TUBERCULOSIS SURVEILLANCE PROTOCOL FOR ONTARIO HOSPITALS

Developed by the Ontario Hospital Association and the
Ontario Medical Association
Joint Communicable Diseases Surveillance Protocols Committee
In collaboration with the Ministry of Health and Long-Term Care

Approved by:
The OHA and The OMA Board of Directors
The Ministry of Health and Long-Term Care –
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This protocol was developed jointly by the Ontario Hospital Association and the Ontario Medical Association to meet the requirements of the *Public Hospitals Act 1990,* Revised Statutes of Ontario, Regulation 965. This regulation requires each hospital to have by-laws that 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. The communicable disease program is to include the tests and examinations set out in any applicable communicable disease surveillance protocol. The regulation states that the communicable disease surveillance protocols that hospitals must adopt are those "published jointly by the Ontario Hospital Association (OHA) and the Ontario Medical Association (OMA) and approved by the Minister (of Health and Long-Term Care)."

This Protocol has been reviewed since the previous version; changes have been highlighted in yellow for easy identification. Protocols are reviewed on a regular basis, every two years or as required.

The protocol reflects clinical knowledge, current data and experience, and a desire to ensure maximum cost effectiveness of programs, while protecting health care workers and patients. It is intended as a minimum standard that is practical to apply in most Ontario hospital settings. It does not preclude hospitals from adopting additional strategies that may be indicated by local conditions.

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Rationale for Tuberculosis Surveillance Protocol

Globally, tuberculosis (TB) continues to be a major health problem. In 2016 there were an estimated 10.4 million new cases of TB and 1.67 million deaths.[1] An estimated one-third of the world's population is infected with *Mycobacterium tuberculosis*.[1] Canada continues to enjoy one of the lowest reported incidence rates of TB in the world. In a 2018 Health Canada surveillance report, approximately 1600 new cases of active TB disease are reported every year. In 2016, 89% of cases affected 2 main populations: 70% were foreign born and 19% are Canadian born indigenous peoples.[2] In Ontario, there were 671 cases of active TB disease reported in 2017, for an incidence rate of 4.75 per 100,000.[3] Changes in epidemiology, human immunodeficiency virus (HIV) co-infection and emerging drug-resistant strains of TB continue to keep TB control and management a challenge.

The majority of TB cases in Canada are in the foreign born, with the highest TB incidence in persons from African countries with high HIV prevalence. Up to 56% of foreign born cases were from five countries: India, Indonesia, China, the Philippines, and Pakistan.[3] A substantial proportion of the reported foreign-born TB cases in a given year is diagnosed within the first few years of arrival in Canada. The majority of TB cases in Ontario also occur in the foreign-born (89% in 2016[3]). This means the geographic distribution of TB in Ontario follows patterns of immigration. Thus TB is primarily an urban disease with Toronto, Peel, Ottawa, York, and Hamilton public health units being the most affected.[3]

HIV co-infection with *Mycobacterium tuberculosis* was reported to be present in 5% of TB cases in Canada in 2010, but HIV status was reported for only 40% of all TB cases; the true co-infection rate is therefore unknown but is estimated to be between 2 and 5%.[4] Worldwide, TB remains the most common cause of death among HIV-infected individuals, accounting for approximately one-third of HIV/AIDS deaths annually.[1]

The emergence of drug-resistant TB is a major challenge. Globally there were an estimated 490,000 cases of multidrug-resistant TB (MDR-TB) in 2016, defined as resistance to at least isoniazid and rifampin.[1] For the period 2005 to 2015, 178 isolates were classified as MDR-TB by the Canadian Tuberculosis Laboratory Surveillance System representing 1.2% of isolates tested over this time and seven isolates were classified as extensively drug resistant TB (XDR-TB) which is defined as resistance to isoniazid AND rifampin AND any fluoroquinolone AND at least one of the three injectable second-line drugs (amikacin, capreomycin or kanamycin).[5] XDR-TB represents less than 0.1% of the isolates tested. An average of 16 MDR-TB isolates were reported each year, ranging from a low of eight in 2012 (0.6% of all isolates tested in 2012) to a high of 22 in 2005 and in 2015 (1.6% of all isolates tested in each respective year) [5]. These data must be considered in the development of surveillance protocols for health care workers (HCWs).

