                              | Demographics: country of origin, occupation, incarceration history and other factors that might increase the person’s risk of TB.
|                              | Medical conditions: conditions which increase risk for developing TB if infected or may affect ability to tolerate TB treatment.
|                              | TB symptom history: fever, weight loss, cough >3 weeks duration, hemoptysis, chest pain.
| Physical Exam                | Cannot be used to confirm or rule out a TB diagnosis but can provide valuable information about the person’s overall health status.
| Tuberculin Skin Test         | Tests can be negative in the presence of active disease or HIV infection. Not needed if disease already confirmed with a positive culture.
| Chest Radiograph            | Posterior / anterior view initially; others as appropriate. Children should routinely have a lateral in addition to a P/A.
| HIV                         | Because of implications of HIV infection for TB treatment, HIV counseling and testing is the standard of care for the initial work-up of TB suspects. If HIV positive, obtain CD4+ and viral load.
| AFB Smears, Cultures and Sensitivities | A positive smear indicates mycobacterial infection which may or may not be tuberculosis. Direct detection by molecular diagnostic methods (e.g., AMTD, Gen Probe) can identify the AFB in the specimen as Mycobacterium tuberculosis complex (MTBC). Bacteriologic culture for M. tuberculosis confirms the diagnosis of TB; however, clinicians should not wait for culture results before initiating therapy if they suspect active disease.*
| Histology                   | Pathology reports indicating caseating or necrotizing granuloma are presumed to be TB unless proven otherwise. Detection by molecular diagnostic methods, such as PCR for MTB in tissue blocks, is available at the Central Public Health Lab.

* A negative culture for M. tuberculosis does not rule out a diagnosis of pulmonary TB. Patients with abnormal chest x-rays and symptom histories compatible with TB should be treated presumptively. Individuals on anti-tuberculosis treatment with CXR improvement and negative cultures are considered to have culture-negative TB.

Used with permission from Maryland 2003 Guidelines for Prevention and Treatment of Tuberculosis

The symptoms of pulmonary disease include cough, chest pain and hemoptysis. Systemic symptoms of active TB include fever, chills, night sweats, loss of appetite, fatigue and weight loss. The clinical presentation of extrapulmonary TB will vary according to the site of disease and should be considered in the differential diagnosis of persons with systemic symptoms who are at risk for TB. Other sites of respiratory TB include the larynx, but not the pleura.

**HIV testing of persons with suspect and confirmed tuberculosis is the standard of care.** Knowledge of HIV status determines risk, alters presentation of disease and influences management and treatment. The provider treating the case should offer HIV testing to all suspects and cases. However, HIV testing should never be done without informed consent. TB treatment regimens are adjusted according to the CD4+ cells/μl count.
3.2 Tests to Determine Infection

3.2.1 Tuberculin Skin Test

For a complete discussion of TB skin testing, please see Chapter 2: Surveillance and Screening.

Since the TST is used to identify infection and not active TB disease, it is not necessary if disease has already been confirmed with a positive culture. Tuberculin testing is best used to diagnose latent TB infection or recent seroconversion. Although a positive TST is often the first step in a diagnostic workup, the test can be falsely negative in the presence of active disease or HIV infection.

The TST is performed to screen persons at increased risk of developing the disease, especially contacts of cases and HIV infected persons. A negative TST does not rule out active TB.

Contraindications for skin testing include a previously documented positive TST or treatment of culture positive TB. For more information on indications and contraindications, refer to Chapter 2: Surveillance and Screening.

A TST must be interpreted by a trained healthcare provider 48-72 hours after administration.

3.2.2 Interferon-γ Assays

The QuantiFERON® test (Cellestis Ltd) is a test which has FDA (U.S.) approval. The test detects latent TB infection but cannot differentiate this from active disease. This is a screening test for latent TB infection that can be used as an alternative to tuberculin skin testing in situations where skin testing is not feasible or is less desirable.

At present the QuantiFERON® test is not available in Canada, unless special arrangements have been made with the Special Access Program. Further Information may be obtained at www.cellestis.com.

A similar test, the Elispot (Wellcome, U.K.), measures the cellular response in blood to MTB antigens.

The test uses a whole blood sample from a patient, which is then incubated in a laboratory with specific proteins from MTBC as well as with an indicator of immune response, mitogen. The sample is then tested for gamma interferon, which indicates exposure to MTBC. The test is invalid if the test for immune response is not positive.

The advantages of the QuantiFERON® test are that it:
- Requires only one patient visit for blood sampling;
- Is not affected by prior BCG immunization;
- Provides a quantitative laboratory result rather than the subjective TST reading;
- Includes a test for immune response to eliminate possible false negative due to anergy.

A number of published studies have shown that the sensitivity and specificity of the QuantiFERON® and TST tests are similar. However further studies need to be done in specific populations such as paediatric and HIV patients.

Additional information may be found in: Section 3.6.
3.3  Tests for the Diagnosis of Pulmonary Disease

3.3.1  Radiology
Radiology is a useful tool to rule out or diagnose active TB. In addition, two views of the chest may show some abnormality that correlates with diagnosis of latent TB. The chest x-ray has limits on effectiveness due to the variability of reading/interpretation of results.

Indications include:
- Assessment tool if person has pulmonary symptoms.
- Assessment tool if person has systemic symptoms; i.e., pain in joint/bone.
- Assessment tool if person has positive TB skin test.
- Assessment tool for person who is being treated for active pulmonary TB to confirm efficacy of treatment/indication of improvement from previous exams.
- Assessment tool for person presenting with extrapulmonary TB to rule out pulmonary involvement.

The procedure includes:
- Requesting physician provides requisition/order for x-ray.
- Technician does the x-ray for a chest, from an anterior/posterior angle and a lateral angle (if recommended) and for any other portion of the body and confirms adequate view.
- Radiologist views the x-ray film and provides interpretation of the results.

Time to Results:
- Dependent on availability of radiologist to view and comment on results.
- Generally within 48 hours.

Interpretation:
Needs to be viewed/interpreted by experienced radiologist who has received sufficient information from the requesting physician on why the x-ray is being done; i.e., if active TB is suspected or if TB skin test is positive.

<table>
<thead>
<tr>
<th>Table 2: Presentation of Changes on Radiology:</th>
</tr>
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<tbody>
<tr>
<td>(a)  In presence of active pulmonary TB:</td>
</tr>
<tr>
<td>Changes in apices of lungs</td>
</tr>
<tr>
<td>Volume loss</td>
</tr>
<tr>
<td>Infiltrates</td>
</tr>
<tr>
<td>Nodules/Densities</td>
</tr>
<tr>
<td>Cavities</td>
</tr>
<tr>
<td>Pleural effusions</td>
</tr>
<tr>
<td>Hilar and/or mediastinal lymphadenopathy</td>
</tr>
<tr>
<td>(b)  In presence of latent pulmonary TB:</td>
</tr>
<tr>
<td>(3) Granuloma</td>
</tr>
<tr>
<td>(4) Fibrosis/scarring</td>
</tr>
<tr>
<td>(5) Calcified lymph nodes</td>
</tr>
<tr>
<td>(c)  In presence of active nonpulmonary TB:</td>
</tr>
<tr>
<td>(6) Abscess; i.e., bone</td>
</tr>
</tbody>
</table>
Special Conditions:

(a) In patients with HIV/AIDS:
The presentation on x-ray may be atypical due to immunocompromised status. Hilar and/or mediastinal lymphadenopathy are more commonly seen. Completely normal chest x-ray may be seen in advanced HIV disease.

(b) Children:
Lymphadenopathy more commonly seen—best viewed with a lateral view along with an anterior/posterior view. Pediatric chest x-rays should be done at a facility equipped to perform pediatric radiology. This is especially important for children younger than six years of age.

(c) CT scan:
Computed Tomography allows more precise assessment of both pulmonary and nonpulmonary disease.

3.3.2. Respiratory Specimen Collection
The collection of respiratory secretions, either via expectoration or during diagnostic procedures, is an important laboratory tool for the purpose of diagnosing active pulmonary TB and for the identification of antibiotic sensitivities to cultured MTB complex.

Indications include:
- Assessment tool if person has respiratory symptoms
- Assessment tool if person has changes on chest x-ray indicative of active or latent TB
- Assessment tool if person has history of pulmonary TB with or without treatment

The procedure includes:
- Have physician complete requisition for Acid-Fast Bacilli (AFB) smear and TB culture.
- Attempt to obtain sputum samples even if person denies having a cough. A series of three (3) specimens is recommended. A single collection should occur in the early morning on three (3) consecutive days.

**NOTE:** In order to collect an adequate sample of secretions and not just saliva, the person should cough deeply, bringing up sputum from the lungs (not saliva or spit from the throat or mouth) and deposit the sputum into specimen container.

- The container must be fitted with a tight lid and secured well, ensuring the container does not leak.
- The container should be properly labeled with person’s name and collection date and placed into the plastic specimen bag, pressing out the excess air and sealing the plastic bag.
- Complete the specimen collection form/requisition and place it in the outside slot of the plastic bag.
- The sample must be delivered to the lab as soon as possible and must be refrigerated if transport is delayed more than 2 hours.
- Person collecting the specimen should be wearing an N-95 mask or collect the sample outside in open air.
Time to Results:
- The AFB smear result is generally available within 24 hours of specimen arriving at the lab.
- The AMTD result, done automatically on the first AFB smear positive sample from a new patient, is generally available within the next 48 hours, depending on how often the lab does this testing. (Check with local public health lab to confirm when testing is done.)
- The TB culture result is generally available within 9-28 days of specimen arriving at the lab. (Mycobacteria are slow growing and the growth time for MTBC in the culture depends on the number of MTB organisms present within the sample.)
- A negative culture result is issued at 7 weeks.
- Antibiotic susceptibility testing is done on the first MTBC culture isolated from a patient. Results are generally available within 7 days of culture growth and are only obtainable on culture positive samples of MTBC.

Special Conditions:
(a) Induced Sputum Collection:
   If a patient:
   - cannot cough to produce sputum; or,
   - if the sputum sample collected is NOT sufficient,

   a saline solution can be inhaled via a nebulizer which will induce the person to cough up sputum for collection and processing in the same manner as noted above. Ensure the requisition indicates that the sputum was induced as the sample may appear watery.

(b) Bronchoscopy:
   If person cannot cough or if induced sputum is not available, a bronchoscopy can be done to obtain sputum samples. However, this procedure is more invasive and expensive.

(c) Gastric aspirate:
   This type of aspirate is often indicated when investigating TB in children less than five years of age, as they cannot cough forcefully enough to bring sputum up. During sleep, sputum from lungs moves up into the mouth and is swallowed into the stomach. Aspirating the stomach contents for sampling may reveal TB organisms. Aspiration is done when person first awakes and requires a special container containing sodium carbonate to neutralize the stomach acid. The sample is then processed in the same manner as noted above.
### Table 3: Interpretation of Lab reports

<table>
<thead>
<tr>
<th>Type of Test</th>
<th>Results</th>
<th>Interpretation</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acid Fast Bacilli smear (AFB)</td>
<td>Not Seen/Negative</td>
<td>No AFB seen in sample. Does not rule out TB—need to have culture results for diagnosis.</td>
<td>Sample may not contain enough organism to be seen by microscopy.</td>
</tr>
<tr>
<td>Scarce/Moderate/Numerous</td>
<td>AFB seen in sample.</td>
<td>Indicates amount of bacilli present. Indicates either MTB complex or non-tuberculosis mycobacteria.</td>
<td>AFB level can be indicator of infectiousness. The higher the number of bacilli, the higher the risk the patient is infectious.</td>
</tr>
<tr>
<td>Amplified Mycobacterium Tuberculosis Direct (AMTD)</td>
<td>Negative</td>
<td>MTB complex rRNA not detected indicates not TB</td>
<td>False negative can occur due to low number of MTB organisms. The presence of non-tuberculosis mycobacteria may cause interference or there may be inhibitors present in the sample.</td>
</tr>
<tr>
<td>Positive</td>
<td>MTB complex rRNA detected indicates is TB.</td>
<td>Sample may also contain non-tuberculosis organisms as well.</td>
<td></td>
</tr>
<tr>
<td>Indeterminate</td>
<td>Unable to interpret result.</td>
<td></td>
<td>Possible that not enough sample was obtained to test, very low number of MTB are present, or amplification inhibitors are present. Specimen collection should be repeated.</td>
</tr>
<tr>
<td>Culture</td>
<td>No growth</td>
<td>Indicates MTBC organisms were not grown</td>
<td>Case may still be clinically to be possible active TB (clinical case of TB).</td>
</tr>
<tr>
<td>Mycobacterium tuberculosis complex</td>
<td>MTBC organisms were grown</td>
<td></td>
<td>Confirm active case of TB.</td>
</tr>
<tr>
<td>Various non-tuberculosis mycobacteria</td>
<td>Non-tuberculosis mycobacteria (NTM) were grown.</td>
<td></td>
<td>Not MTBC, or MTBC may be overgrown by NTM.</td>
</tr>
<tr>
<td>Susceptibility Testing</td>
<td>Chart with susceptibilities to first line TB medications</td>
<td>Susceptible</td>
<td>Indicates which TB medications are effective.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Resistant</td>
<td>Indicates which TB medications are not effective.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Susceptible</td>
<td>Indicates which TB medications are effective.</td>
</tr>
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<tbody>
<tr>
<td></td>
<td></td>
<td>Resistant</td>
<td>Indicates which TB medications are not effective.</td>
</tr>
</tbody>
</table>
3.4 **Non-pulmonary TB**

TB disease of other organs and tissues requires the collection and testing of non-pulmonary specimens. Table 4 indicates the types of specimens which may be indicated and the specific instructions which must be followed in order for testing to be carried out.

It is important that all persons with non-pulmonary TB be screened for pulmonary disease, including chest x-ray and sputum.

*The following table is intended as a reference only (for health unit information). Health units are not expected to obtain these samples.*

<table>
<thead>
<tr>
<th>SPECIMEN TYPE</th>
<th>SPECIMEN REQUIREMENTS</th>
<th>SPECIAL INSTRUCTIONS</th>
<th>UNACCEPTABLE SPECIMENS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abscess contents, aspirated fluid</td>
<td>As much as possible in sterile plastic container</td>
<td>Cleanse skin with alcohol before aspirating sample. Submit in sterile container. If aspiration is not possible, collect specimen of swab and place in aerobic transport medium only if volume is insufficient for aspiration by needle and syringe.</td>
<td>Dry swab</td>
</tr>
<tr>
<td>Blood</td>
<td>10-mL SPS (yellow top) or 10 mL heparin (green top) blood collection tube</td>
<td>Disinfect site as for routine blood culture. Mix tube contents immediately after collection. 5mL blood may be injected directly to MycoF/Lytic media, if available.</td>
<td>Blood collected in EDTA, which greatly inhibits mycobacterial growth even in trace amounts(3). Coagulated blood. Serum. Plasma. Blood in bacterial blood culture medium that is inappropriate culture media for TB.</td>
</tr>
<tr>
<td>Body fluids (pleural, pericardial, peritoneal, etc.)</td>
<td>As much as possible (10-15mL minimum) in sterile container</td>
<td>Disinfect site with alcohol if collecting by needle and syringe.</td>
<td>Note : bloody specimens cannot be tested by AMTD.</td>
</tr>
<tr>
<td>Bone</td>
<td>Bone in sterile container without fixative or preservative</td>
<td>Specimen submitted in formalin.</td>
<td></td>
</tr>
<tr>
<td>Bone marrow</td>
<td>As much as possible in sterile collection tube or SPS or heparin tube</td>
<td>Collect aseptically. Mix anti-coagulant tube contents immediately following collection.</td>
<td></td>
</tr>
</tbody>
</table>

Table 4: Specimens Other Than Sputum
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<table>
<thead>
<tr>
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<th>SPECIAL INSTRUCTIONS</th>
<th>UNACCEPTABLE SPECIMENS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bronchoalveolar lavage or bronchial washing</td>
<td>&gt;5mL in sterile container</td>
<td>Avoid contaminating bronchoscope with tap water. Saprophytic mycobacteria may produce false positive culture or smear results.</td>
<td></td>
</tr>
<tr>
<td>Bronchial brushing</td>
<td>Sterile container. Add sterile saline if small amount</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CSF</td>
<td>&gt;2mL in sterile container</td>
<td>Send maximum volume attainable.</td>
<td>Specimen that has not been neutralized.</td>
</tr>
<tr>
<td>Gastric lavage fluid (for children less than 5 years of age)</td>
<td>5-10mL in sterile gastric container supplied from the Provincial health lab. Collect in the morning, before the patient gets out of bed in order to obtain sputum swallowed during sleep</td>
<td>Collect fasting early-morning specimen on 3 consecutive days. Laboratory provides gastric collection jars containing sodium carbonate. If gastric container not available – adjust specimen to neutral pH with 100 mg of sodium carbonate immediately following collection.</td>
<td></td>
</tr>
<tr>
<td>Lymph node</td>
<td>Node or portion in sterile container without fixative or preservative. A small amount of sterile saline may be added.</td>
<td>Collect aseptically and avoid indigenous microbiota. Select caseous portion if available. Do not wrap in gauze. Freezing decreases the yield.</td>
<td>Specimen submitted in formalin.</td>
</tr>
<tr>
<td>Skin lesion material</td>
<td>Submit biopsy specimens in sterile containers without fixative or preservative. Submit aspirate in syringe with Luer lock cap, needle removed.</td>
<td>Swabs in transport medium (Amies or Stuarts) are acceptable only if biopsy sample or aspirate is not obtainable. For cutaneous ulcer, collect biopsy sample from periphery of lesion or aspirate material from under margin of lesion. If infection was acquired in Africa, Australia, Mexico, South America, Indonesia, New Guinea, or Malaysia note this on the request because <em>M ulcerans</em> may require prolonged incubation for primary isolation.</td>
<td>Dry swab</td>
</tr>
<tr>
<td>Stool</td>
<td>&gt;1g in sterile, wax-free, disposable container</td>
<td>Collect specimen directly into container or transfer from bedpan or plastic wrap stretched over toilet bowl.</td>
<td>Frozen specimen. Specimen that has been in contact with water in the toilet.</td>
</tr>
</tbody>
</table>
### Table 4: Specimens Other Than Sputum

<table>
<thead>
<tr>
<th>SPECIMEN TYPE</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Tissue biopsy sample</td>
<td>1 g of tissue, if possible, in sterile container without fixative or preservative</td>
<td>Collect aseptically and avoid indigenous microbiota. Select caseous portion if available. Do not wrap in gauze. Freezing decreases the yield.</td>
<td>Specimen submitted in formalin.</td>
</tr>
<tr>
<td>Transtracheal aspirate</td>
<td>As much as possible in syringe with Luer lock cap, needle removed, or other sterile container</td>
<td>Do not submit specimens in endotracheal tubes.</td>
<td></td>
</tr>
<tr>
<td>Urine</td>
<td>As much as possible (minimum 40mL) of first morning specimen obtained by catheterization or midstream clean catch in sterile container. For suprapubic tap, as much as possible in syringe with Luer cap or other sterile container.</td>
<td>Collect first morning specimen on 3 consecutive days. Accept only one specimen/day. Organisms accumulate in bladder overnight so first morning void provides best yield. Specimens collected at other times are dilute and are not optimal.</td>
<td>24-h pooled specimens; urine from catheter bag, specimens of &lt;40mL unless larger volume is not obtainable. Urine specimens should only be tested if renal TB is suspected, not as routine screening.</td>
</tr>
</tbody>
</table>

Source: Adapted from publication: Mycobacteriology Laboratory Manual (2005), Laboratories Branch, Ministry of Health and Long-term Care. Reprinted with permission.

[www.health.on.ca](http://www.health.on.ca) & follow the links to Specimen Collection Guide

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**Note:** For queries about specimen collection or to discuss test results, contact the Lab Head or Microbiologist at the TB laboratory
3.5 Laboratory Testing for Tuberculosis

3.5.1 Overview

Laboratory testing is an integral part of the diagnosis of tuberculosis (TB). The acid-fast bacilli (AFB) smear test gives a rapid early indication of possible TB and of a patient’s infective status. Nucleic acid amplification tests (NAAT) can assist in the rapid identification of AFB seen in the smear, as *M. tuberculosis* complex (MTBC). Culture is more sensitive than the smear and a culture is required in order to do susceptibility testing. Susceptibility testing provides a guide to appropriate therapy. Strain typing may be used to assist in outbreak investigations and in tracing the transmission of TB.

The *M.tuberculosis* complex (MTBC) tests used to detect MTBC cannot differentiate the species within this group. The complex consists of *M. tuberculosis*, *M.africanum*, *M.cannettii*, *M.bovis*, *M.bovis* BCG, and several species found only in animals. The first 3 species may be considered the same, for the purpose of clinical significance. *M.bovis* will be identified during susceptibility testing since it is resistant to PZA. The significance is mainly epidemiological. *M.bovis* BCG will also be detected during susceptibility testing and is primarily found in patients undergoing BCG instillation therapy for bladder carcinoma.

3.5.2 Types of Laboratory Testing

(a) The AFB Smear

Specimens are processed in order to achieve decontamination from other organisms that may be present in the specimen, and for homogenization and concentration. A smear is made from the specimen concentrate, and is stained to allow visualization of AFB by microscopy.

Some laboratories perform a ‘direct smear’ from the specimen, without concentration. The result from a direct smear should be considered as preliminary, with transfer of the specimen to a referral lab where a more sensitive, concentrated smear can be performed. A concentrated smear provides detection of AFB in a specimen when the bacterial load is approximately 10,000 AFB per ml.

The smear is reported as “No AFB seen”, or “AFB seen” with the following quantitation: scarce, moderate or numerous. Other quantitation systems such as 1+, 2+, are used by some labs.

The smear report is issued within 24 hours of specimen receipt in the lab. All new AFB positive smear reports are phoned to the ordering physician/health professional. All positive AFB smear reports are copied to the Medical Officer of Health (MOH) where the patient resides and to the MOH where the lab is located, as per regulation.

A smear may be performed as a STAT in urgent cases. At Public Health Labs (PHLs), STAT requests must be telephoned to the lab and a same day, verbal result is given if the specimen arrives by 2:00p.m. (1400 hours).

AFB smears are not routinely performed on urine samples due to commensal nontuberculous mycobacteria (NTM) that may be present in the GU tract. Smears are not done on blood specimens or bloody fluid samples. These specimens are inoculated directly to blood culture media.
AFB seen on a smear may be MTBC, NTM or a few other species such as *Nocardia* spp. which are semi-acid fast. The specificity of the AFB smear for MTB depends on the demographics of the patient population. In Southern Ontario the specificity is approximately 50%, since the region has a high level of NTM. Smear positive specimens may be tested by an amplification test to determine the identity of the AFB as MTBC or NTM.

**Frequency of testing:**

- **For initial diagnosis:**
  Three sputum specimens, on three consecutive days, should be submitted.

- **Subsequent to initiation of treatment:**
  In order to monitor sputum conversion and treatment outcome, all patients with sputum smear and culture positive disease would have repeat sputum examinations performed at the end of the second month. To verify treatment success, additional sputum cultures should be obtained at the end of therapy for both six-month and nine-month regimens. More frequent monitoring is recommended when the clinical and radiographic response is unfavourable.  

  A referral for sputum induction should be made if the patient is unable to produce a sputum sample for examination.

**(b) Nucleic Acid Amplification Tests (NAAT)**

A number of NAAT tests are approved and available commercially. The Amplified Mycobacterium Tuberculosis Direct (AMTD) by Gen-Probe CA. was selected for use in Ontario due to rapid turnaround time, sensitivity and the potential to detect active, viable MTBC directly in clinical specimens. The test is used on concentrated specimens to detect the presence of rRNA from MTBC.

The AMTD is performed routinely on all new AFB smear positive specimens. The sensitivity and specificity are high (95%) on smear positive specimens. Smear negative specimens are only tested upon special request. The sensitivity is significantly lower (range 65-80%) for AMTD’s done on AFB negative specimens.

- **AMTD testing is performed at the Central Public Health TB Lab, Toronto, on Monday, Wednesday and Friday mornings.**
- **The test takes approximately 4 hours and all results are telephoned to the submitter by 2:00p.m. (1400 hours).**
- **AMTD cannot be done on blood or bloody specimens.**

Results are reported as follows:

- rRNA of MTBC detected (positive); or,
- rRNA of MTBC not detected (negative)

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Results may be ‘indeterminate’ due to inhibitors in the specimen or because of a very low bacterial load. In this case, the test will be repeated on the original specimen and, if still indeterminate, a new specimen may be sent for repeat AMTD testing.

- All AMTD results are telephoned to the ordering physician or lab.
- All positive results are copied to the MOH where the patient resides and to the MOH where the lab is located.
- AMTD testing is performed only on specimens from untreated patients and cannot be used to follow therapy.

(c) Culture
All specimens submitted for mycobacterial testing are inoculated to liquid and solid culture media. Inoculated media are monitored for growth for seven weeks. Culture is more sensitive than the AFB smear and can detect 10 to 100 viable organisms/mL. Due to the slow generation time of mycobacteria (18 hours vs. 30 minutes for other bacteria), culture growth and detection may take several weeks.

The average time for growth of MTBC in a liquid culture from a smear positive specimen of an untreated patient, is 10 days. Some NTM grow more slowly, for example *M. xenopi*, which may take 7 weeks for growth detection.

*Identification of growth from cultures: A DNA probe test, AccuProbe (Gen-Probe), is used to identify MTBC in cultures. The test is run daily and takes 2 hours.*

- All MTBC positive culture results from new patients are telephoned.
- All MTBC positive culture results are copied to the MOH

Cultures which are AFB positive but which are negative for MTBC are identified by AccuProbe or by high performance liquid chromatography (HPLC) as non-tuberculosis mycobacteria (NTM) species.

There are currently 113 known species of NTM.

Isolation of NTM from patient specimens may indicate NTM disease or may not be of not clinical significance. The 1997 American Thoracic Society recommendations on the Diagnosis and Treatment of NTM may be consulted.  

(d) Susceptibility Testing of MTBC
The first isolate of MTBCC from each patient, is tested for susceptibility to the 4 first line drugs (isoniazid, rifampin, ethambutol, pyrazinamide). The test takes an average of 7 days and all results are phoned to the submitter and copied to the MOH.

If resistance to isoniazid is found at the critical concentration, repeat testing is done using a higher level of the drug. If resistance is at the lower concentration only, it is reported: “Test results indicate low level resistance to INH”. Some experts believe that patients infected with

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strains exhibiting this level of resistance may benefit from continued therapy with INH. If resistance is found at both concentrations, a report is issued: “Test results indicate a high level of INH resistance”.

Repeat testing to the first line drugs is performed if cultures are still positive at three months. Any isolate found to be resistant to two of the first line drugs or to rifampin, is tested against a further panel of seven second-line drugs (streptomycin, amikacin, capreomycin, clofazamine, ofloxacin, rifabutin, ethionamide).

**Only specimens which produce a viable, pure culture of MTBC can be tested. Mixed cultures, such as MTBCC plus an NTM, cannot be tested for susceptibility.** In this case, more specimens should be submitted in order to enhance the possibility of obtaining pure growth.

**(e) PCR (Polymerase Chain Reaction)**

PCR is used at the Central Public Health laboratory to detect MTBC DNA in specimens that have been fixed in formalin or embedded in paraffin for pathology. These samples cannot be tested by AMTD or by culture, which require fresh, unfixed tissue or specimens. PCR is an NAAT that can be used to detect DNA from MTBCC in a specimen. The presence of DNA from MTBCC may not indicate that the bacteria are viable, or that the disease is in the active phase.

The fixing process can compromise the sensitivity of PCR, when used on these types of specimens, and therefore only a positive result, in conjunction with histopathology and clinical findings, can be used to determine whether a patient has active TB.

**This testing must be approved by the Microbiologist or the TB Lab Head**

(416-235-5993/5841)

**(f) Strain Typing of MTBC**

Strain typing of MTBC isolates can be used to determine whether patient strains are identical, related or unrelated to one another. This information must be used as an adjunct to routine contact tracing and epidemiological information. Strain typing is useful in investigating outbreaks of TB, patterns of transmission, determining whether a patient has reactivated or been re-infected, and in investigating possible laboratory cross-contamination.

The most common method of strain typing for MTBCC is restriction fragment length polymorphism (RFLP) fingerprinting. The method requires extraction of a large amount of DNA, which necessitates a prolonged incubation of cultures. The resulting “DNA fingerprint” can be compared with those of other strains, using computer software analysis. This method is considered the “gold standard”. Some isolates may require typing by secondary methods such as spoligotyping or MIRU/VTNR.

These secondary typing methods are quicker to perform but are less discriminatory than RFLP. MIRU/VTNR may be performed as a rapid, preliminary test, with RFLP typing results being used for confirmation.

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33 NCCLS Approved Standard, 24A. 2003
Requests for strain typing must be approved by the Medical Microbiologist or the Head, Mycobacteriology and should be faxed for comparison, with full patient information and details of which strains are to be used to the lab at: 416-235-6013

Note: Patients can have the same RFLP but have different resistance patterns.

The turnaround time for typing results will depend on the status of the culture (whether actively growing or frozen). Average time for results is three weeks. The first MTBCC isolate from a patient is frozen, so that subsequent analysis such as strain typing, is available.

(g) Serum Drug Levels

- This test is currently not available in Canada
- Samples must be shipped to the National Jewish Medical and Research Center, Denver, Colorado
- Obtain instructions from the Central Public Health TB Laboratory before drawing blood samples
- Serum must be separated from the clot immediately and must be shipped on dry ice

Serum drug level testing is useful for patients who may be failing therapy despite appropriate antituberculous medication. Failure to absorb medications may result in sub-optimal concentrations in the serum. Approximate time for results from serum drug level testing is 3 weeks.
3.6 Appendix A

A. QuantiFERON-TB TEST (QFT) Fact Sheet

*Last Updated: March, 2006*

*Note: At the time of publication the QFT test has not yet been approved by Health Canada for use in Canada*

**What is it?**
The QuantiFERON-TB test (QFT) is a whole-blood test for diagnosing latent tuberculosis (TB) infection (LTBI). If not detected and treated, LTBI may later develop into TB disease. The QFT measures the patient’s immune reactivity to *Mycobacterium tuberculosis*, the bacterium that causes TB. This test was approved by the U.S. Food and Drug Administration (FDA) in 2001.

**How does it work?**
Blood samples are mixed with antigens (protein substances that can produce an immune response) and incubated for 16 to 24 hours. The antigens are specific for *M. tuberculosis*. Controls are also included.

If the patient is infected with *M. tuberculosis*, the blood cells will recognize the proteins and release interferon-gamma (IFN-g) in response. The QFT results are based on the proportion of IFN-g that is released in response to specific proteins as compared to that released in response to mitogen in the controls. Additional tests (such as chest radiograph) are needed to exclude TB disease and confirm the diagnosis of LTBI.

**What are the advantages?**
- Only requires a single patient visit.
- Does not cause the booster phenomenon, which can happen with repeat tuberculin skin tests (TST).
- Is less subject to reader bias and error when compared to the TST.

**What are the disadvantages?**
1. Blood samples must be processed within 12 hours after collection.
2. Currently, there is limited laboratory and clinical experience with the QFT.
3. The ability of the QFT in predicting a patient’s risk of progression to TB disease has not been evaluated.
4. As with the TST, additional tests are needed to exclude TB disease and confirm diagnosis of LTBI.

**When should you use the test?**
Testing programs using the QFT should only be implemented if plans are also in place for the necessary follow-up medical evaluation (such as chest radiograph) and treatment. Before the QFT is conducted, arrangements should be made with a qualified laboratory to ensure proper processing of blood within the required 12 hours.
The role of the QFT in targeted testing has not yet been defined, but the QFT can be considered for LTBI testing as follows:

1. Initial and serial testing of persons with an increased risk of LTBI (such as recent immigrants, injection-drug users, and residents and employees of prisons, jails, and homeless shelters).
CDC discourages use of diagnostic tests for LTBI among populations at low risk for infection with *M. tuberculosis*. However, initial testing is occasionally performed among certain population groups for surveillance purposes or where cases of infectious TB disease might result in extensive transmission to highly susceptible populations, including the following:

2. Initial and serial testing of persons who are by history at low risk for LTBI but whose future activity may place them at increased risk of exposure, and others eligible for LTBI surveillance programs (such as health care workers and military personnel).

   (a) Testing of persons for whom LTBI screening is performed but who are not considered to have an increased possibility of infection (such as persons meeting entrance requirements for certain schools and workplaces).

**When should the test not be used?**

Because of insufficient evidence on which to base recommendations at this time, the QFT is not recommended for the following:

- Evaluation of persons with suspected TB disease.
- Assessment of contacts of persons with infectious TB disease.
- Screening of children under 17 years of age, pregnant women, or persons with clinical conditions that increase the risk of progression of LTBI to TB disease.
- Confirmation of TST results, because injection of tuberculin may affect subsequent QFT results.
- Diagnosis of *M. avium* complex disease.

**What are the steps in administering the test?**

- Select an appropriate patient.
- Draw a sample of whole blood from patient into a tube with an anti-clotting agent (heparin), according to manufacturer’s instructions.
- Deliver processed blood to a laboratory within 12 hours.
- Schedule an appointment for the patient to receive test results and, if infected, medical evaluation and possible treatment for LTBI.

**How do you interpret test results?**

Interpretation of QFT results is influenced by the patient’s estimated risk for LTBI. Patients at low risk need to produce a stronger tuberculin response – as compared to patients at increased risk of LTBI – before they are considered infected.

The QFT and the TST do not measure the same components of the immunologic response and are not interchangeable. However, confirmation of QFT results with a TST is possible because the use of the QFT does not affect subsequent QFT or TST results. The probability of LTBI is greatest when both the QFT and TST are positive. Conducting additional tests and assessments for TB signs and symptoms to rule out TB disease is necessary.

Considerations for confirmation are as follows:

- When the probability of LTBI is low, confirmation of a positive QFT result with a TST is recommended before initiation of LTBI treatment. LTBI therapy is not recommended for persons at low risk who are QFT-negative, or who are QFT-positive but TST-negative.
The TST can also be used to confirm a positive QFT for persons at increased risk for LTBI. However, the need for LTBI treatment when the QFT is positive and the subsequent TST is negative should be based on clinical judgment and perceived risk.

Negative QFT results do not require confirmation, but results can be confirmed with either a repeat QFT or a TST if the accuracy of the initial test is in question.

Additional Information:


4. Tuberculosis Prevention

4.1 Prevention/Health Promotion in the Community

Principles of Health Promotion enable people to increase control over their health and improve their health status. It is an integral component of an effective and comprehensive approach to TB prevention and control. Public Health units will provide services that are accessible and equitable using the following strategies to help prevent TB.

Essential to any health promotion strategy are community participation and access to education and information. These components serve to empower individuals, promote effective community participation and establish a sustainable health promotion program.

TB prevention and health promotion should be based on the local epidemiology of TB and the risk groups present in the population. Health units should target test persons and groups who are the highest risk for TB (including all health care professionals). In areas that are considered to be low risk for TB, a more general approach should be undertaken. However all health care workers should be included in programs and screening.

4.1.1 Health Education

Health education includes communication of information, as well as fostering motivation and skills necessary to take action and improve health. Health Unit TB programs will:

(a) Ensure that staff of the tuberculosis control program has adequate and current knowledge and skills related to tuberculosis including, but not limited to:

- Diagnosis
- Treatment for TB disease and latent tuberculosis infection (LTBI)
- Epidemiology of TB, particularly as it relates to the local situation
- Socio-cultural factors
- Current issues
- Risk factors for infection and disease
- Risk factors for non-compliance with treatment
- The role of public health in tuberculosis control
- Drug resistance
- TB/HIV
- How to order TB medication
- Use of iPHIS for TB reporting
- TB reporting requirements
- Immigration surveillance process
- TB specialists in the community
- Agencies in the community that can assist in the management of TB

(b) Provide or ensure the provision of on-going tuberculosis education for health professionals, which includes the topics listed above.

(c) Provide or ensure the provision of on-going tuberculosis education with community groups, local agencies and institutions at risk for TB.

(d) Make educational materials accessible to the community and relevant to the target population.
4.1.2 Community Development/Community Capacity Building
Community development is a process by which the community defines its own health needs, considers how those needs can be met and decides collectively on priorities for actions. It is a commitment to equality, community participation, valuing of lay knowledge, viewing problems as shared and empowerment of individuals/communities through education, skills development and joint action. TB Programs will utilize principles of community capacity building by enhancing skills, networking and developing partnerships with community members in order to foster leadership, empowerment, self-sufficiency and well-being; e.g., homeless populations and newcomers.

4.1.3 Advocacy
Health units will attempt to mitigate the conditions, attitudes and beliefs that could lead to an increase in the risk of TB infection or its consequences. Health units will:

(a) Support community agencies in improving social conditions such as poverty, homelessness, and overcrowding, which can be a factor in the spread of TB;

(b) Support and promote public policy aimed at addressing factors that contribute to the prevalence of TB; and,

(c) Help people with TB to get access to appropriate health care services for follow-up, regardless of their insurance status, when the cost of tests, drugs or care is a barrier.

4.1.4 Outreach
Health Units will identify and establish relationships to increase the community’s information and access to TB services especially populations at highest risk.

4.1.5 Evidence-Based Practice
Health Units will utilize evidence-based practice (quantitative, qualitative and experiential knowledge) which establishes a link between practice and outcome of client care.

35 ibid
36 Community Health Nurses Association of Canada. (March 2002). Canadian Community Health Nursing Standards of Practice. (Draft), p. 114
4.2 Early Diagnosis and Treatment

Early diagnosis and effective treatment of infectious cases are key to the prevention and control of TB. Screening of high risk populations and case-finding, rapid diagnostic testing, strong and enforceable public health legislation, universal and effective therapy, and comprehensive TB prevention and control programs are all essential components for preventing the transmission of tuberculosis. For more information on population-based screening, see Chapter 2 Surveillance and Screening.

Globally, strategies to address co-infection of TB and HIV, including access to basic primary health care in HIV-endemic countries, are becoming more critical in the context of the HIV-AIDS pandemic.
4.3 Infection Control Measures in Health Care Facilities

Tuberculosis remains an important potential occupational hazard in health care facilities serving populations that are at high risk for tuberculosis. These include health care facilities serving Aboriginal Canadians, the inner city poor, or immigrants from countries in Asia, Eastern Europe, Africa and Latin America where tuberculosis is still common. Each facility should have infection control practices to prevent and detect *M. tuberculosis* transmission.

For the purposes of discussion, Health Care Workers are defined as all paid and unpaid persons working in health care settings who have the potential for exposure to *M. tuberculosis* through air space shared with persons with infectious TB disease.

These practices should include but are not limited to:

- Principles and practices of infection control to decrease the risk of transmission of *M. tuberculosis*, including the hierarchy of TB infection control measures, written policies/procedures, monitoring, and control measures for Health Care Workers (HCW) at increased risk for exposure to *M. tuberculosis*.
- Rationale for infection control measures and documentation evaluating the effect of these measures in reducing occupational exposure.
- Reasons for testing for *M. tuberculosis* infection, importance of a positive test result for *M. tuberculosis* infection, importance of participation in a TB screening program, and importance of retaining documentation of previous test results for *M. tuberculosis*, chest radiograph results, and treatment for LTBI and TB disease.
- Procedures for the investigation of *M. tuberculosis* infection test conversion in the workplace.
- Procedures for the prompt medical evaluation of *M. tuberculosis* test conversion or development of symptoms or signs of TB disease in HCWs.
- Procedures for the prompt reporting of a suspected diagnosis of TB disease to the setting’s administration and infection control program.
- Procedures for the prompt reporting to the local health unit of a suspected case of TB disease in a patient (including autopsy findings) or HCW.
- Policies, both internal and external, to ensure confidentiality for patients and HCWs with TB disease or LTBI.
- Transportation procedures to protect Emergency Management Services (EMS) staff and receiving facilities when patients with suspected or confirmed infectious TB disease require transfer.
- Return to Work policies to ensure that a HCW with TB disease is non-infectious before returning to duty.
- Proper implementation and monitoring of environmental controls.
- Training for safe collection, management and disposal of clinical specimens.
- Required record keeping on HCW test conversions for *M. tuberculosis* infection.
- Record keeping and surveillance of TB cases among patients in the setting.
- Proper use of and the need to inform the infection control program of factors that might affect the efficiency of respiratory protection.
- Success of adherence to infection control practices in reducing the risk for transmission of *M. tuberculosis* in health care settings.

