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Health Canada's Monitoring and Performance Framework for Tuberculosis Programs for First Nations On-Reserve

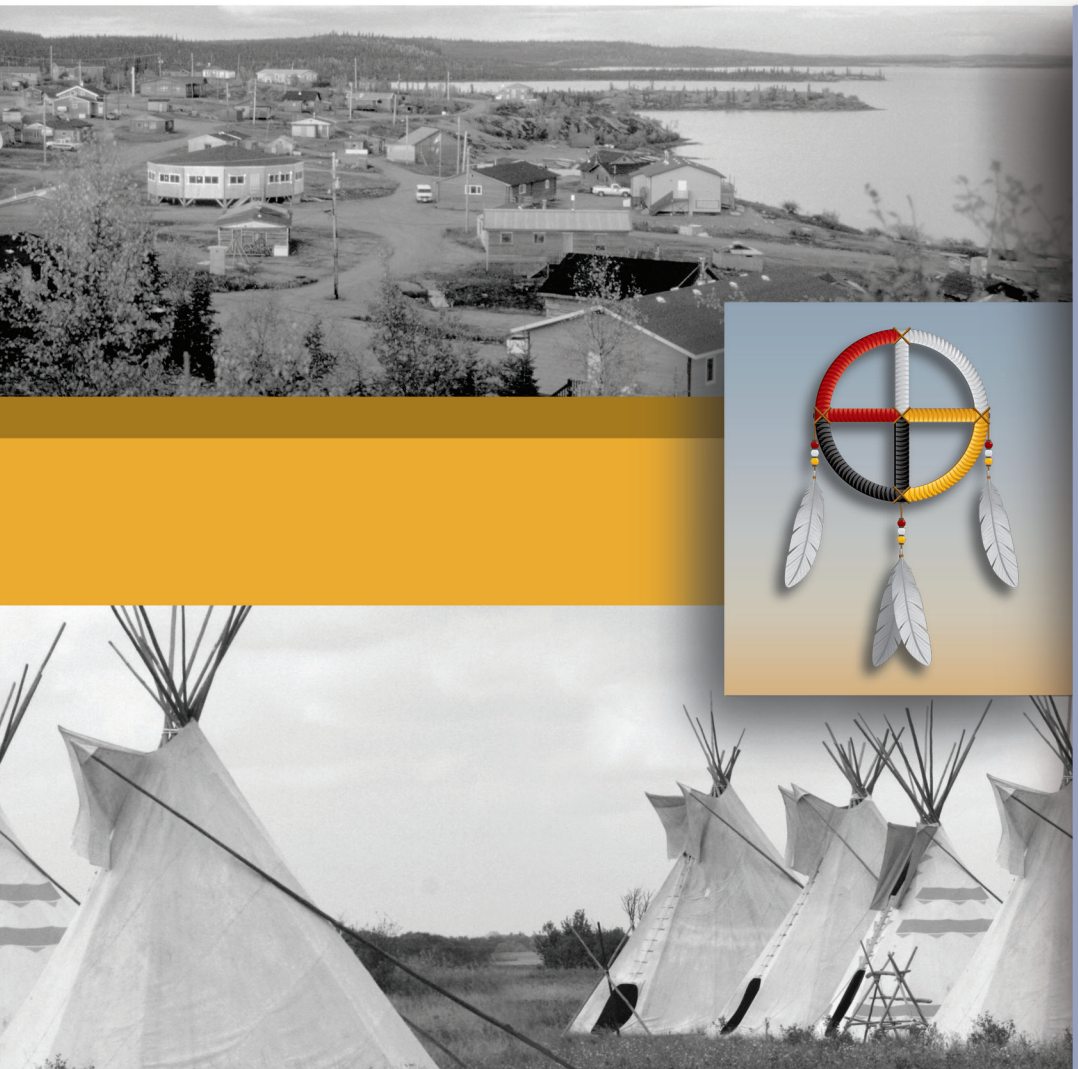

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TABLE OF CONTENTS

ACRONYMS

AFB—acid-fast bacilli

AR—acquired resistance

BCG vaccine—Bacille Calmette-Guérin vaccine

CDCM—Communicable Disease Control and Management

CBRT—Community Based Reporting Template

CDCD—Communicable Disease Control Division

CHN—Community Health Nurse

CNS TB—central nervous system tuberculosis

CTBRS—Canadian Tuberculosis Reporting System

CTS—Canadian Tuberculosis Standards

DOT—Directly Observed Therapy

FNIHB—First Nations and Inuit Health Branch (Health Canada)

HIV/AIDS—Human Immunodeficiency Virus Infection/Acquired Immunodeficiency Syndrome

IGRA—interferon-gamma release assay

INH—isonicotinylhydrazine

LTBI—latent tuberculosis infection

PDSA—Plan-Do-Study-Act (Model for Improvement)

PHAC—Public Health Agency of Canada

PMF—Performance Measurement Framework

PMS—Performance Measurement Strategy

PR—primary resistance

RMP—rifampin

TB—tuberculosis

TST—tuberculin skin test

PREFACE

Given the complexity of tuberculosis (TB) as a disease and public health issue,[i,ii] the importance of a strong commitment to performance measurement, surveillance and evaluation by TB programs cannot be underestimated. Assessing a program as it evolves over time is paramount for ensuring effective and flexible programming that can adapt to a changing disease and population. To this end, *Health Canada's Strategy Against Tuberculosis for First Nations On-Reserve* (the Strategy)[iii] promotes continuous quality improvement as part of the Strategy's strategic direction in moving forward.

Continuous quality improvement for Health Canada's First Nations and Inuit Health Branch (FNIHB) TB programming must reflect the reality of TB in First Nation communities in Canada. Generally, the rate of TB for First Nations on-reserve continues to be higher than that of the overall Canadian population, a fact that prompted the development of Health Canada's Strategy. However, it is becoming increasingly evident that TB is not equally distributed but, rather, clustered in a limited number of communities.[iv] Although TB programming and its associated performance measurement, surveillance and evaluation, are standardized to some extent, flexibility is required to account for regional variability in incidence, history, burden, circumstances, needs, partnerships and health care system structure.

The Health Canada First Nations and Inuit Health Branch performance measurement framework for TB programming, entitled *Health Canada's Monitoring and Performance Framework for Tuberculosis Programs for First Nations On-Reserve*, is based on this commitment to continuous quality improvement specified in Health Canada's TB Strategy.[iii] Developed by Health Canada's TB program in collaboration with partners and TB experts, this Framework represents an agreed upon direction for performance measurement and evaluation for FNIHB programming. While this document was developed primarily for FNIHB TB programming, it can also be used as a reference document for any program working on TB prevention and control, especially with communities experiencing a continuing high incidence of TB.

