

CADTH PROJECT PLAN

Medical Devices and Clinical Interventions Condition-Level Review Project Plan on Tuberculosis

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About CADTH: CADTH is an independent, not-for-profit organization responsible for providing Canada's health care decision-makers with objective evidence to help make informed decisions about the optimal use of drugs, medical devices, diagnostics, and procedures in our health care system.

Funding: CADTH receives funding from Canada's federal, provincial, and territorial governments, with the exception of Quebec.

Background

Tuberculosis (TB) is an infectious disease caused by the bacteria *Mycobacterium tuberculosis* and is transmitted through the air by those who are infected with the bacteria. According to the WHO,¹ roughly one-quarter of the world's population carries *M. tuberculosis* and may be at risk for developing the disease. TB typically affects the lungs of a person (i.e., pulmonary TB), but it can also spread to other parts of the body (i.e., extrapulmonary TB). Individuals with TB fall into two categories: latent TB infection (LTBI) and active TB disease.^{1,2} LTBI refers to an individual who carries the *M. tuberculosis* bacteria but does not have TB disease and may not exhibit any symptoms.² Persons with LTBI cannot spread *M. tuberculosis* to others and are not considered infectious. However, those with LTBI can develop TB disease if they do not receive proper treatment or have a compromised immune system.² TB disease, or active TB, occurs when the bacteria begins to multiply, thus leading to infection.² Symptoms can progress immediately or they can develop long after infection, depending on the individual. Symptoms can vary, but people with active infection often experience weight loss, fever, fatigue, chills, excessive coughing, and chest pain.² In comparison to LTBI, persons with active TB disease are considered infectious and can spread the TB bacteria to others.²

TB is considered an important public health matter. According to the Public Health Agency of Canada (PHAC),³ Canada has one of the lowest rates of active TB in the world. However, annual rates of TB have remained the same in the country since the 1980s.³ In 2017, PHAC reported 1,796 cases of active TB in Canada, with approximately 70% of those cases being pulmonary TB.^{3,4}

Factors that contribute to a higher risk for TB infection include situations of close proximity to others and environmental conditions that enable the transmission of TB bacteria, such as spending time in areas with high infection rates, overcrowded housing, poor sanitation, poor hygiene, homelessness, and incarceration.^{1,3} In addition, individuals who are immunocompromised may be at higher risk.³

Although there are many publications on the management of TB, there are some outstanding questions and gaps. Questions have been raised, for example, about optimal prevention strategies, methods for identifying people at risk, contact tracing, optimal treatment regimens, and adherence support.