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38 “Guidelines for Preventing the Transmission of *Mycobacterium Tuberculosis* in Health-Care Settings, 2005”, MMWR, December 30, 2005/ 54(RR17)
4.3.1 Administrative and Work Practice Measures in Health Care Facilities

All health care facilities should have a tuberculosis management program. Policies and procedures should clearly delineate the administrative responsibility for developing, implementing, reviewing and evaluating the program to ensure that the various program components identified above are coordinated. Persons with day-to-day responsibility for infection control and employee health, representatives from the senior administration of the facility, the laboratory, nursing, medicine, other health disciplines and public health should be part of the expert committee.

The following activities should be included in the program:

- Conducting a TB risk assessment of the setting (see Section 4.3.2 for details).
- Developing and instituting a written TB infection control plan to ensure prompt detection, airborne precautions, and treatment of persons who have suspected or confirmed TB disease.
- Ensuring the timely availability of recommended laboratory processing, testing, and reporting of results to the ordering physician, infection control team and local public health unit.
- Implementing effective work practices for the management of patients with suspect or confirmed TB disease.
- Ensuring the proper cleaning and sterilization or disinfection of potentially contaminated equipment.
- Training and educating HCWs regarding TB, with specific focus on prevention, transmission, and symptoms.
- Screening and evaluating HCWs who are at risk for TB disease or who might be exposed to *M. tuberculosis* (i.e., TB screening program).
- Applying epidemiologic-based prevention principles, including the use of setting-related infection control data.
- Using appropriate signage advising respiratory hygiene and cough etiquette.
- Coordinating efforts with the local health unit. 39

4.3.2 TB Risk Assessment

A TB risk assessment for settings in which patients with suspected or confirmed TB disease are expected to be encountered should include:

- A review of the community profile of TB disease in collaboration with the local health unit.
- Consultation with the local health unit to obtain epidemiologic surveillance data necessary to conduct a TB risk assessment of the health care setting.
- A review of the number of patients with suspected or confirmed TB disease that has been encountered in the setting during at least the previous 5 years.
- Determining if persons with unrecognized TB disease have been admitted to or were encountered in the setting during the previous 5 years.
- Identification of areas in the setting with an increased risk of nosocomial transmission of *M. tuberculosis* and target them for improved TB infection controls.
- Determining which HCWs need to be included in a TB screening program and the frequency of screening (based on risk classification).

39 Ibid
4.3 Infection Control Measures in Health Care Facilities

- Ensuring the prompt recognition and evaluation of suspected episodes of nosocomial transmission of *M. tuberculosis*.
- Assessing the number of isolation rooms needed for the setting.
- Determining the types of environmental controls needed other than isolation rooms.
- Determining which HCWs need to be included in the respiratory protection program.
- Conducting periodic assessments.
- Recognizing and correcting lapses in infection control.\(^{40}\)

An essential part of this program is the annual review of indices of nosocomial transmission (e.g., tuberculin test conversion among clinical personnel, number of exposure episodes, number of TB patients diagnosed only at autopsy). This information should be shared with staff as a means of increasing their awareness of TB in the patient population served by the facility.

In health care facilities where TB patients are rarely admitted, the management program may consist only of the capacity to diagnose patients with TB disease, and an arrangement to transfer all such patients to another centre where the appropriate environmental and personal control measures have been implemented.\(^{41}\)

### 4.3.3 Ventilation, Filters, Ultraviolet Germicidal Irradiation (UVGI)

General ventilation dilutes and removes contaminated air and controls airflow patterns in a room or setting. A single-pass ventilation system is the preferred choice in areas in which infectious airborne droplet nuclei might be present\(^ {42}\). In general hospital areas, at least two air changes per hour are recommended.\(^{43}\)

The great majority of episodes of exposure to unsuspected TB cases and transmission of infection to HCWs occurs outside of isolation rooms, making general ventilation the most significant method of preventing airborne transmission in a hospital.\(^ {44}\)

Environmental controls should include technologies for the removal or inactivation of airborne *M. tuberculosis* such as local exhaust ventilation, general ventilation, HEPA (High Efficiency Particulate Air) filtration, and UVGI.

Standards contained in *Special Requirements for Heating, Ventilation, and Air Conditioning (HVAC) Systems in Health Care Facilities: A National Standard of Canada* (CSA) 1991, outline ventilation requirements for various rooms or areas including:

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\(^{42}\) “Guidelines for Preventing the Transmission of *Mycobacterium Tuberculosis* in Health-Care Settings, 2005”, MMWR, December 30, 2005/ 54(RR17)


\(^{44}\) ibid
Tuberculosis Protocol

4. Tuberculosis Prevention

Issued: 2006
Version: 1.0

4.3 Infection Control Measures in Health Care Facilities

- patient rooms,
- operating rooms,
- intensive care units,
- emergency and other treatment rooms, and
- isolation rooms.

The CSA document recommends that isolation rooms should have nine air changes per hour, ventilation to outside the building and appropriate relative pressurization depending on the isolation technique. It has also been suggested that newly constructed isolation rooms have the nine air changes per hour and that those in existing facilities have at least six air changes per hour. \(^{45}\)

- Patients with TB should be isolated in a room where the air pressure is negative to the corridor, resulting in inward directional air flow.
- Air from the room should be exhausted to the outdoors. \(^{46}\)

The exchange of indoor air with outdoor (fresh) air can reduce the risk of infection by diluting the infectious particles.

The air changes and direction of air flow should be verified at least every six months. Direction of air flow should be tested with smoke tubes at all four corners of the door. \(^{47}\)

In buildings with sealed windows and mechanical ventilation systems, a high percentage of recirculation can contribute to nosocomial infection. \(^{48}\) Therefore, the air should be passed through a HEPA filter before being exhausted.

4.3.4 Local Exhaust Ventilation
This consists of source-control techniques that are used to capture airborne contaminants (e.g., infection droplet nuclei or other infectious particles) before they are dispersed into the general environment. This type of ventilation should be used for cough-inducing and aerosol-generating procedures.

4.3.5 Air Cleaning Methods
(a) High-Efficiency Particulate Air (HEPA) Filters
These devices can be used to filter infectious droplet nuclei from the air and must be used:

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\(^{46}\) Ibid

\(^{47}\) Ibid

\(^{48}\) Ibid, p. 209
When discharging air from local exhaust ventilation booths or enclosures directly into the surrounding room or area, and

When discharging air from negative-pressure rooms into the general ventilation system (e.g., in settings in which the ventilation system or building configuration makes venting the exhaust to the outside impossible).

Recirculation of HEPA filtered air can also be achieved by:

- Exhausting air from the room into a duct,
- Passing it through a HEPA filter installed in the duct, and
- Returning it to the room or general ventilation system.

In addition, recirculation can be achieved by filtering air through HEPA recirculation systems installed on the wall or ceiling of the room or filtering air through portable room-air recirculation units.49

(b) Ultraviolet Light (UVGI)

UVGI can be used in a room or corridor to irradiate the air in the upper portion of the room and is installed in a duct to irradiate air passing through the duct or incorporated into room air-recirculation units. There is good evidence that UV light has excellent germicidal activity against \textit{M. tuberculosis} and can reduce infectious droplet concentrations equivalent to ventilation with 20 air changes per hour. UV light is recommended in bronchoscopy and autopsy areas, particularly if ventilation is inadequate and cannot be upgraded to meet standards. It may be considered in areas where exposure is unpredictable, such as emergency rooms in moderate-to-high risk hospitals. If UV light is used, the units should be installed above head height with baffles to protect against eye contact. The units should be inspected every six months.50

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49 “Guidelines for Preventing the Transmission of \textit{Mycobacterium Tuberculosis} in Health-Care Settings, 2005”, MMWR, December 30, 2005/54(RR17)
4.3.6 Use of Respiratory Protection

Standard surgical masks are effective in preventing larger exhaled droplets from falling into wounds. However, they are less than 50% effective in filtering the much smaller nuclei (1 to 5 microns) containing tubercle bacilli that may be inhaled and reach the alveolus. Current recommendations call for masks that filter 95% of particles of 1 micron or larger and have less than 10% leak. Workers should be instructed on how to wear the masks properly (to reduce facial seal leak) and educated regarding the importance of wearing masks. 51

(1) Indications for Use of N-95 Masks

- All persons, including HCWs and visitors, entering rooms in which patients with suspected or confirmed infectious TB disease are being isolated.
- Persons present during cough-inducing or aerosol-generating procedures performed on patients with suspected or confirmed infectious TB disease.
- Persons in other settings in which administrative and environmental controls probably will not protect them from inhaling infectious airborne droplet nuclei. These persons might also include persons who transport patients with suspected or confirmed infectious TB disease and persons who provide urgent surgical or dental-care to patients with suspected or confirmed infectious TB disease.
- Laboratory staff conducting aerosol-producing procedures might require respiratory protection. 52

(2) Fit Testing

There is a need to determine which respirator fits the user adequately and to ensure that the user knows when the respirator fits properly. It is important to provide a means to determine which respirator model and size fits the wearer best and to confirm that the wearer can don the respirator properly to achieve a good fit. HCWs should be provided with opportunities to handle and wear a respirator until they become proficient. 53

The frequency of fit testing should be supplemented by the occurrence of:

(1) Risk for transmission,
(2) Facial features of the wearer,
(3) Medical condition that would affect respiratory function,
(4) Physical characteristics of the respirator, and
(5) Model or size of the assigned respirator. 54

Note: Each health unit will be required to set up their own arrangement for fit testing of staff e.g., through EMS or a local hospital.

52 “Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health-Care Settings, 2005”, MMWR, December 30, 2005/ 54(RR17)
53 Ibid
54 Ibid.
4.3.7 Screening Programs for TB Support, Surveillance and Clinical Care

The screening program consists of 5 major components:

(1) Baseline testing for *M. tuberculosis* infection
(2) Tuberculin testing following unprotected exposure
(3) Serial testing for *M. tuberculosis* infection
(4) Serial screening for symptoms or signs of TB disease
(5) TB training and education

(1) Baseline Testing for *M. tuberculosis* Infection

Baseline testing results provide a basis for comparison in the event of a potential or known exposure to *M. tuberculosis* and facilitate the detection and treatment of LTBI or TB disease in a HCW before employment begins and reduces the risk to patients and other HCWs. 55

Therefore, at the time of hiring, all employees should have Two-step tuberculin testing unless they have a documented prior tuberculin test. Workers with a reaction of ≥ 10mm induration on the first or second test should be considered tuberculin reactors. They should be referred for chest radiography and medical evaluation, and consideration of INH preventive therapy.

1. Test results for *M. tuberculosis* infection for HCWs with a history of BCG should be interpreted by using the same diagnostic cut points used for HCWs without a history of BCG. 56

2. A second 2-step TST is not needed if the HCW has a documented 2-step TST result from any time during the previous 12 months.57

3. If a newly employed HCW has had a documented negative TST result within the previous 12 months, a single test can be administered in the new setting. This additional test represents the second stage of two-step testing. The second test decreases the possibility that boosting on later testing will lead to incorrect suspicion of transmission of *M. tuberculosis* in the setting.

(2) Tuberculin Testing Following Unprotected Exposure

For tuberculin negative workers, a TST should be done immediately and, if negative, repeated after 8-12 weeks. If the tuberculin test is positive, the worker should be considered a converter, and consideration should be given to preventive therapy. If the worker was previously tuberculin positive, a TST should not be done, but chest

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55 “Guidelines for Preventing the Transmission of *Mycobacterium Tuberculosis* in Health-Care Settings, 2005”, MMWR, December 30, 2005/ 54(RR17); p. 38
56 Ibid.
57 Ibid.
radiography should be performed 3 months after the contact or earlier if symptoms develop, at which time a sputum for AFB testing should also be obtained.

(3) Serial Follow-Up
Annual tuberculin testing is recommended for HCWs involved in moderate risk activities in moderate to high-risk hospitals, and for workers involved in high-risk activities in all hospitals.

A routine screening program can be discontinued if infection prevalence is <5% and/or the annual skin test conversion rate is < 0.5% among staff.

If possible, stagger follow-up testing so that all HCWs who work in the same area or profession are not tested in the same month. Staggered screening increases opportunities for early recognition of infection control problems that can lead to conversions in test results for M. tuberculosis infection.

Health care facilities can be considered to be low risk if there are less than six admissions of patients with active tuberculosis per year. Health care facilities can be considered low risk if there are more than 100 health care workers in patient care areas to which TB patients may be admitted per annual admission of tuberculosis. Moderate to high-risk hospitals have six or more TB admissions per year, or a ratio of less than 100 potentially exposed health care workers per TB admission per year. Also see Chapter 2 (2.2.4) Screening in High-Risk Environments.

(4) Chest Radiography
HCWs with a baseline positive or newly positive TST should receive one chest radiograph to exclude a diagnosis of TB disease (or an interpretable copy within a reasonable time frame, such as six months). Repeat radiographs are not needed unless symptoms or signs of TB disease develop. Instead of participating in serial testing, HCWs with a positive test should receive a symptom screen.

HCWs with extrapulmonary TB usually do not need to be excluded from the workplace as long as no involvement of the respiratory tract has occurred.

(5) Immediate Patient Management
A high index of suspicion must be maintained in order to ensure early identification of patients with suspected TB. All patients with suspected or confirmed infectious TB who are admitted to a health care facility should immediately have appropriate

59 Ibid p. 219
60 Ibid, p. 220
61 “Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health-Care Settings, 2005”, MMWR, December 30, 2005/54(RR17)
63 “Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health-Care Settings, 2005”, MMWR, December 30, 2005/54(RR17)
isolation precautions initiated. Policies should designate who has the authority to initiate and discontinue isolation precautions, monitor compliance with isolation procedures, and manage breaches in isolation precautions. Chest radiography should be carried out and/or three sputum specimens test for AFB in suspected cases.  

Management of Patients with Confirmed TB:

- Infection control personnel should be notified of all patients with confirmed TB who are in the facility.
- Patients should remain in an adequately ventilated respiratory isolation room.
- Visitors and staff entering the room should wear appropriate respiratory protective masks.
- Visits by children should be discouraged because of their increased susceptibility.
- Patients leaving the room should wear a mask. If patients are going to other hospital departments, those departments should be notified.

HCWs that are the first point of contact should be trained to ask questions that will facilitate detection of persons who have suspected or confirmed infectious TB disease.

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65 ibid, p. 213
4.4 Resources, Education and Information

4.4.1 Education and Counselling Programs for Health Care Workers

All HCWs, including physicians, trainees, and students, should receive initial TB training and education. The training should be provided before the HCW starts working. In addition, all settings should conduct an annual evaluation of the need for follow-up training and education for health care workers based on the number of untrained and new health care workers, changes in the organization and services of the setting, and availability of new TB infection control information. 66

The following are suggested components for an introductory TB education program:

(1) Clinical Information

- Basic concepts of M. tuberculosis transmission, pathogenesis, and diagnosis, including the differences between LTBI and TB disease and the possibility of re-infection after previous infection with M. tuberculosis or TB disease.
- Signs and symptoms of TB disease and the importance of a high index of suspicion for patients or HCWs with these symptoms.
- Indications for initiation of airborne precautions of inpatients with suspected or confirmed TB disease.
- Policies and indications for discontinuing airborne precautions.
- Principles of treatment for LTBI and for TB disease (indications, use effectiveness, and potential adverse effects).
- How to diagnose TB (physical examination).
- Proper treatment using four first-line TB drugs.
- HIV/TB risk.
- Importance of drug resistance.
- How to obtain TB medication and arrange for DOT.

(2) Epidemiology of TB

- Epidemiology of TB in the local community, Canada and worldwide.
- Risk factors for TB disease.

(3) TB and Public Health

- Role of the local health unit’s TB control program in screening for LTBI and TB disease.
- Availability of information, advice and counselling from community sources, including universities, local experts and local public health units.
- Responsibility of the settings’ clinicians and infection control program to promptly report to the local health unit a case of suspected TB disease or a cluster of TST conversions.
- Responsibility of the setting’s clinicians and infection control program to promptly report to the local health unit a person with suspected or confirmed TB disease who leaves the setting against medical advice. 67

66 “Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health-Care Settings, 2005”, MMWR, December 30, 2005/ 54(RR17)

67 Ibid
The setting should document that all HCWs, including physicians, have received initial TB training relevant to their work setting and additional occupation-specific education.

### 4.4.2 Local Public Health Unit

The local public health unit can assist health care facilities by providing information and education sessions about TB and infection control. The local Ministry of Labour office can provide information on the requirements under the *Occupational Health and Safety Act*.

Locations for Ministry of Labour local offices can be found at:

http://www.gov.on.ca/LAB/english/about/reg_offices.html
4.5 Vaccines

4.5.1 Bacille Calmette-Guerin (BCG)

See also: Chapter 2: Surveillance, Subsection 2.4.2 4(e) Causes of false positive TST.

Bacille Calmette-Guerin (BCG) is a live vaccine made from a culture of an attenuated strain of living bovine tubercle bacillus, administered as a single intradermal dose over the deltoid muscle of the arm. The one vaccine approved for use in Canada is a freeze-dried product produced by Sanofi Pasteur.

Targeted immunization of some First Nations and Inuit communities in Canada with BCG has been provided after birth, to reduce hematogenous spread of M tuberculosis from the primary site thereby preventing serious complications in persons where delay in diagnosis may occur. Countries experiencing declines in TB rates have discontinued routine BCG programs for a number of reasons.

In 2004, Canada’s National Advisory Committee on Immunization (NACI) issued an Advisory Statement on the use of BCG vaccine. BCG vaccination is recommended in three high risk groups:

1. In immunocompetent infants born in First Nations and Inuit communities where the annual average rate of smear positive pulmonary TB is greater than 15 per 100,000 during the previous 3 years OR the annual risk of TB infection is greater than 0.1% and early diagnosis and treatment is not available. HIV antibody testing of the mother and child should be negative. Routine immunization of First Nations and Inuit communities not meeting these criteria should be discontinued.

2. Health care and laboratory workers with repeated exposures to untreated or drug-resistant TB cases, or to tubercle bacilli in conditions where protective measures are not feasible. These individuals should have their indications for BCG vaccination assessed by a TB and/or infectious disease expert.

3. Travellers planning extended stays in areas of high TB prevalence where chemotherapy is not possible or drug resistance is high. It is recommended that an infectious disease or travel medicine specialist be consulted.

(a) Adverse Effects from BCG Vaccination

Worldwide, the use of BCG has been associated with adverse effects documented in both published and unpublished literature. A survey sponsored by the International Union against Tuberculosis and Lung Disease recorded over 10,000 complications following almost 1.5 billion BCG vaccinations. The most serious complication, disseminated BCG infection, occurred in three per million recipients. Dissemination was fatal in 0.02 per million vaccine recipients due to immunodeficiencies.
In Canada, case reports of disseminated BCG infection identified by IMPACT (Immunization Monitoring Program-Active) hospital-based surveillance prompted a review of adverse events by the Public Health Agency's Advisory Committee on Causality Assessment (ACCA). The ACCA report and a First Nations and Inuit Health Branch review, considered in the 2004 NACI Statement, have estimated that the risk of disseminated BCG infection and death is much greater for Canadian First Nations’ children.

(b) Contraindications

BCG is contraindicated for persons with immune deficiency diseases or impaired immunity secondary to treatment or malignancy. Extensive skin disease or burns are also contraindications. Immunization of pregnant women is not recommended. Persons with positive tuberculin skin tests should not be immunized.

(c) Public Health Issues for BCG vaccination in Canada

The discontinuation of BCG vaccination in populations at high risk of TB outbreaks requires a cautious and collaborative approach between First Nations stakeholders, providers and policy makers. An adequate, effective and well-resourced TB Control program must be available at the community level where ever BCG is withdrawn. In addition, research on resource requirements and the health impacts of BCG withdrawal have been identified by NACI as prerequisites for any planned phase-out.

4.5.2 Other Vaccines against Tuberculosis

BCG has up to 80% efficacy in protection against disseminated forms of TB in childhood and tuberculous meningitis\textsuperscript{70}. However, protection against pulmonary TB is extremely variable (approximately 50% in metanalysis)\textsuperscript{71}, and immunity is not life-long. Given the inability of the existing BCG to control or eliminate tuberculosis, there remains an urgent need for an effective vaccine.

There are at least three points within the TB disease process at which a new vaccine could be targeted. First, a vaccine could be given in the neonatal period to prevent primary infection. Unfortunately, this would not address the millions of people who have latent infection. A post-exposure vaccine to prevent overt disease in those who have already been infected presents a second possible intervention point. Although post-exposure vaccines are an area of strong interest, their development remains largely experimental at this point. And finally, a third possible intervention would be with a vaccine as an adjunct to chemotherapy; e.g., in people infected with multi-drug-resistant strains of \textit{M. tuberculosis}.

The ideal TB vaccine needs to induce high levels of cellular immunity. \textit{M. tuberculosis} is an intracellular organism, replicating and residing within human macrophages. Immunity is therefore dependent on a T-helper cell: specifically, a class II-restricted CD4+ T-cell response. Gamma delta cells and nonclassically restricted T-cells, such as CD1-restricted T-cells, may also play a protective role,\textsuperscript{72} but how to induce these cells by vaccination is still not yet fully understood.

\textsuperscript{70} Mcshane H. Developing an improved vaccine against tuberculosis. Expert Rev. Vaccines 2004 3(3): 299-306
\textsuperscript{71} Long, R. Editor, Canadian Tuberculosis Standards, 5\textsuperscript{th} Edition, Canadian Lung Association, Canadian Thoracic Society, Health Canada, 2000, p. 223
\textsuperscript{72} op cit
There are two main approaches to vaccine production: either by using the whole organism, as in the existing BCG, or by inducing immunity to a few immunodominant antigens through a subunit vaccine.

Attenuated strains of *M. tuberculosis* still require extensive testing to ensure that a return to virulence is not possible. Several recombinant BCG vaccines are in development and one, engineered to over express antigen 85B, has entered clinical trials in the USA. These vaccines are designed primarily for neonates, as a replacement for the existing BCG, with the hope of generating a better and longer-lasting immune response.

Subunit vaccines can be divided into classes according to which antigen delivery system is used to induce cellular immunity: protein vaccines, with or without adjuvant; DNA vaccines; and recombinant bacterial or viral vectors.

Some of the most promising antigens being used for TB vaccine production include the early secreted antigenic target (ESAT)-6, heat shock protein (HSP)-65, antigen 72F and the antigen 85 complex. These antigens, in conjunction with adjuvant, are at various stages of clinical trials.

DNA vaccines, which induce both cellular and humoral immunity, encoding a variety of genes from *M. tuberculosis*, have been developed but have also been shown to induce autoimmune pathology in animal models. Despite initial promise, no new DNA vaccine against TB has demonstrated protection superior to BCG to date.

The use of a prime-boost vaccine strategy, to boost a primed T-cell response, is being studied in TB vaccine research, using nonreplicating poxviruses and adenoviruses as vectors. By using a DNA-vaccine first, linked to a variety of mycobacterial antigens, and then boosting with a modified vaccinia virus vaccine Ankara (MVA) with the same antigens, higher levels of T-cells have been generated in animal models.

One interesting development in TB vaccine research is the utilization of mucosal delivery, via a nasal spray, creating the possibility of needle-less vaccination, which is safer and easier. There are several of these vaccines under development or entering clinical trials.

There are still many unresolved issues in the development of TB vaccines, despite the growing interest and science. Measurement of efficacy poses a significant challenge, whether the outcome is infection (which is difficult to measure) or progression to disease (which can take decades). The identification of proxy markers for use in clinical trials is critical. In addition, the safety and efficacy of any new vaccine in individuals who are HIV positive will be major determinants of a vaccine’s utility. Despite these, and many more challenges, there are over one hundred new candidates undergoing animal model testing and several now entering, or approaching, clinical trial evaluations.
5. Management of Tuberculosis Cases

The basis principles of care for persons with, or suspected of having TB, are the same worldwide: a diagnosis should be established promptly and accurately; standardized treatment regimens of proven efficacy should be used with appropriate treatment support and supervision; the response to treatment should be monitored; and the essential public health responsibilities must be carried out. Prompt, accurate diagnosis and effective treatment are not only essential for good patient care – they are the key elements in the public health response to TB and the cornerstone of TB control. Thus all providers who undertake evaluation and treatment of patients with TB must recognize that, not only are they delivering care to an individual, they are assuming an important public health function that entails a high level of responsibility to the community, as well as to the individual patient.78

5.1 Clinical Management: Physicians’ Roles and Responsibilities

The purposes of TB Management are:

- to cure the patient of TB for a lifetime,
- to prevent drug resistance,
- to minimize the transmission of disease.

Accordingly, physicians who have the primary responsibility for the management of patients with TB must ensure that all cases have been administered an effective treatment regimen over an adequate period of time.

5.1.1 Referral to a Tuberculosis Medical Expert

It is recommended that all active or suspect cases of TB be referred to a medical specialist knowledgeable about TB, especially patients with the following conditions:

(a) Drug resistance and MDR

Resistance is often seen in:
- Patients inadequately or inappropriately treated for tuberculosis
- Contacts of drug resistant cases
- Patients infected in endemic regions (See: WHO website for list of endemic countries - [http://www.who.int/tb/en/](http://www.who.int/tb/en/); See: Data and country profile; detailed estimates of TB burden – data by WHO region and country)

(b) TB treatment failure

If after three months of therapy, cultures remain positive, evaluate the patient carefully for:
- Non-compliance with recommended treatment regimen
- Presence or emergence of resistant strain
- Inappropriate therapy
- Malabsorption

(c) Drug intolerance

The elderly, patients with other medical conditions (e.g. diabetes or those on dialysis), and those taking medications for other medical conditions and patients who have idiosyncratic drug reactions, may experience reactions to anti-tuberculosis drugs. These patients may need specialized treatment regimens.

(d) HIV infection

Patients with HIV infection are at higher risk of developing active disease from recent TB infection and of reactivating any latent tuberculosis infection. TB infection may also hasten the progression of AIDS. National guidelines recommend that everyone newly diagnosed with TB be tested for HIV infection.\textsuperscript{79}

\textsuperscript{79} Long, R. Editor, Canadian Tuberculosis Standards, 5\textsuperscript{th} Edition, Canadian Lung Association, Canadian Thoracic Society, Health Canada, 2000, p. 142
(e) Pregnancy
Untreated active TB poses a much greater risk to the pregnant woman and the fetus compared to the medication used for the treatment of tuberculosis. Therefore, treatment of active disease should be promptly initiated.  

(f) Pediatric TB
Latent TB Infection in children should not be left untreated because the infection is more likely to progress to disease. Children with latent infection or TB disease should be managed by, or under the supervision of, a TB pediatric specialist. Cases of TB in children should trigger contact investigation for an undiagnosed source case. Children with TB are typically asymptomatic and are usually non-infectious.  

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81 Ibid, p. 127 & 130
5.2 Case Monitoring: Public Health Roles and Responsibilities

The purpose of case monitoring is to render and maintain the tuberculosis patient non-infectious through a successful course of treatment and medical follow-up. The TB control staff in public health units has primary responsibility for monitoring TB cases.

A. Respiratory Cases: Investigation and Case Management

5.2.1 Initial Investigation:

Within three working days of receiving the case report from a physician, lab, etc. contact the physician by telephone to ascertain the patient's medical status.

1. Contact Physician at start of treatment to obtain details for the following:
   - Tests for Acid-Fast Bacilli (AFBs)
   - Chest x-ray (within last three months)
   - Smear, culture or pathology reports (all documentation supporting TB diagnosis)
   - Sensitivities
   - Initial liver function tests (LFTs)
   - Symptoms and onset date
   - Level of infectivity (see Chapter 6 – 6.2.1 “Transmission Factors Related to the Case”)
   - HIV status
   - Medication regimen

2. Contact Patient as soon as possible:

Whenever possible, the first patient contact should be a face-to-face visit and should cover all of the items listed below as items (a) to (h) and 5.2.3. If the patient is infectious, an N95 Mask, which has been fit tested should always be used by Health Department staff. CDC guidelines recommend that Health Care Workers wear personal respirators in homes of infectious TB patients.  

Whenever possible conduct the visit in a well ventilated area.

During the initial assessment:

(a) Gather demographic and epidemiological information
(b) Obtain history of any previous TB disease and treatment
(c) Assess symptoms and date of onset
(d) Gather information for contact tracing
(e) Assess the patient’s understanding and beliefs about TB
(f) Advise about side effects of TB medication
(g) Assess the patient's ability to comply with medication and medical follow-up
(h) Assess for directly observed therapy (DOT). See Chapter 8: Treatment of TB Disease for DOT assessment tool.
(i) If infectious, explain the need for isolation precautions.

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82 Core Curriculum on TB. CDC Division of TB Elimination. Chapter 8 Infection Control Personal Respiratory Protection.  
www.cdc.gov/nchs/tp/tb/pubs/ ssmodules
5.2.2 Clinical Guidelines for Releasing Patients with Pulmonary/Laryngeal TB from Isolation:

1. **AFB Positive**
   Isolation can be discontinued if:
   - consecutive sputum smears for AFB on 3 separate days are negative, and
   - there is evidence of clinical improvement, and
   - the medication regimen can be reasonably verified (e.g. patient on DOT).

2. **AFB Negative**
   Isolation can be discontinued after two weeks if there is:
   - clinical improvement
   - adherence to two weeks of a medication regimen where the patient is fully sensitive.

3. **MDR TB**
   Isolation can be discontinued if consecutive smears for AFB *and culture* on 3 separate days are negative.

Following the initial investigation, it then becomes incumbent upon the TB control staff to develop a case management plan for each patient. The following components must be incorporated:

5.2.3 Education

Educate patient and family about:

(a) The disease process of TB
(b) Communicability of TB
(c) The need for isolation in cases of suspected infectious tuberculosis. Note: Those individuals whose occupation or personal circumstances (work in health care field, shelter or those who have young children) pose a risk of infection to highly vulnerable people by virtue of immuno-suppression or age and may require longer periods of isolation. See above: Clinical Guidelines for Releasing Patients from Isolation.
(d) Treatment protocol and side effects
(e) Necessity of compliance with treatment and patient’s responsibility for compliance
(f) Purpose of Directly-Observed Therapy (DOT) if indicated
(g) Necessity of continuing public health supervision
(h) The importance of identifying and screening high risk and close contacts
(i) The importance of compliance and how drug resistance may develop if there is poor compliance.

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5.2.4 Non-Compliance

Cure rates for TB remain unsatisfactory primarily because patients fail to take their medication as prescribed by a physician (either not taking the medication as ordered or not taking the medication for a long enough time period). Therefore, identifying those patients who are at high risk of non-adherence to treatment and placing them on DOT is an effective way of achieving a lifetime cure of TB. (See: Chapter 8: Treatment of TB Disease for tips on improving compliance for TB medication.)

High-risk groups and factors relating to non-compliance include, but should not be limited to the following:

(a) Biases against treatment
(b) Substance abuse and/or mental health issues
(c) Homelessness
(d) Children and Adolescents
(e) Cultural or socioeconomic barriers
(f) Previous non-compliance with drug therapies
(g) Relapse of TB

5.2.5 Minimum Requirements for On going Follow-up

1. Contact the Patient:
   Maintain contact with patients who are not on DOT (as assessed on an individual basis) no less than the following:

   (a) At one month: Interview the patient, preferably in person, or, alternatively, by telephone. The following should be reviewed:
       - compliance,
       - medical status,
       - attendance at medical follow-up appointments,
       - treatment side effects, and
       - DOT reassessment.

   (b) Every two months thereafter until discharged from treatment follow-up by the physician (or on an as needed basis): The patient should be reassessed using the same criteria as at the one-month interview.

   Note: Cases that are more complicated (i.e., have compliance concerns, experience side-effects) may require additional follow-up and should be assessed on an individual basis.

2. Contact the Treating Physician to obtain/discuss/review:

   (a) At one month:
       - Smear and culture results
       - Changes in medication regimen
       - LFTs (if patient experiencing adverse reactions)
       - Ensure the treatment regimen is according to the Canadian TB Standards and is based on the sensitivity testing
       - X-rays
       - Culture conversion
5. Management of Tuberculosis Cases

5.2 Case Monitoring: Public Health Roles and Responsibilities

- Eye examination
- Monitor attendance at follow-up appointment

(b) Every three months or as required to obtain patient follow-up information.
   See: One month criteria for contacting physician.

3. Monitor for Culture Conversion
   Patients with pulmonary tuberculosis should have sputum specimens collected for microscopic examination and culture at the end of the second month of treatment. Additional sputum cultures should be obtained at the end of therapy. More frequent AFB smears may be useful to assess the early response to treatment and to provide an indication of infectiousness. Repeat cultures are essential for patients with documented drug resistance. If a patient's symptoms have resolved and the patient cannot provide a sputum sample, sputum induction may be required to obtain a specimen.

4. Ensure Appropriate Treatment and Compliance
   Ensure that an effective treatment regimen, based on sensitivity testing is prescribed to and received by the patient. (See Chapter: Treatment of TB Disease for common medication regimens and side effects). Assess compliance using the following methods:
   - Information provided by patient
   - Information provided by physician
   - Timely response to treatment
   - Pill count

   - Oversee DOT program on a daily, twice or thrice weekly regimen when indicated for those at high risk of non-compliance. DOT should be the standard of care unless assessment indicates that the likelihood of compliance is high.

   - When the medical officer of health has issued a Section 22 or Section 35 order on a non-compliant patient for whom other voluntary compliance methods have failed, work in conjunction with the attending physician to ensure that the Health Protection & Promotion Act, Sections 22 (4) and 35 (2), are applied appropriately. (See Chapter 12: Use of Orders under the HPPA to Control TB)

   - Should a patient, who resides outside Toronto, be issued a Section 22/35 Order and be admitted to West Park Healthcare Centre (WPHC), Toronto Public Health is to be notified as soon as possible. (See Chapter 12: Use of Orders under the HPPA to Control TB and Chapter 13: West Park Healthcare Centre).

5. Reporting and Documentation
   Report all relevant information to the TB Control Program. The MOHLTC must be contacted if any patient:
   
   (a) does not fully complete the prescribed treatment;

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(b) moves outside province;
(c) is lost to follow-up;
(d) is issued a Section 35 Order

Document cases according to health unit protocols and ministry requirements; ensure that the required data are complete for each case.

Ensure that all relevant information is forwarded to the Ontario Ministry of Health as required via iPHIS.

5.2.6 Recommended Protocol for Directly Observed Therapy (DOT)

Directly observed therapy (DOT) requires that someone directly observe the patient taking tuberculosis medication in prescribed doses and regimens. DOT need not be done by a health professional, but it must be done by an observer trained in DOT. Because DOT assures the consumption of medications, it can increase compliance to close to 100%.

(a) Arrange DOT for all patients with respiratory tuberculosis, unless their assessment indicates that they are highly likely to comply with therapy. This assessment should be based on interviews with the patient, using the DOT Assessment Tool found in Chapter 8: Treatment of TB Disease.
(b) Discontinue DOT at any point during treatment ONLY if the patient’s voluntary compliance can be assured.
(c) Persons administering DOT should record each observed dose.
(d) DOT can be done in the patient’s home or in another agreed upon setting, depending on the best arrangement for the patient and the person observing therapy.

5.2.7 Management of Tuberculosis in the Homeless and Under-housed

(Please see Appendix A Section 5.3 Interim Guidance for the Prevention and Control of TB in Homeless Shelters and Drop-in Centres. Other useful references include Toronto Public Health’s Infection Control Manual for homeless and housing service providers ‘Breaking the Chain’85).

The homeless are at a greater risk than the general population in developing infection and of infection progressing to disease. This is due in part to one or more of the following circumstances:

- The shelter environment, which is often crowded and poorly ventilated;
- Delays in patients seeking medical follow-up, which often leads to delays in medical diagnosis and access to medical care;
- Poor nutrition;
- Alcohol and substance abuse;
- Underlying medical conditions. 86

Therefore,

(a) Ensure that the patient is located and placed in isolation until the patient can be removed from the facility to be medically assessed.
(b) Assess for patient compliance with the recommended medical management.
(c) If the patient is uncooperative, consider preparing a Section 22 order.
(d) The patient must not return to the shelter system until deemed to be non-infectious by a TB medical specialist and, therefore, should be transferred to West Park Healthcare Centre or alternative housing.
(e) Once discharged from hospital, DOT should be the standard of care for all homeless or under-housed patients.
(f) Initiate contact follow-up in shelter system as soon as possible.

Due to the transient nature of this population, regular contact investigation in a shelter can be difficult. Contact the MOHLTC for guidance prior to embarking on a contact investigation in a shelter for homeless persons. See MOHLTC and Ministry of Labour letter to Medical Officers of Health May 11, 2005 for interim guidelines for managing TB in homeless shelters and for helpful websites for more comprehensive information. (See Appendix A at the end of this chapter.)

5.2.8 Discharging Patients from Case Monitoring

Patients may be discharged from follow-up once the prescribed treatment has been completed and all required reporting information has been obtained and transmitted to the Ministry of Health and Long-Term Care (MOHLTC). Please refer to Chapter 1 Tuberculosis: A Brief Background.

B. Non-Respiratory Tuberculosis

5.2.9 In a Child (≤ 5 years of age)

Children may develop various forms of TB after exposure, so a diagnosis of non-respiratory TB in a child should trigger a full contact investigation by public health staff, including all of the components described for infectious TB, with a goal of locating an infectious source.

5.2.10 In Older Children (≥ 6 years of age) and Adults

Non-respiratory TB is usually a later manifestation of primary infection and is not infectious. Nonetheless, it may be life threatening because of a delay or failure to make the diagnosis. Follow-up should include:

(a) Documenting and reporting the case to the TB Control Program, MOHLTC, through iPHIS
(b) Ensuring that the patient is not infectious
(c) Assessing the patient’s understanding and beliefs about TB

(d) Conducting contact investigation for possible source case
(e) Advising the patient (parent/guardian) about side effects of TB medication
(f) Assessing the patient’s ability to comply with medication and medical follow-up
(g) Assessing for Directly Observed Therapy, using the DOT Assessment Tool (See Chapter 8: Treatment of TB Disease for DOT assessment tool)
(h) Contacting the patient (parent/guardian) one month after initial visit to assess the patient’s health status and compliance and every two months thereafter until treatment completion (as advised by physician)
(i) Contacting the treating physician every three months or on an as needed basis.
(j) Discharging from case management and ensuring all iPHIS mandatory fields are complete.
5.3 Appendix A: Interim Guidance for the Prevention and Control of Tuberculosis (TB) in Homeless Shelters and Drop-In Centres

5.3.1 Homelessness and TB
Homelessness is a significant risk factor for TB infection and progression to active TB disease. A homeless person may face an increased risk of TB infection due to: overcrowding in shelters, where the person may be exposed to a person who has active disease; poor ventilation in shelters that can result in the concentration of contaminated air; and underlying medical conditions of homeless persons such as HIV infection, alcohol or drug use and poor nutrition, which make the person more susceptible to developing TB disease. Persons who are homeless also may have difficulty in taking medications on a regular basis or attending scheduled medical appointments resulting in their disease not being recognized or effectively treated.

5.3.2 Reducing the Risk of TB Spreading in Homeless Shelters
Shelters should develop and implement a TB management program based on the recommendations provided in the references below. The Francis J. Curry National TB Center (see reference below) has made the following recommendations that will assist shelter operators and staff to reduce the risk of TB transmission in homeless shelters.