All health care facilities must have a TB management program.[6] The program must be supported at the highest administrative level. Health care facilities should establish policies and procedures in collaboration with local public health authorities to develop a comprehensive regional TB program. Transmission of TB to other patients or HCWs remains a potential risk in Canadian health care institutions where patients with active TB

are admitted. In addition, HCWs may themselves have emigrated from high-TB-incidence countries and have untreated latent TB from prior exposure, placing them at risk of reactivation with active TB disease.

Surveillance of HCWs for TB depends both on knowledge of baseline tuberculin skin test (TST) status and a high level of compliance with the program. Frequency of screening depends on the number of active TB cases in the hospital site, the likelihood of a HCW's exposure (dependent on the type of work done by the HCW), and the TST conversion rate among staff.[6] The goal of screening and ongoing surveillance is to identify HCWs with latent TB infection (LTBI) who are at increased risk of developing active disease, and who may benefit from treatment.

M. tuberculosis infection is acquired through the respiratory route and anyone found to be infectious may already have infected others. TB is an airborne disease, with face-to-face contact considered significant in its transmission. Patients with pulmonary or laryngeal TB are infectious; pulmonary involvement must always be ruled out even for patients who present with extra-pulmonary TB. At the time of patient diagnosis, HCWs who may have been exposed to an infected individual must be identified and monitored for development of infection by the Occupational Health Service (OHS). HCWs who were previously TST negative are best monitored with the TST. For this screening to be useful, the OHS must know whether the person was truly positive or negative in the past. This protocol continues to emphasize the use of the two-step TST for initial testing.[7] The two-step test reduces false positive reactions that may be due to the "booster effect" and thereby provides more reliable baseline data, so that later conversion can be confidently diagnosed. For a more detailed discussion of the method of doing a two-step test, refer to the Glossary.

Blood tests which measure interferon-γ (interferon-γ release assays, IGRAs) can be used to diagnose LTBI, particularly in persons who have received Bacille Calmette-Guerin (BCG) vaccine in whom a TST may be difficult to interpret.[8] This is particularly true if BCG was administered after one year of age, or repeatedly.[7] IGRAs may be used to confirm a positive TST in a HCW who is thought to have a low probability of TB infection.[7,8] They should be used in consultation with a physician with experience and expertise in diagnosis and management of TB. IGRAs are not recommended for serial testing of HCWs due to high conversion and reversion rates that are unrelated to exposure or therapy, and difficulty interpreting test results. [8,9] Thus the TST remains the standard for use in OHS in hospitals.[7]

Routine chest X-rays are not recommended for TB surveillance. The emphasis is on the need for dependable baseline data, including accurate, reliable, consistent recording of TST results in millimetres of induration, the use of a two-step TST where appropriate, and aggressive follow-up of TB contacts.

Individuals with positive TSTs are likely to have some degree of immunity to infection with TB from an exogenous source.[10] Their greatest risk of development of active disease is from reactivation of their own inactive TB infection, but reinfection is possible. LTBI treatment should be discussed and facilitated for HCWs with positive TST results identified at the initial evaluation, and if exposed to an infectious TB case. They should be educated

about the symptoms that might indicate active disease, and be advised to seek prompt medical attention if these occur.

This protocol is only one component of an infection prevention and control program; HCWs must consistently adhere to Routine Practices. Hospitals must emphasize proper patient care techniques (e.g., using Airborne Precautions suspected or confirmed active TB cases in airborne infection isolation rooms) and worker education about significant symptoms that should be communicated to the OHS, rather than depending solely on results of routine TSTs. Regularly scheduled maintenance of ventilation and air filter systems in health care facilities, and regular testing of Airborne Infection Isolation Rooms (AIIR) are required under the Occupational Health and Safety Act, Ontario Regulation 67/93, Health Care and Residential Facilities.[11] Regular evaluation and reporting of the effectiveness of the TB surveillance program is essential.