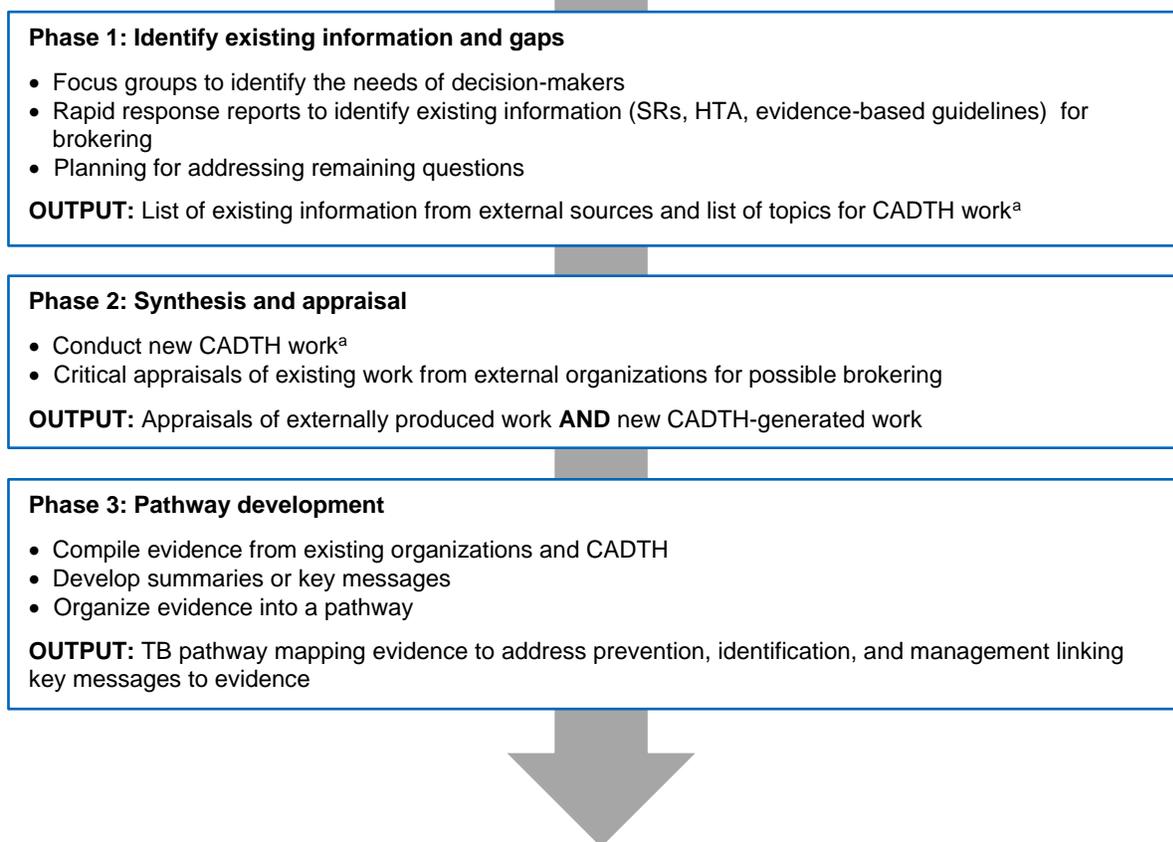
Project Objectives

To help inform decisions about the optimal use of health technologies in the management of TB, a condition-level review will be conducted. A condition-level review is an assessment of health technologies used in all aspects of a condition — from prevention and detection to treatment and management — using a variety of sources of information. This project will incorporate information from multiple sources, including work produced by CADTH and other organizations. The TB condition-level review will report the evidence in a pathway to inform decisions on the optimal use of the various health technologies used in the prevention, identification, treatment, and management of TB.

Approach

The TB condition-level review will be conducted in three phases (Figure 1). Phase I includes identifying existing information and decision problems and gaps. Phase II includes synthesizing information, including existing information, and generating new evidence. Phase III compiles the evidence from prior phases in an organized manner and generates key messages to help inform decisions on the use of health technologies in the optimal management of TB. This condition-level review will be composed of a variety of CADTH work (such as systematic reviews, rapid reviews, environmental scans, qualitative reviews) and information from external sources. As needed, key stakeholders and clinical experts will be contacted throughout the course of the condition-level review to provide feedback and review. Additional information about the project will be posted on the project page: <https://www.cadth.ca/tuberculosis>. This page will house information about planned, ongoing, and completed work for this project and will include research reports, as well as tools and information repositories.

Figure 1: Approach for the Condition-Level Review on the Management of Tuberculosis



HTA = health technology assessment; SR = systematic review; TB = tuberculosis.

^a CADTH work constitutes rapid response products, systematic reviews, environmental scans, qualitative reviews, horizon scanning reports, policy briefs, and other potential products produced by CADTH.

Phase I: Information Gathering

Although information exists on the management of TB, evidence gaps and decision needs remain about the optimal use of specific technologies and interventions for the management of TB. To confirm and consolidate the information published, a series of Rapid Response reports were conducted to map the currently available evidence-based guidelines and associated recommendations for TB. These reports examined guidelines covering the following topics:

- prevention,⁵ identification,⁶ or treatment⁷ of active or latent TB
- prevention, identification, or treatment of drug-resistant pulmonary TB⁸
- prevention, identification, or treatment of TB in people with compromised immunity.⁹