5.3.2.1 General Measures
- **Education:** The shelter should provide education and information on TB to their staff, volunteers and patients.
- **Tissues:** The shelter should make tissues available. Patients, staff and volunteers should be instructed to cover their noses and mouths with tissues when coughing and sneezing.
- **Bed placement:** Beds should be arranged as far from neighbouring beds as possible, with a head to foot arrangement.

5.3.2.2 Administrative and Work Practice Measures Identifying Suspect Cases of TB:
TB should be suspected in any homeless person who has a fever and a productive cough (not a dry cough) that lasts over three weeks. Other symptoms of TB include coughing up blood, night sweats, weight loss, fatigue and loss of appetite. If a person in a shelter has a cough and one or more of the other symptoms, they should be considered a suspect case of TB.

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88 This document has been prepared to assist in the prevention and control of TB in Ontario’s shelters and drop-in centres for the protection of workers and patients. Employers and other workplace parties are reminded that they have legal duties under the Occupational Health and Safety Act (OHSA) to protect workers. The Guidance Document is not a statement of the legal requirements. In this regard reference should be made to the OHSA.
The shelter staff should:

- **Immediately separate the suspect case of TB and arrange for medical care.** The person with TB symptoms should be immediately separated from other staff and residents by placing them in a separate room. A surgical mask should be placed over the patient’s mouth and nose. Medical care should be arranged as soon as possible. This may mean sending the person to the Emergency Department of the hospital as persons with suspect TB are often identified after regular clinic hours.

- **Notify the local public health unit.** The shelter staff should also immediately notify their local public health unit.

### 5.3.2.3 Ventilation, Filters, Ultraviolet Germicidal Irradiation (UVGI)

Ventilation can reduce the spread of TB by diluting the concentration of TB particles and removing contaminated room air. Use of fans, opening windows, and the installation of High-Efficiency Particulate Air (HEPA) filters and UVGI can dilute the air and/or remove TB organisms.

### 5.3.2.4 Use of Respiratory Protection

**TB Suspect case**

It is most important that the suspect TB case wear a regular surgical mask.

**Staff at the shelter**

Staff should only use N95 respirator masks when transporting a resident suspected of having TB or when entering a room in which a suspect case of TB has been placed temporarily to separate him or her from other staff and residents.

Staff assigned to use an N95 respirator mask should be fit-tested to ensure the mask fits properly and be trained in the use, care and limitations of the mask. It is generally not necessary for shelter staff to wear an N95 respirator mask to carry out their duties in other situations. It is not necessary to have all shelter staff prepared to use an N95 respirator mask. One staff person per shift may be sufficient to meet operational needs for most shelters.

### 5.3.2.5 Tuberculosis testing for staff and volunteers pre-placement

Shelter workers and volunteers should be screened for TB infection prior to placement (post-hire); this provides a baseline in the event of a future exposure. A baseline two-step Mantoux test should be performed unless there is appropriate documentation of a previous tuberculin skin test (TST) with the result recorded in mm, not “positive” or “negative”.

#### 5.3.2.5.1 Contraindications to a Mantoux TST per Canadian TB Standards, 5th Edition, 2000 and Chapter 2: Surveillance and Screening

The following persons should not have a TST:

- Persons with severe blistering reactions in the past.
- Persons with documented active TB or a clear history of treatment for TB infection or disease in the past.
- Persons with extensive burns or eczema.
• Persons who have major viral infections or who have had live-virus vaccinations in the past month (this does not include persons with a common cold). These persons can be tested 4-6 weeks after the viral infection or the live-virus vaccination.

5.3.2.5.2 **Negative Mantoux TST:**

An individual who can provide documentation of a Mantoux TST within the preceding year should have a single initial skin test performed and should be managed on the basis of that result. There is no need for a second test (i.e., the second step of the Two-step test) since the earlier test is, in effect, the first of a two-step test. A history of BCG (Bacille Calmette-Guerin) vaccine is not a contraindication to TST.

5.3.2.5.3 **Routine TST:**

Annual routine repeat screening of employees and volunteers would only be recommended after an assessment by the local public health unit. The shelter should contact the TB control program staff of their local public health unit to see if annual screening of employees and volunteers should be conducted in their shelter.

5.3.2.5.4 **Testing Following Contact with an Active Case of TB**

Staff, residents, and volunteers should be tested if they are exposed to a case of TB in the shelter or drop-in centre or elsewhere in the community.

5.3.2.5.5 **Previously Positive Mantoux TST:**

Persons who have a documented positive Mantoux TB skin test should have a baseline pre-placement chest x-ray and be medically assessed in order to rule out active TB disease. They should be instructed to promptly report any symptoms suggestive of TB (e.g., cough, fever, anorexia, weight loss).

5.3.3 **Proper Documentation in Homeless Shelters**

Shelter workers should be reminded to always keep adequate and accurate documentation including bed logs, patient health history and TB symptoms (such as coughing). In the event that there is a case of TB in the shelter, adequate and accurate documentation will assist the local public health unit in carrying out their investigation of the disease, determining the infectious period of the TB case, and identifying the contacts.

5.3.4 **Resources and Information**

5.3.4.1 **Local Public Health Unit**

Your local public health unit can assist you by providing information and education sessions about TB and infection control. Your local Ministry of Labour office can provide information on the requirements under the *Occupational Health and Safety Act*.

5.3.4.2 **Other Resources**

TB in Homeless Shelters: *Reducing the Risk through Ventilation, Filters, and UV.* Francis J. Curry National Tuberculosis Center.

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<td>5.3 Appendix A: Interim Guidance for the Prevention and Control of Tuberculosis (TB) in Homeless Shelters and Drop-In Centres</td>
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[http://www.cdc.gov/mmwr/preview/mmwrhtml/00019922.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/00019922.htm)


Public Health Agency of Canada. Guidelines for Preventing the Transmission of Tuberculosis in Canadian Health Care Facilities and Other Institutional Settings. CCDR Volume: 22S1, April 1996.  

Tuberculosis Prevention and Control Guidelines for Homeless Service Agencies in Seattle-King County, Washington  

San Francisco Department of Public Health. TUBERCULOSIS (TB) INFECTION CONTROL GUIDELINES FOR HOMELESS SHELTERS  

Ministry of Labour local offices  
[http://www.gov.on.ca/LAB/english/about/reg_offices.html](http://www.gov.on.ca/LAB/english/about/reg_offices.html)

Local public health units in Ontario  
6. Contact Management

6.1 Overview

Contact investigation is a major cornerstone of tuberculosis (TB) control. Its aim is to halt transmission of \textit{M. tuberculosis} by treating secondary TB cases, and prevent future cases by identifying and treating latent TB infections (LTBI).

Contact tracing is also used to locate and treat the source case. This is especially important when the index case is a child because the source of infection is usually an adult in the same household or another adult in close contact with the child (e.g. school, daycare, babysitter).

Contact tracing is also an important epidemiological tool in identifying TB disease and infection in a community.

During the contact investigation, up to 1-2\% of close contacts will be found to have active disease. In addition, 5\% to 12\% of contacts found to be infected will develop active disease within 2 years of exposure.\(^8\)

6.1.1 Objectives of Contact Investigation

(a) Identify and initiate treatment of secondary cases.
(b) Identify TB-infected contacts in order to offer treatment for LTBI.
(c) Identify the source case if the index case:
   - is a child,
   - has primary TB,
   - has nonrespiratory TB, or
   - is a new conversion in a high risk environment like a jail or shelter.

6.1.2 Definitions

Contacts are all those who may have been infected by a case of active tuberculosis. Contacts may be classified as "close", "casual or community" contacts.

\textit{Close household contacts} are those who live in the same household, prison cell, shelter, university residence, or army barracks as the infectious case. Household contacts are considered by definition to share breathing space on a daily basis with the source case.

\textit{Close non-household contacts} are those who have regular, prolonged contact with the index case and share breathing space daily, but do not live in the same household. These include regular sexual partners, close friends, children with whom the index case directly works with, persons caring for the index case, those with frequent/regular direct face to face exposure at work, and regular social contacts (bingo, bridge).

Casual or Community Contacts are others who spend time less frequently with the index case or have had less direct exposure to the index case. These may include classmates, colleagues at work, or members of a club or team, or those sharing large air spaces.

Converter
TB conversion is defined as having a skin test reaction of 10mm or greater when a previous test reaction was measured as less than 5mm. If the previous skin test reaction was between 5-9mm then an increase of 6mm or more on the subsequent test is considered to be a conversion.

An individual identified as a contact would be considered a converter if the initial test was 0-4mm and the subsequent test was 5mm or greater (see situation B).

Conversion, within a two year period, is an indicator of recent infection.

<table>
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<th>Examples:</th>
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<td><strong>Situation A</strong>: Patient with a skin test reaction of 12mm; previous reaction was 6 mm.</td>
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<tr>
<td><strong>Interpretation</strong>: Considered a conversion as there was an increase of 6mm.</td>
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<tr>
<td><strong>Situation B</strong>: Patient identified as a contact, initial skin test reaction was 0-4mm; 8-week reaction is 6mm.</td>
</tr>
<tr>
<td><strong>Interpretation</strong>: Considered a new conversion as the 8-week reaction is &gt; 5mm.</td>
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Index Case
The initial patient with active tuberculosis who led to the investigation of contacts.

Source Case
A case of tuberculosis identified as a result of contact investigation and thought to have infected the index case.

Period of Infectiousness
Period of infectiousness/communicability is defined as the period of time during which a case of TB can transmit infection to others.

Cases of pulmonary tuberculosis are generally considered to have become infectious at the time of onset of cough. However, when a case presents with cavitary disease, it is necessary to go back 1-2 months before cough starts because cavities take time to develop. If no cough is reported, or if the duration is difficult to determine, the time of onset of other symptoms may be used to estimate the onset of infectiousness.

For cases that are initially smear-positive, the end of the period of infectiousness is determined by the demonstration of smear negativity (i.e., negative smears on three consecutive days) while the case is receiving adequate treatment. During treatment, up to 20% of initially smear-positive patients will develop a smear-positive, culture-negative state, at which point the organisms seen on sputum smears are considered non-viable and therefore not communicable to others. However, at this time there is no commercially available means, other than
culture, of determining the viability of the mycobacteria, and the demonstration of three consecutive negative sputum smears is still considered the best determinant of the non-infectiousness of initially smear positive patients.

Smear-negative cases are generally considered non-infectious after 2 weeks of adequate therapy. If the index case is suspected or proven to be resistant to one or more of the medications used in treatment, the period of infectiousness must be reassessed. If active disease is suspected at autopsy, and culture results are not available, the assessment of the period of communicability is based on the best available evidence.
6.2 Transmission Factors and Risk to Contacts

The amount of contact necessary for tuberculosis infection to be transmitted is variable and depends on the infectiousness of the source case and the environment in which contact occurs. In general, pulmonary or upper respiratory (laryngeal) tuberculosis are considered the most transmissible by the respiratory route. Cases of laryngeal tuberculosis are considered 4 to 5 times more contagious than smear-positive pulmonary cases. Cases of non-respiratory tuberculosis, are with rare exception, considered non-infectious.

TB staff must understand the principles of transmission and risk factors for transmission in order to:

(a) **Assess** the degree of exposure and risk to contacts;
(b) **Establish priorities** in contact investigation and follow-up; and
(c) **Establish limits** of investigation to avoid complicated or costly additions to existing programs.

In determining the risk of transmission, consider the following factors:

- Transmission Factors Relating to the Case
- Transmission Factors Relating to Shared Air Space
- Transmission Risk Factors Relating to Contacts
- Classification of Contacts

### 6.2.1 Transmission Factors Relating to the Case

1. **Laryngeal TB** has a very high risk for transmission.
2. **Presence of acid-fast bacilli in sputum smear** indicates that the case is more likely to be infectious. It has been found that infectiousness is several times greater in smear-positive than in smear-negative cases. As an indicator of infectiousness, the ability to culture *M. tuberculosis* from secretions is less important quantitatively than a positive sputum smear.
3. **Presence of cough**, especially with sputum production, increases the probability of aerosolization of droplet nuclei.
4. **Cavitary or advanced disease noted on chest X-ray** is a presumptive indicator of a higher transmission risk, with a longer infectious period prior to identification.
5. **Prolonged duration of respiratory symptoms** increases the likelihood of transmission (e.g., delayed diagnosis or delayed recognition of drug resistance)
6. **The use of procedures that may aerosolize infectious droplets** (e.g., sputum induction, bronchoscopy, autopsy, or Pentamidine aerosol treatment) can increase the risk of transmission.
7. **Lack of adequate chemotherapy or non-compliance with chemotherapy** significantly increases the probability of the case producing acid-fast bacilli.
8. **Singing or shouting** increases risk of producing infectious particles.
9. **Patient’s unwillingness or inability to cover mouth and nose when coughing or sneezing** increases risk of transmission.
(10) *Children < 10 years of age are usually less contagious than adults* with the exception of the rare adolescent with cavitary tuberculosis who produces sufficient tubercle bacillus to be detected on sputum smears\(^90\).

### 6.2 Transmission Factors and Risk to Contacts

#### 6.2.2 Transmission Factors Relating to Shared Air Space

The environment in which the contact occurs is also important in assessing infectiousness. Transmission is rarely thought to occur outdoors; however, the presence of indoor environments that are poorly ventilated, dark and damp can lead to increased concentration and survival of mycobacteria. \(^91\)

(a) **Volume of air common to the index case and contact** is critical (i.e., if the volume is low – as in a small shared room, the concentration of infectious particles is greater). By contrast, a workplace exposure in a large warehouse type of space is much less likely to lead to transmission.

(b) **Ventilation** influences the concentration of infectious particles. Exogenous air introduced will dilute the concentration of potential infected particles, reducing transmission risk.

(c) **Re-circulated air** within an essentially closed space may accumulate high concentration of infectious particles.

(d) **Air filtration** may efficiently trap droplet nuclei and counteract the tendency of infectious particles to accumulate within a recirculated air environment.

(e) **Ultraviolet radiation used to irradiate air** within a shared air space may reduce the risk of infection by killing bacilli suspended in droplet nuclei.

#### 6.2.3 Transmission Risk Factors Relating to Contacts

(a) The greater the **amount of time spent with the index case**, the greater the risk.

(b) **Sustained physical closeness or intimacy** may increase the risk, although droplet nuclei eventually undergo random distribution within the shared space.

(c) **Children younger than six years of age and people with impaired immunity** (e.g. HIV positive) have a greater risk of infection. Children and people with impaired immunity should be thoroughly assessed to rule out active disease. \(^92\)

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\(^91\) Ibid p. 176

\(^92\) Ibid p. 181
6.2.4 Classification of Contacts

In identifying and classifying contacts, consider the following factors:

(a) *infectiousness* of case
(b) *frequency and length of exposure* to case
(c) *physical proximity* between case and contact
(d) *immune competence* of exposed persons
(e) *ages* of exposed persons
(f) *quality of ventilation*, i.e., closed poorly ventilated space versus a well ventilated air space.
6.3 Procedure for Contact Investigation

6.3.1 Initiate Investigation

(a) Begin contact investigation as soon as the diagnosis of active or suspected active tuberculosis is made.

(b) Consult with the attending physician and laboratory to establish how infectious the case is. Also, interview the patient about symptom onset.

(c) Identify close contacts within one week of notification and conduct initial evaluation including skin testing within 1 month. Complete second skin test 8 weeks after last exposure to infectious case.

(d) Make a list of all appropriate contacts from information given by the index case, the index case’s relatives, personal physician, or physician, nurse, or employer at the index case’s place of work or school principal.

(e) Classify contacts according to risk of exposure (See 6.2.4).

(f) Visit index case’s home and, if necessary, school, place of work and other institutions to assess transmission risks in those environments and obtain relevant contact information. Ensure confidentiality of index case. (See: Section 6.2)

(g) Assess transmission risk

(h) Inform patients about the exposure via letter; provide information with respect to TB infection and disease; inform patients of skin testing clinics if arranged.

(i) Arrange skin testing for contacts by health unit staff whenever possible, or refer contacts to their family physician, Community Health Centre, or other medical facility for investigation and follow-up of possible infection/disease. See Appendix A for sample letters for contacts.

(j) Request DNA fingerprinting on the samples if TB cases are found during contact investigation. This would confirm or disprove suspected linkages between the cases. (See Chapter 3 Section 3.5.2 (f) Strain Typing of MTBC).

(k) Evaluate the results of the investigation for each circle of contacts to determine the risk of transmission and the attack rates (See: Figure 1).

(l) Ensure all documentation is completed as required by the health unit and the College of Nurses of Ontario. Include all fields required by the Ministry of Health and Long Term care for iPHIS.
6.3.2 Establish Limits of Investigation

Although sometimes difficult to apply in practice, a systematic, organized approach to contact investigation is very important in order to best interpret the results in TST testing.

For sputum smear-positive cases the extent and order of contact investigation is based on the extent of exposure to the case.

Contact investigation must begin promptly with household and non-household close contacts, especially children, and is expanded if transmission to this circle of contacts is demonstrated. Transmission is considered to have occurred if a secondary case is identified, or if the rate of tuberculin reactivity in this circle is greater than expected, or if there is documented conversion.

Contact investigation should then be extended to those who are in regular, but less frequent, contact (the “second circle”). This circle often includes classmates or colleagues at work or in recreational settings that are regularly frequented by the case. The results of the investigation
of this group of contacts are then used to determine the need to expand the investigation yet further.

Public health officials should also consider the probability of finding infected individuals among more casual contacts when deciding whether to extend an investigation. Contacts who have less exposure have a rate of tuberculin positivity that is usually four to six times less than that among household contacts.

The prevalence of tuberculosis infection in various Canadian populations and age groups is not well defined. However, the following broad parameters should assist in providing a baseline for the interpretation of contact surveys 93:

Table 1: Expected prevalence of a Positive TST Among Various Populations

<table>
<thead>
<tr>
<th>Population</th>
<th>Prevalence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Small children (Canadian born or from low-risk countries)</td>
<td>&lt; 5%</td>
</tr>
<tr>
<td>Canadian non-Aboriginal adults</td>
<td>10%</td>
</tr>
<tr>
<td>Aboriginal Canadians (Age 20-40)</td>
<td>20% - 30%</td>
</tr>
<tr>
<td>Foreign born adults who lived for 20 years in a tuberculosis-endemic country</td>
<td>50%</td>
</tr>
</tbody>
</table>

6.3.3 Contact Tracing Priorities

On diagnosis, all cases of tuberculosis must be classified by degree of infectiousness and risk to contacts so that TB control staff can establish priorities for contact investigation. (See Section 6.2 - Transmission Factors and Risk to Contacts.)

Investigating contacts of a highly infectious case and MDR TB cases takes priority over that of contacts of less infectious cases. When contacts are children or people who are immunosuppressed, their investigation takes priority, regardless of the status of the index case.

The following lists priorities for contact tracing.

A. Respiratory Case

1. Highly Infectious (i.e., smear positive, culture positive)
   - Investigate close contacts immediately
   - Investigate casual contacts if rates of infection of the close contacts exceed the expected prevalence rates in the community. Use prevalence data listed above to guide follow-up.

6. Contact Management

6.3 Procedures for Contact Investigation

- In some cases of highly infectious tuberculosis, for example, laryngeal tuberculosis, the contact investigation should include the second circle of regular contacts from the outset. Similarly, in certain settings (shelters for the homeless, for example) in which contacts may be difficult to identify or to find, it may be necessary to do widespread testing from the onset.

2. Less Infectious (i.e., smear negative, culture positive, negative or unknown; clinical diagnosis with respiratory symptoms but no laboratory evidence)
   - Investigate close contacts
   - Investigate casual contacts if rates of infection in close contacts exceed the projected prevalence rates in the community.

3. Infectiousness Unknown (i.e., diagnosis based on autopsy results; smear positive, culture not done; smear and culture not done)
   - Follow contacts based on available information from physician and family.

4. Treatment Failure or non-compliance if sputum remains positive or becomes positive again:
   - Restart contact investigation
   - Investigate newly identified contacts
   - Retest previously exposed uninfected contacts not on chemoprophylaxis

B. Non-Respiratory Case

1. Extrapulmonary Tuberculosis In Children
   - Investigate close contacts to find source case
   - Investigate casual contacts if no source case identified among close contacts.

2. Extrapulmonary Tuberculosis In Adults
   - Investigate close household contacts as a precaution, to identify possible source case and to identify previous infection.

6.3.4 Contact Interview

When interviewing contacts, take a complete history, including:

(a) risk factors for acquiring current infection/disease
(b) nature of exposure
(c) socioeconomic factors; e.g., poverty, homelessness, living in a congregate setting
(d) high risk medical conditions
(e) current symptoms compatible with tuberculosis disease
(f) details of previous contact with tuberculosis
(g) previous tuberculin test dates and results
(h) previous chest X-ray abnormality (including date, place)
(i) details of previous anti-tuberculosis therapy
(j) country of birth and travel history
(k) BCG history
Advise all contacts to seek prompt medical attention if they develop symptoms suggestive of tuberculosis, especially coughing that persists for three weeks or more.

6.3.5 Following Contacts Who Live Outside the Health Unit

A. Within Ontario
   (a) Forward information on contacts living in other health units to those health units for further management.
   (b) The receiving unit is responsible for follow-up and must inform the referring health unit about the results of contact tracing.
   (c) The referring unit will use the information on contact follow-up to decide whether to conclude or expand their contact investigation.
   (d) The referring unit is also responsible for recording the results of contact tracing in iPHIS.

B. Outside Ontario
   (a) Forward information on contacts living outside Ontario in writing by fax or letter to the Nurse Consultant, the TB Control Program, Ministry of Health and Long-Term Care. Include details about the case such as:
      - AFB and culture results
      - Sensitivities
      - Chest x-ray report
      - Last point of contact with index case

The results of the contact follow-up will determine whether to conclude or expand the contact investigation.

6.3.6 Contact Follow-up in Special Settings

TB control staff should take the steps listed below when following contacts in special settings.

A. Work sites, schools, and institutions
   (a) Consult with the program manager, MOH or delegate regarding the plan for contact follow-up.
   (b) Notify appropriate health unit if work site or school is located in that health unit.
   (c) Inform the index case or index case’s parent/guardian if contact follow-up is to be done. If you need to release the name of the index case to the employer or principal in order to identify contacts, please obtain consent from case or parent/guardian beforehand. If consent is denied, please consult with Medical Officer of Health or designate. Obtain the names of designated personnel associated with the setting whose assistance is necessary to conduct contact tracing or for whom it is their responsibility to participate in such investigations as outlined by their professional duties.
   (d) Inform the employer, principal/designate about purpose of follow-up.
(e) Provide the employer/principal with a copy of section 39, HPPA regarding confidentiality requirements under the Health Protection and Promotion Act.

(f) Offer information sessions on tuberculosis and provide written information to contacts. A communication plan should be developed including Fact Sheets and media releases as needed. (Inform the TB Control Unit at the Ministry as per Section 1.7.1e).

(g) Offer on site Mantoux testing by health unit staff whenever possible.

(h) Forward results of follow-up to the health unit where contact lives, if applicable.

B. Hospitals and Long-Term Care Facilities (LTCF)

An essential component of TB management within a hospital or long-term care facility is the identification, assessment and management of patients, visitors, HCWs and other hospital staff.

Personnel such as infection control practitioners/designate and occupational health personnel, in consultation with the public health department, should perform the contact management activities.

Public health should perform these activities for contacts outside the facility; such as: family members, visitors, and patient contacts who are no longer in hospital.

After receiving notification of an active TB case within a hospital or LTCF setting the case investigator will:

(a) Consult with the TB manager/designate and/or medical officer of health/designate regarding the plan for contact tracing investigation within the setting.

(b) Obtain the names of designated personnel associated with the setting whose assistance is necessary to conduct contact tracing or for whom it is their responsibility to participate in such investigations as outlined by their professional duties (i.e. infection control practitioner/designate, occupational health personnel).

(c) If possible, co-ordinate a site visit to meet with the designated personnel in order to:

- determine the case management team for the facility; clarify members’ titles, roles and responsibilities
- determine the best method in which to communicate with one another to ensure that communication is clear and consistent to avoid confusion and inappropriate contact follow-up
- establish the limits of the investigation to include, but not limited to:
  - assessing transmission risk,
  - appropriate classification/identification of close contacts (as per 6.2.4),
  - process for the notification of close contacts,
  - determine contact management recommendations (as per 6.3),
- assist with the co-ordination of a TB skin test clinic for contacts,
6. Contact Management

6.3 Procedures for Contact Investigation

- provide education and counseling as required,
- document in order to ensure everyone is aware of expectations and timelines, and
- provide an avenue for reporting results of the contact investigation conducted within the facility, follow-up meetings as required and/or to formally close out the investigation with a debriefing session.

(d) Ensure all identified staff contacts are actively investigated by the Occupational Health Service (OHS) and confirm that OHS will notify the supplying agency/school of the potential exposure (if agency or students involved). In the case of a contract worker with no supplying agency the OHS should inform the worker of the exposure and the need for follow-up.

(e) Send a letter to family members as well as former patients identified as close contacts, indicating that follow-up with a physician is recommended. Include a fact sheet on TB infection/disease.

(f) Evaluate the results of the investigation for each circle of contacts to determine the risk of transmission and the attack rates.

(g) Document:
   - the number of contacts who were evaluated,
   - number of active cases found,
   - of those tested, how many converted,
   - of the conversions, how many received treatment for LTBI, and
   - number of adverse events following treatment for LTBI.

C. Long distance public transportation

<table>
<thead>
<tr>
<th><strong>Definition of “Significant Travel”</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Significant airline travel is defined as:</strong></td>
</tr>
<tr>
<td><em>a flight of 8 hours or longer in duration.</em></td>
</tr>
<tr>
<td><strong>Significant bus or train travel is defined as:</strong></td>
</tr>
<tr>
<td><em>a journey of 8 hours or longer in length.</em></td>
</tr>
</tbody>
</table>

(a) Airline contacts
   - (Refer to “Tuberculosis Air Travel Guidelines for Prevention and Control” 2nd Edition 2006. Available at: www.who.int/tb/en; Search for Airline Travel Tuberculosis.)

(b) Practical Issues in Conducting Investigations Concerning Exposure to TB\(^94\):
   - Airline companies do not maintain records of passengers’ addresses, telephone numbers or emergency contact information.
   - Although a telephone number is requested at booking, this is not an absolute requirement and the accuracy of the information provided is not known.

\(^94\) Tuberculosis Air Travel Guidelines for Prevention and Control, 2nd Edition, 2006, p. 9
6. Contact Management

6.3 Procedures for Contact Investigation

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- In general, contact information maintained in airline records is inadequate in a high proportion of cases.
- Informing passengers and crew of a potential exposure to TB should be limited to flights that have occurred within the three months before notification of the TB case to health authorities.

(c) Procedures for Informing Passengers and Crew when Exposure to MTBC is Suspected¹⁵
   - Refer to Algorithm, p. 23 of Guidelines.

(d) Criteria for Deciding Whether to Inform Passengers and Crew

(1) Determination of Infectiousness
   - Laboratory AFB Positive Sputum and/or Positive MTBC Culture AND at the time of the flight
   - Clinical: Clinical symptoms including cough and not receiving adequate TB treatment, or, Receiving adequate TB treatment for less than two weeks, or, Receiving adequate TB treatment for more than two weeks but no evidence of response.
   - If MDR TB not receiving adequate treatment OR receiving adequate treatment but no evidence of culture conversion.

(2) Duration of Exposure
   - If total flight duration exceeds eight hours

(3) Time Elapsed Between Flights and Notification of the Case
   - Informing passengers and crew should be limited to flights that took place during the three months before notification of the TB case to the health authorities.

(4) Proximity of Other Passengers and Crew to the Index Case
   - Contact examination is required for all passengers in the same row as the index case and those seated two rows ahead and two rows behind, as well as cabin crew members working in the same cabin section.
   - If the health unit determines a passenger meets the above criteria, report this immediately to the senior medical consultant or designate, TB Control Program, at the MOHLTC.
   - Report initially by telephone and then by completing the “Reporting Form For A Passenger With Infectious TB On An Aircraft”. This form is available on the Public Health Agency of Canada web site, as follows:

```
"Reporting Form for Passenger With Infectious TB On An Aircraft":

- Go to Public Health Agency of Canada www.phac-aspc.gc.ca
- Go to A-Z index and type in T
- Under Tuberculosis, go to: Tuberculosis Prevention and Control
- Click on: Publications and Educational Resources
```

¹⁵ Ibid, pp. 23-27
6.3 Procedures for Contact Investigation

- Under Travel Health you will find Reporting Form for a Passenger with Infectious TB on an Aircraft
- Fax this form to: TB Control Program, PHD at (416) 327-4687

(b) Train or Bus contacts
- Report immediately, to the TB Control Program, at the MOHLTC, any significant travel via bus or train, by the index case during the period of communicability/infectiousness (see definitions - “Period of Infectiousness”).
- When determining risk to train or bus contacts ensure transmission factors have been considered (see 6.2).

6.3.7 Managing Contacts who Refuse Follow-up

(a) Encourage medical follow-up by home visit, telephone contact, or written request. Notify contact in writing that further follow-up is the responsibility of the contact and provide information on signs and symptoms of TB. Consult with medical officer of health or designate to determine if further attempts are warranted.

(b) If the contact is a child and the parent/guardian refuses follow-up, immediately consult the medical officer of health/designate who can consider issuing an order.

(c) If the contact has symptoms suggestive of tuberculosis disease and refuses follow-up, immediately consult the medical officer of health/designate who can consider issuing an order.

(d) Ensure that cultural issues have been considered. Translators and community representatives may be of assistance with contacts who are refusing follow-up.

6.3.8 Contact Management Recommendations

A. Previous documented TST reported as positive (or ≥ 10mm induration)
Refer for assessment to rule out active disease and need for chemoprophylaxis.

(a) Offer INH if indicated for 6 to 12 months if there is no history of completed chemoprophylaxis.

(b) If index case has INH-resistant organisms, consult an expert in tuberculosis for management.

(c) If signs and symptoms of TB are evident or contact is immunocompromised, refer for medical assessment for active tuberculosis.
B. Previous skin test not done, not documented, or negative (0-9mm)
   Do Mantoux skin test as soon as possible after exposure.

   **HIGH-RISK CONTACT is:**
   A close contact of a smear positive pulmonary TB case who has:
   - impaired immunity, such as HIV infection; or,
   - high probability of infection without skin test conversion yet; or,
   - ≤5 years old or an infant born to case with infectious tuberculosis

   **Note:** Infants born to infectious mothers should only be separated from their mothers if the mother continues to be smear positive or where compliance with treatment cannot be assured.

1. For high-risk contacts of any age.
   If negative (0-4 mm): Do history, physical exam, CXR, assess sputum if obtained (CTS)
   
   (a) If physical exam reveals no signs of active disease and chest x-ray is normal:
       i. Recommend INH until reevaluated by repeat skin test 8 weeks after break in contact.
       ii. If repeat skin test is negative (<5mm), INH may be discontinued unless there is continuing exposure to an infectious source or the contact has HIV infection.

   (b) If INH is refused or contraindicated
       i. Do Mantoux skin test at 8 weeks after the break in contact.  
       ii. If skin test is positive (<5mm) at any point, proceed as in section "C" below new positive reactors.

2. Other contacts
   i. Repeat skin test 8 weeks after the break in contact.
   ii. If skin test is still negative, no further follow-up is required.
   iii. If positive (≥5mm), proceed as below.

C. New positive reactors and identified converters
   Take history, do physical exam, order CXR, sputum exam if indicated.
   
   (a) If physical exam, chest x-ray or sputum (if obtained) are abnormal

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Assess for active disease and treat appropriately.

(b) If INH is refused or contraindicated
- Advise the contact in writing that he/she is responsible for further management.
- Counsel contact about the signs and symptoms of TB and when to seek medical attention.
- If contact is high risk, advise the contact in writing of the need for periodic medical follow-up over the next two years, to assess active disease and provide information on the signs and symptoms of TB.

(c) If physical exam, chest x-ray or sputum (if obtained) are normal
- Offer INH if indicated for 6 to 12 months.
- If index case has INH-resistant organisms, consult an expert in tuberculosis for management.

For contact management and follow-up, see the following algorithm.  (Figure 2)
Figure 2: Contact Management Algorithm

**Tuberculin Skin Test 5 TU PPD**

- **Reaction of ≥5mm**
  - Chest x-ray
  - Symptom Enquiry
  - Sputum Culture

- **Reaction of 0-4 mm**
  - Repeat test in 8 weeks after break in contact.

- **Reaction of ≥5mm**
  - Chest x-ray
  - Symptom Enquiry
  - Sputum Culture

- **Reaction of 0-4 mm**
  - No further follow-up required if immunocompetent.
  - If immunocompromised, assess need to continue INH for up to 12 months.

**If TB disease ruled out**
- Offer INH or appropriate prophylaxis

**If TB diagnosed**
- Treat as active TB disease

**ACCEPT:**
Follow up for side effects and compliance

**REFUSE:**
Advise contact in writing re further management.
Counsel re signs and symptoms of active disease
If contact high-risk advise re follow up for next 2 years and provide info on signs and symptoms of TB

NOTE: Any contacts who are children ≤5 years of age or persons who are immune compromised should be given INH during the 8 weeks between tests.
6.4 Appendix A: Sample Contact Letter

<Date>

<Contact’s Address>

<Greeting>

You have been named as a «type of contact_casual_close_household» contact of a person with active pulmonary tuberculosis (TB). You had contact with this person from «Contact_start_date» to «Contact_end_date».

It can take 8 weeks after contact for a TB infection to show up. Depending on an assessment of the situation by your doctor, you will need one or two TB skin tests.

YOU NEED TO:

Phone the <name of Health Unit>, TB Control Program upon receipt of this letter. Please ask to talk with a TB Nurse at <phone number> Monday to Friday between 8:30a.m. and 4:30p.m. See your family doctor or go to a walk-in clinic to have a TB skin test. Bring this letter AND the Form to your doctor (TB Contact Follow-up Form). Ask the doctor/nurse to send the completed form to our health department.

We have sent you a fact sheet on TB infection and TB disease.

YOUR DOCTOR NEEDS TO:

Do a TB skin test and remind you to come back within 48-72 hours later to have the test read. Complete the Form and FAX it to the <name of Health Unit>

FAX: <fax number>

Repeat the TB Skin test 8 weeks later if your test is negative.

Sincerely,

PHN/PHI, Designation
Health Protection Branch
6.5 Appendix B: Paediatric TB Contact

TB Control Program
For __________________, Designation
Medical Officer of Health
City of ______________

<Date>

RE: __________________________ D.O.B.: ______________________

The above child has been identified as a household/casual contact of a person with active pulmonary tuberculosis. A tuberculin skin test now and again in 8 weeks (if the first skin test is < 5 mm) is recommended to determine if infection occurred.

According to the “Canadian Tuberculosis Standards” (5th Edition 2000) exposed children 5 years of age or younger who are tuberculin negative on the first skin test should begin preventive therapy with INH until the second skin test is performed after active tuberculosis has been ruled out. If the second skin test is negative (<5mm), INH may be discontinued. Should consultation be required please consider calling either __________________, Pediatrician, at <phone number> Fax number is <fax number> or __________________, Internal Medicine/Infectious Diseases, at <phone number> Fax number is <fax number>.

Please complete the attached form and return it to the >>Health Unit<< at the address or fax above. All residents of Ontario are entitled to medication free of charge for the treatment of active and inactive tuberculosis. If there are any questions or concerns please call >>Health Unit Phone Number<< , Monday through Friday, 8:30 a.m. to 4:30 p.m.

Sincerely,

>>PHN/PHI<<
>>Designation<<
For
>>MOH Name<<
Medical Officer of Health
>>City<<
7. Latent Tuberculous Infection (LTBI)

7.1 Introduction

7.1.1 Definition
Persons who have a positive tuberculin skin test (TST), and have no clinical, bacteriological, or radiographic evidence of active disease are considered to have latent tuberculous infection.

Chemoprophylaxis or preventive treatment refers to the treatment after the tuberculous infection has occurred but before tuberculous disease is present. The term “latent tuberculous infection” replaces “tuberculous infection” and “inactive TB”. The term “treatment of latent tuberculous infection (LTBI)” replaces “chemoprophylaxis” and “preventive treatment”.97

7.1.2 Purpose
The purpose of treating latent tuberculosis infection is to prevent disease in people who are infected, but who do not yet have active TB. It can also be used to prevent the initial infection in high-risk contacts (e.g. children <6 years of age and people with HIV) who have been exposed to an infectious case and who are awaiting follow-up skin-testing.98

7.1.3 Rationale
In persons infected with tubercle bacilli there is a variable risk of active tuberculosis. Without risk factors, about 10% of infected persons develop tuberculosis, 5% within 2 years of infection and 5% after 2 years.99 An HIV infected person who is also infected with M. tuberculosis has an 8 – 10% risk of developing active disease each year.100 The therapeutic effect of INH has been shown to persist for at least 30 years. It is presumed to endure for the lifetime of the treated patient.101

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98 Ibid p. 181
99 Ibid, p. 97
100 Ibid, p. 142
101 Tuberculosis Control in Alaska, July 2001, p. 27
7.2 Role of Public Health Units in Treatment for LTBI

When treatment for LTBI is prescribed for a patient, the health unit should be notified by one of the following:

- Receipt of a drug order,
- Report from a physician,
- Result of contact investigation,
- Report from other public health units, or
- Follow-up of school or worksite screening programs.

Public Health Units will:

(a) Reinforce with physicians the requirement to report TB infection to the medical officer of health, whether or not treatment is prescribed.
(b) Refer infected individuals for medical assessment and consideration for treatment of LTBI unless the report is coming from the physician who has already made the assessment.
(c) Promote the use of treatment for LTBI according to current guidelines.
(d) Educate the patient and family about the purpose of treatment and the possible side effects of the medications.
(e) Ensure that anti-tuberculous drugs are available free of charge.
(f) Ensure the drugs are appropriate and in the recommended dosage.
(g) Assess the need for directly observed prophylactic treatment (DOPT).
(h) Ensure that baseline liver function testing is done prior to initiation of treatment for LTBI.
(i) Ensure patients with a history of alcohol abuse, pre-existing liver disease or age of ≥ 35 years are monitored for the course of treatment.
7.3 Treatment of Latent Tuberculosis Infection

7.3.1 Indications for Treatment

Treatment of latent tuberculous infection is recommended for persons at greatest risk of tuberculosis disease. Close contacts (those without risk factors) of a case of infectious TB are at increased risk of active disease. 5% of contacts found to be infected will develop active disease within 2 years of exposure and another 5% after 2 years.102

Table 1:  
Indications* for Treatment of Latent Tuberculous Infection  
In High-Risk Groups

<table>
<thead>
<tr>
<th>Tuberculin Reaction Size</th>
<th>Indication</th>
</tr>
</thead>
</table>
| ≥ 5 mm                  | HIV infection  
|                         | Recent contact of infectious TB  
|                         | Presence of lung scar (compatible with old healed TB but not previously treated) |
| ≥ 10 mm*                | Convertors (within 2 years)  
|                         | Immunosuppression:  
|                         | ▪ organ transplantation  
|                         | ▪ chronic renal failure  
|                         | ▪ prolonged corticosteroid or immune suppressive drug therapy  
|                         | ▪ hematologic malignancies: leukemia, lymphoma  
|                         | ▪ silicosis  
|                         | ▪ diabetes mellitus  
|                         | ▪ < 90% of ideal body weight |

* Consider treatment of LTBI in other persons, particularly those ≤ 35 years of age, who have a tuberculin reaction size ≥ 10 mm and are from one of the following groups: foreign-born from TB-endemic countries, Aboriginals, health care workers, and residents in communal care.103

7.3.2 Individuals Who Should Start Preventive Treatment, Regardless of the TST Result

Individuals recently exposed to TB may have a false-negative reaction to the initial TST, if tested < 8 weeks after their last exposure, even if they are truly infected. These individuals should be retested 8 weeks after their last exposure. During the window period between the two TSTs, the following individuals should start preventive therapy, even if the first TST is negative:

103 Ibid, p. 98
7. Latent Tuberculosis Infection (LTBI)

7.3 Treatment of Latent Tuberculosis Infection

- All household contacts < 5 years of age
- Contacts with HIV infection or who are otherwise immunocompromised (e.g., persons on dialysis, those with diabetes)

These contacts should undergo a clinical exam and a chest x-ray to rule out TB disease before starting preventive therapy.