The goal and vision of Health Canada's TB Strategy is to significantly reduce the incidence and burden of TB in First Nations on-reserve through sustainable, equitable and effective TB control.[iii] Without a successful means of sharing data and assessing programming, the achievement of this goal and vision will be difficult to attain. For this reason, the purpose of *Health Canada's Monitoring and Performance Framework for Tuberculosis Programs for First Nations On-Reserve* is to outline established reporting requirements that provide the foundation for performance measurement, surveillance and evaluation for FNIHB TB programming as well as describe a new, flexible approach for enhanced monitoring of outbreaks and high incidence communities.

Over time, TB programs must necessarily adjust to reflect changes in populations and health care system structures. While performance measurement and evaluation are pivotal in determining the "hows" and "whys" of these adjustments, these processes must also evolve over time as programs and needs change. As such, certain aspects of this Framework (e.g., indicators used to measure progress or improvement) should be considered evergreen. To the extent possible, concepts and approaches that may be expected to change most over time have been placed in the appendices.

In conclusion, this Framework aims to contribute to the reduction of TB in First Nations on-reserve by providing guidance on and support for the role of continuous quality improvement in FNIHB TB programming.

EXECUTIVE SUMMARY

The overall purpose of *Health Canada's Monitoring and Performance Framework for Tuberculosis Programs for First Nations On-Reserve* is to:

1. Outline current reporting requirements for FNIHB TB programming.
2. Describe a new set of recommendations that can be used to guide TB programs through an enhanced approach to monitoring TB in high incidence communities.
3. Support FNIHB TB programming with the process of continuous quality improvement.

CURRENT REPORTING REQUIREMENTS FOR FNIHB TB PROGRAMS

FNIHB TB programs are required to report on cases of TB at a variety of levels, including:

- ***Mandatory case reporting and the Canadian Tuberculosis Reporting System.*** As part of the legislation of each province and territory in Canada, it is mandatory that cases of active TB be reported to respective provinces or territories. Provinces and territories voluntarily report on active TB cases to the Public Health Agency of Canada (PHAC) via the Canadian Tuberculosis Reporting System (CTBRS).
- ***For Health Canada programming.*** Reporting requirements are based on FNIHB's Program Alignment Architecture with indicators determined at the departmental/branch level with input from programs. Data for national level reporting are collected from both national and regional components of the FNIHB program. In addition, the Government of Canada's *Financial Administration Act* requires that each department complete evaluations for any programs involved in grants and contributions. The FNIHB TB Program is evaluated as part of the Communicable Disease Control and Management Program (CDCM) evaluation. Finally, each First Nations community with a contribution agreement with Health Canada is required to complete FNIHB's Community Based Reporting Template (CBRT).

ENHANCED MONITORING FOR TB OUTBREAKS AND HIGH INCIDENCE— DEFINITIONS AND RECOMMENDATION

Evidence suggests that rates of TB for First Nations on-reserve are driven by events in a limited number of communities experiencing repeated TB outbreaks or a higher incidence of TB over time.[iv] Targeting approaches for reducing TB in these communities is a commitment made in *Health Canada's Strategy Against Tuberculosis for First Nations On-Reserve* (the Strategy)[iii] as it is expected that reducing TB in these communities will significantly contribute to decreasing the overall rate of TB for First Nations on-reserve.

As part of the early implementation of the Strategy, a discussion group of Health Canada TB program staff, policy analysts and epidemiologists from both national and regional levels, as well as external TB experts, collaborated in reviewing the outbreak definition from the *Canadian Tuberculosis Standards, 6th Edition* (CTS 6th)[v] for its use in First Nations communities and in developing a definition of high incidence for surveillance purposes.

Outbreak: The *Canadian Tuberculosis Standards, 7th Edition*[i] defines an outbreak of TB as:

A community is considered to be experiencing an outbreak when one or both of the following criteria are met:

- *During and because of a contact investigation, two or more of the identified contacts are diagnosed as secondary cases of active TB;* ***OR***
- *Any two or more cases occurring within one year or less of each other are discovered to be linked, but the linkage*

is established outside of a contact investigation (e.g., two patients who received a diagnosis of TB outside of a contact investigation are found to work in the same office, yet they were not identified as contacts of each other). The linkage between cases should be confirmed by genotyping results if isolates have been obtained.

High incidence: Prior to this Framework, no agreed upon definition of TB high incidence existed, thus making a targeted and standardized approach to high incidence communities difficult to develop. Outlined below is a set of definitions of high incidence that was developed by the FNIHB TB Outbreak and High Incidence Definitions Discussion Group described above.

A community can be considered high incidence under any of the three following scenarios:

1. *Two or more cases of active TB in the current (reporting) year, of which at least one is primary TB or smear-positive pulmonary TB;* ***OR***
2. *A five-year average incidence of TB that is* ***greater*** *than 100 cases per 100,000 population with at least one case in the previous three years;* ***OR***
3. *A five-year average incidence of TB that is* ***less*** *than 100 cases per 100,000 population but with two or more cases per year in at least two of the previous three years.*

AN APPROACH FOR ENHANCED MONITORING OF TB IN HIGH INCIDENCE COMMUNITIES

The FNIHB TB program, in collaboration with partners and TB experts, has developed an approach for enhanced monitoring of TB in high incidence communities that can be used by TB programs to help determine underlying issues perpetuating TB in a community. This approach should be treated as a set of recommendations to help guide and complement local TB program activities. These recommendations are not currently linked to any reporting requirements. Regions and/or communities can use or adapt this approach based on their needs, circumstances and resources. This approach has two levels of analysis: **Primary Analysis** and **Secondary Analysis**.

Primary level of analysis: The purpose of the primary level of analysis is to identify areas of concern for a TB program where more investigation is warranted. Based on evidence and expert opinion, the following categories were identified as essential overarching program areas that should be investigated:

- Diagnosis and Treatment Initiation
- Treatment Completion
- Contact Tracing/Investigation
- Populations at Greatest Risk
- Awareness and Capacity

A set of surveillance and high-level indicators was identified for each of these categories. The purpose of these indicators is to trigger further investigation into whichever area(s) of programming needs adjustment.

Secondary level of analysis: If any of the indicators and/or data collected for each category through the primary level of analysis triggers concern, a more in-depth analysis is essential. The purpose of the secondary level of analysis is to identify questions that can pinpoint specific issues that may be contributing to high levels of TB in a community. Once these issues are identified, programs can adjust programming by implementing activities, approaches, strategies and/or policies to address these issues and, subsequently, break the cycle of transmission of TB within the community.