Nine consultations were held with key stakeholders to determine the information needs in regards to the optimal use of health technologies in the management of TB. Representation was sought from stakeholders across Canada and included participants from a variety of backgrounds including clinicians and policy-makers. The consultations were organized and facilitated by members of the CADTH Implementation Support and Knowledge Mobilization team and focused on gathering information on three main areas of interest: context (understanding the current TB situation in each jurisdiction), evidence needs, and requirements for tools to support clinical work, implementation, and education. The questionnaire template used for the consultations is included in Appendix 1. The transcripts of these sessions were analyzed and a list of topics requiring more research was created. Details on ongoing and planned work is posted on the project page:

<https://www.cadth.ca/tuberculosis>.

Phase II: Synthesis and Appraisal

The synthesis phase will comprise:

- new CADTH work to address aspects of the use of health technologies for the management of TB and may include, as appropriate:
 - systematic reviews
 - rapid reviews
 - other CADTH work (such as a policy brief, environmental scan, horizon scan)
- appraisal of existing systematic reviews, HTAs, or guidelines from external organizations that address the use of technologies for the management of TB.

The work will incorporate various perspectives such as ethical, patient, clinical, and economic. Specific methods and protocols will be developed for each report.

Phase III: Pathway Development

The findings of the individual CADTH and external reports will be compiled to provide an overview of the evidence along the pathway of TB management. Key messages or summaries will be developed for each aspect and linked to the supporting information. The information will be organized for publication on the CADTH website to facilitate navigation through the various aspects and reports, and will address the specific decision problems.

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Appendix 1: Tuberculosis Stakeholder Consultation Question Guide

Context

1. Can you share the current situation regarding tuberculosis (TB) in your community or jurisdiction?
2. What are some key success factors or strategies used to address TB in your facility, community, or jurisdiction? What is working well?
3. What are some of the barriers to managing TB in your facility, community, or jurisdiction (e.g., funding, facility, geography, public health education, access, etc.)? What is not working well?
4. What are some of the major factors that you think contribute to the rates of TB infection in your community or jurisdiction (e.g., overcrowded homes, poverty, malnutrition, poor access to health care, ability or willingness to access services at outpost nursing station or hospital, treatment compliance)?

Evidence Needs

5. Who would you consider to be the most vulnerable populations in your area? How can we effectively identify those who are at high risk of active infection (e.g., children, Indigenous people, hard-to-reach populations [homeless, people who use drugs], people who are immunocompromised, people who have recently arrived in Canada from countries with high TB incidence)?
 - Are there any problems or gaps you think exist with your current methods of screening? Is there a specific aspect of screening you would like to know more about or think that CADTH could help in by providing more evidence for decision-making?
6. How do you treat active cases in your community? How are latent cases managed? How do you conduct contact tracing? How do you define an optimal treatment regimen?
 - Is there a specific aspect of TB treatment you would like to know more about or think that CADTH should explore further (e.g., latent TB)?
7. Are there any problems you feel exist with your current methods of screening, diagnosis, treatment, or follow-up for people with TB? Are there certain clinical areas where you feel that CADTH could help provide in by providing more evidence for decision-making (e.g., clinical effectiveness of a specific screening or treatment approach, cost-effectiveness of a specific drug or vaccine)?
8. Are there any new or emerging issues regarding TB management you would be interested in CADTH exploring (e.g., newly approved drug treatments or dosing regimens, rapid diagnosis tests)?

Tools, Implementation, and Education

9. How could CADTH assist in sharing successes to help others build on the successful work that has already been done?
10. What are the educational needs for the public, patients, families, and providers (e.g., locum physicians, hospital nurses, nurses become TB specialists, directo observational thereapy [DOT] providers, other lay support persons)?
11. What evidence resources do you currently access for TB management (e.g., guidelines, patient and provider tools)?
12. What would you consider the current gaps to be in evidence and tools or resources that would help guide the management of TB in your area (e.g., summaries of the evidence, prevention resources, resources on diagnosis and treatment, follow-up contact tracing, guideline summaries)?