If the second TST result is negative (<5mm), the contact is immunocompetent and no longer exposed to infectious TB, treatment for LTBI can be discontinued, and further follow-up is unnecessary. If the second TST result is negative but the contact is immunocompromised (i.e., HIV infection), a course of therapy for LTBI should be completed.

If the second skin test result is negative but the person remains in close contact with an infectious patient, treatment for LTBI should be continued if the contact is: aged < 5 years; aged 5-15 years, at the clinician’s discretion; or HIV-seropositive or otherwise immunocompromised.

7.3.3 BCG-Vaccinated Person

A history of BCG vaccination, with or without a BCG scar, should not influence the decision regarding LTBI treatment. No criteria can reliably distinguish tuberculin reactions caused by vaccination with BCG from those caused by natural mycobacterial infections. Persons at increased risk for recent infections or with medical conditions that increase the risk of disease should be considered for treatment of LTBI regardless of BCG vaccination status.

7.3.4 Individuals Who Should NOT Start Preventive Treatment:

- Persons who abuse alcohol daily
- Persons who are pregnant (see Section 7.4.6)
- Persons with acute liver disease
- Those who have had an adverse reaction to INH in the past
- Those with low likelihood of compliance (consider DOPT if risk of non-compliance is high)
- Persons on medications that may result in serious drug interactions
- Persons with peripheral neuropathy of any etiology or a condition that might predispose him/her to peripheral neuropathy such as peripheral neuropathy associated with diabetes.

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104 Ibid, p. 134
7.4 Patient Management

7.4.1 Medical History

Before starting treatment for LTBI, the treating clinician should determine:

- **Is there active disease?**
  Pretreatment evaluation must, at a minimum, include a chest x-ray. If the chest x-ray was taken more than 2 months prior to evaluation or if the language in the x-ray report is ambiguous, regardless of the date the x-ray was obtained, the patient should have a repeat x-ray.
  If there are symptoms suggestive of either pulmonary or extra-pulmonary tuberculosis disease, further diagnostic evaluation is needed. Such evaluation may include comparison of current and previous chest x-rays, bacteriologic examination of sputum or biopsy of a sample from a non-respiratory site.

- **Has the individual been treated for LTBI or TB disease in the past?**

- **Does the person have risk factors for the development of TB disease?**
  Persons who have completed a documented course of preventive treatment in the past do not need to be treated again, unless there has been recent exposure to TB. Treatment of LTBI will only remove bacilli currently present in the body; therefore, subsequent contact with TB disease may require another course of treatment. An example of this would be:
    - Subsequent close contact with a person who has AFB smear-positive pulmonary or laryngeal TB disease and the contact is:
      - HIV seropositive or has another medical risk factor for developing TB disease.
      - Younger than 18 years.
      - HIV seronegative but has had significant exposure to a patient with highly infectious TB.

  If there is uncertainty whether a person requires treatment for LTBI, consult a TB specialist.

| When preventive treatment is repeated, an entire course should be given on the assumption that exogenous re-infection may have occurred. |

- Are there any pre-existing medical conditions that would be a contraindication for treatment or are associated with an increased risk of adverse effects of treatment?

- **What drugs is the person currently taking?**
  The patient should inform their family physician that they are on prophylaxis for TB. Drug interactions may occur between the following drugs, see the Compendium of Pharmaceuticals and Specialties (CPS) for details:
INH and Dilantin/INH and Tegretol - INH blocks the excretion of these drugs by the liver causing an increase in serum concentration levels. Therefore, serum levels of these medications should be monitored and the dose of these medications adjusted if necessary.106

Aluminum hydroxide gel decreases gastrointestinal absorption of isoniazid. Isoniazid should be administered at least 1 hour before the antacid.

Rifampin is sometimes used for LTBI. It may accelerate clearance of drugs metabolized by the liver (e.g., anticoagulants, oral antidiabetics, corticosteroids, digitalis compounds, oral contraceptives, ethambutol, methadone, estrogen, sulfonyleureas, digoxin, antiarrhythmic agents, such as quinidine, verapamil, mexiletine, theophylline, anticonvulsants, ketoconazole, and cyclosporin). By accelerating estrogen metabolism, rifampin may interfere with the effectiveness of oral contraceptives.107

Is there any alcohol abuse or illicit drug use? The risk of INH-induced hepatitis is increased in persons with daily alcohol consumption.108

What is the person’s HIV status? All patients should be counseled and offered HIV testing unless they have documentation of either a positive HIV antibody test or a negative result to an HIV antibody test obtained < 6 months ago. The identification of latent TB infection and the implementation of measures to prevent development of active disease are of high priority in the case of HIV infected individuals.109

7.4.2 Baseline Liver Function Testing
Baseline liver function (AST, ALT) testing is recommended for all persons prior to starting treatment for LTBI. Regular monitoring is suggested in those:

- with pre-existing liver disease,
- with a history of alcohol abuse,
- who are ≥ 35 yrs of age,110
- with a history of substance abuse which would affect the liver.

Baseline and monthly liver function testing is recommended for pregnant and post-partum women, individuals with liver disease, or those who are malnourished or underweight or who have clinical evidence of hepatotoxicity.

LTFs should be done, as deemed appropriate, if the patient is taking other medications with the potential of hepatotoxicity.111

107 Ibid, p. 90-91
108 Ibid, p.101
109 Ibid p. 142
110 Ibid p. 102
111 Indiana State Department of Health Tuberculosis Control and Prevention Manual, 2003 p.33
7.4.3 Side Effects

Patients should be advised to notify their physician immediately if they experience any side effects from INH therapy, such as:

(a) Unexplained anorexia, nausea, vomiting, fatigue, or weakness of more than 3 days duration
(b) Persistent paraesthesia of hands and/or feet
(c) Dark urine
(d) Jaundice
(e) Headache
(f) Rash
(g) Fever of more than 3 days duration
(h) Abdominal tenderness, especially right upper quadrant discomfort
(i) Arthralgia

Toxic effects and, rarely, death have been reported from INH-induced hepatitis. Hepatitis occurs mostly in adults, but has been reported in children as young as 2 years. Hepatitis is non-predictable but correlated with age. It has been rare in persons under the age of 20, 0.2% in the 20 to 34 year age group, 1.5% in the 35 to 49 age group and 2.4% in the over 50 age group. 113

Patients should be advised to discontinue medicines temporarily (until medical evaluation is possible) if they experience possible medication-associated side effects and cannot immediately contact their health-care provider.

It is not necessary to discontinue treatment unless:

- AST exceeds 5 times the upper limits of normal, or when
- clinical jaundice develops, or when
- the patient is experiencing symptoms of hepatotoxicity. 114

Consideration for Directly Observed Prophylactic Therapy (DOPT):
Persons at high risk of tuberculous disease should be considered for DOPT including:

- Household contacts of patients who are receiving DOT
- Close contacts if compliance is a concern
- Persons attending methadone clinics,
- Persons prescribed an intermittent regimen. 115

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113 ibid
114 ibid, p. 90
115 ibid, p. 100
7.4.4 Treatment Regimens

Treatment of LTBI is started only after tuberculous disease has been excluded. Isoniazid (INH) is recommended in a dose of 10-15mg/kg daily for children, up to a maximum of 300mg daily. For adults, the dose is 300mg daily. The twice weekly dose is 20-40mg/kg, to a maximum of 900mg/dose in children and 900mg/dose in adults.

The addition of vitamin B₆ (pyridoxine) in a dose of 25mg is indicated when there is poor nutrition, alcoholism, pregnancy, diabetes, uremia, or other disorders that might predispose to neuropathy. It is also recommended in the neonatal period.

The optimal protection is probably achieved by 9 or 10 months, and this is the recommended benchmark.¹¹⁶

Table 3
Recommendations for Treatment of LTBI in HIV Seronegative Persons

<table>
<thead>
<tr>
<th>Drug</th>
<th>Duration</th>
<th>Interval</th>
<th>Mode*</th>
<th>Doses</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>INH</td>
<td>9 months</td>
<td>Daily</td>
<td>SAP</td>
<td>270</td>
<td></td>
</tr>
<tr>
<td></td>
<td>6 months</td>
<td>Daily</td>
<td>SAP</td>
<td>180</td>
<td></td>
</tr>
<tr>
<td>INH</td>
<td>9 months</td>
<td>2/week</td>
<td>DOPT</td>
<td>90</td>
<td></td>
</tr>
<tr>
<td></td>
<td>6 months</td>
<td>2/week</td>
<td>DOPT</td>
<td>52</td>
<td></td>
</tr>
<tr>
<td>RMP</td>
<td>4 months</td>
<td>Daily</td>
<td>SAP, + DOPT</td>
<td>120</td>
<td></td>
</tr>
<tr>
<td>INH, RMP</td>
<td>6 months</td>
<td>2/week</td>
<td>DOPT</td>
<td>52</td>
<td></td>
</tr>
</tbody>
</table>

* SAP: Self-Administered Prophylaxis
* DOPT: Directly Observed Prophylaxis Treatment
* +: For INH resistance or intolerance¹¹⁷

Note: A 6 month regimen of INH is not acceptable for children or for persons with fibrotic lesions visible on their chest x-ray.¹¹⁸

In situations in which Rifampin cannot be used (e.g., HIV infected persons receiving protease inhibitors), Rifabutin may be substituted.¹¹⁹

- Pyrazinamide (PZA) and Rifampin (RMP) for a 2 month period are not recommended for general use.

¹¹⁷ Ibid, p. 98
¹¹⁸ Indiana State Department of Health Tuberculosis Control and Prevention Manual, p. 31
¹¹⁹ MMWR, June 20, 2003 / Vol. 52 / No. RR-11, pp. 735-739
7.4.5 Resistance to Isoniazid, and Isoniazid and Rifampin

In persons infected with INH-resistant organisms and a high risk of tuberculous disease, Rifampin daily for at least 4 months is an acceptable alternative regimen. For preventive therapy in persons thought to be infected with an isolate resistant to drugs other than INH, consultation with a tuberculosis specialist is recommended.

7.4.6 Pregnancy

(a) Women who are pregnant at diagnosis of LTBI

Except for patients co-infected with HIV or those with recent tuberculous infection, the recommendation for management of LTBI during pregnancy is to postpone treatment until after delivery. Pregnancy probably does not increase the risk of progression to disease and there is a suggestion that pregnant women show a higher rate of INH hepatotoxicity effects.

In some situations, preventive treatment should begin during pregnancy. It should be started in the first trimester for TST positive (≥ 5 mm) pregnant women who:

- are HIV seropositive or who have behavioral risk factors for HIV infection but decline HIV testing
- have been in close contact with a smear-positive pulmonary TB patient

Preventive treatment should be started promptly after the first trimester of pregnancy in women who have had a documented conversion in the past 2 years. If preventive treatment has been restarted, a full course should be given (previous doses ignored). In pregnant women who are at high risk of tuberculosis, Vitamin B₆ is recommended with INH-containing regimens.

Preventive treatment, if indicated, should be started 2-3 months after delivery for all other pregnant women, including those with x-ray evidence of old, healed TB.

In pregnant women known or suspected to be infected with a TB strain resistant to at least INH and RMP, preventive treatment should be delayed until after delivery because of possible adverse effects of these medications (i.e. ethambutol, pyrazinamide etc.) on the developing fetus.

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120 MMWR, August 8, 2003 / Vol. 52 / No. RR-31, pp. 735-739. Adverse Event Data and Revised American Thoracic Society/CDC Recommendation Against the Use of PZA and RMP for LTBI because of Severe Liver Injury and Death.

121 Ibid, p. 98, 99

122 Ibid, p. 101

(b) Women Who Become Pregnant While Taking Preventive Treatment

In general, treatment should be discontinued in women who become pregnant while taking INH and/or RMP. To reduce the risk of peri-partum hepatitis, preventive treatment should not be restarted until 2 or 3 months after delivery. When preventive treatment is restarted, a full course should be given (previous doses ignored).124

(c) Perinatal Exposure

If a pregnant woman has LTBI or tuberculosis disease, her newborn will need special follow-up. The infant should be skin tested at 4-6 weeks of age, and if negative, retested at 3-4 months and 6 months of age. The infant should not be placed on INH unless he/she has a positive skin test.

An infant born to a woman being treated for tuberculosis disease should be treated presumptively with INH unless there is evidence of congenital tuberculosis. The child should be checked monthly and then be given a TST and chest x-ray at 3-4 months of age. If the TST is negative, it is recommended that Isoniazid be continued and the TST be repeated at 6 months. If the skin test is positive at 6 months, the child should be reassessed for active disease. If disease is absent, an additional 3 months of INH should be administered. If it is negative, INH may be discontinued.

An infant born to a woman found to have untreated infectious tuberculosis should be managed the same as an infant whose mother is being treated for tuberculosis with one additional provision. The mother should be isolated from her infant until treatment of the mother renders her non-infectious.125

Breast feeding should not be discouraged, as the very small concentrations of antituberculous drugs in the breast milk do not produce toxic effect on the newborn. It should also be emphasized that the small amount of medication that may be found in breast milk should not be considered effective treatment or prophylaxis in a nursing infant.126

7.4.7 Children

A diagnosis of LTBI or tuberculosis disease in a child is a sentinel event usually representing recent transmission of M. tuberculosis.127 Active TB disease can be severe in young children. In children, especially those ≤5 years of age, infection is not only more likely to progress to disease, but to severe forms of disease; e.g., CNS and disseminated (miliary) TB.128 Among children, efficacy of treatment approaches 100% with appropriate adherence.129

For children with HIV infection or other immunocompromising conditions, a minimum of 9 months of INH preventive therapy is recommended. In situations of uncertain adherence,
INH can be administered twice weekly (20-40mg/kg/day, maximum 900mg/day) under Directly Observed Prophylactic Therapy (DOPT). \(^\text{130}\)

For children infected with what is likely to be an INH-resistant strain, or who are intolerant of INH, rifampin (10-20mg/kg/day, maximum 600mg/day) is recommended for 6 months.\(^\text{131}\)

INH may interfere with pyridoxine metabolism and produce peripheral neuropathy and other significant reactions (i.e., psychotic episodes). B6 (pyroxidine) should be given to persons with:
- diabetes
- pregnancy
- renal failure
- malnutrition
- substance abuse
- seizure disorders\(^\text{132}\)

Pyridoxine therapy is generally not indicated except in breast fed infants or malnourished children.

### 7.4.8 Completion of Treatment

The important variable is duration rather than continuity. A full course of therapy is determined more accurately by the total number of doses taken, not solely by the duration of therapy.\(^\text{133}\) Extend INH treatment long enough to ensure the equivalent of 9 months of treatment with 100% compliance.\(^\text{134}\)

To be considered adequate, the 9 month daily INH regimen, consisting of 270 doses, should be administered over no more than 12 months. Likewise, to be considered adequate, the 6 month INH regimens should be administered over no more than 9 months. Regimens of 2 or 4 months should be administered over no more than 3 or 6 months respectively to be considered adequate.\(^\text{135}\)

Interruptions in treatment may have significant affect on the duration of treatment. Reinstitution of treatment must take into account:
- the bacillary load of the patient
- the point of time when the interruption occurred
- duration of the interruption

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\(^{131}\) Ibid

\(^{132}\) ibid p. 90

\(^{133}\) MMWR, June 20, 2003/Vol. 52/No. RR-11, p. 8


\(^{135}\) Tuberculosis Control in Alaska, July 2001, p. 36
In general, the earlier in the treatment and the longer the duration of the interruption, the more serious the effect and the greater the need to restart the therapy from the beginning.\textsuperscript{136}
8. Treatment of TB Disease

8.1 Introduction

Treatment of TB is aimed at achieving a lifetime cure of the disease, preventing drug resistance, and preventing further transmission of the infection in the community. Therefore, successful treatment of a TB patient benefits the patient and the community.

Cure can be achieved in different ways, all of which include ingestion of drugs to which the TB organism is susceptible. The medications against TB are always given in combination for a period of several months. *M. tuberculosis* is usually slow to produce disease and equally slow to respond completely to drug treatment. Several factors must be taken into account in determining which drugs are to be used and the length of treatment. These include:

- The type of disease being treated
- The drugs that are available for treatment (Cases due to drug-resistant isolates will need longer courses of treatment than those due to drug-susceptible isolates.)
- Patient adherence to treatment
- Potential drug interactions
- Patient tolerance of TB medications (because of side effects the treatment may not always be the most optimal treatment)

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138 Ibid.
139 Ibid.
8.2 Treatment for TB

Treatment for TB should be based on:

- Clinical, pathological and radiographic findings;
- Results of microscopic examination of acid-fast bacilli smears and cultures for mycobacteria; and,
- Epidemiologic information.

8.2.1 Responsibility for TB Treatment

In 2002, the American Thoracic Society published their treatment guidelines for TB. Central to these guidelines is that the responsibility for the treatment of TB is on the provider or program that provides TB treatment.

“…. It is well established that appropriate treatment of TB rapidly renders the patient noninfectious, prevents drug resistance, minimizes the risk of disability or death from TB and nearly eliminates the possibility of relapse. For these reasons, antituberculosis chemotherapy is both a personal and a public health measure that cannot be equated with the treatment of, for example, hypertension or diabetes mellitus, wherein the benefits largely accrue to the patient...All reasonable attempts should be made to accommodate the patient so that a successful outcome is achieved. However, interventions such as detention may be necessary for patients who are persistently nonadherent.”

8.2.2 Treatment Regimens

There are two phases of TB treatment:

(a) The Initial or Intensive Phase, and
(b) The Maintenance or Continuation Phase.

(a) Initial or Intensive Phase

The Fifth Edition of the Canadian TB Standards recommends that 3 or 4 drugs (isoniazid, ethambutol, rifampin and pyrazinamide) be given daily (using Directly Observed Therapy [DOT]) for 2 months (60 doses). This phase allows the TB drugs to kill rapidly replicating populations of \( M. tuberculosis \) and to prevent the emergence of drug resistance.

The choice of drugs depends on drug susceptibility testing. **If susceptibilities are not known at the onset of treatment, four drugs are usually prescribed and adjustments are made once susceptibility test results are available.** The drugs are to be taken daily. The bactericidal effect leads to rapid bacteriologic sputum conversion and decreasing clinical symptoms.
### 8. Treatment of TB Disease

**8.2 Treatment for TB**

Because of the relatively high proportion of adult patients with TB caused by organisms that are resistant to INH, four drugs are necessary in the initial phase for the 6 months regimen to be effective.  

This initial phase is important because it:

- Results in rapid, symptomatic relief, rapid reduction in infectiousness and reduced mortality;
- Reduces the possibility of the individual developing drug-resistant TB; and,
- Significantly increases the possibility that the client will complete treatment in 6 months.  

**Maintenance or Continuation Phase.**  
Two drugs (usually isoniazid [INH] and rifampin [RMP], if the organism is susceptible) are given daily or twice weekly using DOT for an additional 4 to 7 months. The longer regimen is used if the sputum was AFB positive. This eliminates any persisting bacteria not destroyed in the initial phase, and reduces the likelihood of relapse. Medication can be given daily or twice weekly. Any intermittent delivery MUST be by DOT. The sterilizing effect of therapy eliminates the remaining bacilli and prevents subsequent relapse.  

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145 Alberta TB Control Manual, p. 3-8
146 Ibid
8.3 Medications Used To Treat TB

8.3.1 ‘First Line TB Drugs’
Isoniazid (INH), rifampin (RMP), ethambutol (EMB) and pyrazinamide (PZA) are the ‘first line’ TB drugs. At the present time, they are the most effective drugs with which to combat TB. They should not be used indiscriminately. If resistance to these drugs develops, the treatment of TB is often more expensive, more complicated and its duration much longer.148 It is also very important that a single drug is not added to a failing regimen. Doing so can lead to acquired resistance.

All residents of Ontario with TB disease or infection will be provided with drugs free of charge (including ‘second line’ drugs to treat TB) for the treatment and chemoprophylaxis of TB infection with M. tuberculosis. These drugs, which are provided by the Ontario Ministry of Health and Long-Term Care and distributed by public health units, are also available to visitors (i.e., non-residents) who are unable to pay on a case-by-case basis. Drugs used to treat atypical mycobacterial infections, also known as MOTT (mycobacteria other than TB), including M. avium complex, are NOT provided free of charge. An uninsured person does NOT need to be enrolled in the TB-UP program in order to get free TB medications in Ontario.

It is important that local public health units ensure that all hospitals, physicians, and pharmacists in Ontario are aware that the MOHLTC provides TB drugs free of charge to TB patients and their contacts.

8.3.2 Availability of ‘First Line’ TB Drugs
First line TB drugs can be ordered by local public health units upon the receipt of a prescription from the health care provider. The drugs are available free of charge from Ontario Government Pharmaceutical and Medical Supplies Services (OGPMSS) using the Public Health Division Requisition for Drugs to Treat TB (see Appendix A).

To obtain these drugs, physicians and hospitals must order their drugs through their local health unit. In Toronto, some physicians and hospitals may receive drugs directly from OGPMSS through a special arrangement with their local health unit.

(a) Isoniazid (INH)
Isoniazid is an active bactericidal anti-tuberculous agent that was first used in 1952. Its mode of action is still not completely understood, and it is effective only against the genus Mycobacterium.149 The drug is firmly bound to the actively growing, sensitive tubercule bacilli.150 It is rapidly and almost completely

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148 Alberta TB Control Manual, p. 3-9
149 Ibid
absorbed, and peak blood levels are reached within 30-60 minutes after ingestion. Absorption is inhibited by the presence of food in the stomach.\textsuperscript{151}

There is natural occurrence of resistance to INH in about 1 in a million organisms. The assumption is made that more than 1 million organisms must be present before TB disease is seen. Therefore, INH is always used in combination with another drug when used for treating active TB disease. The second drug will destroy any naturally occurring drug resistant mutations in the population of bacteria. If infection has occurred, but NO disease is detected, it is safe to assume that fewer than 1 million organisms are present, and the use of INH alone to prevent future reactivation is acceptable practice.\textsuperscript{152}

\textbf{(b) Rifampin (RMP)}

Rifampin has been in general use since 1970. It acts by inhibiting DNA-dependent RNA polymerase activity in dividing cells, and it is effective against mycobacterium as well as some gram positive and gram negative organisms. It is readily absorbed and reaches peak blood concentrations 2 to 4 hours after ingestion. Absorption is inhibited by the presence of food in the stomach. There are many potential drug interactions with RMP and the prescribing physician should take a careful medication history and consult with a pharmacist to discuss potential drug interactions.\textsuperscript{153}

When given intermittently, usual doses are used because intermittent high dose administration is likely to cause hypersensitivity reactions, including thrombocytopenia and anaphylaxis.\textsuperscript{154}

Rifampin is a liver enzyme inducer and increases the metabolism (thus decreasing the blood levels) of other drugs metabolized in the liver, such as anticoagulants, oral hypoglycemic agents, corticosteroids, oral contraceptives, phenytoin etc. Patients on birth control pills will have to use alternate forms of birth control while on RMP.\textsuperscript{155}

\textbf{(c) Pyrazinamide (PZA)}

Pyrazinamide has been used since 1952. Its mechanism of action is unknown, but it is active only at acid ph.\textsuperscript{156} The accumulation of pyrazinoic acid (the active derivative of PZA) through the action of the amidase pyrazinamide by susceptible \textit{M. tuberculosis} leads to its intracellular bactericidal action.

Absorption of PZA is not influenced by food intake.\textsuperscript{157} Pyrazinamide inhibits the renal excretion of urates, and will often lead to high levels of uric acid in the blood. This is usually of no consequence. On rare occasions, it may lead to

\textsuperscript{151} Albertas TB Control Manual, p. 3-9.
\textsuperscript{152} Ibid.
\textsuperscript{153} Ibid, p. 3-10.
\textsuperscript{154} Ibid.
\textsuperscript{155} Ibid.
\textsuperscript{156} Albertas TB Control Manual, p. 3-10.
\textsuperscript{157} TB Control and Elimination, Nunavut Manual, p. 5-4.
acute episodes of gout in persons predisposed to gout; in which case, the drug may need to be discontinued.  

(d) Ethambutol (EMB)  
The synthesis of ethambutol was reported in 1961. Ethambutol is bacteriostatic at low dosage (15mg/kg). It diffuses into actively growing mycobacterium cells where it inhibits the synthesis of one or more essential metabolites, causing impairment of cell metabolism, arrest of multiplication, and cell death. It is active only against organisms of the genus *Mycobacterium*. It is about 75-80% absorbed after an oral dose, and reaches blood concentrations about 2 to 4 hours after ingestion. Absorption does not seem to be affected by food in the stomach.

Ethambutol is excreted from the body mainly in the urine. There is a fine line between the blood level needed to be effective and the toxicity level. In individuals with impaired renal function, there is marked accumulation of medication in the system. For this reason, renal function (serum creatinine) should be measured before beginning treatment.

Ethambutol may cause optic neuritis (in about 6% of patients), with decreased visual acuity and loss of red-green colour discrimination. These effects are uncommon at the lower dosage (15mg/kg), and for this reason, dosages are usually reduced after the initial phase of treatment. They are usually reversible when detected early and the drug is discontinued promptly.

- Visual acuity and red-green colour discrimination should be tested monthly while on treatment, and the patient should be advised to report promptly any changes in vision.

- Because these changes may be unilateral or bilateral, **each eye must be tested separately and both eyes tested together.**

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158 Alberta TB Control Manual, p. 3-10.
159 TB Control and Elimination, Nunavut Manual, p.5-4.
160 Alberta TB Control Manual, p. 3-10.
162 Alberta TB Control Manual, p. 3-10.
163 Ibid, p. 3-11.
164 Alberta TB Control Manual, p. 3-11.
8.4  Treatment Regimens (Cases) 165

8.4.1  Length of Treatment
- If fully susceptible, treat for at least 6 months with INH, RMP and PZA (can be discontinued after 6 months).
- INH and RMP can be discontinued after 9 months.
- If INH and RMP are NOT used, then extend treatment to a minimum of 12 months

Table 8-1: Duration of Treatment (In Months)

<table>
<thead>
<tr>
<th>Regimen</th>
<th>Intensive</th>
<th>Continuing</th>
<th>Total</th>
<th>Number of Doses</th>
</tr>
</thead>
<tbody>
<tr>
<td>INH/RMP/PZA ±EMB</td>
<td>2</td>
<td>4</td>
<td>6</td>
<td>95</td>
</tr>
<tr>
<td>INH/RMP ±EMB</td>
<td>1-2</td>
<td>7-8</td>
<td>9</td>
<td>120</td>
</tr>
</tbody>
</table>

Table 8-2: Dosing Interval Options

<table>
<thead>
<tr>
<th>Regimen</th>
<th>Option</th>
<th>Number of Doses</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>INH/RMP/PZA</td>
<td>1</td>
<td>95 doses</td>
<td>Daily INH, RMP, PZA x 2 months</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Then INH and RMP daily or 2x/weekly for 4 months</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>60 doses</td>
<td>Daily INH, RMP and PZA x 2 weeks</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Then INH, RMP and PZA 2x/week for 6 weeks</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Then INH and RMP 2x/week for 4 months</td>
</tr>
<tr>
<td>INH and RMP</td>
<td>1</td>
<td>120 doses</td>
<td>Administer daily INH and RMP x 2 months</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Then INH and RMP 2x/week for 7 months</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>100 doses</td>
<td>Daily INH and RMP x 1 month</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Follow with INH and RMP 2x/week for 8 months</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>180 doses</td>
<td>Daily INH and RMP for 9 months</td>
</tr>
</tbody>
</table>

All regimens administered intermittently (e.g. 2 x/week) must be administered by DOT.

Ethambutol should be added to the initial regimen until drug susceptibility tests exclude the presence of resistance. In all cases of suspected drug resistance, the treating physician should consult a TB specialist prior to starting a treatment regimen.

8.4.2 Response to Treatment and Treatment Failure

In order to monitor sputum conversion and treatment outcome, all patients with sputum and culture positive disease should have repeat sputum examinations at the end of the second month of treatment. To verify treatment success, additional sputum cultures should be done at the end of the 6 and 9 month regimens. However, the patient must be monitored more frequently if the clinical and radiologic response is unfavourable. If the patient is unable to cough or produce a sputum sample, consider arranging for sputum induction.

Treatment failure is defined as two or more positive sputum cultures over an interval of 1 month, after 5 or 6 months of treatment, or two positive sputum cultures in different months during the last 3 months of treatment. If TB symptoms continue and/or failure of radiographic improvement in association with persistently positive sputum smears or cultures should raise the question of treatment failure as early as the third month of therapy.

Table 8-3: Doses and Common Adverse Reactions to Antitubercular Drugs

<table>
<thead>
<tr>
<th>Daily Dose Adults and [children] Mg/kg</th>
<th>Usual adult daily dose mg</th>
<th>Twice Weekly Dose mg</th>
<th>More Common Side Effects</th>
<th>Less Common Side Effects</th>
<th>Monitoring</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>INH Supplied: Tablets: 100 &amp; 300 mg Liquid: 10mg/1ml (Parenteral formulation also available)</td>
<td>5 [10-20]</td>
<td>300</td>
<td>900</td>
<td>Heptotoxicity (nausea, vomiting, abdominal discomfort, anorexia, fatigue) accompanied by increased transaminase (AST, ALT ) levels</td>
<td>Peripheral neuropathy (controlled by co-administration of pyridoxine)</td>
<td>Arthralgia Convulsions Psychotic symptoms (rare) Rash</td>
</tr>
</tbody>
</table>

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166 Ibid, p. 95.
167 Adapted from Alberta TB Control Manual, pp. 3-12, 3-13.
<table>
<thead>
<tr>
<th>Daily Dose Adults and [children] Mg/kg</th>
<th>Usual adult daily dose mg</th>
<th>Twice Weekly Dose mg</th>
<th>More Common Side Effects</th>
<th>Less Common Side Effects</th>
<th>Monitoring</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>INH (Continued)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RMP Supplied Capsules 150 &amp; 300 mg</td>
<td></td>
<td></td>
<td>Hepatotoxicity (as with INH)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Syrup formulated from capsules: 10 mg/ml</td>
<td></td>
<td></td>
<td>Orange discoloration of urine and body secretions (tears, urine, saliva, perspiration)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Parenteral formulation also available)</td>
<td></td>
<td></td>
<td>• Hypersensitivity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10 [10-20]</td>
<td>600</td>
<td>600</td>
<td>• Purpura</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PZA Supplied: Tablets 500 mg</td>
<td></td>
<td></td>
<td>Hypeuricemia Arthralgia</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15-30g</td>
<td>1500-2000</td>
<td>2500</td>
<td>• Hepatotoxicity</td>
<td></td>
<td>Baseline measurements for adults</td>
<td>Exclude interactions with other medications (e.g., decreased effectiveness of birth control pills)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Photosensitivities</td>
<td></td>
<td>• Uric acid if gout is suspected</td>
<td>Orange discoloration of tears will stain soft contact lenses; sweat can stain white shirts.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Gout</td>
<td></td>
<td>• Transaminase levels as with INH and RMP</td>
<td>Significant interactions with methadone and many other drugs.</td>
</tr>
</tbody>
</table>

Orange discoloration of tears will stain soft contact lenses; sweat can stain white shirts.

Significant interactions with methadone and many other drugs.
<table>
<thead>
<tr>
<th>Daily Dose Adults and [children] Mg/kg</th>
<th>Usual adult daily dose mg</th>
<th>Twice Weekly Dose mg</th>
<th>More Common Side Effects</th>
<th>Less Common Side Effects</th>
<th>Monitoring</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>EMB</td>
<td>800-1200</td>
<td>2400</td>
<td>Retrobulbar neuritis</td>
<td>Slight uric acid</td>
<td>Baseline visual acuity and colour discrimination</td>
<td>Exclude interactions with other medications</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Nausea</td>
<td>elevation</td>
<td>Repeat visual acuity and colour discrimination monthly</td>
<td>Report any visual changes immediately</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Not recommended for children who are too young to be monitored for changes in vision (unless TB is drug resistant)</td>
</tr>
</tbody>
</table>
8.5 Drug Resistant TB

Drug resistance is caused by germ mutation following drug exposure. TB germs are able to alter their structure so that they are able to destroy that drug. The drug can no longer contribute to cure and active disease may continue or worsen.\textsuperscript{170} Multi drug resistance (MDR) is defined as resistance to INH and RMP. In 2006, the CDC encountered reports of multiple cases of TB with resistance to virtually all second-line drugs (SLDs). Extensively drug-resistant (XDR) TB cases are defined as cases in persons with TB whose isolates were resistant to INH and RMP, and at least three of the six main classes of SLDs (aminoglycosides, polypeptides, fluoroquinolones, thioamides, cycloserine, and para aminosalicylic acid).\textsuperscript{171} XDR has emerged world-wide as a threat to public health and TB control, raising concerns of a future epidemic of virtually untreatable TB.

Common causes for drug resistance are:

- Patients who are inadequately or inappropriately treated for TB (including prior treatment for TB)
- Contacts of drug resistant cases
- Patients infected in areas of the world where drug resistance is high e.g., Asia, Africa, Russia
- Persons infected in inner cities and prisons in the United States

If a person with TB disease is given a drug regimen for Latent TB Infection (LTBI), drug resistance may develop. It is critical that PRIOR to starting treatment for LTBI, a diagnosis for active TB disease is excluded.

- ALL PERSONS WITH DRUG RESISTANT TB SHOULD BE MANAGED BY, OR IN CONSULTATION WITH, A TB SPECIALIST WHO HAS EXPERIENCE TREATING DRUG RESISTANT TB. TREATMENT SHOULD BE BY, OR UNDER THE ADVISEMENT, OF THE TB MEDICAL CONSULTANT AT WEST PARK HEALTHCARE CENTRE (WPHC). HOSPITALIZATION AT WPHC SHOULD BE CONSIDERED.

- PERSONS WITH DRUG RESISTANT TB MUST BE ON DOT.

- THE BASIC PRINCIPLE FOR TREATMENT OF DRUG RESISTANT TB IS THAT IF THERE IS RESISTANCE TO ONE OR MORE TB DRUGS, THEN AT LEAST 2 OTHER DRUGS THAT THE PERSON IS SUSCEPTIBLE TO, SHOULD BE PRESCRIBED.

8.5.1 Acquired Resistance

Persons whose initial culture show sensitive bacilli and then develop resistance during treatment are said to have acquired resistance. Resistance develops from taking fewer than 2 drugs to which the bacilli are sensitive. This may be due to inadequate, inappropriate, or irregular treatment or non-adherence to drug taking.\textsuperscript{172}

\textsuperscript{170} Regional Tuberculosis Control Manual FNIHB Ontario Region March 2002, p. 91.
\textsuperscript{171} MMWR, March 24, 2006, Vol. 55/ No. 11.
8.5.2 Primary Resistance
This type of resistance occurs in persons previously untreated for TB who have drug resistant organisms, presumably since they have been infected from an outside source of drug resistant bacilli. \(^173\)

8.5.3 Management of Contacts of Person with Drug Resistant TB
The management of these contacts should be discussed with a TB specialist to determine the best treatment regimen. Contacts of MDR TB should be followed for at least 2 years, irrespective of treatment. This may include evaluating the contact every 6 to 12 months and, if symptoms warrant, obtain chest x-rays and sputum specimens for culture and sensitivity.

8.5.4 ‘Second Line’ TB Medications
Second line TB medications are used to treat patients who are resistant to one or more of the first line TB drugs or those who cannot tolerate the regular first line TB medications. The prescribing of ‘second line’ TB drugs should be done ONLY by a TB specialist or by a provider who has consulted with a TB specialist. These drugs are available free of charge (see procedure for reimbursement in Section 8.5.6, following). The following information with regard to the most commonly used second line TB drugs is for basic information only. Please consult the Compendium of Pharmaceuticals and Specialties, the prescribing pharmacist and the product monograph for complete drug information.

(a) Streptomycin (SM) \(^174\)
Streptomycin was discovered in 1944. It works by interfering with bacterial cell proteins. It is not absorbed in the gut and is, therefore, given only in parenteral form. Peak blood concentrations are reached about 1 to 2 hours after administration.

It is excreted from the body mainly through the urine. If a person has impaired renal function, SM will accumulate and may reach dangerously high blood levels. For this reason, persons with any renal impairment need to be monitored very closely.

There is also the risk of 8th nerve toxicity when using SM (especially if the patient has renal impairment). This may lead to permanent loss of inner ear function. Symptoms include: nausea, vomiting, vertigo, nystagmus and ataxia, tinnitus, and varying degrees of hearing impairment. Monthly audiograms are necessary. SM is also teratogenic to the fetus’ 8th cranial nerve and should not be used in pregnancy.

(b) Fluroquinolones \(^175\)
The most common fluroquinolones used are: levofloxacin, gatifloxacin and moxifloxacin. These drugs should not be considered as first line TB agents for the treatment of drug susceptible TB, except in patients who are intolerant or resistant to the first line drugs. The most commonly used drug is levofloxacin. The adult dose is 500 – 1000mg/day. Antacids and other

\(^{173}\) Ibid.
\(^{174}\) Alberta TB Control Manual, p. 3-11.
medications can cause a marked decrease in the absorption of the fluoroquinolones and may cause treatment failure. It is important to caution the patient not to take this drug within two hours of a dose of antacids, the chewable tablet form of didanosine, suclalfate, iron, magnesium, calcium, zinc or vitamins or other dietary supplements (e.g. Ensure, Sustical).

In 2006, the Product Monograph for Tequin® (gatifloxacin) was revised. Serious cases of both hypoglycemia and hypercalcemia were reported in persons receiving Tequin®. Tequin® is now contraindicated in patients with diabetes mellitus.

(c) Rifabutin (RIF) \(^{176}\)
This drug is often substituted for RMP due to drug resistance. It is generally reserved for those patients receiving medication with unacceptable interactions with RMP or those who experience intolerance to RMP. The maximum adult dose is 5mg/kg to a total of 300mg daily, 2 times or 3 times a week. The dose may need to be adjusted with concomitant use of protease inhibitors or nonnucleoside reverse transcriptase inhibitors. Persons taking RIF may experience hemotologic toxicity (neutropenia), gastric symptoms, uveitis, polyarthralgias, hepatotoxicity, skin discoloration with normal bilirubin, rash, flu-like symptoms and orange discoloration of bodily fluids.

(d) Aminogycosides (Amikacin and Kanamycin) \(^{177}\)
These two drugs are closely related and are given IM or IV. The maximum adult dose is 15mg/kg/day (1.0g/day IV or IM). The drug is usually given in a single, daily dose for 5-7 days/week then reduced to 2-3 times per week after the initial first 2 to 4 months or depending on culture conversion. It is important that patients on these drugs have audiology testing as ototoxicity is a side effect and deafness can result.

(e) Cycloserine \(^{178}\)
The adult maximum dose is 10-15 mg/kg/day to 1000 mg. The usual dose is 500-750 mg/day given in 2 doses. Patients may complain of CNS effects such as headache and restlessness. This drug may exacerbate underlying seizure disorders or mental illness.

8.5.5 How to Obtain ‘Second Line TB Drugs’
‘Second line TB drugs are provided free of charge for patients infected with *M. tuberculosis* complex. These drugs are not stocked at OGPMSS and must initially be purchased by the patient, the health department, hospital or physician. The PHD will reimburse the cost of the drug and the dispensing fees.