Maintaining "no" incidence: One of the distinct features of TB as a disease is the fact that when infected, people can develop either active TB or latent tuberculosis infection (LTBI). As such, communities that experience an increased and/or sustained level of TB run a strong risk of developing a reservoir of LTBI. Since a reservoir of LTBI represents a potential source of active TB, TB programs need to recognize the risk a community carries for TB based on its history and resiliency in coping with TB in the past and remain vigilant through consistent monitoring and proactive prevention efforts. It is strongly recommended that enhanced monitoring be maintained after communities are no longer considered to be in an outbreak situation or experiencing a period of high incidence. How long this enhanced monitoring continues should be negotiated with

partners and be reflective of the community's risk for TB and the broader context of TB in the surrounding area.

CONTINUOUS QUALITY IMPROVEMENT AND FNIHB TB PROGRAMMING

Confirming that all components of a quality TB program are in place and working effectively is essential to reducing the incidence and burden of TB in First Nations on-reserve. As a response to the commitment made in *Health Canada's Strategy Against Tuberculosis for First Nations On-Reserve*[iii] *Health Canada's Monitoring and Performance Framework for Tuberculosis Programs for First Nations On-Reserve* is another tool to support continuous quality improvement by supporting FNIHB TB programming in using data and information for the improvement of policies and programming.

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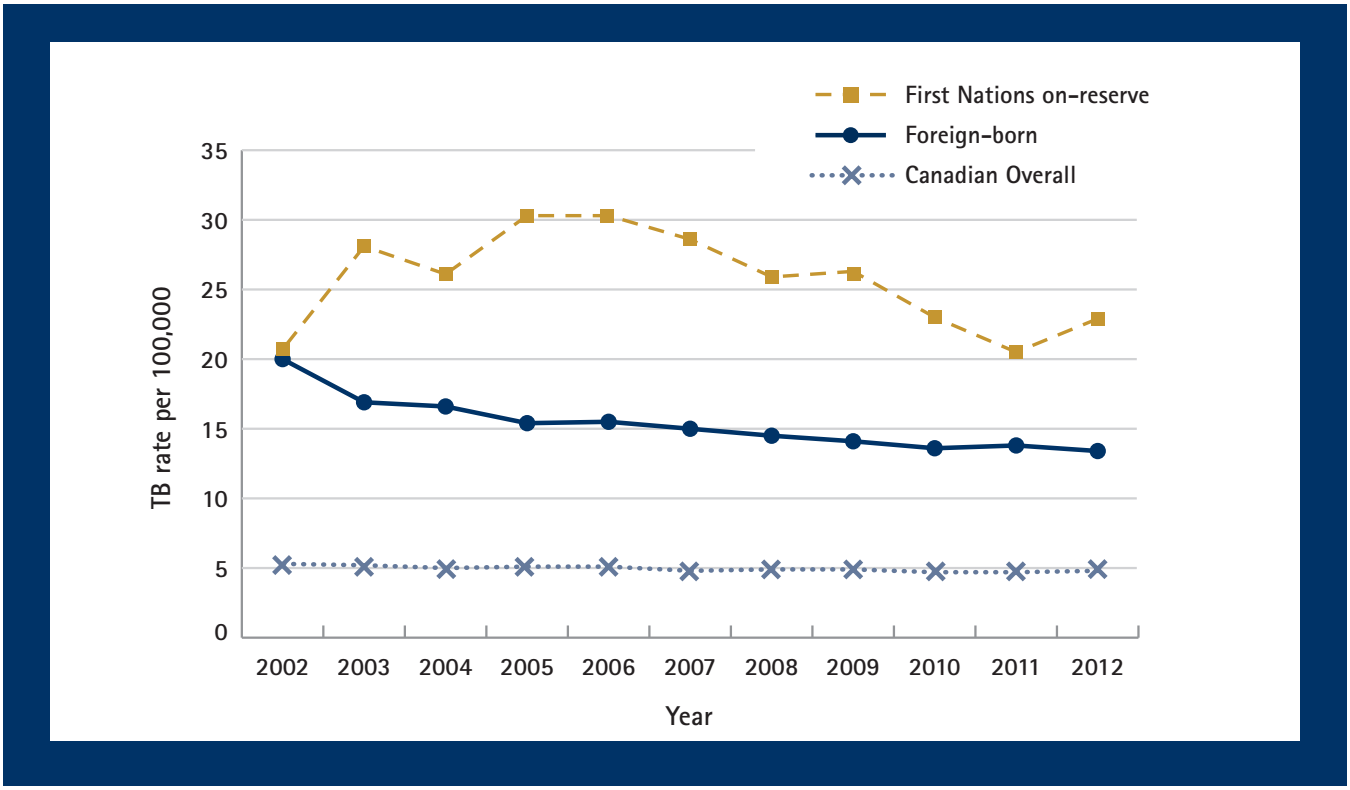
PART 1: Overview of Tuberculosis Programming for First Nations On-Reserve

A. TB in First Nations populations in Canada

TB is an airborne, bacterial infectious disease. Individuals with active TB disease require a prolonged period of treatment that will last, on average, between six and nine months.[1] In some cases where drug resistance has developed, the disease is much more complicated and requires a much longer period of treatment with drugs.[1]

While tuberculosis rates in Canada are generally low, specific sub-populations continue to show higher rates than the general population, including the on-reserve population. Tuberculosis rates among First Nations on-reserve decreased from 74.1 cases per 100,000 in 1990 to fewer than 30 cases per 100,000 in 2000.[2,3] The TB rate among First Nations on-reserve in 2012 was 4.8 times higher than in the general Canadian population (22.9 per 100,000 versus 4.8 per 100,000) and 1.7 times higher than in foreign born populations (see Figure 1).[3]

Figure 1: Annual Reported TB incidence rates per 100,000, First Nations on-reserve, 2002–2012



Source: Public Health Agency of Canada. *Tuberculosis in Canada 2012*

It is important to note that tuberculosis cases are not evenly distributed across the country. In 2012, just over half of the cases reported on reserve (58 of 113 or 51%) were in Manitoba, followed by Saskatchewan with 25 cases (22%) and British Columbia with 21 cases (19%).[3] As well, there is evidence that in some regions, TB rates are driven by the occurrence of repeated outbreaks or continuing high incidence in a limited number of communities.[4]

The rates of TB on reserve are influenced by a number of complex factors, including related health conditions and environmental conditions. Latent TB is more likely to be activated if there are underlying health conditions such as HIV or diabetes, which are more prevalent in many First Nations communities.[1] As well, social determinants of health such as overcrowded housing increases the risk of exposure to TB.[4]

More detail on the epidemiology of TB in First Nations can be found in Epidemiology of Tuberculosis in First Nations Living On-Reserve in Canada, 2000–2008.[2] Also, the Chief Public Health Officer's Report on the State of Public Health in Canada for 2013 includes a section on Tuberculosis - Past and Present.[5]