Tuberculosis Surveillance Protocol for Ontario Hospitals

Developed by
The Ontario Hospital Association and The Ontario Medical Association
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I. Purpose

The purposes of this protocol are to:

i. provide direction to hospitals in conducting a tuberculosis (TB) surveillance program based on risk for the institution and for the health care workers(HCW) , in accordance with the 2014 Canadian Tuberculosis Standards of the Canadian Thoracic Society (Canadian Lung Association) and the Public Health Agency of Canada;

ii. aid in identification of HCWs who may be infectious with, or may become infectious with, TB; and

iii. establish a system that would allow for the identification and prevention of TB through evaluation and follow-up of close contacts of active cases, in order to identify secondary cases and to provide therapy for latent TB infection (LTBI).

The infected HCW's personal health care provider and the local Medical Officer of Health are responsible for follow-up investigation, care and therapy.

II. Applicability

This protocol applies to **all HCW carrying on activities in the hospital**, including employees, physicians, nurses, contract workers, students, post-graduate medical trainees, researchers and volunteers. The term health care worker (HCW) is used in this protocol to describe these individuals. This protocol does not apply to patients or residents of the facility or to visitors.

When training students or hiring contract workers, the hospital must inform the school/supplying agency that the school/agency is responsible for ensuring that their student/contractors are managed according to this protocol.

This protocol is for the use of the Occupational Health Service (OHS) in hospitals. It is expected that OHS collaborate with Infection Prevention and Control and other departments, as well as local public health tuberculosis programs as appropriate.

III. Preplacement

The importance of conducting proper baseline TST for all potentially exposed HCWs in all health care settings cannot be overemphasized.[6] The TST should be administered by trained staff in a setting where the HCW can be observed for 15 minutes and staff are trained to deal with anaphylactic reactions (with epinephrine 1:1000 available). TST results must be read by trained staff 48-72 hours after being administered.

The following should be done pre-placement/pre-appointment, or within 14 days of that time, to provide an accurate baseline.

a) Unknown or Previous Negative TST

HCWs whose TST status is unknown, and those previously identified as TST negative, regardless of history of BCG vaccine, require a baseline two-step TST (See Glossary), provided no contraindications to TST exist, unless they have:

- documented results of a prior two-step test; OR
- documentation of a negative TST within the last 12 months; in which case a single-step test may be given.

Interpretation of Size of Tuberculin Skin Test
(Adapted from the Canadian Tuberculosis Standards Table "Interpretation of tuberculin skin test results and cut-points in various risk groups"[7])

TST result	Situation in which reaction is considered positive*
0-4 mm	In general this is considered negative, and no treatment is indicated.
≥5 mm	HIV infection
	Contact with infectious TB case within the past 2 years
	Presence of fibronodular disease on chest x-ray (healed TB, and not previously treated)
	Organ transplantation (related to immune suppressant therapy)
	TNF alpha inhibitors
	Other immunosuppressive drugs, e.g. corticosteroids (equivalent of ≥15 mg/day of prednisone for 1 month or more; risk of TB disease increases with higher dose and longer duration)
	End-stage renal disease
≥10 mm	All others, including the following specific situations: – TST conversion (within 2 years) – Diabetes, malnutrition (<90% ideal body weight), cigarette smoking, daily alcohol consumption (>3 drinks/day) – Silicosis – Hematologic malignancies (leukemia, lymphoma) and certain carcinomas (e.g. head and neck)

*The goal of testing for LTB is to identify individuals who are at increased risk for the development of tuberculosis and therefore would benefit from treatment of LTB. Only those who would benefit from treatment should be tested, so a decision to test presupposes a decision to treat if the test is positive (see text).

b) Positive TST, or TST Contraindicated

For HCWs who are found to be TST positive in (a), medical assessment should be performed by OHS under the direction of a physician, or by the HCW's personal health care provider. Assessment should include a history of risk factors for TB, symptoms of active TB disease, and a chest X-ray. In the absence of active TB disease, a referral should be facilitated for assessment of and treatment for LTBI.