\(^{177}\) Ibid, p. 624
\(^{178}\) Ibid, p. 623
8.5.6 Reimbursement for Second Line TB Drugs

To obtain reimbursement for these drugs, the local public health unit should send an invoice to the TB Control Unit PHD together with:

- A photocopy of the prescription (all identifying information of the patient must be removed, including the name, address and phone number);
- The iPHIS TB identifier (to ensure that the drugs are being used only for the treatment of TB cases) should be written on each prescription; and,
- The total amount to be reimbursed and the address where the reimbursement should be sent.
8.6 Treatment of TB in Special Situations
The treatment of TB is special situations such as:

- Persons who are HIV+ve,
- Pediatric cases,
- Persons with extrapulmonary TB,
- Pregnancy and breastfeeding,
- TB in persons with liver disease, and/or
- TB in persons who have renal failure

is beyond the scope of this protocol. Information for these special situations can be found in the Canadian TB Standards\(^{179}\) and the American Thoracic Society Treatment of Tuberculosis\(^{180}\).
8.7 Anti-TB Drugs through the Special Access Program

Practitioners occasionally require drugs that are not approved in Canada to treat TB. The Therapeutic Products Directorate of Health Canada has a mandate to authorize the sale of these drugs to practitioners. This mandate is managed by the Special Access Program (SAP). SAP is responsible for authorizing the sale of pharmaceutical, biologic, and radiopharmaceutical products that are not approved in Canada.

8.7.1 How to Request a Drug Through SAP
Practitioners may fax, phone or write to SAP to request the medication. Most requests can be handled by fax but urgent requests should be followed up by telephone. After consideration, an authorization may be granted. The manufacturer has the final word on whether or not the drug will be supplied.

The SAP request forms are available online at [www.hc-sc.gc.ca](http://www.hc-sc.gc.ca); Drugs and Health Products; Special Access to Drugs and Health Products). The following information must be supplied when requesting a drug from the SAP:

- Practitioner’s name and phone number
- Address of physician’s office or hospital pharmacy where the drug is to be delivered
- The name of the drug and the dosage
- Manufacturer’s name
- Total quantity of the drug requested
- Intended dosage
- Patient’s initials, date of birth and sex
- The medical indication for the drug
8.8 Dispensing of TB Drugs
The OGPMSS cannot legally label drugs with dispensing instructions. To ensure that the patient receives proper instructions, boards of health have three options at the present time:

(a) The public health unit can make arrangements with a local pharmacy to dispense the TB drugs at the pharmacy (including proper labeling, repackaging, and blister packing as required). All costs incurred will be paid for by the local public health unit.

(b) The physician or clinic who orders the drug, labels the drugs and gives them to the patient along with the relevant drug information sheets, including signs and symptoms of adverse drug reactions.

(c) A nurse at the local public health unit can provide the drugs directly to the patient, giving the patient the relevant drug information sheets, including signs and symptoms of adverse drug reactions. Any repackaging of the medication is considered dispensing and can only be done under the delegation of the Medical Officer of Health.

Current information about nurses’ responsibility in dispensing drugs can be obtained at the College of Nurses of Ontario’s web site: www.cno.org; Publications and Services; Documents; Medication – dispensing.

8.8.1 Labeling Information to be Included on Each TB Drug
- Name of patient
- Name of the drug, the tablet size and the quantity of medication dispensed
- The dose, frequency, and duration of medication
- The expiry date for the medication
8.9 Provision of TB Medications for Persons Leaving Ontario (Cases and LTBI)

Persons with TB disease can only leave Ontario with the permission of their treating physician. They must NOT be infectious at the time of travel. Only one month’s supply of medication is to be given to a person with TB disease or infection who is leaving Ontario. Treatment details must accompany the patient. The TB Control unit can assist the health unit in contacting the health authority or practitioner where the person is going to ensure there is no disruption in treatment. If the patient is not able to make these arrangements, the PHD will contact PHAC to assist in locating a practitioner in the region where the patient will be located.

If the TB patient DOES NOT return to Ontario when expected, the local public health unit should notify the PHD immediately. The patient may have run out of medication and become infectious (or resistant to the existing treatment). PHD can alert the necessary public health authorities (PHAC, CDC, Quarantine Office), as deemed necessary. The patient may be denied re-entry into Canada until the person has documented proof of treatment and proof that they are not infectious.
8.10 Need for Referral/Consultation with TB Specialist

A referral with a TB specialist should be sought for any TB patient who has, or may:

- Have resistance to more than one TB drug
- Have resistance to INH and RMP (MDR TB) – in this situation, treatment should be by, or under the advisement of, the TB specialist at West Park Healthcare Centre (see Section 8.5)
- Have cavitation on initial or subsequent chest x-rays
- Have a positive TB culture after 2 months of treatment
- Be HIV-positive
- Have a condition such as end stage renal disease which could make treatment fail
- Be a child < 18 years of age. Because of the high risk of disseminated TB in infants and children < years of age, treatment must be started as soon as the diagnosis of TB is suspected. Treatment should be by (or under the advisement of) a pediatric TB specialist.
- Have liver disease
- Be pregnant or breastfeeding
- Have relapsed/reactivated TB/ treatment failure:
  - **Relapse**: Patient becomes and remains culture negative during therapy but becomes culture positive again; or has evidence of radiographic deterioration consistent with active TB. This usually occurs within the first 6-12 months after completion of therapy
  - **Treatment Failure**: continued or recurrently positive cultures during the course of anti-tuberculosis therapy. This may be due to non adherence, drug resistance, malabsorption of drugs, or extreme biological variation in response.  

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8.11 Directly Observed Therapy (DOT)

Directly observed therapy (DOT) is the most effective strategy available for ensuring adherence to treatment. DOT means that all doses of medications are swallowed in the presence of a trained observer.

DOT is the recommended method and is considered the standard of medication delivery in Ontario for all cases of TB. DOT should be the standard of care unless assessment indicates that the likelihood of compliance is high.

Recommendations for DOT are not based on the assumption that any particular patient may be non-compliant with treatment. Nevertheless, treatment regimens are always long, require the patient to take more than one drug, continue long after the patient feels well, and may even make them feel a little unwell. Even the most motivated individual often has difficulty completing a full treatment regimen under these circumstances.\(^{182}\)

DOT is a strategy which is supported by the World Health Organization. It is becoming widely used worldwide, as more countries develop the capacity to detect TB and provide medications to all who need it.\(^{183}\)

8.11.1 DOT Assessment Guide

An assessment tool has been developed by the Ministry and several health units to determine those persons who should be on DOT. (See: Appendix B). DOT must always be considered for any person who scores ‘YES’ on any category in this assessment tool.

However, DOT must always be used when the person\(^{184}\):

- Has sputum smear positive pulmonary TB. This person is considered to be very infectious and is therefore a public health risk.
- Has TB and HIV co-infection.
- Is on an intermittent drug regimen.
- Is known to be non-adherent with treatment regimens. This person is at higher risk of developing drug resistant TB.
- Shows relapse of disease (documented)
- Is an Intravenous drug user
- Is a homeless or under-housed person
- Is a child
- Has mental health problems which would lead you to question either the ability of the person to be adherent, or the safety of the self-administered therapy.
- Has multi-drug resistant TB.

\(^{182}\) Alberta TB Control Manual, p. 3-14.
\(^{183}\) ibid
\(^{184}\) ibid
8.11.2 The Benefits of DOT

Use the following to explain the benefits of DOT to a patient:

- DOT encourages successful completion of treatment by providing assistance with taking the medication.
- With DOT, intermittent dosage is an option, and most patients need only take their medication 2 or 3 times each week in the continuation phase and often the regime will often be shorter than for the daily, self-administered treatment.
- The person providing DOT ensures that the patient keeps their MD or clinic appointments; and they watch for side-effects and provide information.
- DOT gives the patient the opportunity to ask questions and reduce fears about TB and the treatment regime.
- DOT improves the likelihood of a permanent cure.
- DOT will reduce the likelihood of acquired drug resistance. \(^{185}\)

\(^{185}\) Alberta TB Control Manual, p 3-14
8.12 Barriers to Completion of TB Treatment

The circumstances surrounding each patient that may affect their ability to complete treatment becomes the most important consideration in completing TB treatment. Factors that interfere with adherence to the treatment regimen include:

- Cultural and linguistic barriers to cooperation
- Lifestyle differences
- Homelessness
- Substance abuse

For the patient, a large number of other conditions and circumstances are priorities that compete with taking their TB treatment. For example:

(a) Patient Related Barriers:
- Conflicting health beliefs
- Alcohol or drug dependence
- Mental illness
- Immigration and resettlement issues.

(b) System Related Barriers:
- Lack of transportation
- Inconvenient MD or clinic hours for follow up appointments
- Lack of interpreters

8.12.1 Challenges to Administration of TB Medications

- Cannot readily predict who will or who will not adhere to the treatment regimen.
- Adherence to therapy is not related to education, socioeconomic status, race, gender etc.
- TB treatment is lengthy and adherence to therapy decreases as treatment length increases.
- Problems with compliance are likely to increase as the number of TB drugs changes or increases.
- Patients may feel well or be in denial and not perceive the need to take any medication.
- There may be mild side effects, especially in the beginning of the treatment regimen.
- Treatment may cause disruptions to the patient’s lifestyle, especially when they have to be available at a scheduled time for DOT.

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8.12.2 Administering TB Drugs with Food

Taking TB drugs with food can delay or moderately decrease their absorption. However, the effects of food are of little clinical significance. Therefore if a patient has epigastric distress or nausea with their first line TB drugs, dosing with meals, or changing the time of the administration of the medication is recommended. This is preferable to splitting a dose or changing to second line TB drugs. Note that the absorption of INH can be substantially decreased when the drug is given with glucose or lactose.

8.12.3 Improving Adherence to Therapy

“It is important to make clear to the patient that the treatment is to keep them, their family, and the community healthy. By agreeing to take the medication the patient is helping themselves and everyone they know. Health workers must be sensitive to patient needs and beliefs, which may affect adherence to therapy. The patient may think that tuberculin skin reaction means disease. They may relate treatment to the days of the sanatoria when people were removed from their home and community for months to years and many died away from home. The stigma attached to TB may lead to fear of being rejected and ostracized by family, work and community, which may give rise to feelings of isolation and depression. Patients need reassurance, support, and accurate information about TB. As well, they must trust that confidentiality will be maintained.”

Tips to Improve Adherence

- Develop a trusting relationship with the patient and family over time using the daily period of medication delivery to get to know the family.
- Indulge and accommodate the patient’s needs whenever possible.
- Consider using incentives (i.e., anything that motivates the patient) such as transit tokens, food vouchers, toys for children, phone cards. Providing cash to patients for compliance at appointments is especially useful with certain clients e.g. the homeless.

8.12.4 Dealing with Common Problems Associated with Medication

(a) Nausea/Vomiting

Nausea may be related to drug-induced hepatitis especially if it related to abdominal pain. The prescribing MD should be informed. If a patient vomits within one hour of ingesting the medication, the dose is counted as missed.

- Try giving the medication at mealtime or with food
- Ask the prescribing MD if dimenhydrinate or other anti-nausea medication would be helpful before meals
- Try giving medications during the late afternoon or evenings as some patients tolerate this better

(b) Fatigue

This can be a problem that interferes with the patient’s work/school.

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189 TB Control and Elimination, Nunavut Manual, pp. 5-10 - 5-11
190 Ibid, p. 5-11
191 Ibid, pp. 5-11 - 5-14
8. Barriers to Completion of TB Treatment

Adjust the time of day medications are given to suit the patient’s schedule.
An evening dose may be necessary if fatigue is severe and interfering with daytime activities.

(c) Difficulty Swallowing Pills
This can be a significant problem for patients who have nausea and gagging.
- Try giving the medication in applesauce or with juice/soda/or crackers
- Sometimes the medication can be crushed but Rifampin has a bitter aftertaste
- Some medications are available in liquid form

(d) Infants/Toddlers
Often there is a “Fear of Strangers”, especially at the beginning of the treatment. Usually the problem is not with the taste of the medication but the unfamiliarity with the medication. It is important to take time to develop a trusting relationship with the infant and the family.
- Expect the child to spit out the medication!
- Try to select the best time of day for the infant, avoiding nap times or after meals when they are full.
- Learn the infant’s routine and be prepared before the visit with toys etc.
- Small doses of liquid medication may be mixed with baby food. **DO NOT put the medication in the baby’s bottle** because that means you have to stay and watch until the baby finishes the bottle.
- Distraction works very well!

(e) Younger Children
May behave better at the beginning of treatment because the health care worker is providing a lot of attention. This may wear off!! ‘Control’ is important at this stage.
- Try crushing pills or using liquid forms.
- Give choices such as medication cup, syringe, favorite snack, spoon.
- Let them take the medications themselves if trustworthy. They may like squirting the syringe in their mouths.
- Use incentives such as stickers, treats etc.
- Alternate the incentives.
- Be attentive and creative, taking time to make the visit fun.
- Remember their birthday.

(f) Older Children
Can be the most problematic age group for TB medications; embarrassment can be an issue.
- Let them choose liquid or tablets/capsules
- Can be given with food or drink
- Use incentives
Try reasoning/rewards. Involve them in the plan of care and provide basic information on treatment and disease.

Always be discreet if giving medications at school – offer different options for place of delivery of medication.

(g) Missed Doses
The treating MD must be aware of the number of doses the patient has missed so these doses can be added to the end of the treatment to complete the treatment regimen.

(h) Interruptions in Treatment
Interruptions in treatment may have a significant effect on the duration of therapy. Reinstitution of treatment must take into account the bacillary load of the patient, the point in time the interruption occurred, and the duration of the interruption. In general, the earlier in the treatment and the longer the duration of the interruption, the more serious the effect and the greater the need to restart therapy from the beginning. This decision should be made by the treating physician in consultation with a TB specialist as deemed necessary.

8.12.5 Completion of Treatment
Treatment is completed when the patient has taken all the drugs prescribed.

_A full course of treatment is determined more accurately by the total number of doses taken, not solely on the duration._

Treatment protocols should continue for 6-9 months or until an absolute minimum of 80% of the prescribed doses have been taken. If there are missed doses or if there is a gap in treatment, all missed doses should be made up. If MORE than 50% of doses have been missed, or if treatment is not completed within the recommended time, consultation with a TB expert is recommended to determine the appropriate action to be taken: either the continuation of the treatment for a longer duration OR restarting treatment from the beginning.

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193 Ibid, p. 634.
## Appendix 8-A: MOHLTC Public Health Division Requisition for Drugs to Treat TB

### Public Health Division Requisition for Drugs to Treat Tuberculosis

### Demande de médicaments antituberculeux pour le service de santé publique

<table>
<thead>
<tr>
<th>CATALOGUE NUMBER</th>
<th>DESCRIPTION</th>
<th>TABLETS PER BOTTLE</th>
<th>BOTTLE UNITS</th>
<th>BOTTLE UNITS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 6506-1017-D</td>
<td>Isoniazid Tablet</td>
<td>300 mg</td>
<td>100/bottle</td>
<td>100/bottle</td>
</tr>
<tr>
<td>2 6506-1501-D</td>
<td>Isoniazid syrup</td>
<td>10 mg/mL</td>
<td>500mL/bottle</td>
<td>500mL/bottle</td>
</tr>
<tr>
<td>3 6506-1001-D</td>
<td>Pyrazinamide HCL Tablet</td>
<td>25 mg</td>
<td>100/bottle</td>
<td>100/bottle</td>
</tr>
<tr>
<td>4 6506-1014-D</td>
<td>Pyrazinamide HCL Tablet</td>
<td>500 mg</td>
<td>120/bottle</td>
<td>120/bottle</td>
</tr>
<tr>
<td>5 6506-1018-D</td>
<td>Ethambutol HCL Tablet</td>
<td>100 mg</td>
<td>100/bottle</td>
<td>100/bottle</td>
</tr>
<tr>
<td>6 6506-1019-D</td>
<td>Ethambutol HCL Tablet</td>
<td>400 mg</td>
<td>100/bottle</td>
<td>100/bottle</td>
</tr>
<tr>
<td>7 6506-1101-D</td>
<td>Rifampicin Capsule</td>
<td>150 mg</td>
<td>100/bottle</td>
<td>100/bottle</td>
</tr>
<tr>
<td>8 6506-1102-D</td>
<td>Rifampicin Capsule</td>
<td>300 mg</td>
<td>100/bottle</td>
<td>100/bottle</td>
</tr>
<tr>
<td>10 6506-3311-D</td>
<td>Tuberculin P.P.D. (Monteaux)</td>
<td>6TU/0.1mL</td>
<td>1mL/1flacon</td>
<td>1mL/1flacon</td>
</tr>
</tbody>
</table>

### For Ministry Use Only

*Serve au Ministère*

### Customer - Authorized Official

*Automate l'autorisé*

### Signature

*Signature*
Appendix 8-B: MOHLTC DOT Assessment Form

- Assess the need for DOT initially and on ongoing basis (at least monthly or as often as necessary).
- Use these assessment factors as well as your comprehensive assessment.
- The presence of any of these assessment factors is an indication that the person should be considered for DOT.
- The higher the risk of non-adherence or the potential for disease progression, the more important it is for the person to be on DOT.

<table>
<thead>
<tr>
<th>ASSESSMENT FACTOR FOR DOT</th>
<th>NO</th>
<th>YES</th>
<th>IF YES, DOT IS A PRIORITY</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. MDR resistant (resistant to INH and Rifampin)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Resistant to more than one TB drug</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Resistant to one TB drug</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. AFB+ve and culture +ve (pulmonary)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. AFB-ve culture +ve pulmonary TB</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Noncompliant with treatment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Substance abuse (alcohol e.g. alcohol or drugs)</td>
<td></td>
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<tr>
<td>8. Slow progress with treatment (e.g. person with repeat +ve culture on treatment)</td>
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<tr>
<td>9. Transient/homeless/underhoused</td>
<td></td>
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<tr>
<td>10. Persons who are too frail, elderly, impaired or forgetful to manage own care; no caregiver; mental illness</td>
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<tr>
<td>11. Previous long term treatment failure e.g. diabetes or hypertension medication non compliance</td>
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<tr>
<td>12. Prescription for intermittent therapy</td>
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<tr>
<td>13. Flight risk</td>
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<tr>
<td>14. Child/adolescent</td>
<td></td>
<td></td>
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<tr>
<td>15. Person whose TB has reactivated</td>
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<td></td>
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<tr>
<td>16. Person who denies diagnosis of TB</td>
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<tr>
<td>17. Person recently discharged from correctional facility</td>
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<tr>
<td>18. Person who has difficulty swallowing pills</td>
<td></td>
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<tr>
<td>19. Person who avoids gov’t or authorities for fear of revealing immigration status</td>
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<tr>
<td>20. Person under S.22 or 35 order under the Health Protection and Promotion Act</td>
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<tr>
<td>21. Non compliant with appointments</td>
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<tr>
<td>22. Side effects with TB medications</td>
<td></td>
<td></td>
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<tr>
<td>23. HIV+ve</td>
<td></td>
<td></td>
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<tr>
<td>24. Lack of trust of health care professionals</td>
<td></td>
<td></td>
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<tr>
<td>25. No family MD or consistent care provider</td>
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<tr>
<td>26. Immune Compromised e.g. diabetes or cancer</td>
<td></td>
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<tr>
<td>27. Inadequate social supports; financial difficulties</td>
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<tr>
<td>28. Language and/or cultural issues</td>
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</table>

“DOT should be the standard of care unless assessment indicates that the likelihood of compliance is high.” Ontario’s TB Protocol
9. Medical Surveillance for Inactive Tuberculosis

TB prevention and control is a public health responsibility. The purpose of Medical Surveillance is to provide new immigrants to Canada with appropriate medical follow-up to rule-out active TB disease and to determine the ongoing follow-up if either active or inactive TB is confirmed. By screening new arrivals for TB, persons can be offered treatment and therefore prevent the spread of TB in Canada.195

9.1 Roles and Responsibilities in Medical Surveillance

9.1.1 Citizenship and Immigration Canada (CIC)

(a) Outside Canada Procedure:
All immigrant applicants to Canada, those who come as refugees and certain visitors, are required to undergo an Immigration Medical Examination (IME) prior to entry. The IME, completed in the country of origin before arrival in Canada for those who apply from abroad consists of:

- Medical history
- Physical examination
- 4 age-related routine tests:
  - Urinalysis for applicants > 5 years of age
  - Chest x-ray for applicants > 11 years of age
  - Syphilis serology for applicants > 15 years of age
  - HIV test

If active TB disease is found, the person is denied entry until they have received adequate treatment and have been reassessed. If there is no active disease, but the x-ray appears abnormal or the person has a history of previously treated TB or the report of a positive skin test (TB skin tests are not undertaken routinely as part of the immigration medical examination) the person receives medical clearance to go to Canada with a condition of entry, that they contact their local public health authority (in Ontario, this is the local public health unit in the area they reside) within 30 days of their arrival. The person is provided with a copy of the Medical Surveillance Undertaking Form (IMM 535) (See: Appendix A for a sample form) which notes the type of medical surveillance in Box 8 with an “S” code of 2.02 for inactive TB. The person may also present with a Permanent Residency form which notes the “S” code in Box 28 and Field 43.

Citizenship and Immigration Canada (CIC) notifies the TB Control Program, Ministry of Health and Long Term Care (MOHLTC) of these persons by faxing a copy of the IMM 535 form for each individual placed on medical surveillance. The MOHLTC then forwards the forms to the respective health unit so that medical surveillance for TB can be initiated.

(b) Urgent Immigration Medical Surveillance Referrals
CIC will notify PHD by phone if a person is deemed to be an urgent referral. An urgent medical referral means that a person had a chest x-ray during their immigration medical overseas that was rated 4.3 to 4.6. The ratings are described below:

4.3 Isolated hilar or mediastinal mass/lymphadenopathy (noncalcified).
4.4 Single/multiple pulmonary nodules/masses greater than or equal to 1cm.
4.5 Non-calcified pleural fibrosis and/or effusion.
4.6 Interstitial fibrosis/parenchymal lung disease/acute pulmonary disease.
4.7 ANY cavitating lesion OR “Fluffy” or “Soft” lesions felt likely to represent active TB.

PHD will notify the TB Manager of the public health unit where the person resides by phone that an urgent referral has been received and then will fax the referral to the health unit. The health unit should attempt to contact this patient as soon as possible and arrange for the person to be medically assessed. PHD will follow up with a phone call to the health unit and notify CIC when the person has been medically assessed.

(c) In-Canada Procedure:
Some individuals have their initial Immigration Medical Examination (IME) and chest x-ray done while in Canada by Designated Medical Practitioners (DMPs).

A list of Designated Medical Practitioners (DMPs) is on the Canadian Citizenship and Immigration (CIC) web site: www.cic.gc.ca.
On the main menu, click on: ‘Medical Practitioners in your area’.

Examples include:
- refugees,
- students or visitors who decide to stay longer than 6 months, or,
- family members who were visitors and have applied for permanent residency to stay in Canada.

Following the IME, the person is provided with an In-Canada Public Health Follow-up form and instructions on contacting their local public health authority.

A sample In-Canada Public Health Form is found in Appendix B.

Persons placed on medical surveillance after arrival in Canada must be followed up with a medical assessment and chest x-ray the same as those persons who arrive from outside Canada (see algorithm). Remember: the DMP is under contract by CIC. It is the physicians at CIC who decide if a person is placed on medical surveillance. ALL in Canada referrals must follow the same process as those who apply from outside Canada and who are placed on medical surveillance.

Due to the fact that these persons are being screened after arrival in Canada, active TB disease may be detected. Accordingly, the following happens:
Citizenship and Immigration Canada (CIC) notifies the MOHLTC by forwarding an In-Canada Public Health Follow-up Form, noting whether the medical surveillance is for inactive TB (by “S” code 2.02) or if the medical surveillance is for active TB (by “S” code 2.01).

Upon receipt of an In-Canada report of active TB, the Public Health Division will **telephone the health unit involved** directly, notifying them of the person with active TB disease in their jurisdiction.

The notification will be faxed immediately to the health unit.
Algorithm 1: Follow-up of individuals placed under medical surveillance for TB

- History of active TB not previously treated
- Inadequate treatment of active TB
- Abnormal chest x-ray suggestive of inactive TB
- Recent contact with infectious TB

**Rule out active TB**
- History
- Physical examination
- Chest x-ray
- Smear/cultures, as appropriate

- Consult with infectious disease specialist/respirologist/TB expert
- Consider possibility of drug resistance
- Treat according to Canadian TB Standards

**Active TB**

**Latent TB infection**
- Consider treatment of LTBI according to Canadian TB Standards
- If likely multidrug-resistant TB infection, consult with an infectious disease specialist/respirologist/TB expert

If treatment for LTBI refused/not tolerated, counsel regarding signs and symptoms of TB; follow-up for 3 to 5 years

Once treatment of LTBI satisfactorily completed, counsel regarding signs and symptoms of TB, and discontinue follow-up

Symptoms suggestive of TB should be evaluated immediately to rule out active TB

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196 Ibid, CMAJ, p. 1564
9.1.2 Ontario Ministry of Health and Long Term Care

The TB Control Program, Ministry of Health and Long Term Care (MOHLTC) is responsible for ensuring that the IMM 535 forms have complete, accurate information. IMM 535 forms that have complete information (i.e., an address and an accurate “S” code) are forwarded to the appropriate health unit for follow-up via an iPHIS referral.

If a health unit receives a IMM 535 form from a person that has with missing data, contact the TB Nurse consultant at the MOHLTC for clarification (e.g. no “S” code noted, no address noted).

The MOHLTC will notify CIC of any information received from the health units on the Reporting Forms (see Appendix C) e.g. person cannot be located, documentation that the person has been medically assessed, etc.

| Once the person has been medically assessed in Ontario, the condition of entry is removed by CIC. |

The following algorithm outlines the procedure to be followed, which is explained further in this document.
9.1.3 Local Health Unit

The local health unit initiates and continues medical surveillance for a period of up to five years from the date of the initial clinical evaluation for medical surveillance, or until the person has been discharged. (See section 9.2.3 for conditions of discharge). Although there are no specific regulations for the length of follow-up, the highest incidence of active tuberculosis in recent arrivals to Canada develops within the first 3 to 5 years of their immigration.\textsuperscript{197}

Priorities of Medical Surveillance

\textsuperscript{197} Ibid, CMAJ, p. 1564
A greater priority should be placed on the identification and TB testing of persons at increased risk of progression to active disease if infected. Factors that increase the risk of progression to active disease include the following:

- HIV
- Recent TB infection
- Upper lung zone fibronodular changes on chest x-ray
- Previously inadequately treated active TB
- Organ transplantation
- Prolonged use of corticosteroids or other immunosuppressing agents
- Chronic renal failure
- Hematologic malignancies
- Silicosis
- Diabetes
- Malnutrition

When the health unit receives a referral from iPHIS or a complete IMM 535 form from the person under medical surveillance, the health unit shall:

(a) **Contact the person by letter, telephone or in person.**
   If the person is contacted by letter, attach a medical assessment form to be completed by the physician. (Note: Each health unit is to develop its own form for use in its health unit jurisdiction).

(b) **Advise the person of the following:**
   - The signs and symptoms of active disease which would include cough, weight loss, fatigue, fever, night sweats or hemoptysis
   - Requirements of medical surveillance
   - Instructions about obtaining OHIP coverage
   - The need for the person to contact the health unit to provide any change of address as well as the name of the family physician

(c) **Information to be included on the medical assessment form:**
   - The requirements of medical surveillance
   - Complete history and physical examination results
   - Dates and results of chest X-ray and other appropriate radiological investigation
   - At least one but preferably three sputum specimens for smear and culture for *Mycobacterium tuberculosis*
   - Other appropriate laboratory tests as deemed necessary by the treating physician
   - Medical information and chest x-rays from the country where immigration medical assessment was carried out (if requested/obtained)
   - Written recommendations regarding prophylaxis for clients with inactive TB
   - Current recommendations if chemoprophylaxis is refused or is medically contraindicated

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198 Ibid, CMAJ, p. 1564
Reporting to MOHLTC using the Reporting Form (that is faxed to the MOHLTC):
(a) When a person has made contact with the health unit, report to MOHLTC as soon as possible indicating that contact has been made
(b) If no contact has been made with the person within 4 months of notification of the person being under medical surveillance, report to MOHLTC
(c) When documentation is received by the health unit that medical assessment has been made, report to MOHLTC. This information should be received at the MOHLTC no longer than 6 months after notification that contact has been made.
(d) Upon discharge from medical surveillance: When follow-up is complete/person is lost to follow-up/person moves within Ontario or Canada or person is deceased.

No Contact Made with Person:
(a) If the unit receives no response from the person by one month after the first contact attempt (by letter, phone or in person), the health unit will make a second attempt to contact the client.
(b) If person cannot be located, notify the MOHLTC by faxing the Immigration Medical Surveillance Reporting Form (Reporting Form) (Sample of form in Appendix C)
(c) Complete iPHIS Medical Surveillance episode (see appendix E-Bulletin #8)
(d) MOHLTC will notify CIC that the person has not been found.
(e) If CIC has new information on the person, it will be forwarded to MOHLTC.
(f) MOHLTC will forward any update to health units.

Contact Made with Person:
(a) Advise person of the requirements of medical surveillance.
(b) Determine current immigration status (i.e. permanent resident, visitor, student, temporary worker).
(c) Counsel person regarding TB disease, transmission, treatment and chemoprophylaxis.
(d) Assess person for active TB by reviewing a checklist of signs and symptoms.
(e) If there is an indication of active TB or if person is a contact of a case of TB and the person has no health insurance coverage, refer him/her to Tuberculosis Diagnostic and Treatment Services for Uninsured Persons Program ("TB-UP") for immediate medical assessment. (See Chapter 11 for TB-UP procedures).
(f) If there is no indication of active TB, refer person for medical assessment once Ontario health insurance coverage has been obtained.
(g) Request name of person’s family physician.
(h) If contact is made by phone, send letter and medical assessment form to person.
(i) As soon as possible, notify MOHLTC that person has been contacted by faxing the Reporting Form to the MOHLTC.
(j) MOHLTC will notify CIC.
(k) Complete iPHIS Medical Surveillance episode (see attached iPHIS Bulletin for Immigration Medical Surveillance Appendix E)

**Medical Assessment Completed**
Once the local health unit receives documentation of the completed medical assessment report, TB control staff will:

(a) Review the results of the medical assessment
(b) If active TB is diagnosed, fax the Reporting Form to the MOHLTC indicating that the person has newly diagnosed active TB. **Do NOT send** if the individual had TB diagnosed in the past; send only the current episode of TB.
(c) Contact physician or person, if necessary, for further information.
(d) If person is on treatment or chemoprophylaxis for LTBI, monitor as per guidelines.
(e) If person is not on treatment or chemoprophylaxis, follow-up should be individualized.
(f) Notify MOHLTC of assessment done, using Reporting Form.
(g) Update iPHIS medical surveillance episode.
9.2 Follow-up Procedures

9.2.1 Person Lost to Follow-up or Non-compliant

If, prior to discharge, the person:

- moves to an unknown area or moves back to their country of origin,
- is lost to follow-up,
- is non-compliant with requests for repeat examinations, or,
- is deceased,

then, inform the MOHLTC by faxing the Reporting Form and update iPHIS (see appendix E)

9.2.2 Person Changes Address

(a) If person changes jurisdictions with Ontario:

- Notify the receiving health unit with a referral form including all pertinent information.
- Notify the MOHLTC by faxing the Reporting Form and update iPHIS

(b) If the person moves out of Ontario but within Canada:

- Notify the MOHLTC by faxing Reporting Form and a referral form including all pertinent information and update iPHIS and discharge (see appendix E)
- The MOHLTC will forward the referral to the appropriate provincial authority.

(c) If the person moves out of the country for more than a month:

- Notify the MOHLTC by faxing Reporting Form and discharge the person in iPHIS.
- The MOHLTC will notify the CIC.

(d) If the person comes back into Canada:

- It is the responsibility of the individual to notify the local public health unit of their location so Medical Surveillance can recommence.

9.2.3 Discharge from Medical Surveillance

1. Discharge persons from public health medical surveillance follow-up when:

(a) The person's chest X-ray is normal;
(b) The person has completed an adequate course of chemoprophylaxis;
(c) TB control staff can obtain reliable documentation of previous treatment and compliance;
(d) There is no change in the person's chest X-ray over the follow-up period (usually 3 to 5 years);
9.2 Follow-up Procedures

(e) The person has died.
2. Notify the person that their medical surveillance is complete.
3. Notify MOHLTC, by faxing the Reporting Form of discharge.
4. Update iPHIS medical surveillance episode and close.

9.2.4 Self-referral for Medical Surveillance

1. With Copy of IMM 535
If an individual has the IMM 535 or In Canada notification form and contacts with the health unit directly:

   (a) Ask the person for a copy of IMM 535 form (this ensures accurate information is entered in iPHIS)
   (b) Send a referral to PHD via iPHIS
   (c) Conduct surveillance as described above.

2. Without Copy of IMM 535
If the person has a Permanent Residency form but does not have a copy of the IMM 535 form, then:

   (a) Ask the person for a copy of the Permanent Residency form.
   (b) Check Field 28 for the “S” code.
   (c) If confirmed as inactive TB (i.e., “S2.02”), conduct surveillance as described above.
   (d) If “S” code is missing, contact the MOHLTC TB nurse consultant by telephone or fax (not by email) with the name, date of birth and country of origin of the individual. The MOHLTC will request the specific disease code from Citizenship and Immigration Canada and will then notify the health unit.
9.3 Obtaining Previous Immigration Medical Exam Assessment

The Immigration Medical Exam assessment information done prior to arrival in Canada or done within Canada as an In-Canada processing can be obtained for review.

9.3.1 Immigration Medical Exam done outside Canada
Fax the office where the medical assessment was performed, noting the information in Box 9 of IMM 535 (IMS file #). When a referral is sent in iPHIS, the IMS file number from Box 9 is entered by PHD in the ‘Notes’ tab of the person’s demographic section. A package of information will be sent by CIC which may include actual x-ray films. These films should be returned to the originating office.

A list of international Immigration offices is found in Appendix D.

9.3.2 Immigration Medical Exam done within Canada
Fax Citizenship and Immigration Canada, Ottawa, at 613-952-3891. CIC will forward a copy of the medical assessment. If x-ray films are included, they must be maintained at the requesting Health Unit or returned to CIC (they should not be sent to MOHLTC).
9.4 Appendix A: Sample IMM 535 Form

Appendix A:
Sample IMM 535 Form
9. Medical Surveillance for Inactive Tuberculosis

9.4 Appendix 9-A: Sample IMM 535 Form

[Image of the IMM 535 form with various fields and documents related to medical surveillance.]
9.5 Appendix B: Sample In-Canada Form

Appendix B:
Sample In-Canada Form

Public Health Authority Notification Letter for Medical Surveillance
(In Canada Public Health Follow-Up)

The following is for your information and action as deemed necessary.

An immigration medical examination conducted in Canada has recently been completed on the following individual who is currently residing in your jurisdiction.

This examination has revealed the presence of a condition which would normally result in a medical surveillance notification by Citizenship and Immigration Canada.

As the individual resides in Canada, this notification is being issued before the immigration application is completed.

The client has been provided with an informational handout entitled “IN-CANADA PUBLIC HEALTH FOLLOW-UP”

FAMILY NAME: Doe
GIVEN NAMES: JOHN
DATE OF BIRTH: 01/JAN/1952 (DD/MMM/YYYY)
SEX: ☐ MALE ☐ FEMALE
“S” CODE: S 2.02
ADDRESS: 1 ANY STREET
OTTAWA, ONTARIO
POSTAL CODE: K1A 1A1
TELEPHONE: (613) 925-1234
IMS FILE NO.: 7001-123456

UPON INITIATION OF MEDICAL SURVEILLANCE, PLEASE RETURN THIS SHEET BY FAX TO CIC MEDICAL SURVEILLANCE UNIT. FAX: (613) 952-3891

DATE SURVEILLANCE INITIATED: PUBLIC HEALTH AUTHORITY STAMP:

(DD/MMM/YYYY)
### 9.6 Appendix C: Sample Immigration Medical Surveillance Reporting Form

**NOTIFICATION TO TB CONTROL UNIT AT THE MOH FROM HEALTH UNIT**

Complete this form and fax to the Ministry of Health each time information is received about a patient who is under Medical Surveillance.

Please fax this to the Ministry of Health and Long-Term Care c/o Joy Marshall 416-327-4687.

*(If you have any questions please call Joy at 416-327-7053)*

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**INITIAL REPORT from Health Unit to PHD**

<table>
<thead>
<tr>
<th>Health Unit</th>
<th>Date (YYYY/MM/DD)</th>
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<table>
<thead>
<tr>
<th>Contact Person at Health Unit</th>
<th>Name</th>
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<table>
<thead>
<tr>
<th>Patient’s Immigration Serial Number (Box 10 on IMM form)</th>
<th>OR Inland Processing No.</th>
<th>Date IMM 535 Form Rec’d at Health Unit (YYYY/MM/DD)</th>
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<table>
<thead>
<tr>
<th>Family Name</th>
<th>Given Name</th>
<th>Middle Name</th>
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**DOB:** YYYY MM DD

**Country of birth:**

Citizenship and Immigration Canada (CIC) has advised the Ministry of Health and Long Term Care (MOHLTC) that the above named person arrived in Canada with a diagnosis of inactive Pulmonary Tuberculosis (IMM 2.02) and agreed to medical surveillance undertaking.

**The person has: (check as many as apply)**

**CONTACT:** *(please complete this section especially if any medical assessment done)*

- Had personal contact (by phone or in person) with this or another Health Unit in Ontario.
  - Date of initial contact

- Had personal contact (by phone or in person) with health unit outside of Ontario.
  - Date of initial contact

**ASSESSMENT FOR TB:**

- Has gone for medical assessment and initial chest x-ray  DATE
- Follow-up chest x-ray done or requested
- Has been recommended for annual chest x-ray for 3-5 years *(no need to send updates annually)*

**LTBI:**

- Has started prophylaxis for tuberculosis infection. ____Has completed LTBI

**ACTIVE DISEASE:**

- Has active disease and has been reported in RDIS
HAS NOT BEEN LOCATED:
- Has never been located at (indicate address)
- Was located but now Lost To Follow Up

HAS MOVED:
- Has moved to:
- Has moved (no available address)

HEALTH UNIT DID NOT RECEIVE IMM 535 FORM FROM PHD FOR THIS PATIENT:
(please send a copy of IMM 535 to PHD with this reporting form)
- Patient self reported from Ontario
- Patient self reported from another province
- Patient self reported from outside Canada
Other_________________________________________________________________________

HAS BEEN DISCHARGED FROM MEDICAL SURVEILLANCE AT HEALTH UNIT
- Date____________________  File #____________________
### 9.7 Appendix D: List of Overseas Medical Offices and Addresses

<table>
<thead>
<tr>
<th>City</th>
<th>Address and Fax Number(s)</th>
</tr>
</thead>
</table>
| **Beijing** | Overseas Medical Services International Region  
      The Canadian Embassy  
      19 Dongzhimenwai Dajie  
      Chaoyang District  
      Beijing, PRC 100600  
      Fax: 011-86-10-6532-6148 |
| **London**  | Overseas Medical Services International Region  
      The Canadian High Commission  
      MacDonald House  
      1 Grosvenor Square  
      London, England  
      W1X 0AB  
      Fax: 011-44-20-72-58-6358 |
| **Manila**  | Overseas Medical Services International Region  
      The Canadian Embassy  
      Level 7 Tower 2, RCBC Plaza  
      6819 Ayala Avenue cor. Sen. Gil J. Puyat Avenue  
      Salcedo Village, Makati City  
      1200 Philippines  
      Fax: 011-632-843-1103 |
| **Nairobi** | Overseas Medical Services International Region  
      The Canadian High Commission  
      Limuru Road  
      Gigiri, Nairobi  
      Kenya  
      Fax: 011-254-20-366-3445 |
<table>
<thead>
<tr>
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<tbody>
<tr>
<td>New Delhi</td>
<td>Overseas Medical Services \nInternational Region \nThe Canadian High Commission \n7/8 Shantipath \nChanakyapuri \nNew Delhi 110021, India \nFax: 091-011-4178-2033</td>
</tr>
<tr>
<td>Paris</td>
<td>Overseas Medical Services \nInternational Region \nThe Canadian Embassy \n35, Avenue Montaigne \n75008 Paris, France \nFax: 011-33-1-44-43-29-83</td>
</tr>
<tr>
<td>Port of Spain</td>
<td>Overseas Medical Services \nInternational Region \nThe Canadian High Commission \nMaple House, Tatil Centre \n3-3A Sweet Briar Road \nP.O. Box 1295 \nPort of Spain, Trinidad, W.I. \nFax: 1-868-628-6993</td>
</tr>
<tr>
<td>Singapore</td>
<td>Overseas Medical Services \nInternational Region \nThe Canadian High Commission \n1 George Street #11-01 \nSingapore 049145 \nFax: 011-65-6854-5911</td>
</tr>
<tr>
<td>Vienna</td>
<td>Overseas Medical Services \nInternational Region \nThe Canadian Embassy \nLaurenzerburg 2/3A-1010 \nVienna, Austria \nFax: 011-43-1-531-38-3912</td>
</tr>
</tbody>
</table>
9.8 Appendix E: iPHIS Bulletin #8

iPHIS Bulletin

Ministry of Health and Long-Term Care
Public Health Division

September 19, 2005

In This Issue:
- Immigration Medical Surveillance for Tuberculosis (TB)
- Process Overview
- Process for Entering Information in iPHIS

Immigration Medical Surveillance for Tuberculosis (TB)

This document is intended to ensure that all the data elements required for TB immigration medical surveillance reporting are consistently and appropriately captured using the iPHIS application. The instructions for data entry are structured according to the iPHIS modules, and directions for navigating to the appropriate field are included.