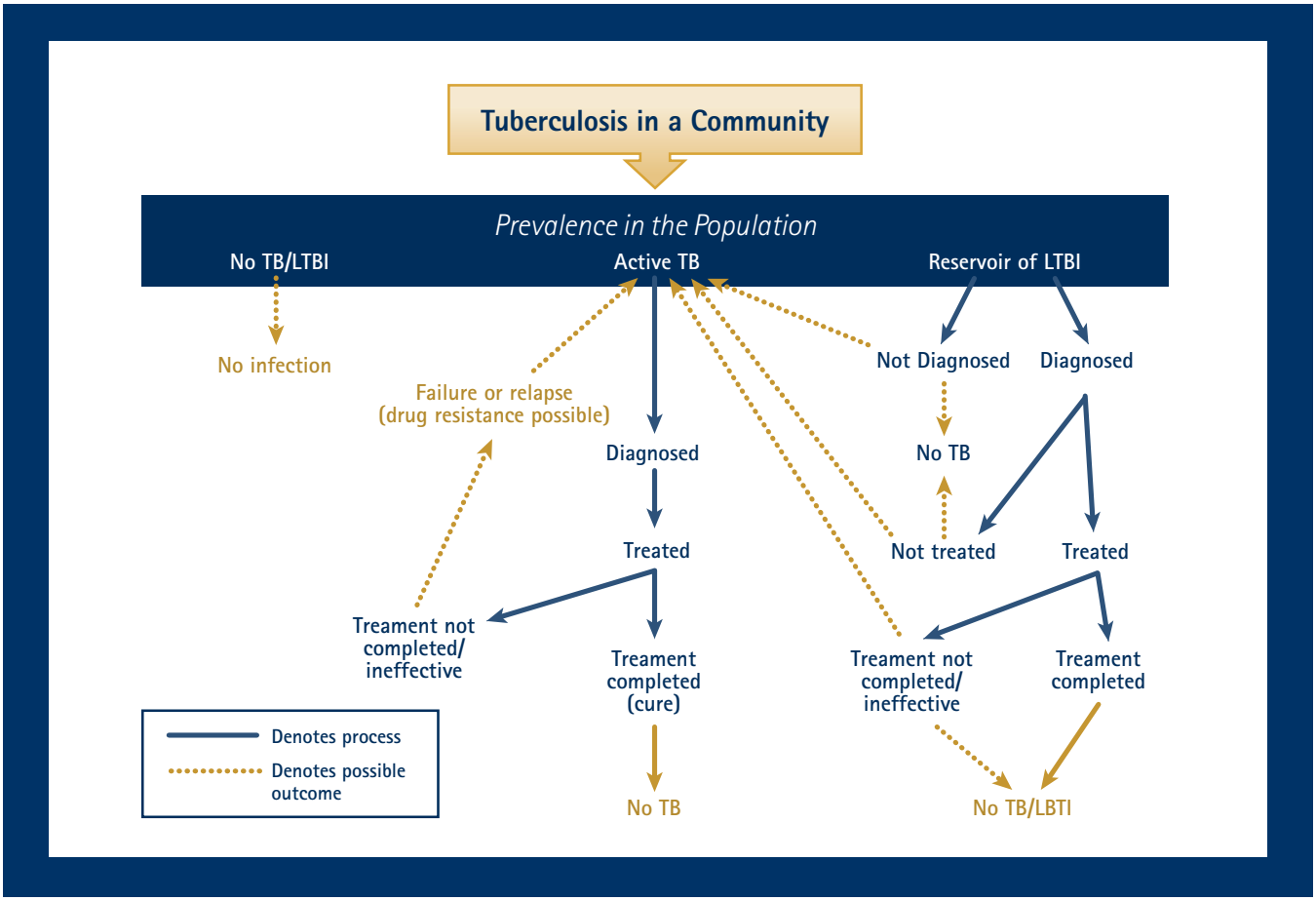
B. Tuberculosis in a Community

Exposure to TB does not always result in infection or active disease. If infection does occur, the immune system is often able to suppress it. Suppressed TB is called latent tuberculosis infection (LTBI) and is not infectious. However, individuals with LTBI can develop active TB with the highest risk for progression to active disease found in the first two years following infection, in the young pediatric population (less than 5 years of age) and/or in those who have co-morbid conditions that weaken the immune system, such as HIV/AIDS.[1]

There are three possible outcomes following exposure to infectious TB in a community: no TB or LTBI; cases of active TB; and a "reservoir" of LTBI. The prevalence of these outcomes can shift based on many factors, such as underlying determinants of health and/or a program's ability to prevent and control the transmission of the disease in the community (see Figure 2).

How TB spreads throughout a community can also depend on the presence or absence of multiple inter-related factors.[6]

Figure 2: Possible Outcomes of Exposure to Infectious TB in a Community



The pattern of these factors varies across communities; each community is unique in its risk for developing and/or maintaining high levels of TB. While the approaches for reducing TB are relatively standard (i.e., prevention, timely diagnosis, effective contact tracing and treatment, and strong surveillance, performance measurement and program evaluation),[1,7] due consideration must be given to the characteristics of each community when planning, implementing and adjusting programming.

Moreover, communities cannot be considered in isolation. Inherent to its definition, communicable disease does not recognize geographic boundaries and can easily spread from community to community. With respect to the transmission of TB in First Nation communities, population mobility is an important consideration. For example, TB can be introduced into a community via visitors and/or returning community members. For the purposes of planning, especially when there is elevated risk, TB programs must consider both TB in the community itself, and possible external sources of TB, such as surrounding communities and/or urban centres. By knowing the state of TB within a region and the mobility pattern of its population, a community will be better equipped to address and anticipate issues and challenges for TB prevention and control. However, care needs to be taken with handling health data in order to preserve the privacy of all individuals, to respect confidentiality of clients and to maintain the trust of the community.