For HCWs who are known to be previously TST positive, or for whom TST is contraindicated (see below), further assessment should be done by the OHS under the direction of a physician, or by the HCW's personal health care provider.

Certain medical conditions predispose persons infected with *M. tuberculosis* to develop active disease (See Glossary). Treatment of LTBI should be considered in individuals with these conditions who are TST positive and have not had previous treatment of LTBI. **Active TB must be ruled out before treating LTBI.**

All HCWs with a positive TST should be advised to report any symptoms of pulmonary TB (See Glossary) to the OHS, and should be managed using current guidelines.

c) Contraindications to TST:[7]

- history of severe blistering reaction or anaphylaxis following the test in the past
- documented active TB
- clear history of treatment for LTBI or active TB in the past
- extensive burns or eczema over the testing site (use an alternate site)
- major viral infection (note that a HCW with a common cold may be tested)
- live virus vaccine in the previous 4 weeks

A history of Bacille-Calmette-Guerin (BCG) vaccine is **not** a contraindication to a TST. HCWs who have had BCG vaccine may still be at risk of infection.

Note: BCG vaccination is an unlikely explanation of a positive TST if BCG was given in infancy.

NOTE: Pregnancy is NOT a contraindication to a TST.

d) Chest X ray

A chest X-ray should be taken on any HCW who has:

- never been evaluated for a positive TST;
- had a previous diagnosis of TB but has never received adequate treatment for TB; or
- pulmonary symptoms that may be due to TB. In this situation, three sputum specimens obtained at least one hour apart should also be sent for acid fast bacilli (AFB) smear and culture.[12]

If the X-ray suggests pulmonary TB, the HCW should be evaluated by the OHS under the direction of a physician to rule out the possibility of active TB. Documentation of the results of this evaluation should be in place before the HCW is cleared for work.

For HCWs who have previously been assessed for a positive TST and have a documented CXR on file, there is no need to repeat the CXR unless clinically indicated.

e) Fit Testing

As part of a comprehensive respiratory protection program, HCWs who may, in the course of their duties, provide direct care to patients with active pulmonary TB must receive fit testing for a N95 respirator and instruction in its use, including performing a seal check with each use. HCWs who cannot be fit tested should not provide care for patients with suspected or confirmed active pulmonary TB. Refer to the Canadian Standards Association standard (CSA Z94.4-02).[13]

IV. Continuing Surveillance

a) Periodic TSTs

The frequency of ongoing TST surveillance for TST negative individuals depends on the health care facility's risk (that is, the number of patients with TB seen annually), and the person's activity risk within the facility.[6]

Annual TSTs should be performed on all HCWs (with negative baseline TSTs) who perform high risk activities in any healthcare facility, and those in healthcare settings that are not considered low risk who perform intermediate risk activities.[6] Follow individuals for whom TST is contraindicated and those known to be TST positive clinically, at intervals as per the table below.

FREQUENCY OF ONGOING HEALTH CARE WORKER SURVEILLANCE FOR TB [6]

Activity Risk	**Health Care Facility Risk** (site specific*)	
	Not considered low • ≥ 200 beds and ≥ 6 active TB cases present annually **or** • < 200 beds and ≥ 3 active TB cases present annually	Low • ≥ 200 beds and < 6 active TB cases present annually **or** • < 200 beds and < 3 active TB cases present annually
High	annually and post-exposure	annually and post-exposure
Intermediate**	annually and post-exposure	post-exposure
Low	post-exposure	post-exposure

* In health care facilities with more than one physical site, the risk should be

assessed separately for each site.