Health units are able to record information regarding immigration medical surveillance for TB in iPHIS. Health units will continue to use the Immigration Medical Surveillance Reporting Form to report TB Medical Surveillance information to the Public Health Division (PHD) of the Ministry of Health and Long-Term Care.

Process Overview:

Citizenship and Immigration Canada (CIC) notifies PHD by fax, sending either the IMM 535 Form or the Inland Processing Form, of clients that require medical surveillance for TB as a condition of landing in Canada. These clients have one month after arrival in Canada to contact the local health unit and arrange for medical assessment. PHD mails either the IMM 535 Form or the Inland Processing form to the appropriate health unit on a weekly basis. The health unit then creates a client in iPHIS.

The information that is required for reporting to CIC should be entered into iPHIS (e.g. contact has been made; person cannot be located) as described in the following sections. The health unit is able to set up self-referrals as a reminder of the four-month “cannot locate” timeline, or the six-month “assessment complete” deadline. Health units will continue to send the Immigration Medical Surveillance Reporting Form to PHD.

This bulletin only highlights the mandatory fields for reporting to CIC through PHD. Additional information can be entered as available.
9. Medical Surveillance for Inactive Tuberculosis

9.8 Appendix E: iPHIS Bulletin #8

Process for Entering Initial Information in iPHIS

A. Creating / Opening a Client

- IMM 535 Form or the Inland Processing Form sent from PHD to the health unit (HU) to initiate medical surveillance or client self-refers to health unit to initiate immigration medical surveillance for TB.
- TB investigator at health unit reviews the form and navigates to the Demographics module in iPHIS.
- Verify or enter client demographic information (e.g. phone number, address, etc.).
- Click on the plus sign to expand the Immigration and Other node.

1. **TB Number** – Leave this field blank; TB number is not used in Ontario.
2. **Immigration File Number** – Enter information from either Box 10 of Form 535 or Inland Processing (IMS) Number, as appropriate.
3. **Immigration Form Received Date** – Must match the Episode Start date.
4. **Birth Country (if born outside Canada)** – Select from drop down list.
5. **Date Reported For Surveillance** – The date of first contact between health unit and client.
B. Adding Address Information for the Client

- In the Demographics module select Addr/Tel.

1. **Effective From** – Enter the date the health unit was informed of the address.
2. **Effective To** – Enter the date the address is no longer current.
C. Creating a New TB Episode for the Client

- In the TB module select Client Episodes/Encounters > Episode/Encounter Summary and click New Episode.

1. **Episode Type** – Select “MEDICAL SURVEILLANCE”
2. **Episode Status** – Select “OPEN”
3. **Episode Start** – Date that the form was received by HU (from client or from PHD). If no form is received, enter the date the client presented (in person or by phone) to the HU.
4. **Episode Reported Date** – Will not be used for medical surveillance. When reporting on medical surveillance to PHD, encounter information will be used.
5. **Episode Reason** – Select “IMMIGRATION FORM 535 RECEIVED” (includes Inland Processing Form) or “IMMIGRATION SELF REFERRAL”
6. **Method of Detection** – Select “IMM. SCREENING”
D. Creating a TB Encounter for the Client

- From the TB Episode select Encounter > Encounter Details.

1. **Encounter Type** - Select “CHART REVIEW”
2. **Encounter Category** – Select “OTHER (SPECIFY)”
3. **Service Provider** – Name of investigator
E. Entering a New Radiology Result for Client

- From the TB Episode select Client > Radiology
- Click New Study from the Radiology Studies Results screen to enter radiology results

1. **Exam Date** – Enter date of exam
2. **Date Received** – Enter date exam information was received by health unit
3. **Area** – Select “CHEST”
4. **View (1 and/or 2)** – Select from drop down list as appropriate
5. **Indication** – Select “SCREENING NEW”
F. Entering a New Radiology Report

- From the Radiologist Technologist Study page, click Radiologist Report

1. **Result** – Select from drop down list as appropriate.
2. **Comments** – Indicate if client has been recommended for annual chest x-ray, and if so, record duration in years.
3. **Repeat x-ray in (Months)** – Enter number of months until next recommended follow-up x-ray.
B. Process for Entering Follow-Up Information in iPHIS

A. Client Follow-up

- Change **Episode Type** to **CASE** or **LTBI** if the client is an active case of TB or LTBI.
- Change **Episode Status** to capture follow-up status of clients under immigration medical surveillance. Select:
  1. **OPEN – UNTRACEABLE**: If unable to locate client four (4) months after the Episode Start date.
  2. **OPEN – LOST TO FOLLOW-UP**: If contact with client was made, but the assessment required to fulfill medical surveillance was not completed by four (4) months after the Episode Start date despite attempts by the health unit to contact the client.
  3. **CLOSED – UNTRACEABLE**: If unable to locate client six (6) months after the Episode Start date.
  4. **CLOSED – FOLLOW-UP INCOMPLETE**: If contact with client was made, but the assessment required to fulfill medical surveillance was not completed by six (6) months after the Episode Start date.
  5. **CLOSED – LOST TO FOLLOW-UP**: If contact with client was made and client has been medically assessed, but follow-up deemed incomplete as per the **TB Protocol**.
  6. **OPEN – FOLLOW-UP COMPLETE**: Once the client’s initial medical assessment has been completed and client remains on medical surveillance as per the **TB Protocol**.
  7. **CLOSED – FOLLOW-UP COMPLETE**: Under any of the following circumstances:
     1. The medical surveillance episode is closed as per the **TB Protocol**
     2. The client has died before the medical assessment was completed.
B. Report to PHD

- Add a New Encounter each time information is received and entered, contact occurred with the client, or when reports are sent to PHD.
  1. When updating PHD, use CHART REVIEW for Encounter Type and OTHER (SPECIFY) for Encounter Category.
  2. Update PHD when:
     - Client has a change of address
     - Cannot locate client
     - Client lost to follow-up
     - Contact made with client
     - Client medically assessed
     - Client dies
     - Any other reportable information changes

**TIP:** Use the Referral function within iPHIS to track the four month and six month follow-up deadlines easily.
C. Create an Alert

- Create an alert to indicate the client is on medical surveillance

1. **Distribution Type** – Select TB if sensitive information is part of the content of the Alert message.
2. **Priority** – Select “Popup”
3. **Message** – Indicate that client is on medical surveillance for TB.

   **Note:** Pop-up Alerts can be used if the client cannot be located or has not undergone the required medical assessment. In this case, set **Distribution Type** to “DEMG”. Ensure that the **Message** only contains the relevant investigator contact information and does not contain sensitive personal health information about the client.

For more information, please contact the iPHIS Help Desk at 1(888)272-2794
In the GTA: (416)327-3512
Email: moh-IIPHISsupport@moh.gov.on.ca
or
Joy Marshall, TB Nurse Consultant (416) 327-7053
Joy.Marshall@moh.gov.on.ca
10. Ventilation Standards in Shelters for the Homeless

Note: This chapter will be available in a subsequent version of this protocol.
11. Tuberculosis Diagnostic and Treatment Services for Uninsured Persons (TB-UP) Program

11.1 Introduction

11.1.1 Purpose of the TB-UP Program

The purpose of the Tuberculosis Diagnostic and Treatment Services for Uninsured Persons (TB-UP) Program is to:

(a) Reduce the public health risk due to transmission of tuberculosis (TB) from uninsured persons within Ontario;

(b) Ensure that TB diagnostic and treatment services are available for all persons residing in Ontario who are not covered by the Ontario Health Insurance Plan (OHIP), Interim Federal Health (IFH) or any other provincial/territorial/private health insurance plan; and,

(c) Eliminate the financial barrier for uninsured persons in Ontario, as well as facilitate the early diagnosis and initiation of treatment (as required) of all persons with active/suspect TB.

11.1.2 Description of the TB-UP Program

The TB-UP program consists of processing payments to physicians, laboratories and radiology service providers for services provided to uninsured individuals who require assessment and/or treatment for active/suspect or latent TB infection (LTBI), including contacts of infectious TB. The program is intended to facilitate prompt diagnosis and treatment for the uninsured group of persons, thus reducing the risk of transmission of TB from uninsured cases to other Ontario residents, as well as the related costs to Ontario’s health insurance plan (OHIP).

The TB-UP program will ensure that all uninsured persons in Ontario have access to diagnostic and treatment services required to determine whether they have TB disease or latent TB infection (LTBI), to prescribe the required treatment, and to provide the required follow-up so that the appropriate course of treatment is completed.

11.1.3 Eligible persons covered under the TB-UP program:

The TB-UP program will be implemented in two phases at the local level, through the TB Control Program staff of the board of health.

Phase 1 includes persons who are uninsured and one of the following:

(i) an active case or potential/suspect case of TB (pulmonary or extra-pulmonary);
(ii) a contact of an active TB case; or
(iii) any other person at high risk of developing active TB as determined by the TB Control program staff of the board of health.
Phase 2 includes uninsured persons referred under the medical surveillance process who have LTBI, but who do not meet the other criteria listed above (i.e., case/suspect case or contact).

11.1.4 Eligible services and service providers covered under TB-UP:

The following services and service providers will be covered under the TB-UP program:

- **Out-patient Services:**
  Out-patient medical clinical (physician) services (provided by physicians who are paid on a fee-for-service basis), as well as laboratory and radiology services for the diagnosis and treatment of TB disease or LTBI; or

- **In-patient Services:**
  Medical clinical services which are provided by a physician who is a specialist paid on a fee-for-service basis (e.g., respirologist, ID physician, internist, paediatrician, etc.) for services related to the diagnosis or treatment of TB or LTBI.

The following services and service providers will not be covered under the TB-UP program:

- any services/expenses for uninsured persons who receive hospital in-patient services; or
- services provided by physicians or other service providers (i.e., laboratories and radiology facilities) who are normally compensated through a global budget or an alternative payment process through an organization/agency and are not paid on a fee-for-service basis.

**NOTES REGARDING SERVICE PROVIDERS FOR TB-UP PROGRAMS**

*Service providers must be licensed within their province of practice* to be eligible for payment under the TB-UP program (Section 94, Claims for service providers licensed outside Ontario).

*Physicians who have opted out of OHIP can participate in the TB-UP program*; however they must submit the Health Care Provider Claim form (Appendix A) to the Ministry of Health and Long-Term Care, Registration and Claims Branch (RCB) for payment. These physicians should not bill the patient directly, as RCB will not reimburse the individual TB-UP patient.
11.2. Governing Legislation

11.2.1 Health Legislation

TB is a reportable disease. Therefore, under Sections 25 to 31 of the Health Protection and Promotion Act (1990), physicians, laboratories and others are required to notify their local medical officer of health of any suspect and active TB cases, as well as of any persons infected with TB. In addition, persons who are identified with suspect latent TB on immigration medical examination are referred to their local health unit for follow-up as part of the medical surveillance process.

Tuberculosis control activities are mandated under Sections 5 and 7 of the HPPA and are set out in the Tuberculosis Control program portion of the Mandatory Health Programs and Services Guidelines, December 1997. Under these requirements, every board of health in Ontario is required to have in place an effective program for persons with active tuberculosis and for TB prevention. This will include:

- case finding, case holding, monitoring of drug treatment, and follow-up of contacts and infected individuals for TB prevention;
- ensuring the provision of TB drugs for persons with TB disease or infection at no cost to the patient; and
- ensuring that patients who are placed under medical surveillance (as a result of their immigration medical examination) are referred to a physician for follow-up assessment.

It is important from a public health perspective to render all persons (regardless of their medical insurance status) with active TB non-infectious as soon as possible to reduce the further transmission of the disease to the public. The early diagnosis and treatment of all cases/suspect cases of TB disease and TB LTBI are critical to achieving this objective.

11.2.2 Collecting and Releasing Confidential Information

The TB-UP program is authorized pursuant to the following provisions of HPPA:

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<td>Section 5.2</td>
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<td>Sections 25 to 31</td>
<td>Reporting of Disease</td>
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and under the Ministry of Health and Long-Term Care Act:

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<td>Section 6</td>
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The application for coverage through the TB-UP program and the provision of consent to collect, use, share and disclose a patient’s personal health information among the patient’s local board of health, health care provider and the MOHLTC is covered when the patient signs the TB-UP Application and Consent Form. The authority for obtaining a minor’s consent from a person who has the lawful custody of that individual, who is less
than sixteen years old, is under Section 66 of the *Freedom of Information and Protection of Privacy Act*.

Collection of personal information is only for the purpose of determining eligibility registration in the TB-UP program and the provision of TB-UP health services. This personal information is required to support TB-UP program administration in the provision of the patient's health care, payment of provincially funded compensation to the patient's health care providers under the TB-UP program, and the evaluation and planning of the program. The authority for the collection and use of this information is the *Ministry of Health and Long-Term Care Act*, Section 6, and the HPPA, Sections 2, 4, 5.2, 5.4.1, 25 to 31.
11.3 Roles and Responsibilities for the TB-UP Program

11.3.1 Board of Health:

The board of health will:

(a) Be notified of uninsured persons requiring TB services either from the patient themselves, or from a service provider or service agency (Section 4.1, Patient Referral to the TB-UP Program);

(b) Assess if the patient is eligible for coverage under the TB-UP program (Section 4.2, Assessment of Potential TB-UP Patient by the Board of Health to Determine Eligibility for the TB-UP Program);

(c) Verify the patient’s identification (Section 5.2.1, Registration into the TB-UP program by the board of health);

(d) Obtain the TB-UP Application and Consent for the TB-UP Program (Appendix C) from the patient and manage the TB-UP Withdrawal from the TB-UP program as required (Appendix D);

(e) Register eligible individuals into the TB-UP program and assign a TB-UP registration number (Section 5.3, Assigning the TB-UP Registration Number);

(f) Notify the Ministry of Health and Long-Term Care, Registration and Claims Branch (RCB) of TB-UP program registrants on a monthly basis (Section 8: TB-UP data Transfer);

(g) Ensure the appropriate number of Health Care Provider Claim forms have been issued for each TB-UP patient (Section 6, Board of Health Distribution of Claim Forms); and

(h) Collect and submit TB-UP data to the Ministry of Health and Long-Term Care, Public Health Division (PHD) for the purposes of program monitoring and evaluation (Section 8.1.2, Provision of TB-UP program data to the PHD).

11.3.2 Service Providers

If a patient presents at the office of a service provider (e.g., due to symptoms from TB) and has not notified the board of health, the attending physician will:

(a) Verify the patient’s OHIP status and personal identification (Section 5.2.2, Registration into the TB-UP program from the service provider’s office/clinic);

(b) Notify the board of health of the uninsured person who has either suspect/active TB or who is a contact of an active TB case and request a TB-UP Application and Consent form (Appendix C) for this patient;

Note: All persons who are infected with TB or who have TB disease are to be reported to the local medical officer of health, as required under the requirement of the Health Protection & Promotion Act (1990).

(c) Return (fax/mail) the patient signed TB-UP Application and Consent form to the board of health (TB Control Program staff), who will then register the patient into
the TB-UP program, assign a TB-UP Registration Number and initiate first mailing of Health Care Provider Claim forms (Appendix A).

For all TB-UP patients registered in the TB-UP program (i.e., who have a TB-UP registration number and claim form), the attending physician will:

(a) Ensure the TB-UP registrant’s Name, Date of Birth, Gender, Registration Number and Eligibility Expiry Date (i.e., Part A of the claim form) has been completed by the board of health on all Health Care Provider Claim forms. Incomplete Health Care Provider Claim forms will be returned to the service provider by the RCB (Section 9.3, Returned Health Care Provider Claim Forms by the RCB);

(b) Complete Part B of the Health Care Provider Claim form and include only those services which are related to the investigation and/or treatment of TB disease/infection or complications that arise as a result of treatment for TB disease/LTBI. The diagnosis and treatment of unrelated diseases are not covered for payment under the TB-UP program;

(c) Submit completed Health Care Provider Claim form(s) to the RCB, for assessment for payment and processing of payment under the TB-UP program (Section 9.1, Health Care Provider Claim Submission by Service Provider);

(d) Notify the board of health (TB Control Program staff) of the patient’s treatment plan and request the required number of Health Care Provider Claim forms to cover subsequent visits for the next four week period. Claim forms will be issued monthly by the board of health on a request basis (Section 6, Board of Health Distribution of Claim Forms); and,

(e) Return all Health Care Provider Claim forms that have not been used to the local board of health.

11.3.3 Ministry of Health and Long-Term Care, Registration and Claims Branch (RCB):

The Registration and Claims Branch will:

(a) produce and control the distribution of the Health Care Provider Claim form to boards of health (Section 11, TB-UP Form Production, Distribution, Control and Retention);

(b) act as the claims payment-processing agent for the TB-UP program;

(c) check each claim received to determine whether the patient is eligible for payment through OHIP and, if so, advise the service provider;

(d) verify claims received to ensure the following:

   (i) patient eligibility (as per the TB-UP registration information received from boards of health);

   (ii) OHIP eligibility;

   (iii) service claim code eligibility (claim code is listed in the OHIP Schedule of Benefits);

   (iv) service eligibility (e.g., service is rendered prior to the eligibility expiry date on the claim form);
11.3.4 Ministry of Health and Long-Term Care, Public Health Division (PHD):

Public Health Division will:

(a) establish provincial standards (i.e., TB-UP policies and procedures) for the TB-UP program, and review and update as required;

(b) produce and distribute the following forms to the board of health:
   (i) TB-UP Application and Consent form; and
   (ii) TB-UP Withdrawal form.

(c) cover costs of monies paid to service providers by RCB for all eligible claims through the TB-UP program;

(d) utilize the information received monthly from RCB for the financial monitoring of the TB-UP program expenditures;

(e) provide program consultation to boards of health, other Ontario Ministry of Health branches (e.g., Registration and Claims Branch) and other stakeholders (e.g., Ontario Medical Association) as needed;

(f) monitor and evaluate the TB-UP program, based on information received from boards of health and RCB;

(g) provide the final decision in a dispute resolution process if the board of health or the RCB is unable to resolve disputes related to their respective areas of responsibility with respect to the TB-UP program (Section 12.3, Final Decision Regarding Unresolved Disputes); and

(h) provide support and educational updates to groups and individuals involved in TB control.
11.4 Process for Registration into the TB-UP Program

11.4.1 Patient Referral to the TB-UP Program
(a) Registration into the TB-UP program at the board of health (Algorithm 1)

The board of health may be notified of a potential TB-UP patient through one of the following:

- Patient contacts the board of health directly: either by coming in person to the health unit or by phone; or,
- Board of health is notified by way of service provider or service agency.

**Note:** If the TB-UP patient does not have a physician, the TB Control Program staff of the local board of health will assist him/her in finding a physician.

(b) Registration into the TB-UP program from the service provider’s office/clinic (Algorithm 2)

The initial service provider may see an uninsured person in their office or clinic (i.e., a person may present due to symptoms of TB). The attending physician will call the board of health to determine if this person would be eligible for coverage under the TB-UP program.

11.4.2 Assessment of Potential TB-UP Patient by the Board of Health to Determine Eligibility for the TB-UP Program

To be eligible for coverage under the TB-UP program, the patient must meet the following criteria, with respect to both their:

- TB status, and
- medical insurance coverage status.

The TB Control Program staff will interview the patient, in person or by phone, to determine the patient’s eligibility for coverage under the TB-UP program by:

(a) Assessing the patient’s TB status (i.e., risk of TB disease/LTBI). The TB-UP patient must be one of the following:

- an active/suspect case of TB (pulmonary or extra-pulmonary);
- a contact of an active case of TB;
- any other person at high risk for developing active TB as determined by the TB Control Program staff; or,
- Person under immigration medical surveillance for TB (Phase 2).

(b) Determining the patient’s medical insurance coverage status (i.e., patient does not have coverage under OHIP, IFH, or other provincial/territorial/private health insurance). Patients are eligible if they are currently in Ontario, meet one of the TB status requirements above and are not covered by any medical health insurance for TB services.
These persons would not have coverage for TB diagnostic or treatment services under OHIP, the IFH program, medical insurance plan of another province/territory, private medical insurance or other medical insurance plan. This includes persons such as the following:

- persons currently in the 3 month waiting period for OHIP (e.g., landed immigrant, live-in caregiver such as a nanny);
- homeless and do not have OHIP coverage, IFH or other medical insurance coverage for TB services;
- foreign student without OHIP coverage, IFH or other medical insurance coverage for TB services;
- visitor without medical insurance coverage for TB services*;
- persons who do not have legitimate immigration status (long-term visitor); or
- persons who have been discharged from prison but are not currently eligible for OHIP.

* Some private medical insurance plans do not cover TB services if these services are considered to be for a pre-existing medical condition. This may include persons such as visitors or foreign students who require TB services while in Ontario. The TB-UP program will cover eligible TB services provided to these persons.

**NOTE:** The TB-UP program will not issue retroactive payments for persons who receive TB diagnostic and/or treatment services prior to registration in the TB-UP program.
11.5 Registration of Eligible TB-UP Patients

11.5.1 Application and Consent Procedure for the TB-UP Program:
In order to obtain coverage under the TB-UP program, eligible patients must first apply for coverage and provide consent to share information among health units, service providers and the Ministry of Health and Long-Term Care.

11.5.2 Obtaining Application and Consent for the TB-UP Program
(a) Registration into the TB-UP program at the board of health (Algorithm 1):
The TB Control Program staff of the board of health will review the TB-UP Application and Consent form (Appendix C) with the patient by phone or in person. The patient must sign the TB-UP Application and Consent form to be registered in the TB-UP program. The patient can sign the form either at the office of the board of health or at the office of the attending physician. The patient must be informed that by signing the TB-UP Application and Consent form, the patient:

- confirms that they do not have OHIP, IFH or any other form of health insurance to cover TB related diagnostic or treatment services;
- requests to be registered in the TB-UP program;
- provides authority to the board of health, health care providers providing services under the TB-UP program and the Ministry of Health and Long-Term Care (MOHLTC) to collect, use, share and disclose the TB-UP patient’s personal health information among themselves for the purposes of the TB-UP program; and
- agrees to the release of their health number to health care providers providing TB diagnostic and treatment services in the event that they are or become insured under OHIP.

Once the patient has signed the TB-UP Application and Consent form they will be registered in the TB-UP program and assigned a TB-UP Registration Number. The Board of Health TB Control Program staff must enter the TB-UP Registration Number on each Health Care Provider Claim form (Appendix A) prior to issuing to the service provider or TB-UP patient. The board of health cannot issue a TB-UP Registration Number without a signed TB-UP Application and Consent form. The signed TB-UP Application and Consent form will be retained by the board of health in the patient’s file.

The board of health will also need to verify the individual’s personal identification before the patient signs the TB-UP Application and Consent form for the TB-UP Program. Acceptable forms of personal identification include:

(a) passport;
(b) landed immigration papers/student visa/work permit; or
(c) confirmation/referral from service agency (e.g., homeless persons).

(b) Registration into the TB-UP program from the service provider’s office/clinic (Algorithm 2):
In general, the eligible patient should register at the board of health office during regular business hours. However, under exceptional circumstances (e.g., a highly infectious TB
case) the patient may register while at the physician’s office/clinic. In this situation, the attending physician will verify with the patient that they are not covered under OHIP, IFH or any other provincial/territorial or private health insurance. The physician will call the local board of health to notify of uninsured persons with either suspect/active TB or contact of active TB and request a TB-UP Application and Consent form (Appendix C). The board of health can fax a blank TB-UP Application and Consent form to the attending physician’s office or hospital out-patient clinic. The TB Control Program staff at the board of health should confirm that the physician or their support staff verified the individual’s personal identification (Section 5.2.1 above for acceptable forms of personal identification). The attending physician or their support staff will review the TB-UP Application and Consent form with the patient and request the patient’s signature.

Once the consent form is signed it can either be mailed or faxed to the board of health for retention in the patient’s file. A faxed TB-UP Application and Consent form with the patient’s signature will be adequate for the board of health to register the patient in the TB-UP program and initiate first mailing of the Health Care Provider Claim forms (Appendix A).

(c) Process if patient declines signing the TB-UP Application and Consent form for the TB-UP Program
The patient cannot be registered in the TB-UP program if they do not sign the TB-UP Application and Consent form for the TB-UP Program. The board of health cannot assign a TB-UP program registration number or provide any Health Care Provider Claim forms without a signed TB-UP Application and Consent form. Without a signed TB-UP Application and Consent form, there is no mechanism for the RCB to pay the claims submitted by service providers.

11.5.3 Assigning the TB-UP Registration Number
Once the board of health has received the signed TB-UP Application and Consent form and the patient meets the eligibility criteria, the TB Control Program staff can proceed with registering the patient in the TB-UP program and assigning a TB-UP Registration Number. The board of health will:

(a) Search for and select the patient in iPHIS TB module; then
(b) Enter the detailed information about the TB-UP registration in the iPHIS TB Uninsured Person Registration Details screen and save.

The system will auto-generate a TB-UP registration number after the information in the TB Uninsured Person Registration Details screen is saved (i.e., by clicking on the SAVE button). The iPHIS TB-UP registration number is in numeric format, the health unit letter code is no longer required as part of the registration number. The 8-digit TB-UP registration number should be entered on each Health Care Provider Claim form (Part A) prior to issuing to the service provider or patient.

The board of health will notify the RCB of the patient’s registration in the TB-UP program (Section 8.1.1, Provision of TB-UP registration data to RCB).
11.5 Registration of Eligible TB-UP Patients

Algorithm 1: Enrolment & Registration into the TB-UP Program at the Board of Health

A. Board of Health TB Control program staff will assess TB status:
- Active /suspect TB case;
- Contact of case of TB; or
- Person at high risk of developing TB (as determined by TB program staff);
- Person on Immigration medical surveillance (phase 2)

If patient does not meet eligibility criteria for TB-UP then no need to enroll in TB-UP program.

Eligible TB status, now determine medical health insurance coverage

B. Board of Health TB Control program staff will determine medical insurance coverage:
- Patient has NO health insurance e.g. OHIP, IFH or private health insurance.

If patient does not have health insurance coverage and meets one of the TB status requirements then the Board of Health TB Control program staff will proceed with registration.

C. Registration into the TB-UP Program (Section 5):
- Verify patient’s personal identification.
- TB-UP Application & Consent form signed by patient for TB-UP registration.
- Patient assigned TB-UP registration number.
- Notify the RCB of TB-UP registrants.

D. Issuing Health Care Provider Claim forms (Section 6):
- Health unit TB Control program staff can either:
  - Give a package of 7 forms to patient to provide at first physician visit;
  - Mail a package of 7 forms to the attending physician.

(All claim forms must have TB-UP registration #; expiry date, board of health address, name of pt, DOB & gender. This information must appear on each page of the claim forms).

E. Subsequent visits to service provider and issuing claim forms (Section 6):
Service provider contacts TB Control program staff at the board of health to discuss treatment plan and request additional claim forms as needed.

If patient does NOT sign the consent form, they cannot be registered in TB-UP program and no TB-UP registration number will be assigned.

If patient HAS health insurance then service provider can bill through patient’s insurance (i.e., OHIP, IFH or other health insurance).
Algorithm 2: Registration into the TB-UP Program from the Service Provider’s Office/Clinic during regular business hours.

Patient referral to TB-UP Program (Section 4):
- Self reports in person; or
- By service agency.

NOT ELIGIBLE

Eligible TB status, now determine medical health insurance coverage.

Patient HAS Health Insurance

Not Eligible

If patient HAS health insurance then provider can bill through patient’s insurance (i.e., OHIP, IFH or other health insurance).

B. Service provider will verify no medical health insurance:
- Patient has NO health insurance e.g. OHIP, IFH or private health insurance.

If patient does not have health insurance coverage and meets one of the TB status requirements, then the service provider contacts board of health.

C. TB-UP Registration from service provider’s office/clinic (Section 5):
- Service provider contacts the board of health to fax the TB-UP Application & Consent form.
- Service provider verifies patient’s personal identification.
- Signed consent form can be faxed to the board of health to initiate TB-UP program registration.
- Original consent form will be mailed to the health unit for retention in the TB-UP patient’s file.

If patient does NOT sign consent form, they cannot be registered in TB-UP and no TB-UP registration number will be assigned.

D. Board of health registers patient in the TB-UP program and issues claim forms to service provider (Section 4 & 6):
- Once the board of health has received the signed consent form, the patient will be registered into the TB-UP program and assigned a TB-UP registration number.
- The board of health will mail required number of claims forms to the service provider.

Service provider will forward laboratory and radiology requisitions with the claims forms to the Laboratory and Radiology departments or send along with the patient.

E. Subsequent visits to service provider and issuing claim forms (Section 6):
- Service Provider contacts the TB Control program staff at the board of health to review the treatment plan and request additional claim forms as needed.
- Additional claim forms mailed out to service provider.

Submitting Claim Forms to RCB (Section 9):
- Service provider sends completed claims forms to the Registration & Claims Branch of the MOHLTC (RCB) for payment under the TB-UP program.

RCB verifies claim forms and will process the payment.

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NOTE: The preferred method for registration is at the board of health. However, if the patient presents at the office/clinic of a service provider and has not previously contacted the board of health, this procedure should be followed.
11.6 Board of Health Distribution of Claim Forms

11.6.1 Information to be included on the Health Care Provider Claim Form prior to distribution

The board of health TB Control Program staff must complete Part A on ALL Health Care Provider Claim forms before claim forms are issued. This includes the following:

(a) Program Identification Code (i.e., TB-UP);
(b) Disease under Investigation/Treatment (i.e., TB);
(c) Referring Health Unit, Name of TB Control Staff Person, Telephone Number;
(d) Patient’s Name, Date of Birth and Sex;
(e) Registration Number (i.e., TB-UP Registration Number); and
(f) Eligibility Expiry date (i.e., TB-UP End Date).

NOTE: A new claim form will be required if the board of health staff should make a mistake in recording the registration number on the claim form. The RCB will not accept any claim forms in which the registration number shows signs of being altered (i.e., if white-out was used or if number has been crossed out and a new number written over) (Section 9.3, Returned Health Care Provider Claim Forms by the RCB).

11.6.2 Distribution of Health Care Provider Claim Forms

Once the patient is registered in the TB-UP program (i.e., assigned a TB-UP Registration Number), the board of health will distribute a package of Health Care Provider Claim forms to the attending physician. The board of health will either:

(a) give the package of Health Care Provider Claim forms to the patient (in person) to take to their physician; or
(b) mail the package of Health Care Provider Claim forms directly to the attending physician’s office/clinic.

11.6.3 Health Care Provider Claim Forms for the First and Second Visit to Physician’s Office/Clinic

As noted above, the board of health will provide the required number of the Health Care Provider Claim forms to the patient directly or send by mail to the attending physician. This initial claim form package will consist of 7 Health Care Provider Claim forms and a Health Care Provider Claim Form Instruction (Appendix B) sheet for each claim form. The 7 Health Care Provider Claim forms will cover the following services:

- 3 Health Care Provider Claim forms for physician services (2 forms to cover first and second (follow-up) visit with the attending physician and 1 form to cover radiologist services);
- 3 Health Care Provider Claim forms for laboratory services (a separate claim form must be submitted for each date of service, 3 claim forms may be required if 3 sputum specimens are obtained and tested on different days); and,
Chapter 11: Tuberculosis Diagnostic and Treatment Services for Uninsured Persons (TP UP) Program

11.6: Board of Health Distribution of Claim Forms

- 1 Health Care Provider Claim form for the radiology facility.

An Instruction sheet should accompany each Health Care Provider Claim form. The Instruction sheet will provide assistance to the service provider as to how each claim form should be used.

(a) At the first visit, the attending physician will keep two Health Care Provider Claim forms for billing services for the first and second (follow-up) visit (note: a service provider must use a separate claim form for each date of service). The attending physician should order the required laboratory tests or x-rays using the standard requisition form. The following claim forms should be attached to the standard requisition form for:

(i) Laboratory requisitions attach:
- 3 Health Care Provider Claim forms to bill laboratory services and the Health Care Provider Claim Form Instruction sheet.
(ii) Radiology requisitions attach:
- 1 Health Care Provider Claim form for radiologist (physician) services and a Health Care Provider Claim Form Instruction sheet; and
- 1 Health Care Provider Claim form for the radiology facility and a Health Care Provider Claim Form Instruction sheet.

The TB-UP patient will take the remaining 5 Health Care Provider Claim forms and the Instruction sheets along with the standard requisition to the laboratory and/or radiology facility as required.

(b) The attending physician can bill the second (follow-up) visit using the additional Health Care Provider Claim form for physician services. On the second visit the physician will review the results of the initial diagnostic testing (e.g. TB skin test, chest x-ray, laboratory tests) with the patient and determine whether further follow-up is required. The physician’s office/clinic will contact the local board of health - TB Control Program staff to provide an update of the TB status and treatment plan for the patient. At this time, the physician’s office will need to provide the board of health with an estimate for the number of Health Care Provider Claim forms needed to cover physician visits and/or further laboratory/radiology services for the next four week period.

11.6.4 Health Care Provider Claim Forms for Subsequent Visits to Physician’s Office/Clinic

(a) Once the attending physician has provided an update of the patient’s TB status and treatment plan, the board of health will mail out the estimated number of additional Health Care Provider Claim forms requested by the physician’s office/clinic. The board of health can send out additional claim forms on a monthly basis as requested by the attending physician.

(b) For all other subsequent physician visits, the board of health may provide Health Care Provider Claim forms to the physician’s office directly. The number of claim forms provided each time should only be the number...
required to cover the next four week period of visits, as outlined in the
treatment plan or updates from the attending physician.

(c) The board of health TB Control Program staff must include the information
listed in Section 6.1 above on all Health Care Provider Claim forms before
issuing to the physician’s office/clinic.

(d) The board of health should advise the physician’s office/clinic that only
original Health Care Provider Claim forms not photocopies* must be
submitted to the RCB for assessment and payment under the TB-UP
program.

(e) The service provider will return all Health Care Provider Claim forms that
have not been used to the local board of health. The board of health will
retain these unused claim forms in the TB-UP patient’s file for further use
until the patient is discharged from the TB-UP program. Once the TB-UP
patient is discharged, the board of health will destroy all unused Health
Care Provider Claim forms made out to the specific TB-UP patient. The
board of health should delete unused and/or destroyed Health Care
Provider Claim Forms that were recorded as issued on the iPHIS TB-UP
Claim Form Details screen.

* Photocopies of the Health Care Provider Claim form may be accepted by the RCB in
exceptional circumstances (e.g., lost in mail). However, the copy must clearly state “duplicate”
and be resigned by the service provider.
11.7 iPHIS TB-UP Screen Data Entry by the Board of Health

Board of health staff will first open a TB episode for the patient by entering the required patient information into the Integrated Public Health Information System (iPHIS) TB module. The following information must be entered into iPHIS: patient’s name, address, telephone number, date of birth, gender as well as status at time of arrival (i.e., immigrant, visitor, etc.) as per regular iPHIS reporting and management of a TB case.

Board of health TB Control Program staff will obtain the following information from the patient and record the information into the iPHIS TB Uninsured Person Registration Details screen. This data will be included in the regular iPHIS reporting to the PHB for the purpose of monitoring and evaluating the TB-UP program (Section 8.1.2, Provision of TB-UP program data to the PHB). Below is a detailed description of the data to be collected and entered by the board of health TB Control Program staff.

NOTE: All fields marked with (*) are mandatory. Please ensure these are completed in the “TB Uninsured Person Registration Details” screen.

11.7.1 TB-UP Status*
- not eligible for program
- eligible/active patient
- discharged

11.7.2 Medical Coverage Status at time of registration*
- persons in the 3 month waiting period for OHIP
- homeless without OHIP, IFH or other health insurance for TB services
- persons who have been discharged from prison but are not currently eligible for OHIP
- visitor without health insurance for TB services
- foreign student without OHIP, IFH or other health insurance for TB services
- persons who do not have legitimate immigration status (long-term visitor)

11.7.3 TB-UP Consent Signed/Start Date*
Enter the date when the patient signed the TB-UP Application and Consent form and was registered in the TB-UP program.

11.7.4 Status Review Date (SRD)
The status review date (SRD) is the date when the insurance status of the patient should be checked by board of health staff to determine ongoing eligibility for the TB-UP program. The SRD:

(i) will default to 90 days from the date on which the patient was registered in the TB-UP program (i.e., 90 days for the date indicated in the Consent Signed/Start Date field) ; this date must be 30 days prior to the TB-UP End Date.
(ii) can be set at one year from the program registration date for active/suspect TB cases (e.g., visitors or foreign students), since active TB treatment may take one year or longer.

The board of health staff will review the TB-UP patient file two weeks prior to the SRD to determine if the patient is now covered by OHIP or any other health insurance. Once the patient is covered for TB service under OHIP or any other health insurance plan, they will no longer be eligible for coverage under the TB-UP program. The patient will then be discharged from the TB-UP program (Section 10.1, Process for Discharging the Patient from the TB-UP Program).

**NOTE:** The SRD can be extended at the discretion of the board of health, for example if the patient has not received OHIP coverage within 90 days and/or treatment for TB has been extended beyond the review period. The new SRD must be reported to the RCB by updating the list of TB-UP registrants (Section 8.1.1, Provision of TB-UP registration data to the RCB). The board of health must also update the Health Care Provider Claim form if extending the SRD results in the extension of the end date (i.e., expiry date). The board of health will indicate the extended SRD and if necessary the revised TB-UP End Date in the iPHIS TB Uninsured Person Registration Details screen.

### 11.7.5 TB-UP End Date*

Enter the date when it is anticipated the patient should be discharged from the TB-UP program (i.e., expiry date). When the patient is actually discharged from TB-UP program this will become the discharge date and should be updated appropriately. The TB-UP End Date should be entered as a date 4 months from the start date during the initial save in iPHIS.

### 11.7.6 Reason for Referral*

- active case
- suspect case
- contact of case
- medical surveillance
- LTBI (other)

### 11.7.7 Diagnostic Outcome

- active pulmonary TB
- active extra pulmonary TB
- LTBI on treatment
- LTBI without treatment
- assessment complete findings negative
- assessment not complete, further assessment results required

### 11.7.8 On Medical Surveillance*

- yes
- no
11.7.9 Available Reasons for Discharge
- medically assessed – no further follow-up
- medically assessed – on treatment
- medically assessed – treatment completed
- consent withdrawn
- deceased
- moved outside Ontario
- patient covered by OHIP, IFH or other medical insurance for TB services

In the TB Uninsured Person Claim Form Details screen:

11.7.10 Invoice Number*
Enter pre-printed number on claim forms in the TB Uninsured Person Claim Form Details screen.

11.7.11 Invoice Given To*
- patient
- initial physician
- subsequent physician
- parent/guardian

11.7.12 Invoice Given Physician
Only appears if ‘initial physician’ or ‘subsequent physician’ is selected from the Invoice Given To drop list above. Select the name of physician to whom claim forms were sent.