C. TB Prevention and Control in Canada

Provinces and territories have the legislated authority for TB prevention and control within their jurisdictions, with the exception of populations falling under the mandates of Health Canada, Citizenship and Immigration Canada and Correctional Services Canada. Health Canada is mandated through FNIHB to either provide TB services or assure they are accessible to First Nations on-reserve. FNIHB works closely with partners, including First Nation organizations, provincial programs and regional health authorities, to support the reduction of TB on-reserve through programs, services and strategies that align with provincial programming and the *Canadian Tuberculosis Standards*.[1,8]

D. Health Canada's TB Programming

Health Canada's TB Program is housed within FNIHB and supports TB prevention and control for First Nation communities either directly through the provision of services through regional and community level programming or indirectly through the provision of funding. The FNIHB TB Program promotes a vision of sustainable, equitable and effective TB control with a goal of significantly reducing the incidence and burden of TB in First Nations on-reserve.[6] Examples of activities that define the role and responsibilities of the TB program at the national level include:

- working as a liaison between regional and national initiatives
- partnering with First Nation national organizations and other government departments on awareness, educational and policy development
- developing and reviewing national policy and guidelines
- remaining up to date on best practices, current evidence and emerging innovations

Regionally, the program works directly with communities, health authorities and/or provincial partners to assure the delivery of TB services to First Nations on-reserve. However, the specific role and responsibilities of each regional office depend on details found in agreements, the state of transfer of communities, provincial health care systems and partnership structures. Regional programs also undertake activities on awareness and education.

The FNIHB TB Program is guided by the strategic direction provided by *Health Canada's Strategy Against Tuberculosis for First Nations On-Reserve*[8] (see Appendix A). In addition, the FNIHB TB Program also aligns with the following:

- The *Canadian TB Standards*[1]
- *Guidance for TB Prevention and Control Programs in Canada*[7]
- Provincial TB programs (FNIHB regional level)
- FNIHB's Program Alignment Architecture
- The FNIHB Strategic Plan[9]
- FNIHB Quality Improvement Policy Framework[10]

PART 2: Performance Measurement and Evaluation for FNIHB TB Programming

The overall purpose of *Health Canada's Monitoring and Performance Framework for Tuberculosis Programs for First Nations On-Reserve* is to set out required and recommended reporting and approaches for enhanced program monitoring for all levels of FNIHB TB programming by:

- demonstrating how current reporting requirements align with Health Canada's priorities, support informed program adjustment and promote continuous quality improvement
- presenting a recommended approach for enhanced monitoring of outbreaks and high incidence with the aim of accounting for regional variability and supporting each community's needs and priorities

Collecting and analyzing data is vital for developing policy, improving programs, responding to emerging issues, as well as for informing partners and senior management about progress and effective programming. Assessing a TB program can be approached in several ways. Determining the most useful method of assessment must be based on the goals and expected outcomes of the assessment. An overview of the purpose of each component of program assessment used by FNIHB TB programs is set out in Table 1, below.

Table 1: Overview of Program Assessment for FNIHB TB Programming

Performance Measurement and Surveillance			
	Monitoring for All Programs	Monitoring for High Incidence Communities	Evaluation
Purpose	To track programming in order to increase ongoing effectiveness and efficiency To provide a baseline for evaluation	To provide timely information in situations where adjustments to programming need to be made quickly and effectively	To assess programs against needs, priorities, goals, objectives, strategic direction, outcomes and impacts
	Identify gaps, challenges and opportunities	Discover what is contributing to ongoing high incidence	Recognize progress, best practices and lessons learned
	Pinpoint areas where programming can be adjusted	Use monitoring on a shorter time scale	Detect issues that are systemic and/or cross-cutting
Cycle	Annual	Weekly/monthly/quarterly*	Three to five years

*Determined with partners.

Performance measurement for FNIHB TB programming is embedded into Health Canada's broader monitoring and evaluation efforts. Necessarily, performance measurement at a departmental level does not capture the nuances and details needed to adjust and adapt programming to changing circumstances and needs at a regional and/or community level. For this reason, performance measurement for FNIHB TB programming balances departmental requirements with specific and practical requirements that support sustainable, equitable and effective TB control for First Nations on-reserve. As partnerships are essential for TB prevention and control for First Nations on-reserve, performance measurement at a regional and/or community level must also consider the role of external partners, such as First Nations leadership, communities, provincial programs, and/or regional health authorities.

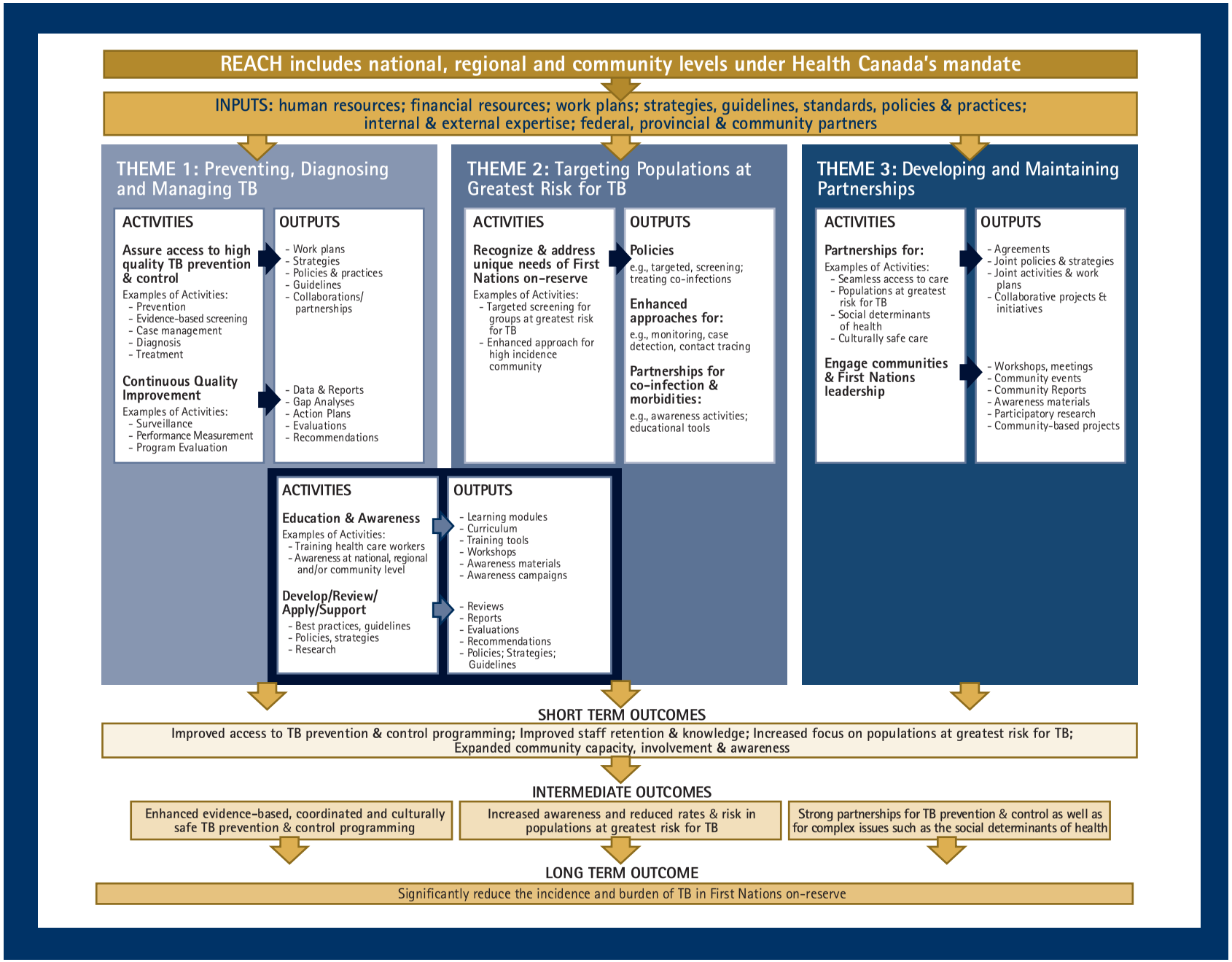
A. FNIHB TB Logic Model

A logic model shows the logical flow of how a program's inputs and activities lead to outputs and outcomes, ultimately representing how a program plans to meet its goal(s). More specifically:

- inputs include a program's resources, plans, practices and partnerships
- activities and outputs are the results and products of programming
- outcomes represent the expected impacts of the program over the short, intermediate and long term

The FNIHB TB Program Logic Model is depicted in Figure 3, on the next page.

Figure 3: The FNIHB TB Program Logic Model



The FNIHB TB logic model reflects certain assumptions that contribute to a concise, coherent and representative picture of the relationships between its various elements. Given the variability inherent in programming at the regional and community level, this logic model is high level and relatively simple. By not including timelines for outcomes to be achieved, the logic model is flexible. Examples of activities are included to support regional/community level programs in developing their own logic models to reflect their unique local needs and circumstances.

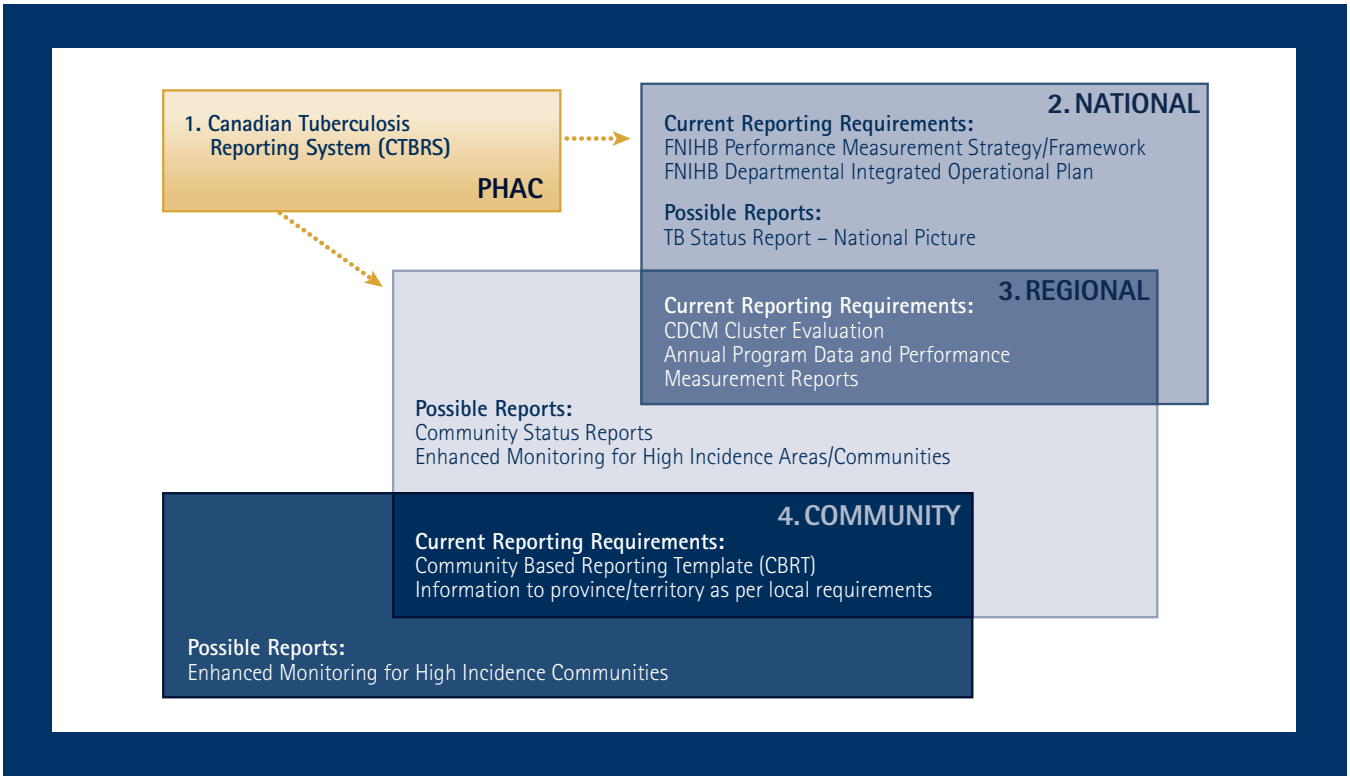
Activities and outputs included in the logic model are organized according to the three themes outlined in Health Canada's Strategy Against TB, 2012.[8] These themes represent priority areas identified by Health Canada, its partners and TB experts to guide FNIHB TB programming. Both the Strategy and the logic model reflect that many activities and outputs cut across more than one theme. For practical purposes, the logic model assigns activities and outputs to the theme determined as "best fit."

Finally, the logic model provides a foundation to guide performance measurement, surveillance and evaluation. Logic model activities and outputs will be assessed through performance measurement and surveillance, while outcomes will be assessed through evaluation. The specifics of performance measurement for FNIHB TB programming are outlined in Parts B and C, as well as in Appendix B; a brief overview of FNIHB's process for evaluation is outlined in Part D, below.

B. Reporting Requirements

Current reporting requirements for TB at the national level are shown in Figure 4, below. Examples of possible and ongoing reporting at the regional and/or community level are also presented.

Figure 4: Current and Possible Reporting Requirements and Data Sources for TB



CURRENT REPORTING REQUIREMENTS

Mandatory reporting and the Canadian Tuberculosis Reporting System

Under legislation in each province and territory in Canada, it is mandatory that cases of active TB be reported to the province or territory. The Public Health Agency of Canada (PHAC) is responsible for collation of TB data at the national level through the Canadian Tuberculosis Reporting System (CTBRS). Provinces and territories voluntarily submit data to the CTBRS on active TB cases that meet the case definition for national level surveillance.[1] TB surveillance reports are published by PHAC on an annual basis based on data from the CTBRS (www.phac-aspc.gc.ca/tbpc-latb/surv-eng.php).