High-risk activities[6] include cough-inducing procedures such as sputum induction, bronchoscopy, administration of aerosolized therapies, respiratory therapy, chest physiotherapy, autopsy, morbid anatomy and pathology examinations, bronchoscopy and designated mycobacterium laboratory procedures (manipulation of *M. tuberculosis* cultures.)

Intermediate risk activities[6] include the activities of HCWs who have regular direct patient contact on units (such as emergency departments) where patients with respiratory TB disease may be present, including support personnel (e.g., housekeepers, clerks, receptionists, dietary, maintenance).

Low risk activities[6] include the activities of HCWs who have minimal patient contact (such as clerical, reception and administration staff), or work on units where patients with respiratory TB disease are unlikely to be present (e.g., obstetrical, nursery or neonatal workers). Classification of such units as low risk may be inaccurate if the population they are serving has a high incidence of TB (e.g. patients born or previously residing in countries with a high TB incidence or other at-risk populations). Some of the longest delays in diagnosis may occur in such settings.

Note: As per the Canadian Tuberculosis Standards,[6] after 2 or more years of annual screening, if the annual risk of infection (based on the TST conversion rate in those screened) is shown to be less than 0.5%, consideration could be given to reducing the frequency of screening to every other year or to developing criteria that restrict annual screening to fewer workers who are at higher risk, and not testing the remaining workers except after exposure.[6]

V. Exposure to Active Tuberculosis

Any HCW who has had unprotected contact with a person with active respiratory TB in hospital, i.e. without wearing a fit-tested, seal-checked N95 respirator, should be considered potentially exposed and must be actively investigated by the OHS and reported to the local PHU[15].

Potential for transmission must be assessed on a case-by-case basis. When deciding whether a person has had a significant exposure to a potential transmitter, consideration should be given to the following:

- the frequency of patient contact;
- the proximity to patients involved;
- the duration of face-to-face contact;
- the use of personal respiratory protective devices (i.e., fit-tested, seal-checked N95 respirator);
- the number of air changes per hour in the area of exposure, and
- infectiousness of the contact patient

Risk of transmission is highest from an individual with active pulmonary or laryngeal TB disease, whose sputum shows AFB on smear, has cavitary or extensive

pulmonary disease, who has been treated with appropriate chemotherapy for ≤ 2 weeks (or for > 2 weeks without clinical response), or is undergoing a cough inducing procedure (e.g. sputum induction, bronchoscopy). TB patients who are AFB smear negative but who are coughing may also transmit. TB patients who are also infected with HIV or who have a drug resistant strain of *M. tuberculosis* may transmit for longer. Transmission may also occur during open suctioning of intubated patients and during surgical or other wound irrigation of tuberculous lesions.

a) Perform a single TST 8 weeks after exposure (i.e. contact without adequate protection) for TST-negative HCWs exposed to people with respiratory TB disease.[6]

b) Previously TST-positive HCWs exposed to people with respiratory TB disease (without adequate protection) should be assessed and educated on signs and symptoms of active TB disease.

VI. HCWs who Convert to TST Positive

TST Conversion on Routine Screening

A converter is defined as an individual whose TST changes from "negative" (usually induration of 0-4 mm in diameter) to "positive" (usually induration of ≥10 mm in diameter) within 24 months.

For HCW with previously documented induration between 5-9 mm, any increase of induration ≥ 6 mm diameter is considered a TST conversion.[7] (See also section III for interpretation of TST in particular clinical circumstances.)

TST Conversion Following Known Exposure

When testing is done as a result of a known contact with a potential transmitter, a person with no previous induration who has a reaction of ≥ 5 mm induration should be considered to have acquired LTBI, and treatment of LTBI should be strongly recommended. The individual should be referred for assessment and treatment in accordance with current guidelines, preferably to a physician with knowledge and experience in TB management. Treatment of LTBI is started only after active TB has been excluded.

For TST conversion after contact with a potential transmitter of drug resistant *M. tuberculosis*, consultation with a physician experienced in TB management should be sought.