11.7.13 Invoice Paid Date
Enter the date when the invoice was paid from the claim forms returned to the board of health from RCB (i.e., pink copy).
11.8 TB-UP Data Transfer

(a) On a monthly basis, the PHD will submit a list of TB-UP registrants to the RCB in MS Excel Spreadsheet format that can be generated from ReportNet. This spreadsheet is saved on a password-protected diskette and sent to RCB by the first of every month.

(b) A cumulative list of all TB-UP registrants, both current and discharged, will be included in the file sent to RCB. The RCB will use the TB-UP registrant information from the MS Excel Spreadsheet (i.e., ReportNet) to confirm that the TB-UP patient information on the submitted claim form corresponds to the patient information provided in the spreadsheet from the PHD. This information will assist the RCB staff in verifying patient registration in the TB-UP program by a board of health.
11.9 Submitting and Processing of Claims for the TB-UP Program

11.9.1 Health Care Provider Claim Submission by Service Provider

Claims will be submitted by service providers to the RCB for assessment for payment under the TB-UP program using the Health Care Provider Claim - Diagnostic and Treatment Services for Uninsured Persons form (Appendix A).

11.9.2 Health Care Provider Claim Payment under the TB-UP Program by RCB

RCB will assess and process claim payments for services rendered under the TB-UP program. Services provided will be paid at same rate as the Schedule of Benefits fee value for the same service provided to an insured person. Service providers will receive payment for processed claims on a regular schedule. Payments for services under the OHIP and the TB-UP programs will be included in a single remittance to the provider. The payment details for the amount paid under the TB-UP program will be included in detail line under TB-UP. Best efforts will be made on behalf of the RCB to ensure that claims will be paid to service providers who provide services under the TB-UP program within 8 weeks of receipt.

Service providers must submit all claims to the RCB within 6 months of the date of service. This includes original claims and resubmitted claims (e.g., if original was lost). Payment for claims submitted more than 6 months following the date of service will be refused unless the RCB service manager is satisfied that there are extenuating circumstances.

Once the RCB has processed the Health Care Provider Claim forms submitted by service providers, a copy (pink) of the claim form will be sent to the appropriate board of health. This copy of the paid form will be retained by the board of health in the TB-UP patient’s file.

11.9.3 Returned Health Care Provider Claim Forms by the RCB (Algorithm 4):

1. Reasons for a Health Care Provider Claim form to be returned:

The RCB may return a claim submitted by a service provider for reasons such as the following:

- Patient was not enrolled in the TB-UP program at the time the TB service was rendered;
- Patient is covered under OHIP;
- Claim form is not complete or information is missing;
- TB-UP Registration Number has been altered;
- More than one date of service is listed on the claim form (NOTE: A separate claim form must be used for each date of service);
- Claim form is a photocopy;
- Claim is stale dated (i.e., claim received more than 6 calendar months after date of service);
- Service code submitted does not correspond to the service code in the OHIP Schedule of Benefits; or
Service provider is not listed in the ministry provider database (NOTE: An exception letter (see Appendix F) from the Medical Officer of Health/designate must accompany a claim for services that are rendered outside the province of Ontario by a service provider licensed within their province of practice) (Section 9.4, Claims for service providers licensed outside Ontario).
Algorithm 4: Returned Health Care Provider Claim Forms by the RCB

A. Health Care Provider Claim Form returned by RCB (Section 9.3)

RCB may return a claim form to the service provider for reasons such as the following:

- Patient is not enrolled in the TB-UP program at the time the TB service was rendered;
- Patient is covered under OHIP;
- Claim form is not complete or information is missing;
- TB-UP Registration number has been altered;
- More than one date of service is listed on the claim form. NOTE: A separate claim form must be used for each date of service;
- Claim form is a photocopy;
- Claim is stale dated (i.e., claim received more than 6 calendar months after date of service);
- Service code submitted does not correspond to the service code in the OHIP Schedule of Benefits; and
- Service provider is not listed in the ministry provider database. NOTE: A letter from the Medical Officer of Health/designate (see Appendix F) must accompany a claim for services that are rendered outside the province of Ontario by a service provider licensed within their province of practice.

B. RCB returns claim form to the service provider:

- If claim form is returned, RCB will send the returned claim form to the service provider along with a “Claim Forms Returned” letter (see Appendix E) that outlines reasons for returned claim.

C. Service provider receives returned claim form from the RCB:

- Service provider is notified of the reasons for the returned claim form in the “Claim Forms Returned” letter (see Appendix E)
- Once conditions outlined in the “Claim Form Returned” letter are met, service provider can re-submit the completed/corrected claim form to RCB for payment.

D. If the service provider cannot provide the information then the service provider will:

- contact the board of health where the patient is registered for assistance; or
- send the returned claim form to the board of health for them to provide the required TB-UP patient information.

NOTE: The service provider may return claim form to the board of health for exception letter, extension of expiry date or to add missing/correct TB-UP patient information (e.g., registration number).

E. Board of health receives returned claim form from service provider:

- A service provider may send their returned claim form (along with "Claim Form Returned" letter –see Appendix E)) to the board of health for inclusion of missing information or an exception letter as required.
- Once conditions outlined in the “Claim Form Returned” letter are met, the service provider can re-submit the claim form to RCB for payment.
2. Process for re-submission of returned Health Care Provider Claim forms:

If a Health Care Provider Claim form is not eligible for payment, the RCB will return the claim form to the service provider along with a Claim Forms Returned letter (see Appendix E). The Claim Forms Returned letter will outline the reason RCB returned the claim. The service provider will provide the necessary information or correct the claim and re-submit to the RCB for payment under the TB-UP program.

If the service provider cannot provide the necessary information then the service provider will need to contact the board of health for assistance. Once the conditions outlined in the Claim Form Returned letter are met, the service provider can re-submit the corrected/completed Health Care Provider Claim form to the RCB.

NOTE: If the service provider has questions related to claim payments they can contact the Ministry of Health and Long-Term Care, Toronto District Office (TDO) of the Registration and Claims Branch by phone at (416) 314-7770.

11.9.4 Claims for service providers licensed outside Ontario

(a) In order to receive payment through the TB-UP program, claims submitted by service providers licensed outside the province of Ontario must include an original letter signed by the local Medical Officer of Health (MOH) or designate authorizing the out of province TB related service(s) for the uninsured patient (see Appendix F). Service providers must be licensed within their province of practice to be eligible for payment under the TB-UP program (Section 1.2.2, Eligible service providers for payment under the TB-UP program).

(b) In the event that a service provider disagrees with the decision from the MOH/designate regarding non-approval of TB-UP services rendered outside Ontario, the MOH/designate will consult with the Senior Medical Consultant at the Public Health Branch (PHB) to discuss the specific issue (Section 12, Dispute Resolution).
11.10 Discharge of Patient from TB-UP Program

11.10.1 Process for Discharging the Patient from the TB-UP Program

(a) Patient may request to be withdrawn from the TB-UP program (Section 11.2.1: Withdrawal from the TB-UP Program) or the board of health may initiate discharge due to one of the following reasons, patient:

- completed treatment;
- is deceased;
- moved outside Ontario;
- completed assessment and findings were negative; or
- is covered under medical insurance such as OHIP or IFH.

(b) The board of health must ensure the following fields in the iPHIS TB Uninsured Person Registration Details screen are completed, if the TB-UP patient is to be discharged (Section 7, iPHIS TB-UP Screen Data Entry by the Board of Health):

- TB-UP End Date
- TB-UP Diagnostic Outcome
- Reasons for Discharge

(c) The board of health TB Control Program staff should ensure that claim information (i.e., invoice paid date) from all paid claims sent by RCB for services rendered prior to the patient’s discharge is entered into the TB Uninsured Person Claim Form Details screen.

(d) The TB Control Program staff must notify the RCB of the patient’s discharge from the TB-UP program through the TB-UP registrant report sent monthly to the RCB (Section 8.1.2. Provision of TB-UP Registration Data to RCB). The TB Control Program staff must also contact the attending physician to inform of TB-UP patient’s discharge from the TB-UP program.

11.10.2 Withdrawal from the TB-UP Program:

Patient withdraws from the TB-UP program (Algorithm 5)

The patient may withdraw from the TB-UP program in either one of the following ways:

(a) At the board of health:

The TB-UP patient may contact the board of health directly to request to be withdrawn from the TB-UP program. The TB Control Program staff will review the TB-UP Withdrawal form with the patient (Appendix D). The patient must be informed that once they have signed the TB-UP Withdrawal form the patient is agreeing to withdraw:

- registration from the TB-UP program;
- authorization for the board of health, health care providers providing services under TB-UP and the MOHLTC to collect, use, share and
disclose personal information among themselves for any purpose relating to the TB-UP program; and

- coverage under the TB-UP program for diagnostic and/or treatment services for TB.

Once the patient has signed the TB-UP Withdrawal form, the board of health TB Control Program staff will proceed with discharging the patient from the TB-UP program (Section 10.1, Process for Discharging the Patient from the TB-UP Program). The signed TB-UP Withdrawal form will be retained by the board of health in the patient’s file. The board of health will update the iPHIS TB Uninsured Person Registration Details and the TB Uninsured Person Claim Form Details screen. Notification of the patient’s withdrawal/discharge from the TB-UP program must be sent to the RCB as well as the attending physician (Section 10.1, Process for Discharging the Patient from the TB-UP Program and Section 8.1.2, Provision of TB-UP registration data to RCB).

(b) At the service provider’s office:
The TB-UP patient may request to withdraw from the TB-UP program while in the service provider’s office. The attending physician may direct the TB-UP patient to the board of health for withdrawal. Alternatively, the attending physician may contact the local board of health to inform of patient’s wish to withdraw from the TB-UP program and request a TB-UP Withdrawal form (Appendix D). The board of health will fax a blank TB-UP Withdrawal form to the attending physician’s office. The attending physician or their support staff will review the form with the patient and explain that by signing the TB-UP Withdrawal form the patient agrees to withdraw:

- registration from the TB-UP program;
- authorization for the board of health, health care providers providing services under TB-UP and the MOHLTC to collect, use, share and disclose personal information among themselves for any purpose relating to the TB-UP program; and
- coverage under the TB-UP program for diagnostic and/or treatment services for TB.

The signed TB-UP Withdrawal form can be mailed or faxed to the board of health for retention in the patient’s file. A faxed withdrawal form with patient’s signature will be adequate to initiate discharge from the TB-UP program (Section 11.1, Process for Discharging the Patient from the TB-UP Program). The board of health will update the iPHIS TB Uninsured Person Registration Details, the TB Uninsured Person Claim Form Details screen and send notification to the RCB (Section 10.1, Process for Discharging the Patient from the TB-UP Program and Section 8.1.2, Provision of TB-UP registration data to RCB).
Algorithm 5: Patient Withdraws from the TB-UP Program

PATIENT WITHDRAWS OR IS DISCHARGED FROM TB-UP PROGRAM

Reasons for discharging TB-UP patient from the TB-UP program (Section 10):
The board of health may discharge a TB-UP patient due to the following reasons, patient:
- Medically assessed – no further follow-up
- Medically assessed – treatment completed
- Medically assessed – on treatment
- Consent withdrawn
- Deceased
- Moved outside Ontario, or
- Covered under medical insurance such as OHIP or IFH.
(Board of health will update the iPHIS TBUninsured Person Registration Details screen for discharging patient and notify RCB.)

OR

TB-UP Patient may request to be withdrawn from the TB-UP program (Section 10.2.1):

AT BOARD OF HEALTH

Patient requests to withdraw from TB-UP Program:
- Signs TB-UP Withdrawal Form.

Patient is discharged from TB-UP Program:
- Board of health updates iPHIS TB Uninsured Person Registration and Claim Form Details screens and notifies the RCB via monthly report (i.e. diskette).
- Board of health notifies service provider that patient has withdrawn from TB-UP Program.

AT SERVICE PROVIDER’S OFFICE/CLINIC

Patient requests to withdraw from TB-UP Program:
- Service provider has patient go to board of health.

Patient requests to withdraw from TB-UP Program:
- Service provider calls the board of health and requests a TB-UP Withdrawal form.
- Board of health faxes withdrawal form to service provider.
- Provider faxes the signed TB-UP Withdrawal form to the board of health.
- Board of health proceeds with discharging patient from TB-UP program.
- Service provider mails original signed TB-UP Withdrawal form to the board of health.
11.11 TB-UP Form Production, Distribution, Control and Retention

11.11.1 Production of TB-UP Forms

(a) The RCB will manage the stock and on-going production of the Health Care Provider Claim – Diagnostic and Treatment Services for Uninsured Persons form (Appendix A).

(b) Each Health Care Provider Claim form will have a pre-printed unique sequential number called the "invoice number" which will be used for monitoring and tracking of claim forms within the iPHIS TB Uninsured Person Claim Form Detail screen. This number should not be altered by the board of health or service provider.

(c) The PHD will manage the stock and on-going production of the TB-UP Application and Consent form and the TB-UP Withdrawal form (Appendix C & D).

11.11.2 Process for the Board of Health to obtain TB-UP Forms

(a) Health Care Provider Claim forms can be ordered from the Ministry of Health and Long-Term Care. The board of health staff can order these forms using either one of the following methods:

(i) complete a Stationery and Publications Requisition form 0350-93 which is available in paper copy or can be obtained online at:

http://intra.forms.ssb.gov.on.ca/mbs/ssb/forms/FormsReposi
tory.nsf/ Forms/MOH-014-0350-93/$File/0350-93_.pdf?OpenElement

The electronic form can be filled in and then mailed to address on form or faxed to the number on the form; or

(ii) call the Adesso warehouse customer service line with the information at (416) 327-0837 or fax (416) 327-0329 the ordering information on board of health letterhead.

The following information is required:

- form number which is 3977-84
- catalogue number which is 7530-5626
- form title which is Health Care Provider Claim form

The board of health will need to provide the quantity, budget code to ship under (individual board of health budget code for shipping forms), board of health address for shipping as well as contact name & telephone information.

(b) TB-UP Application and Consent and TB-UP Withdrawal forms for the TB-UP program:
These forms can be obtained from the Ministry of Health and Long-Term Care. The board of health can request a supply of these forms by quoting the catalogue number (see bottom right side of the form, e.g., 7530) and faxing the request to (416) 327-0329 on board of health letterhead. Further ordering information can be found on the web site at http://www.gov.on.ca. The board of health can search the web site by form name or by form number.

11.11.3 TB-UP Forms Control

- The board of health offices will control the distribution of claim forms to service providers. Each Health Care Provider Claim form has a pre-printed unique invoice number. The board of health will enter this unique invoice number into the iPHIS TB Uninsured Person Claim Form Details screen for each claim form issued (Section 7.11, Invoice Number). The board of health will also indicate (in the iPHIS TB Uninsured Person Claim Form Details screen) the person they gave the claim forms to (Section 7.12, TB-UP Invoice Given To). For example, if the board of health issued the claim form to the attending physician then the name of physician receiving the claim form must be included in the iPHIS TB Uninsured Person Claim Form Details screen (Section 7.13, TB-UP Invoice Given Physician).

- The individual TB-UP Application and Consent form and the TB-UP Withdrawal form will not be tracked by the PHD.
11.12 Dispute Resolution

11.12.1 Policy and Program Inquiries
(a) Inquiries relating to the TB-UP policy or program procedures will first be directed to the local boards of health for resolution.

(b) For escalated inquiries the board of health will discuss with the PHD (Senior Medical Consultant: VPD/TB Unit) by phone at (416) 327-7419.

11.12.2 Payment Inquiries
Inquiries relating to claim payment will be directed to the Ministry of Health and Long-Term Care, Toronto District Office (TDO) of the Registration and Claims Branch by phone at (416) 314-7770.

11.12.3 Final Decision Regarding Unresolved Disputes
The PHD will provide a final decision in unresolved disputes. This would include escalated disputes which the board of health or RCB is unable to resolve.
11.13 Appendix A: Health Care Provider Claim

Health Care Provider Claim:
Diagnostic and Treatment Services for Uninsured Persons

See Section 11.2 for process for Board of Health to obtain TB-UP Forms.

A sample cannot be produced in this protocol but a supply should be available at the local public health unit.
11.14 Appendix B: Health Care Provider Claim Form Instruction Sheet

This instruction sheet should accompany each Health Care Provider Claim form in the initial claim form package. Service providers who provide out-patient services to TB-UP patients can bill for these services by submitting the completed Health Care Provider Claim forms to the Registration and Claims Branch of the Ministry of Health and Long-Term Care for payment under the TB-UP program. Detailed submission instructions including Terms and Conditions for billing through the TB-UP program can be found on the Health Care Provider Claim form.

The initial claim form package contains 7 Health Care Provider Claim forms that will cover the following services:

1. Physician Services:
   - 2 Health Care Provider Claim forms to cover first and second physician visits; and
   - 1 Health Care Provider Claim form to cover the radiologist service.

2. Laboratory Services:
   - 3 Health Care Provider Claim forms for laboratory services (a separate claim form must be submitted for each date of service, 3 claim forms may be required if 3 sputum specimens are obtained and tested on different days).

3. Radiology Services:
   - 1 Health Care Provider Claim form to cover radiology facility.

At the initial TB-UP patient visit, the attending physician will retain 2 Health Care Provider Claim forms and give the remaining claim forms to the patient to provide to laboratory and radiology service providers as required. The attending physician should order the required laboratory tests or x-rays using the standard requisition forms and attach the standard requisition form(s) to the appropriate Health Care Provider Claim form(s).

Ordering additional Health Care Provider Claim forms:

The attending physician should contact the local public health unit to obtain additional Health Care Provider Claim forms.

**NOTE:** A service provider must use a separate claim form for each date of service.
11.15 Appendix C: TB-UP Application and Consent Form
# TB-UP Application and Consent

## Part A - To be completed by Board of Health

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<th>Name of Health Unit</th>
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## Part B - To be completed by TB-UP Registrant

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- At present, I am not an insured person under the Ontario Health Insurance Plan (OHIP).
- I am not entitled to health services under the Interim Federal Health Plan.
- I do not have any other health insurance that will cover these services.
- Should I become an insured person under the Ontario Health Insurance Plan or any other health care coverage that will pay for these services, I agree to immediately advise the board of health or my health care providers.
- I hereby ask to be registered in the Tuberculosis Diagnostic and Treatment Services for Uninsured Persons ("TB-UP program").
- I authorize the board of health, health care providers providing services to me under TB-UP and the Ministry of Health and Long-Term Care to collect, use, share and disclose my personal health information among themselves only for the purposes of the TB-UP program, including purposes related to my health care, payment of provincially funded compensation to my TB-UP health care providers and provincial health program evaluation and health planning.
- I also agree that if I become an insured person under the Ontario Health Insurance Plan, the Ministry of Health and Long-Term Care may release my health number to health care providers providing tuberculosis diagnostic and treatment services.
- I wish to withdraw this application and authorization. I will notify the Board of Health named above.

**Signature (Registrant or Guardian/Parent if under 16 yrs.)**

**Date - month/day/year**

## Part C - To be completed by Witness

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**Signature (Witness)**

**Date - month/day/year**

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*The TB-UP program is authorized pursuant to the provisions of sections 2 (purpose), 4 (duty of boards of health), 5.2 (control of disease), 5.4 (collection and analysis of data), 7 (guidelines for provision of mandatory programs) and 20, 26, 28 and 31 (reporting of disease) under the Health Protection and Promotion Act, and section 6 (duties and functions of the Minister) under the Ministry of Health and Long-Term Care Act.*

Collection of the personal information on this form is for determination of eligibility and registration in the TB-UP program, provision of TB-UP health services, TB-UP program administration and health program evaluation and planning. The authority for collection and use of this information is the Ministry of Health and Long-Term Care Act, section 6, and the Health Protection and Promotion Act, sections 2, 4, 5.2, 5.4.1 and 20, 26, 28 and 31. For information about collection practices contact the TBUP Program: Nursing Consultant at telephone 410-327-7410.
11.16 Appendix D: TB-UP Withdrawal Form

**Ontario Ministry of Health and Long-Term Care**

**TB - UP Withdrawal**

**WITHDRAWAL OF REGISTRATION and/or AUTHORIZATION for the Tuberculosis Diagnostic and Treatment Services for Uninsured Persons (TB-UP) Program**

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- I no longer wish to be registered in the Tuberculosis Diagnostic and Treatment Services for Uninsured persons (TB-UP) program and
- I withdraw my authorization for the board of health, health care providers providing services to me under TB-UP and the Ministry of Health and Long-Term Care to collect, use, share or disclose my personal health information among themselves for any purpose as of

**Signature (Registrant or Guardian/Parent if under 16 yrs.)**

**Date - month/day/year**

*The TB-UP program is authorized pursuant to the provisions of sections 2 (purpose), 4 (duty of boards of health), 5.2 (control of disease), 5.4.1 (collection and analysis of data), 7 (guidelines for provision of mandatory programs) and 25, 26, 29 and 31 (reporting of disease) under the Health Protection and Promotion Act, and section 6 (duties and functions of the Minister), under the Ministry of Health and Long-Term Care Act.*

Collection of the personal information on this form is for determination of eligibility and registration in the TB-UP program, provision of TB-UP health services, TB-UP program administration and health program evaluation and planning. The authority for collection and use of this information is the Ministry of Health and Long-Term Care Act, section 6, and the Health Protection and Promotion Act, sections 2, 4, 5.2, 5.4.1 and 25, 26, 29 and 31. For information about collection practices contact the TBUP Program Nursing Consultant at telephone 416-327-7416.
11.17 Appendix E: Claims Form Returned Letter

<date>

Dr <name>  
<address>

Dear Service Provider:

Your Tuberculosis for Uninsured Persons Program (TB-UP) Claim Form is being returned for the following reason(s):

☐ Form is not complete (or TB-UP Registration number has been tampered with or changed)

☐ Claim contains more than one service date.

☐ Form is not an original form (or clearly marked DUPLICATE containing an original provider signature, or an original faxed copy from a PHU containing an original provider signature).

☐ Claim is stale dated (claim service greater than 7 calendar months from date received by the processing site). No Public Health Unit exception letter authorizing payment attached.

☐ The Client has Ontario Health Insurance (OHIP). The OHIP number is ______________.

☐ Fee Code submitted is invalid. No Public Health Unit exception letter authorizing payment attached.

☐ Service provider is ineligible (not listed in the provider database). No Public Health Unit exception letter authorizing payment attached.

☐ Service provider is ineligible (ineligible on the provider database).

☐ Patient not listed on TB-UP Registration Report, or not enrolled in program at time of service (service date is prior to program start date, or after program end date as listed on the TB-UP Registration Report). No Public Health Unit exception letter authorizing payment attached.

☐ Other _________________________________________________________

Please return the completed/corrected form as soon as possible. Your claim cannot be processed without your completed/corrected claim form.
The fee submitted on your TB-UP claim is not equal to the amount in the Schedule of Benefits. Your claim is being processed, but the amount paid will not be as billed (photocopy of claim attached).

If you have any questions, please contact our office.

Ministry of Health and Long-Term Care
47 Sheppard Ave East Suite 505
Toronto ON  M5W 1G9
(416) 314-7770
11.18 Appendix F: Sample Exception Letter

Dear <personalized health care provider>

The Tuberculosis Diagnostic and Treatment Services for Uninsured Persons (TB-UP) program enables health care service providers licensed in Ontario to receive payment for services they provide to uninsured individuals who have been identified as requiring follow-up for tuberculosis infection or disease. Under this program, physicians, laboratories and radiology clinics will be paid for specific outpatient services rendered to individual patients registered in the TB-UP program. Specific outpatient services are listed on TB-UP claim forms.

Claims for 'exceptional' services (i.e., services not indicated on the claim forms) require prior approval by the local Medical Officer of Health indicating that the 'exceptional' service was required for the diagnosis/treatment of the particular client. Claims by service providers' licensed outside the province of Ontario also require prior approval in order to receive coverage through the TB-UP program for services rendered for the diagnosis/treatment of the particular client.

Please accept this 'exception' letter granting approval for the following:

☐ Claims for specific 'exceptional' service (specify the service(s) required and the corresponding code from the OHIP fee schedule along with the current fee, and provide rationale)

☐ Claims by service providers licensed outside the province of Ontario to receive coverage through the TB-UP program for services rendered for the diagnosis/treatment of the particular client.

The above indicated approval has been determined by the local Medical Officer of Health as required for the diagnosis/treatment of TB for the particular client and can receive coverage through the TB-UP program.

Thank you,

________________________________
Medical Officer of Health/Designate
iPHIS Bulletin

Ministry of Health and Long-Term Care
Public Health Division

November 24, 2005

Bulletin #11

In This Issue:
- TB-UP Functionality in iPHIS
- Process Overview
- TB-UP Reference Materials

TB-UP (TB Uninsured Persons) Functionality in iPHIS

TB-UP functionality was developed in iPHIS through consultation with the TB program consultants at the Public Health Division (PHD). The TB-UP functionality (available in iPHIS Release 2) consists of three new iPHIS screens: a summary screen to quickly view a client’s TB-UP registrations, a registration screen and a claim form screen.

In iPHIS, TB-UP registration records are tracked and managed in the TB module. The TB-UP screens have been developed to work with the specific information requirements of the TB-UP Protocol, thereby allowing Health Unit staff to provide effective public health service.

Health units should begin using the TB-UP functionality in iPHIS starting January 1, 2006. This will allow health units time to manually convert TB-UP registrations from RDIS to iPHIS in time for the first reporting period. Reports sent to the Registration and Claims Branch (RCB) will be produced from ReportNet by the health units for January 31, 2006. These reports are then sent to RCB using the current process as outlined in the TB-UP Protocol.

Process Overview

The TB-UP screens are accessed through the TB module. Therefore, users who require access to TB-UP must be set up with access to the TB module. Please note that to enter a new TB-UP registration the client must have an open TB episode. Refer to the iPHIS User Guide: Tuberculosis Management for details on creating a TB episode. All training materials are available on www.iPHISOntario.ca.
TB Uninsured Person Registration Summary Screen

To access the summary screen:

- Search for and select a client.
- Navigate to the client’s open TB Episode and click Details.
- From the Client menu select Uninsured Person.

From this screen a user can create a new TB-UP registration, access the details of an existing registration or access the claims information for a particular registration.

Please note that a client can have only one eligible / active TB-UP registration at a time.
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TB Uninsured Person Registration Details

- From the TB Uninsured Person Registration Summary screen click New or Details.

To enter TB-UP registration details:

1. From the TB Uninsured Person Registration Details screen, select the appropriate TB-UP Status.
2. Enter the TB-UP Consent Signed / Start Date in YYYY-MM-DD format.
3. Select a value for Medical Cvg Status at Reg’n, On Medical Surveillance, and Reason for Referral.
4. Enter the TB-UP End Date in YYYY-MM-DD format.
5. Complete the remaining fields on the page, as required.
6. Click Save.

The mandatory information for a client’s TB-UP registration is entered on this screen. A TB-UP Registration # will be generated upon save.
The Status Review Date is the date at which point the health unit should verify the client's continued eligibility in the TB-UP program. If a Status Review Date is not entered it will auto-populate on save with a date 90 days (3 months) from the start date.

During the initial save the TB-UP End Date should be a date four months from the start date.

It is recommended that users create a self-referral for the status review date to verify the client’s continued eligibility in the TB-UP program. If the status review date is extended then the end date must also be verified.

Not Eligible for Program should only be selected as a TB-UP Status when investigating a possible duplicate. Please see duplicate management procedures for further information.

To update TB-UP registration details:

1. From the TB Uninsured Person Registration Summary screen, click Details next to the appropriate registration.
2. Update the information on the page, as required.
3. Verify the TB-UP End Date, and click Save.
4. If needed create a new self-referral as a reminder to review the registration at a certain date.

To discharge a TB-UP client:

1. From the TB Uninsured Person Registration Details screen, select Discharged from TB-UP Status.
2. Select the DX Outcome if not previously entered.
3. Verify the TB-UP End Date is accurate to the actual discharge date, and click Save.
4. Select the Reason for Discharge from the Available Reasons for Discharge list and click . Multiple reasons can be selected. Each reason appears in the Currently Assigned Reasons for Discharge list.
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TB Uninsured Person Claim Form Details

- From the TB Uninsured Person Registration Summary screen or the TB Uninsured Person Registration Details screen click **Claims**.

Health units can enter and track TB-UP claims information using this screen. If a value of *Initial Physician* or *Subsequent Physician* is selected for **Invoice Given To** then the physician filter will display.

**To update TB-UP claim form details:**

1. From the **TB Uninsured Person Registration Summary** screen, click **Claims** next to the appropriate registration.
2. Click **Update** next to the appropriate claim form.
3. Update the information on the page, as required. For example, enter the **Invoice Paid Date** when the invoice is received from RCB.
4. Click **Save**.
|-----------------------|------------------------------------------------------------------------------------------|--------------------------|

## TB-UP Reference Material

**TB-UP Protocol**
- Contains details on the TB-UP program and procedures.

**iPHIS User Guide Tuberculosis Management**
- Contains details on iPHIS TB-UP functionality.
- Available on [www.iPHISOntario.ca](http://www.iPHISOntario.ca)

For more information, please contact the iPHIS Help Desk at 1(888)272-2794 or in the GTA at (416)327-3512

Email: [moh-iPHISsupport@moh.gov.on.ca](mailto:moh-iPHISsupport@moh.gov.on.ca)
- Long Distance: 1-888-272-2794
- Toronto Area (GTA): 416-327-3512
  Email: [moh-iPHISsupport@moh.gov.on.ca](mailto:moh-iPHISsupport@moh.gov.on.ca)
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12. Use of Orders under the Health Protection and Promotion Act to Control Tuberculosis

The purpose of the Health Protection and Promotion Act (HPPA), as set out in Section 2, is to provide for the organization and delivery of public health programs and services. The goal of such services is the prevention of the spread of disease, and the promotion and protection of the health of the people of Ontario.

The Medical Officer of Health (MOH) is an important statutory official under the HPPA and possesses authority under HPPA to act, among other things, to prevent the spread of disease, decrease the effects of health hazards and protect the public’s health.

The HPPA lists the reporting requirements for communicable diseases (See Chapter 1). It also gives:

(a) The medical officer of health the authority to issue orders against anyone who has a communicable disease, such as TB, and who is putting others at risk;
(b) The medical officer of health the authority to access personal information that will assist in contact tracing and;
(c) People with a communicable disease the right to appeal an order issued by a medical officer of health, however the order remains in force pending the appeal.

Where the public’s health and safety are at risk and the situation is urgent, or if other measures to achieve compliance have failed, an MOH may rely on the more intrusive provisions of the HPPA. It has been customary practice for an MOH to use all reasonable measures to obtain voluntary compliance before using the more intrusive statutory powers of the MOH to ensure appropriate treatment and medical follow-up for tuberculosis.

12.1 Section 22 Orders

The following considerations reflect common public health practice relating to the issuance of a Section 22 Order:

- Any intervention should be the “least intrusive, most effective” option.
- More intrusive interventions should be adopted only after less intrusive alternatives have been unsuccessfully attempted.

12.1.1 Preparing to Issue a Section 22 Order

For diseases designated as communicable under O. Reg. 558/91, a MOH has the power under Section 22(1) of the HPPA to issue a written order requiring an individual to take or to refrain from taking certain actions. A Section 22 Order can be issued when the MOH is of the opinion, based upon reasonable and probable grounds, that:

(a) A communicable disease exists or may exist or that there is an immediate risk of an outbreak of a communicable disease in the health unit served by the MOH.
(b) The communicable disease presents a risk to the health of persons in the health unit served by the MOH and that the requirements specified in the order are necessary in order to decrease or eliminate the risk to health presented by the communicable disease.

(c) A Section 22 Order may specify the time or times when or the period or periods of time within which the person to whom the order is directed must comply with the order R.S.O. 1990, c.H.7, s.22(3).

12.1.2 Situations in which a Section 22 Order would be Appropriate to Control and/or Treat Tuberculosis:
The following situations illustrate (but do not limit) the situations appropriate for issuing a Section 22 Order.

- Explicit refusal or demonstrated inability to comply with isolation measures as directed by the attending physician and/or Public Health staff during the period of communicability;
- Explicit refusal to co-operate in providing names and contact information for identifiable household and close non-household contacts;
- Explicit refusal to comply with medical appointments and/or diagnostic tests as recommended by the attending physician or other specialist involved in the client’s care;
- Explicit refusal to comply with taking anti-tuberculous medication therapy as prescribed;
- Explicit refusal to comply with directly observed therapy arrangements;
- Explicit refusal, by a symptomatic contact, to follow-up with a physician to rule out active TB disease; and/or
- Explicit refusal, by parents of a child contact, to follow-up with a physician to rule out active TB disease.

12.1.3 Provisions which may be included in a Section 22 Order
Pursuant to Section 22(4), an order pertaining to a communicable disease, may include, but is not limited to, the following:

(a) Requiring the person to whom the order is directed to submit to an examination by a physician and to deliver to the MOH a report by the physician as to whether or not the person has a communicable disease or is or is not infected with an agent of a communicable disease;
(b) Requiring the person to isolate himself/herself and remain in isolation from other persons until such time the person is deemed non-infectious;
(c) Requiring the person who has or may have TB (a virulent disease) to immediately place himself/herself under the care and treatment of a physician, and to attend medical appointments and appointments with public health departments (i.e. DOT appointments);
(d) Requiring the person to comply with taking the prescribed anti-tuberculous medication therapy;
(e) Requiring the person to identify all contacts and provide comprehensive contact information;

(f) Requiring the person to conduct himself/herself in such a manner as not to expose another person to infection; and/or,

(g) Any other requirement that will decrease or eliminate the risk of tuberculosis infection to the public.

Pursuant to subsection 22 (5) of the HPPA, an order may be directed to a person or a class of persons who reside, or are present in the health unit served by the MOH. Notice of the Order made to a class of persons must be delivered to each member of the class where it is practicable to do so in a reasonable amount of time, pursuant to Section 22(5.2) of the HPPA.

12.1.4 Process for Completing the Section 22 Order

Once reasonable measures to obtain voluntary compliance are attempted, the TB Control program manager/designate and the case investigator in consultation with the MOH/designate and legal services should prepare the Order for the signature of the MOH/AMOH. A copy of the signed Order should be included in the client’s file. (Refer to Section 22 Template). A Section 22 order should:

- Contain the full name (ensure correct spelling), date of birth and most current address of the individual to whom the Order is being issued;
- State the reason(s) why the Order is being issued; include all the measures that were taken by the health department to obtain voluntary compliance;
- Include the specifics of the evidence (e.g. chest x-ray results, laboratory results and dates of these tests) identifying that the individual has or is suspected of having a communicable, virulent disease;
- Detail action to be taken and in what time frame; and
- Clearly identify what is expected of the person with regard to action and time frame; for example: person to keep appointment with Dr. X at (specified street address) on (specified date and time). Please note: specific details and the requirements are important here.
- Inform the person that he/she has the right to a hearing before the Health Services Appeal and Review Board (HSARB) (HPPA Section 44).

12.1.5 Process for Serving the Section 22 Order

Whenever possible, public health staff should serve the Section 22 Order in person to explain and discuss the Order’s requirements. A process server may also be engaged by the health department to serve the Section 22 Order in circumstances where the address of the client being served is known.

If it is not possible to serve the Order personally by health unit staff, then it may be sent by regular mail. An Order issued by regular mail is effectively served on the seventh day after the date of mailing. Health unit staff must contact a person who has been served an order by mail, to ensure that he/she understands the Order.
12. Use of Orders under the Health Protection and Promotion Act to Control Tuberculosis

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12.1 Section 22 Orders

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If a client has difficulty understanding English, the services of a professional interpreter (not a family member) should be used to ensure that the person understands the contents of the Order.

The Order takes effect on the date it has been served, even if there is a request for a hearing by the individual to whom the Order is directed.

12.1.6 Non-Compliance with a Section 22 Order

Any person who fails to obey an Order made under the HPPA is guilty of a provincial offence and upon conviction, may be liable to a fine of up to $5000 for every day or part of a day on which the offence occurs or continues R.S.O. 1990, c.H.7 s.101(1).

Appeal Process

Health Services Appeal and Review Board (HSARB) is a tribunal of record and all written documentary evidence is available to anyone who is a party to the proceedings. Any person against whom an order is issued must be informed of his/her right to appeal R.S.O. 1990, c.H.7 s.44(1).

- The person may request a hearing by the Health Services Appeal and Review Board (HSARB) by written notice to the MOH within 15 days after the Order is served. Anyone served with an order by a MOH can request a hearing from the HSARB.
- The hearing must occur within fifteen working days after receipt by the Board of a notice requiring the hearing.
- Although the Order takes effect when served, a person who requests a hearing may seek a stay of the Order from HSARB to prevent the Order from taking effect until the hearing has taken place and a determination has been made as to its validity.
- The person may appeal the decision of the HSARB to Divisional Court and that right to appeal is broad, allowing the Divisional Court:
  - To confirm, alter or rescind the decision of HSARB;
  - To exercise all of the powers of HSARB to confirm, alter, or rescind the Order as the court considers proper; or
  - To refer the matter back to the HSARB for re-hearing in whole or in part, as the court considers proper.

In situations where there is non-compliance with a Section 22 Order:
Legal services should be consulted to determine if further action is warranted, which may include but is not limited to:

- Issuing another Section 22 Order
- Fine (HPPA Section 100)
- Initiating a proceeding to restrain the contravention (HPPA Section 102)
- Making an application for an Order by the Ontario Court of Justice – Section 35 Order
12.2 **Section 35 Order: Order by the Ontario Court of Justice**

When a person who has a communicable disease that is designated as a virulent disease, and continues to pose an infectious disease risk, such as TB, and fails to comply with a Section 22 order requiring the person to:

(a) Isolate themselves and remain in isolation from other persons;
(b) Submit to an examination by a physician;
(c) Place themselves under the care and treatment of a physician; and/or
(d) Conduct themselves in such a manner as not to expose another person to infection,

the MOH may apply to a judge of the Ontario Court of Justice to issue an order under Section 35 of the HPPA.

**12.2.1 Contents of a Section 35 Order**

Under Section 35, a judge may order that the person who has failed to comply with the Section 22 order of the MOH:

(a) To be taken into custody and admitted to and detained in a hospital or other appropriate facility named in the order;
(b) To be examined by a physician to ascertain whether or not the person is infected with an agent of a virulent disease; and
(c) To be treated for the disease if found, on examination, to be infected with an agent of a virulent disease.

A Section 35 order is valid only if it is signed by the judge. Section 35 orders are often signed by the court at the conclusion of the Section 35 application and provided to legal counsel for the MOH and the respondent.

A copy of the Order should be served on the respondent.

The order to detain someone in a hospital or other facility takes effect when the order is served. The person may be detained for not more than four months R.S.O. 1990, c.H.7, s35(7) however the order may be extended by a judge following an application for extension by the MOH.

The MOH in the health unit where the hospital (or other facility) is located must apply to the Ontario Court of Justice to extend the period of detention. The judge must be satisfied that the person continues to be infected and that discharging him/her from hospital would present a significant risk to the health of the public R.S.O. 1990, c.H.7 s35(11).

---

**Any MOH considering an order under Section 35 should advise the TB Control Program, Ontario Ministry of Health and Long-Term Care (MOHLTC).**
12.2.2 Procedures for a Section 35 Order
When considering a Section 35 order, the health unit should:

(a) Clearly document the patient’s failure to comply with a Section 22 order.
(b) Discuss the situation with a legal representative for the health unit who is familiar with the provisions of the Health Protection and Promotion Act.
(c) Discuss the decision to proceed with a Section 35 application with the TB Control Program, Ontario MOHLTC.
(d) Identify a hospital that meets the following criteria:
   ▪ Can provide the required medical care/expertise and treatment;
   ▪ Has a secure bed where the patient may be kept without the possibility of leaving; and,
   ▪ Can provide negative pressure ventilation.