Health Canada—national level

Reporting requirements are based on FNIHB's Program Alignment Architecture with indicators determined at the departmental/branch level with input from programs. Mechanisms to collect data are in place at the departmental (Health Canada), branch (FNIHB), and divisional (Communicable Disease Control Division, or CDCD) levels. In addition, data from the CTBRS are also used to respond to this reporting requirement. Currently, FNIHB reporting requirements at a national level include:

- FNIHB's Performance Measurement Strategy (PMS) and Performance Measurement Framework (PMF) which are used to assess the progress of FNIHB programs over the long term
- FNIHB's Departmental Integrated Operational Plan which is used to track information on the current fiscal year
- Communicable Disease Control and Management (CDCM) Program Evaluation which is undertaken every five years

Health Canada—regional level

In addition to using the CTBRS as a data source for national level reporting, data for national level reporting are also collected from both national and regional components of the FNIHB program. For regional programs, data are collected annually at a national level through the Program Data and Performance Measurement Reports (see Appendix B for a description of data collected).

Health Canada—community level

Each First Nations community with a contribution agreement with Health Canada is required to complete FNIHB's Community Based Reporting Template (CBRT), providing data that are aggregated at a regional level and then reported at a national level. This template currently includes a mix of performance measurement and health data indicators.

POSSIBLE ADDITIONAL REPORTING

Nationally reported data alone are not detailed and timely enough to inform regional and community TB programming, policies and approaches in support of continued efforts to reduce TB in First Nations on-reserve. For example, in 1999 and 2012, detailed epidemiological reports on TB in First Nations communities were released by Health Canada. These reports provided an in-depth look at trends in TB at a national and regional level; however, since they did not provide an up-to-date assessment at the time of release, their utility for regional and community level programming and planning on a day-to-day basis may have been limited. Collecting, analyzing, reporting, and using more detailed and timely information by and for programs and policies are important. Reports that may be useful include:

1. ***Epidemiological reports:*** Reports similar in content and format to those released in 1999 and 2012, but with more timely release.
2. ***Community status reports:*** Some regions currently provide their communities with health status and/or wellness reports—a practice that could be standardized across regions to ensure information is included on TB.

This type of report would be most relevant for high incidence communities.

3. ***Regional high incidence reports:*** Regions could work with partners to develop a report that outlines the state of high incidence at a regional level. Frequency and format of such reports are to be determined. In addition, it may be beneficial for communities to work with regions and other partners to develop reports on high incidence that are specific to a community. This level of detail would accurately capture the unique characteristics and structures of the community, and could outline steps to address the issues underlying the high incidence. Alternatively, information on high incidence could be included as part of the community status reports described above.
4. ***National reporting of regionally aggregated high incidence:*** This type of reporting could be similar to the format of data currently collected on outbreaks in the annual CDCD Program Data Reports. The application of a standardized surveillance definition for national reporting of regionally aggregated high incidence would inform programming and allow for the analysis of trends over time.

ENHANCED MONITORING FOR TB OUTBREAKS AND HIGH INCIDENCE

Despite significant reductions over time, the rate of TB for First Nations on-reserve continues to be higher than that of the overall Canadian population.[2,3] At the same time, rates of TB across First Nation communities vary considerably. Evidence suggests that rates of TB for First Nations on-reserve are driven by events in a limited number of communities experiencing repeated TB outbreaks or a higher incidence of TB over time.[4] Targeted approaches for reducing TB in these communities is a commitment of Health Canada's Strategy Against TB, 2012;[8] it is expected that reducing TB in these communities will significantly contribute to decreasing the overall rate of TB for First Nations on-reserve, as well as supporting communities to address TB in their area.

As part of the implementation of the Strategy, a discussion group of Health Canada epidemiologists, analysts and TB Program representatives—as well as external experts—was formed to develop a surveillance definition for high incidence and to review the outbreak definition outlined in the 6th edition of the *Canadian Tuberculosis Standards*,[11] within the context of TB in First Nation communities.

DEFINITION OF TB OUTBREAK AND HIGH INCIDENCE FOR SURVEILLANCE

Outbreak: Generally speaking, a TB outbreak constitutes an increase or higher number of cases of active TB in a community or a group of communities than expected in a given period. More specifically, the *Canadian Tuberculosis Standards*[1] define an outbreak of TB as:

A community is considered to be experiencing an outbreak when one or both of the following criteria are met:

- *During and because of a contact investigation, two or more of the identified contacts are diagnosed as secondary cases of active TB;* ***OR***
- *Any two or more cases occurring within one year or less of each other are discovered to be linked, but the linkage is established outside of a contact investigation (e.g., two patients who received a diagnosis of TB outside of a contact investigation are found to work in the same office, yet they were not identified as contacts of each other). The linkage between cases should be confirmed by genotyping results if isolates have been obtained.*

High incidence: Prior to the development of the current Framework, there was not an agreed upon definition of TB high incidence, making it difficult to develop a targeted and standardized approach to high incidence communities. While many regions already identify high incidence communities based on judgment and expertise, the application of a standardized surveillance definition would allow the identification of communities that fall into a high incidence category using a standardized and consistent methodology, allowing for the aggregation of data at a national level (denominalized) and an analysis of trends over time. The definitions set out in Table 2, below, have been tested with simulated and actual data and will undergo further validation.

A community can be considered high incidence under any of the three following scenarios:

1. *Two or more cases of active TB in the current (reporting) year, of which at least one is primary TB or smear-positive pulmonary TB;* ***OR***
2. *A five-year average incidence of TB that is* ***greater*** *than 100 cases per 100,000 population with at least one case in the previous three years;* ***OR***
3. *A five-year average incidence of TB that is* ***less*** *than 100 cases per 100,000 population but with two or more cases per year in at least two of the previous three years.*

Table 2: Definitions for High Incidence

	Year 1 Current year	Year 2 1 year ago	Year 3 2 years ago	Year 4 3 years ago	Year 5 4 years ago	Report as:
Number of new cases of active TB	≥2 cases at least one of which is primary TB or smear-positive pulmonary TB					High incidence
		5-year average incidence rate **>100 cases per 100,000** with at least 1 case in previous 3 years				High incidence
		5-year average incidence rate **<100 cases per 100,000** but ≥2 cases in at least 2 of the previous 3 years				High incidence

It should be noted that by virtue of these definitions, some communities will be simultaneously classified as "outbreak" and "high incidence." Also, as part of future reporting requirements, aggregated surveillance data on outbreaks and high incidence communities may be collected at the national level in order to determine trends and commonalities over time.