VII. Evaluation of Program

Ongoing evaluation of the surveillance program is essential to ensure effectiveness. Surveillance data should be analyzed and presented on an annual basis to the

hospital's Infection Prevention and Control Committee and Joint Health and Safety Committee. Evaluation might include the following:

(a) Compliance with screening:
(# screened/# eligible for screening) x 100
(b) Results of baseline screening:
positive/# tested
(c) Conversion rate of susceptibles:
(# of converters/# of HCW with known previous negative TST screened in that interval) x 100
(d) Compliance with treatment of LTBI:
# of staff completing a course of treatment of LTBI/# of staff for whom treatment of LTBI is recommended

Each conversion should be investigated to establish the source of infection and identify any breakdown in infection control measures. Conversions can identify high risk areas in the hospital which require screening of HCWs at regular intervals. All cases of HCWs with active TB should be investigated for source and contacts. Cases and conversions should be evaluated in a timely fashion by the Infection Prevention and Control Committee and the Joint Health and Safety Committee. Following known TB exposures, the outcomes of the contact screening should be evaluated in collaboration with Infection prevention and control and the local PHU TB program to determine if expanded contact follow-up is indicated.

VIII. Reporting

Active TB and cases of TST conversion are reportable to the local Medical Officer of Health (as per Ontario Regs 559/91 and amendments under the Health Protection and Promotion Act).

In accordance with the Occupational Health and Safety Act and its regulations, an employer must provide written notice within 4 days of being advised that a worker has an occupational illness, including an occupationally-acquired infection, and/or a Workplace Safety and Insurance Board (WSIB) claim has been filed by or on behalf of the worker with respect to an occupational illness, including an occupational infection to the:

- Ministry of Labour
- Joint Health and Safety Committee (or health and safety representative), and
- trade union, if any.

Occupationally-acquired TB disease, including occupationally acquired TST conversions, are reportable to the Ministry of Labour and WSIB.

Some local public health units may choose to have all positive TSTs reported; this should be ascertained by the local public health unit.

IX. Glossary

Direct Patient Contact

TB is an airborne disease, with face-to-face contact considered significant in its transmission.

When deciding whether a person has had a significant exposure to a potential transmitter, consideration should be given to the following:

- the frequency of patient contact;
- the proximity to patients involved;
- the duration of face-to-face contact;
- the use of personal respiratory protective devices (i.e., fit-tested, seal-checked N95 respirator);
- the number of air changes per hour in the area of exposure, and
- infectiousness of the contact patient:
    - pulmonary or laryngeal tuberculosis
    - cavitary or extensive pulmonary disease
    - presence of AFB on direct sputum examination
    - presence of coughing
    - cough inducing procedures (e.g., sputum induction, bronchoscopy)
    - open suctioning of intubated patients
    - wound irrigation.

Two-Step Tuberculin Skin-Test (TST)

An initial TST (5TU PPD) is given. If this test result is 0 - 9 mm of induration, a second test is given in the opposite arm at least one week and no more than four weeks after the first. The results of the second test should be used as the baseline test in determining treatment and follow-up.

Symptoms of active TB Disease

A diagnosis of TB may be considered for any individual who has a persistent cough (for example, lasting $\geq$ 3 weeks), bloody sputum, night sweats, weight loss, anorexia or fever. Immunosuppressed individuals may have an atypical presentation.

Conditions Predisposing to Active TB

The following conditions predispose individuals infected with *M. tuberculosis* to develop active disease: HIV infection, immunosuppressive therapy, haematological or reticuloendothelial malignant disease, corticosteroid therapy, treatment with tumor necrosis factor (TNF) alpha inhibitors, silicosis, diabetes mellitus, chronic renal failure requiring hemodialysis, carcinoma of the head and neck, conditions associated with nutritional deficiency and substantial weight loss, underweight (<90% of ideal body weight; for most people this is a body mass index ≤20), intravenous drug abuse, cigarette smoker, heavy alcohol consumption (≥3 drinks/day).[14]

Latent Tuberculous Infection (LTBI)

Infection with *M. tuberculosis* has occurred, but active TB disease is not present.

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