A judge may not sign an order unless s/he is satisfied that the hospital is able to provide detention, care and treatment. Therefore, it is critically important to discuss the security, care and treatment arrangements with hospital administration and the attending physician before applying for the order.

West Park Healthcare Centre (WPHC) is the only provincially-designated in-patient treatment facility for complex TB patients. It is also the only healthcare facility in Ontario that is able to detain persons with TB that are held under a Section 35 Order under the HPPA. Please refer to Chapter 13 for details of admitting a patient who is under a S. 35 order to WPHC. WPHC will only admit patients during the week during business hours. If a patient is apprehended under a S.35 order outside of these times, the health unit will have to make alternative arrangements to detain and isolate the patient until WPHC is able to admit him/her.

(e) Prepare the Section 35 application. Ensure that a lawyer knowledgeable about Section 35 orders prepares the application and has the relevant information on the case from the patient’s chart and from the professionals involved to draft the application. This may be done in consultation with public health unit lawyers who are experienced in preparing orders under the HPPA.

12.2.3 Serving and Enforcing a Section 35 Order
Any notice, order, or other document under the HPPA is sufficiently given, served or delivered if delivered personally or sent by ordinary mail addressed to the person at the person’s last known address.

A process server can also be engaged by the health department to deliver the Section 35 Order in circumstances where the address of the client being issued is known. Section 35 orders may also be directed to a police force to do what is reasonably necessary to locate, apprehend and deliver the person in accordance with the order. Health units may request the police to escort the patient to the hospital or other facility.
To ensure a smooth patient transfer:

(a) Speak with the police prior to bringing the court application and advise their assistance may be required.

(b) Provide a copy of the signed order to the police.

(c) Ensure that police personnel take appropriate infection control measures.

(d) Ensure that all parties are aware e.g. the MOHLTC, Toronto Public Health (if applicable) and West Park Healthcare Centre (WPHC). A teleconference is very useful to inform all involved.

### 12.2.4 Appealing a Section 35 Order

Section 35 applications take priority over appeals before the HSARB. An appeal before the HSARB is stayed if the subject matter of the appeal is elevated to a Section 35 application however the order remains in effect pending the judge’s decision in appeal.

### 12.2.5 Extending a Section 35 Order/Certificate of MOH

A Section 35 order is in force for a period of up to four months from the date it is served. It may be extended by a judge, upon application by the MOH serving the health unit in which the hospital or appropriate facility is located. An order may be extended if the court is satisfied that:

- The person continues to be infected with an agent of a virulent disease; and,
- The discharge of the person from the hospital or appropriate facility would present a significant risk to the health of the public [HPPA 35 (11)].

A Section 35 order may be extended for not more than four months. Further motions to extend the order may be brought by the MOH who has jurisdiction where the person is detained. These extensions must not exceed four months.

A MOH having jurisdiction where the individual is detained may release a patient from the hospital or other facility prior to the expiry of the order. An attending physician does not have this authority.

The release and early discharge of the individual is authorized by a Certificate of the Medical Officer of Health provided two conditions are met:

1. The individual is no longer infected; and.
2. The individual does not present a significant risk to the community.

Before discharging a patient from hospital, notify the MOH of the health unit where the patient will reside after discharge to ensure continuity of care and follow-up. If the person is in WPHC, see Chapter 13: West Park Healthcare Centre concerning discharging a patient from WPHC under a Section 35 order.
12.3 Appendix A: Sample Health Unit Letter

SAMPLE (CAN BE ADAPTED)
HEALTH UNIT LETTERHEAD

ORDER
Made pursuant to Section 22 of the
Health Protection and Promotion Act, R.S.O. 1990, c.H.7

(DATE)

(PATIENT NAME)
(ADDRESS)

I, DR. _______________________, MEDICAL OFFICER OF HEALTH (or delegate) FOR THE CITY OF ____________________, ORDER YOU TO COMPLY WITH THE FOLLOWING ACTIONS:

1. Attend (West Park Healthcare Centre/TB clinic/physician’s office) and submit yourself to an examination by Dr. (Name), insert specific date and time as recommended by the (Name of) Public Health Department, and cooperate fully with the recommended investigation and treatment for your (multidrug resistant or pulmonary tuberculosis), and

2. Conduct yourself in such a manner as not to expose another person to infection from a communicable and virulent disease, namely tuberculosis, by following instructions given to you by the nursing and medical staff at (Name of Facility) and/or (Name of Health Unit) TB staff, and

3. That you continue to be treated by Dr. (Name) including submitting to any diagnostic tests deemed to be necessary by Dr. (Name) or his/her delegate, in order to assess whether your pulmonary tuberculosis is/has/had again become infectious, as a result of your failure to comply with antituberculous therapy; and

4. That you continue to report each week, by …….a.m., on each day of treatment to the (Public Health and Community Services Department or specify location) for directly observed therapy for your tuberculosis at the frequency prescribed by Dr. (Name) or his/her delegate until your treatment regimen has changed and Directly Observed Therapy (D.O.T.) can be reduced. Your treatment will not be considered completed prior to (month/year) unless explicitly stated by Dr. (Name) or his/her delegate. If therapy is required beyond this date according to the judgment of Dr. (Name) or his/her delegate, you must continue to comply with the recommended treatment; and

5. That you provide the staff at the (Public Health Department) as well as staff at the (TB clinic/treating physician’s office) with complete and up-to-date information regarding your current address and telephone number at least 72 hours prior to move, and that you continue to update this information in the event of future changes so long as you are requiring therapy for active pulmonary tuberculosis (as per (__) above); and
6. That as long as you are considered to require therapy for active pulmonary tuberculosis (as per (__) above), you inform staff at the (Public Health Department) as well as staff at the (TB clinic/treating physician’s office) of any and all plans to travel outside the City of (Name of City), at least 72 hours prior to departure, that would prevent your receipt of antituberculous therapy according to section (__) above, and to develop a plan, acceptable to public health, for treatment while away, including providing said staff with a means of contacting you while you are outside of the City; and

7. Isolate yourself at home, do not go to work, do not have visitors come to your home until you are advised by (Public Health Department staff or attending physician Dr. .. or delegate), that your pulmonary tuberculosis no longer poses a risk to others; and

8. Do not leave (West Park Healthcare Centre or other treatment facility) to which you may be transferred until you are advised by (Public Health Department staff or attending physician Dr. ..) that your multi-drug resistant pulmonary TB or pulmonary TB no longer poses a risk to others.

THE REASONS FOR THIS ORDER ARE THAT:

1. Based on medical examinations and laboratory evidence, including that outlined below, you have a communicable and virulent disease, namely active pulmonary tuberculosis:
   - Many/Moderate/Few AFB (acid fast bacilli) in a sputum sample obtained from you on (Date), and laboratory results received (Date) that report the presence of MTBC Complex; sensitive to all first line drugs or resistant to (Name of Drugs).
   - An initial chest x-ray on (Date) showed bilateral pulmonary infiltrates, one infiltrate occupied the (Location). There was evidence of cavitation within the infiltrate. There was also an additional infiltrate within the midzone of the left lobe.
   - Medical assessments completed by (TB clinic/Physician/Infectious Disease Services) at the (Name of Facility) resulting in a diagnosis of active pulmonary tuberculosis (date) and consequent isolation and treatment with a full-regimen of anti-tuberculosis medication from (Date) to (Date) while in hospital.

2. Since your diagnosis, I have received reports pursuant to the Health Protection and Promotion Act indicating that:
   - A repeat chest x-ray taken on (Date) showed bilateral pulmonary infiltrates with two ill-defined cavities in the right upper lobe. The upper cavity measures 4 cm in greatest dimension and the lower one 5 cm in diameter. As per the radiology report, all the changes represent active tuberculosis with bronchogenic spread.
   - Upon follow-up by the public health nurse (PHN) managing your case, the importance and necessity of your full compliance with medical follow-up and appropriate antituberculous drug therapy was explained to you. You failed to comply with D.O.T. as noted by the following:
     - Your failure to attend DOT (Directly Observed Therapy) appointments at (Location) on (Provide Dates).
   - On (Date/s), you could not be reached at your address by telephone or in person.
   - On (Date), you were advised by (Physician’s name) of your diagnosis of tuberculosis, started on TB medication and informed to isolate yourself at home until you were deemed no longer infectious.
(e) On (Date/s) health department TB staff was informed that you had gone to work even though you were informed that you were infectious and therefore posed a risk to others.

3. The nature of your disease requires that you be treated for a prolonged duration with multiple drugs to which the infecting organism is susceptible. The required duration of therapy for your disease has been estimated by Dr. (Name), a physician expert in the treatment of tuberculosis, to be approximately ...... months. Premature interruption of therapy, as represented by your failure to attend DOT appointments at the Health Department, poses the following risks to persons in the health unit that I serve:

(a) Because your active pulmonary tuberculosis is not completely treated, it is considered possible that your disease will reactivate, and that you will become infectious to those around you. The likelihood that you pose a risk to those around you increases as your time without medical therapy increases; and

(b) Because of your failure to arrive at the Health Department for scheduled DOT appointments and the possibility that on those days you are not taking your TB medication, it is possible that infection transmitted by you would be resistant to the antituberculous agents that you have been receiving namely Isoniazid and Rifampin, two of the most powerful medications in the control of tuberculosis.

THIS MEDICAL OFFICER OF HEALTH is of the opinion, on reasonable and probable grounds:

1. That a communicable disease exists, or may exist, or that there is an immediate risk of an outbreak of a communicable disease in the health unit served by me; and

2. That the communicable disease presents a risk to the health of persons in the health unit served by me; and

3. That the requirements specified in this order are necessary in order to decrease or eliminate the risk of transmission of this communicable disease from you to others.

NOTICE

TAKE NOTICE THAT you are entitled to a hearing by the Health Services Appeal and Review Board if you deliver to me and to the Health Services Appeal and Review Board, 151 Bloor Street West, 9th Floor, Toronto, Ontario, M5S 2T5, notice in writing, requesting a hearing within 15 days after a copy of this Order is served on you.

AND TAKE FURTHER NOTICE THAT although a hearing may be requested, this Order takes effect when it is served upon you.

FAILURE to comply with this Order is an offence under the Health Protection and Promotion Act R.S.O. 1990, for which you may be liable, on conviction, to a fine of not more than $5,000.00 for every day or part day on which the offence occurs or continues to occur.

__________________________________
Name and Designation of Medical Officer or Health or Delegate
Medical Officer of Health
Name of Public Health Department
OFFICE USE ONLY:

Served upon: ________________________________________________________________

Time: ____________________ On: __________________________________________

Hand delivered by: ________________________________________________________
13. West Park Healthcare Centre (WPHC)

13.1 Introduction

Toronto’s West Park Healthcare Centre Tuberculosis Service is the only provincially-designated inpatient treatment facility for complex TB patients. It is also the only healthcare facility in Ontario that is able to detain persons with TB that are held under S. 35 orders under the HPPA.

The types of patients that are usually seen at WPHC would include persons who:

- Have a multi-drug resistant form of TB (MDR TB);
- Are co-infected with TB and HIV or other complex medical conditions;
- Have experienced side effects from TB medication and are unable to take regular first-line TB drugs;
- Are not responding to treatment;
- Have had a Section 35 order served to them under the Health Protection and Promotion Act (HPPA) to be confined to hospital under guard; and/or
- Live in congregate settings or who are under-housed (i.e. homeless persons).

West Park Healthcare Centre is located at:
82 Buttonwood Avenue,
Toronto, M6M 2J4
Telephone Number: (416) 243-3600
Fax Number: (416) 243-8947
13.2 West Park Healthcare Centre’s Admission Policy

13.2.1 For Patients Not Under S.35 Orders

(a) Inpatient
WPHC should have the most up to date and accurate information possible about persons being considered for admission to their facility. The admission form for WPHC is available at www.westpark.org. On the left side of the page click on “Patient Services” and then click on “Admission Forms”. The TB inpatient referral form is located at the bottom of Page 4 on the web site and is also available in Appendix A at the end of this chapter. You may also contact WPHC for admission forms. Once the forms are completed, fax them to WPHC at (416) 243-8947 prior to the patient being admitted.

(b) Outpatient
For outpatient referrals, a physician or public health nurse letter with pertinent information should be faxed to WPH’s Care Coordinator or their nurse practitioner at 416-243-8947.

13.2.1 West Park Healthcare Centre’s Admission Policy For Persons Admitted Under a S.35 Order

It is important that WPHC be notified in advance that a TB patient is being considered for a S.35 order under the HPPA to be detained and treated at the healthcare centre.

The following admission policy ensures that the necessary planning and communication have taken place in order that WPHC can arrange the care and services for TB patients detained there.

1. The Medical Officer of Health (MOH) of the jurisdiction applying for a S.35 order contacts the WPHC TB Service Physician in Charge or delegate and advises of the pending order.

2. The WPHC TB Service Physician in Charge or delegate provides the MOH with the contact information of the TB Service Care Coordinator at WPHC who acts as the single designated contact person for all persons being admitted under a S.35 order.

3. The referring MOH will arrange a teleconference to alert the TB Control Unit of the MOHLTC, Toronto Public Health, the physician currently treating the patient and the TB Service Physician in Charge of the impending admission.

4. A formal intake process is initiated. The referring health unit is advised of the information and documentation required by WPHC to assess whether the TB service is the most appropriate facility to detain and treat the patient at the current time.

5. The information/documentation required to organize a plan of care includes:
   - History of facts leading to the issuing of the S.35 order
   - History of previous TB
   - Patient demographic information (i.e., gender, age)
   - Patient’s first language
   - If the patient is apprehended and is found intoxicated, injured, or in an acute psychiatric state, then assessment at an acute care
facility/emergency room will be necessary to determine the patient's medical stability and immediate need for treatment (injuries, withdrawal prevention). Copies of any relevant information from this assessment must be forwarded to WPHC.

- Patient's housing status/homelessness, current living arrangements, presence of children or elderly persons in the household
- Information on any pre-existing conditions or known history of:
  - Mental illness
  - Cognitive impairment
  - Substance abuse and current management
  - Violent or criminal behaviour.
  - Previous incarceration
- Current mental status and evaluation of any current psychiatric symptoms
- Forensic psychiatric assessment, if indicated
- Patient’s willingness to undergo TB assessment and to take TB medications as prescribed by the WPHC TB Service Physician
- Potential for discharge barriers (e.g. homelessness, financial problems)

The Care Coordinator receives this information and/or documentation and forwards this to WPHC’s TB physician.

6. The WPHC physician:

- reviews this information,
- determines if the patient being served with the S.35 order can be cared for at WPHC, and
- advises the MOH accordingly.

If it is determined that the psychiatric status of the patient cannot be managed appropriately at WPHC, the physician at WPHC will discuss this with the referring MOH so alternative plans can be made.

7. Once the patient is accepted for admission, WPHC is listed as the detaining facility in the S.35 order. The physician at WPHC and the public health unit arrange for the actual admission. A copy of the S.35 order will be faxed then mailed to West Park.

13.2.3 Role of Toronto Public Health (TPH) and WPHC with regard to S.35 Patients

- All patients at WPHC who are under a S.35 order become the responsibility of Toronto Public Health (TPH) as the hospital is within TPH’s jurisdiction. Therefore, if a patient being detained under a S.35 order leaves hospital property without permission, WPHC must notify TPH. TPH will then attempt to locate the patient.

- If located, the patient will be isolated and returned to the hospital. If unable to locate the patient TPH will notify both the health unit who initiated the S.35 order and the Ministry of Health.

- TPH also becomes the health unit responsible for applying for an extension of the order or the rescinding of the order.
Therefore it is essential that TPH be informed and aware of all S.35 order persons being detained at WPH as soon as admission is being considered (see: Admission Policies above). TPH will review S.35 orders that are nearing expiry and arrange extensions of the orders if necessary (in consultation with the originating health unit).
13.3 Discharge Planning for All Patients from WPHC

Discharge planning must begin as soon as a person is admitted to WPHC. Most persons are admitted due to complex medical and/or social problems that render TB treatment more difficult. Discussion with WPHC and the health unit where the patient is going to live after discharge should begin when the patient is admitted so that there is ample time to arrange for the patient’s care once in the community again. The care of complex TB patients can sometimes take a year or more AFTER discharge, so it is important that planning start early to ensure that the person’s treatment after discharge is not interrupted.

Because such care is often complex, it is essential that the MOH of the jurisdiction in which the person is going to reside is:

- Involved with the discharge planning, and
- Agrees to provide the necessary treatment in its jurisdiction.

The patient should not be discharged from WPHC until the accepting health unit is able to make the necessary arrangements for medical follow-up, DOT, housing, etc.
13.4 APPENDIX A: Letter

West Park Healthcare Centre
TB Service
Inpatient Referral Form

Addressograph:

Name of Referring Physician:

Unit Patient Coming From: ___________________________ Unit Tel. #: __________________

Diagnoses:

Reason for Transfer: (Check all that apply)
☐ Infectious and living with at risk individuals
☐ Advanced Disease
☐ Drug Resistance
☐ Drug Toxicities
☐ Co-morbidities
☐ Other: ________________________________

Level of Nursing Care Required:
(Check all that apply)
☐ Independent
☐ Ambulatory. Some assistance needed with ADLs
☐ Non-Ambulatory. Assistance needed with ADLs
☐ Bedridden. Full care required
☐ Behavioural Challenges
### Medications

<table>
<thead>
<tr>
<th>Name</th>
<th>Dose</th>
<th>Date Started</th>
<th>Date of Last Dose</th>
<th>Time of Last Dose</th>
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</tbody>
</table>

**Drug Allergies:** ____________________________________________________________

**First Language:** ____________________________________________________________

**Patient’s English:** None__ Some__ Fluent__

**Interpreter Required?** Yes__ No__

Please complete this form and attach the following documents.

- ☐ Admission History
- ☐ Course in Hospital
- ☐ Copy of MAR
- ☐ Copies of consultants’ reports
- ☐ Chest x-ray/CT scan reports
- ☐ Most Recent Blood Work

**HIV Test Submitted?** Yes__ No__ If yes, date: _________________________

**Result:** Neg__ Pos__ Pending__

**Sputum AFB submitted?** Yes__ No__

If yes, date: ____________________ PHL #(s): ______________

**Treatments:** (Check all that apply)

- ☐ O2 @_____L/minute
- ☐ IV/Saline lock. Date inserted: _______________________
- ☐ G-Tube. Date Inserted: _______________________
- ☐ Formula and Rate: __________________________________
- ☐ Special Diet: _____________________________________
- ☐ Wound Care: _____________________________________
- ☐ Blood Sugar Monitoring: _____X per ______________

Is patient booked for any external appointments in the next 8 weeks?

**Date:** ____________________ **Location:** ____________________

**Reason:**

_____________________________________________________________________

_____________________________________________________________________

_____________________________________________________________________

_____________________________________________________________________

**Other Information:**

_____________________________________________________________________

_____________________________________________________________________
Fax Referral and required documents to:
The Care Coordinator or Nurse Practitioner, at:
(416) 243-8947

Patients will not be accepted for transfer
until referral and required documents are received.

West Park does not accept admissions after 2:00p.m. (14:00h),
Monday to Friday (excluding statutory holidays).
Please make ambulance bookings accordingly.
14. The Quarantining of Persons with Tuberculosis Under the Federal Quarantine Act

14.1 Legislative Background

The Federal Quarantine Act of 1872 is the federal legislation that is designed to prevent the introduction of infectious or contagious diseases into Canada. Under the Quarantine Act, persons arriving in Canada from outside of the country who are suspected of having a disease that could constitute a danger to Canadian public health can be sent for a medical assessment or they can be detained.

For more information with regard to the sections of the Quarantine Act that impact on Tuberculosis management, please see Chapter 1, SS 3.1: Federal Legislation.

14.1.1 Pending Revisions to Federal Legislation: Bill C-12

Bill C-12, the new federal Quarantine Act, received royal assent on May 12, 2005. The intent of this federal public health legislation is to prevent the introduction and spread of a communicable disease in persons arriving in or departing from Canada. This new law will provide the Public Health Agency of Canada (PHAC) with new authorities and modern tools to respond to public health risks.

Bill C-12 will not come into force until new quarantine regulations have been drafted and approved. PHAC anticipates that this legislative process will be completed late fall, 2006.

14.1.1 “Infectious or Contagious” versus “Dangerous” Diseases

A person may be detained under the Quarantine Act, if he/she has any of the five diseases that are deemed to be infectious or contagious. Each of these diseases has a known incubation period. They are as follows:

Table 1: Diseases Deemed to be Infectious or Contagious Under the Quarantine Act

<table>
<thead>
<tr>
<th>Disease</th>
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<tbody>
<tr>
<td>Cholera</td>
</tr>
<tr>
<td>Plague</td>
</tr>
<tr>
<td>Smallpox</td>
</tr>
<tr>
<td>Yellow Fever</td>
</tr>
<tr>
<td>SARS</td>
</tr>
</tbody>
</table>

If a person has a disease that is considered infectious or contagious under the Quarantine Act, he/she can be prevented from entering or leaving Canada.

A dangerous disease is any disease that the federal Quarantine Officer suspects may pose a risk to public health. TB is considered under the Quarantine Act to be a
dangerous disease. If a person has a dangerous disease (i.e., TB), then he/she can only be prevented from entering the country. The person cannot be legally prohibited from leaving Canada.

Under the federal Quarantine Act in Canada, tuberculosis (TB) is considered to be a dangerous disease. It is NOT deemed to be infectious or contagious.
14.2 Management of Persons with Infectious TB Leaving or Entering Canada

14.2.1 Person with suspected or diagnosed TB leaving Canada while still infectious

If the local public health unit is aware that a person with infectious pulmonary TB is planning on leaving the country, the health unit should educate the person and try to persuade him/her to change the travel plans until he/she is no longer infectious. However, if these attempts fail, then the person may continue to plan to travel while still infectious.

There is no jurisdiction under the federal Quarantine Act to prevent a person with infectious pulmonary TB from leaving the country. The local public health unit can use Section 22 and 35 orders under the Health Protection and Promotion Act (HPPA) (See Chapter 12 Use of Orders) to prevent the person from leaving.

- A S.22 order should be prepared and served to the person immediately. The order should clearly specify that the person has infectious TB and is considered to be a public health risk and that the person should not be traveling by public conveyance.

- If the person declares intent to travel despite the S.22 order, the health unit can ask a judge for a S.35 order under the HPPA, as the person is deemed to be a flight risk and a public health risk.

The Tuberculosis Control Unit of the Ministry of Health and Long-Term Care (MOHLTC) should be notified as soon as the health unit considers writing a S.22 order. A teleconference will be arranged by the MOHLTC which will include representatives from the following:

- The local public health unit
- The MOHLTC
- Peel Regional Health Department  
  (Note: Peel is the jurisdiction in which Pearson Airport is located.)
- Toronto Public Health Department if the person requires hospitalization or is to be detained under a S.35 order.  
  (Note: Toronto is the jurisdiction in which both William Osler Hospital, where persons requiring isolation are taken from Pearson Airport, and West Park Hospital are located.)
- Quarantine Station at Pearson Airport or border crossing point that person is expected to use

As each situation is unique, the teleconference allows all concerned parties to be aware of the specific details of the situation and to formulate a plan of action.
If a S.35 order is issued, then the following procedure is used:
1. A copy of the S.35 order is sent to Peel Regional Health Department.

2. Peel Regional Health Department then notifies Peel Regional Police (who also need a copy of the order). This will depend on the unique circumstances in each situation. The procedure of 'who does what' is decided upon during the teleconference.

3. The Quarantine Medical Officer at Pearson can email conveyance operator desk agents to be on the lookout for ‘Person 'X' - for communicable disease reasons' and indicate that this person should not be allowed to leave the country or board the plane. Although the Quarantine Act may not prevent a person leaving Canada with TB, individual airlines may decide not to allow a person with infectious TB to board the plane. Under International Health Regulations, an air carrier should not board a traveler known to be ill with an infectious communicable disease. This action is at the discretion of the airline. Note: although the Quarantine Act cannot prevent a person with infectious TB from leaving the country, a S. 35 order under the HPPA can. The Quarantine Division (NHQ Ottawa) can work with the air carrier industry networks for wider notification if required.

4. If the person is apprehended at Pearson airport, Peel Regional Police or EMS with the support of a Peace Officer would be instructed to bring the person to either William Osler or West Park Healthcare Centre, depending on the situation or when the detention takes place.

14.2.2 Person with suspected or diagnosed TB attempting to enter Canada while still infectious

Persons with infectious TB can detained at a Canadian port of entry under the Quarantine Act. If a traveler is identified as having a communicable disease, or is displaying symptoms of a communicable disease by a public health authority, then the traveler will be assessed at the port of entry by the Quarantine Service and referred for medical examination and treatment.

If the Quarantine Service has been notified and has knowledge of a traveler, ill with a communicable disease wanting to return to Canada, they will work with Foreign Affairs Canada, PHAC, international public health partners and air carriers to ensure the individual has appropriate treatment before traveling on a commercial aircraft.

Outside Canada

PHAC (Quarantine Divison/NHQ) will notify the affected airlines that a person who may pose a public health risk is planning on traveling to Canada. Under International Health Regulations, an air carrier should not board a traveler known to be ill with an infectious communicable disease. This action is at the discretion of the airline. The person may be required to provide documentation that he/she is not infectious (proof that at least two smear negative sputum specimens have been obtained). The Quarantine Division may post an alert in the Border Advance Passenger Notification system through the Canadian Border Agency National Risk Assessment Center- see Algorithm 1.
Arrival at an airport or border crossing in Canada

Algorithm 2 summarizes the steps that can be taken when a person with known or suspected infectious TB attempts to enter Canada at a Canadian airport or border crossing. As stated above, the best course of action is for the parties involved to have an initial planning teleconference.

If advance notification information is available, the Public Health Agency of Canada (PHAC) will alert the MOHLTC that a person with suspected TB is on an aircraft. The MOHLTC will contact all the jurisdictions involved. The teleconference is important for all jurisdictions involved (i.e., PHAC, MOHLTC, Peel Regional and Toronto Public Health Departments, and the destination health unit).
Algorithm 1
Person with infectious TB attempts to enter Canada

MOHLTC notifies PHAC that a person with infectious disease is planning on traveling to Canada.

PHAC communicates with airlines and with health authorities in country where patient currently is residing. PHAC posts an alert with CBSA.
- Person must produce documentation that they are not infectious (usually 3 negative smear specimens or that they have been on an approved TB treatment regimen for at least 2 weeks).
- PHAC sends a letter to the family of the person (if address in Canada is known) or to address where person currently residing outside Canada notifying them of conditions of entry into Canada.

If person deemed to be non infectious
- PHAC notifies MOHLTC who informs health unit
- Once person has arrived in Canada, the health unit arranges for medical follow-up and appropriate case management

If person is deemed to be infectious
- PHAC will work with medical personnel, air carriers, and public health to have the traveler treated before returning to Canada.
- If the person does manage to elude officials in their country of origin they may be detained by Quarantine Officials in Canada – see Algorithm 2.
Algorithm 2:
Person at Canadian Border Crossing with Infectious TB

PHAC is notified that person suspected of having TB is on board plane or at border crossing

Person arrives at Pearson

Person arrives at other border crossing
- PHAC will detain and transport to local hospital
- MOHLTC notifies local health unit

Person not detained at airport or border crossing and arrives home
- Local health unit to manage the case
- MOHLTC will liaise with PHAC and health unit
- Health unit may have to issue orders under HPPA to detain person for diagnosis and treatment

Detained (by PHAC)
- Quarantine Officer will board plane and assess person.
- Quarantine Officer (QO) makes brief announcement to the other passengers and gets contact information in the event contact tracing is needed (2 rows in front and 2 rows behind where TB suspect sat on the plane)

Transported (by PHAC)
- Passenger removed by QO to ambulance (prearranged to be waiting on tarmac)
- Person will be brought to West Park or William Osler Hospital)

Secured (by PHAC)
- Passenger will be secured by a peace officer for 48 hrs. under Quarantine Act. Local public health unit to start proceedings for S. 22 & S.35 orders if infectious.

ROLE OF HEALTH CANADA
- Detains person, transports to hospital and secures under federal Quarantine Act until person is deemed to be non infectious until the local public health unit issues a S. 35 under the HPPA
- Issues statement to the media as necessary

ROLE OF THE MOHLTC
- Communication liaison between PHAC and local public health units

ROLE OF PUBLIC HEALTH UNITS
- Toronto or Peel to obtain a S.22 or S.35 order as necessary under HPPA in order to ensure person is detained and treated as needed
- Contact investigation as necessary
- Arrange for AMTD testing of sputums at William Osler
- Communication between hospital and MOHLTC
- Issue statements to media, as necessary
14.3 Detention under the Federal Quarantine Act

Depending on the situation, PHAC can detain a person with a **dangerous disease** (i.e., TB) under the federal **Quarantine Act** from 48 hours to indefinitely. If PHAC suspects a person with infectious TB is traveling on an airplane or is at a border crossing, they can immediately detain that person for 48 hours until initial test results are obtained. If a longer period of detention is necessary, PHAC can apply for an extension, but this can be a lengthy process. Once the person is safely isolated in hospital, the local public health unit should initiate a S. 22 order (and a S.35 order, if necessary) after consulting with all levels of authority involved.

14.3.1 Examples of Recent Situations

The algorithm above outlines the responsibility of the various levels of authority. However, every situation is unique. This is illustrated in the following situations. They underline the need for communication among all jurisdictions involved to ensure that the necessary interventions are in place to reduce the risk of exposure of infectious TB.

1. MOHLTC notified by PHAC that a person is at Customs at Pearson Airport with an immigration file that indicates that this individual left Canada three years earlier with a diagnosis of untreated infectious pulmonary TB. The MOHLTC verified with the local public health unit that this person had left Ontario when the initial diagnosis of infectious TB was made. The person was now willing to seek immediate assessment and treatment for TB in Ontario. The normal 30-day immigration condition of landing was shortened to one week. The local public health unit arranged for the immediate medical assessment of this person.

2. A person leaves Canada not knowing they have infectious TB. This person saw their local physician who did preliminary tests for cancer of the lung. The patient left for a previously arranged vacation in South America. The next day test results showed that the person had highly infectious pulmonary TB. The local public health unit was able to contact the patient and inform him/her of the diagnosis. PHAC was able to locate a TB specialist in the visiting country and treatment was started immediately. PHAC also arranged for contact tracing on the aircraft for the trip to South America. After the person was on treatment for 3 weeks, the physician treating the patient provided a letter that indicated the person could safely return to Canada. The local public health unit arranged for medical care in their jurisdiction.

3. A person arrived at Pearson airport with several bottles of TB medication that had been prescribed in the country of origin. This person told Customs Agents that he/she had been diagnosed two months earlier with pulmonary TB and had been provided with enough medication for the duration of the visit. The person had no obvious symptoms of TB. PHAC notified the MOHLTC who contacted the health unit where the person was visiting. The health unit made arrangements for the person to be followed by a local TB specialist who confirmed that the person was not infectious and the prescribed medication was appropriate.
14.3 Detention under the Federal Quarantine Act

14. The Quarantining of Persons with Tuberculosis under the Federal Quarantine Act

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(4) A physician in Russia notified the Canadian Consulate in Russia that a person visiting as part of a Canadian tour was suspected of having pulmonary TB. This person became ill during the tour and was brought to the physician who suspected TB after doing a chest x-ray. The person was advised not to proceed on the tour but to remain in isolation, be tested for TB and start treatment at a local hospital. The person declined and left with the tour to return to Canada. PHAC notified the MOHLTC and the person was removed from the plane at Pearson and detained in hospital under guard until TB was ruled out.

(5) A landed immigrant from Ontario with active, untreated, infectious drug resistant TB disease (with cavitary lesion on chest x-ray) left Canada against the attending physician’s advice, and against health unit orders. The MOHLTC notified PHAC. Arrangements were made with the airline that the person shows proof of freedom from TB before being allowed to board the aircraft. The Canadian Consulate in the country of visitation notified this individual of the conditions for returning to Canada. An attempt to return to Canada without the required documentation was unsuccessful. This person was able to return to Canada several months later, once the necessary proof of freedom from infection was produced. This situation required tremendous co-operation among staff of PHAC, the airlines, the MOHLTC and several local public health units.

(6) A patient on treatment for drug resistant TB left Ontario to visit a sick relative in another province – then returned to their country of origin

A person with drug resistant TB pleaded with their physician to be allowed to visit a sick relative in another province. The physician provided two weeks worth of medication to an accompanying family member with instructions on how to observe the administration of the medication (intermittent doses). The person and their family member left for their country of origin. After two weeks the local health unit discovered that the person was not in Canada. They notified the MOHLTC who notified PHAC. PHAC was able to determine which airline the person left Canada on and the expected date of departure to Canada and issued an alert that this person was not allowed to enter Canada without documentation that they were free of infectious TB. A letter was sent by PHAC to the person’s address in Ontario with this information. The relatives in Ontario called the health unit with information where the patient was staying. PHAC provided the family with the name and location of a local physician who would provide TB care. PHAC and the MOHLTC held regular discussions about this situation and monitored the situation closely. Once documentation was provided that stated the person was on adequate treatment and was not infectious, the person was allowed to return to Canada.
15. First Nations and Inuit Health Branch (FNIHB) Tuberculosis Control in Ontario Region

Multi – Jurisdictional Partnerships in Tuberculosis Control

15.1 Introduction

Although health care is a provincial responsibility, First Nations and Inuit Health Branch (FNIHB) of Health Canada is responsible to ensure that the mandatory programs of Communicable Disease Control, Environmental Health and Emergency Response are in place for health protection in First Nations’ communities.

Across Canada, there are seven regions in FNIHB of Health Canada. The province of Ontario, known federally as Ontario Region, is comprised of 134 First Nations communities (population approximately 80,000) and divided into four Zones:

(1) Southern Ontario Zone,
(2) Thunder Bay Zone,
(3) Moose Factory Zone, and
(4) Sioux Lookout Zone.

Each Zone has unique characteristics and challenges regarding geography, demography, health status, and access to services. Each First Nations community receives nursing services by Community Health Nurses (CHN) who are either employed by FNIHB or Band employed by a First Nations community.

For further details as to the Ontario FNIHB regional TB Control program, please contact the FNIHB regional office at (613) 954-8574.
15.2 Epidemiology of TB in Ontario First Nation Communities

First Nations TB rates remain 8 to 10 times higher than overall Canadian rates and 20-30 times higher than Canadian-born, non-Aboriginal rates. Despite this, 2000 national TB case tally of 86 is the lowest ever reported in the First Nations, on-reserve population. The notification rate in 1999 was very high, due to the occurrence of several large outbreaks. Of the areas where Health Canada’s First Nations and Inuit Health Branch (FNIHB) provides TB programs, TB rates are highest in the four western provinces (British Columbia, Alberta, Saskatoon and Manitoba) and in northwestern Ontario (the communities of the Sioux Lookout zone). ¹⁹⁹

¹⁹⁹ FNIHB web page; www.hc-sc.gc.ca; First Nations and Inuit Health; Diseases and Health Conditions; Topics TB.
15.3 Legal Issues

Public health information must often be shared between the province and the federal government. General authority is found in the (Federal) Privacy Act, under section 8. For routine matters, consent (whether verbal, written or implied) is usually required. However, section 8 does provide for situations in which consent is not necessary for example, sharing information about a TB client who lives on a First Nations reserve.

Subsection 8 (a):
- Permits disclosure “for the purpose for which the information was obtained or compiled by the institution or for a use consistent with that purpose”.

Subsection 8 (b):
- Permits “for any purpose in accordance with any Act of Parliament or any regulation made there under that authorizes its disclosure”.

Subsection 8 (m):
- Allows disclosure, where “in the opinion of the head of the institution, the public interest in disclosure clearly outweighs any invasion of privacy that could result from the disclosure or disclosure would clearly benefit the individual to whom the information relates”.

This authority is reinforced by Ontario’s Personal Health Information Protection Act, 1990 further to section 38 which details how personal health information may be disclosed and shared by health information custodians. For example, if it is not reasonably possible to obtain the individual’s consent in a timely manner, this information may be disclosed if it is necessary for the provision of health care to a patient living on a reserve and being cared for by the community nurse, provided the individual has NOT expressly instructed the custodian not to make the disclosure.

In practical terms, this legislation allows disclosure of a client’s personal medical information between FNIHB community health staff and their provincial counterparts, under communicable diseases regulations or on a need-to-know basis for disease control.

When dealing with a challenging case, the CHN and/or attending physician, working in consultation with the TB Control Nurse and the Regional Community Medical Specialist (RCMS) may request the support from the community Chief and Council, elder or family member to influence the individual to cooperate. When all possibilities to encourage cooperation have failed, the Medical Officer of Health (MOH) for each health unit has the authority, in collaboration with the Zone Medical Officer (ZMO) /RCMS, to invoke the Health Protection and Promotion Act (HPPA) (section 22 first, followed by section 35). This provincial legislation provides the legal basis for controlling communicable diseases, including TB.\(^{200}\) The MOH signs and enforces Orders under the HPPA on the reserve.

\(^{200}\) Dr. Roger Johnson, RCMS, Memorandum, The Legality of Sharing Public Health Information Between Federal and Provincial Jurisdictions, April 7, 1997.
15.4 TB Medication

TB medication is available free of charge to people diagnosed with either active TB or LTBI. The medication can be obtained through the local health unit, or in the case of remote isolated communities, through local pharmacies at no charge.
15.5 Communication between Local Health Unit and FNIHB / Community Health Nurses

Communication between the respective federal and provincial partners is essential to ensure the appropriate and complete follow up of active TB cases or LTBI. Many First Nations people who are diagnosed with either active TB or LTBI live both on and off-reserve during their course of treatment and, as such, can easily be lost to follow up. This applies to a non-First Nations individual living on-reserve, e.g., teachers or nurses. Therefore, communication between FNIHB and TB Control staff of the local public health unit is critical.

The follow up of TB cases and LTBI are the same both on and off reserve. FNIHB does not collect TB case and contact information through the provincial iPHIS data base. As such, exchange of information can only occur through verbal or written reports.

All individuals living on-reserve and assessed on-reserve as being TST positive (LTBI) and all probable/suspected and confirmed cases of active pulmonary and extra-pulmonary tuberculosis are to be reported to the respective health unit by the Zone TB Control Nurse as soon as possible.

All individuals living on-reserve and assessed off-reserve as being TST positive (LTBI) and all probable/suspected and confirmed cases of active pulmonary and extra-pulmonary tuberculosis are to be reported by the health unit to the respective Zone TB Control Nurse, who will forward the information to the respective Community Health Nurse.

All infectious cases of active disease living off-reserve but known to have resided for a period of time on-reserve are to be reported to the respective Zone TB Control Nurse.

The mechanism used for reporting is by telephone (especially for active cases) followed by a faxed laboratory report and/or radiological report.
Zones and Public Health Units in Ontario with Regional Ontario Contacts

*Indicates health unit has a First Nation Community within its jurisdictional boundaries*

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<td>Zone TB Nurse: (705) 658-4544 Ext. 2313</td>
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<td><strong>Thunder Bay Zone</strong></td>
<td>Algoma *</td>
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<td>Zone TB Nurse: (807) 343-5353</td>
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<td><strong>Sioux Lookout Zone</strong></td>
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<td>Zone TB Nurse: (807) 737-1802</td>
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<td><strong>Southern Ontario Zone</strong></td>
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<td>Zone TB Nurse: (519) 751-6526</td>
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15.6 Bacille Calmette-Guérin Vaccine (BCG)

BCG vaccination of newborns has been discontinued in most of Ontario’s on-reserve population. The National Advisory Committee on Immunization (NACI) provided new recommendations in December of 2004 to continue the use of BCG only in specific circumstances. At the present time, First Nations communities in Ontario are looking to move towards the discontinuation of this routine vaccination where appropriate in support of these new recommendations. BCG vaccine is presently being used only in northern Ontario First Nations communities.
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