IMPLICATIONS FOR DEFINITIONS FOR TB PROGRAMMING

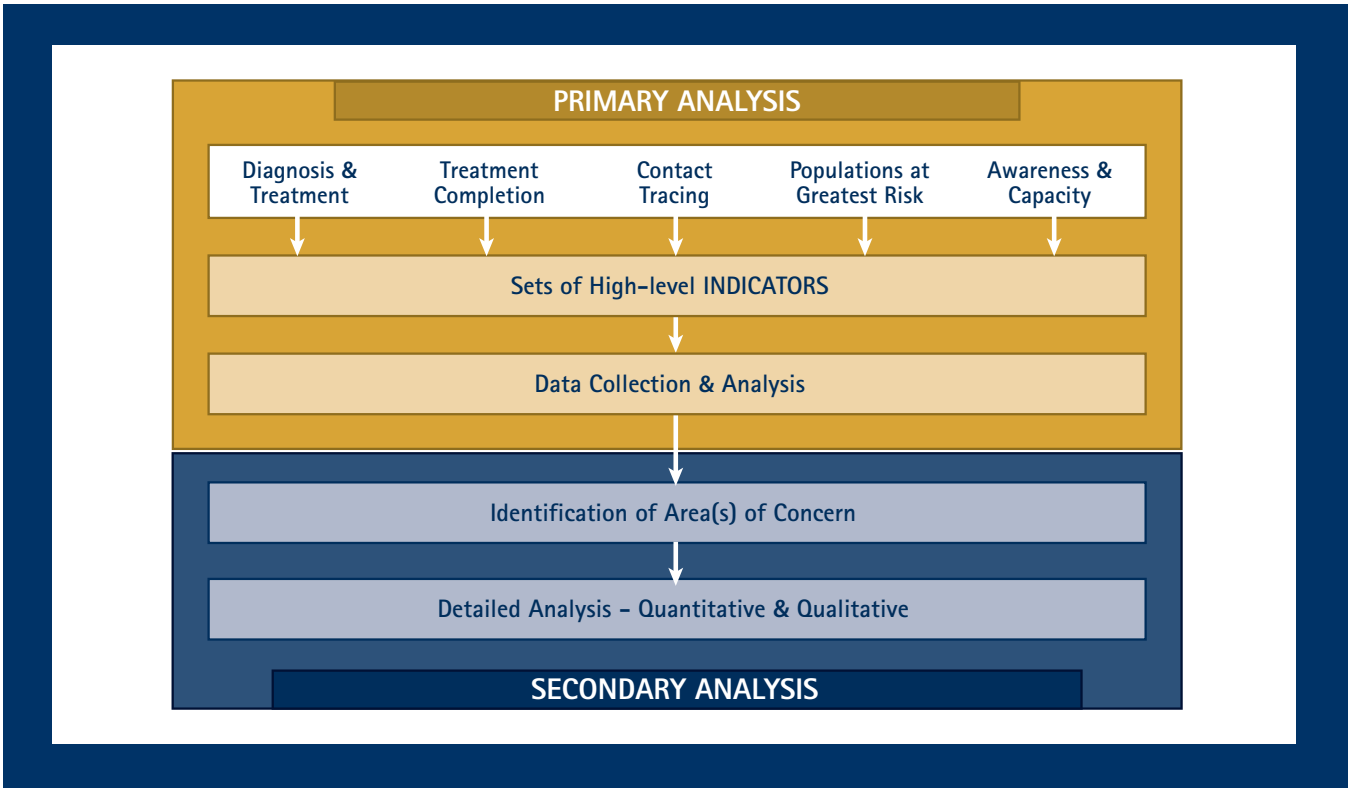
From a program perspective, the outbreak and high incidence definitions provide a first step for determining which communities require a more in-depth investigation and/or increased vigilance. When a community is identified as high incidence (see Appendix C for examples), the respective TB program should take a closer look at the pattern of TB cases within that community. For example, the response to a diagnosis of one case of active TB disease in a community that has not had any cases in the previous five years will likely be different than in a community that has been experiencing a succession of cases over the previous five years. The pattern of cases will determine how a program responds (see Appendices C, D and E). For some communities, being identified as high incidence will mean that no adjustments need to be made to programming. However, this can only be determined if a more in-depth investigation takes place. Ways of determining the factors that are creating high incidence are outlined and discussed below in Part C.

C. Enhanced Monitoring for Outbreaks and High Incidence

While useful for scoping the issue at a national level, high level indicators do not provide enough detail for regional and community-level programs to adjust their activities and approaches in order to break the cycle of transmission in high incidence communities. The FNIHB TB Program, in collaboration with partners and TB experts, has developed an approach for enhanced monitoring of TB in high incidence communities that will help determine underlying issues perpetuating TB in a community.

The components of this approach are set out as recommendations, enabling regional and/or community programs to tailor it to fit their unique needs, challenges and opportunities. Moreover, while this approach was developed with high incidence communities in mind, it can also be applied to any community. The approach has two levels of analysis: **Primary Analysis** and **Secondary Analysis** (see Figure 5 and further explanation, below).

Figure 5: Overview of Primary and Secondary Levels of Analysis



Primary Level of Analysis: The purpose of the primary level of analysis is to identify areas of concern that warrant further investigation by a TB program. Based on evidence and expert opinion, the following categories were identified as essential overarching program areas that should be investigated:

- ***Diagnosis and Treatment Initiation:*** encompasses any elements that lead to diagnosis (e.g., symptoms, accessing health care), pertain to diagnosis (e.g., TB expertise, laboratory), and involve treatment initiation (e.g., initial drug regimen).
- ***Treatment Completion:*** includes any factors that influence treatment completion (e.g., drug resistance, compliance with treatment, complications arising from treatment).
- ***Contact Tracing/Investigation:*** involves any components required to initiate and complete a contact investigation (e.g., identification of contacts, recommendations for treatment of contacts).
- ***Populations at Greatest Risk:*** highlights any issues, unique needs or circumstances that need to be considered for TB prevention and control when a sub-population is at greater risk of being infected with, developing and/or transmitting TB (e.g., testing for TB in individuals with HIV, screening at-risk groups). Populations at greater and increased risk are identified in Health Canada's Strategy Against TB, 2012[8] and the *Canadian Tuberculosis Standards*[1] and can be based on local epidemiology.
- ***Awareness and Capacity:*** identifies any concerns surrounding awareness within a community and/or health care professionals, as well as the capacity to provide quality TB prevention and control. It should be noted that strong awareness and capacity are essential factors across all functions of TB programming; concerns surrounding awareness and capacity will also be captured in other categories.

Focusing on cases that are potential transmitters within these categories—most often adults with pulmonary TB and who are culture positive—is important as they are the cases with the potential to transmit in the community.

A set of surveillance and high level indicators is identified for each of the categories described above (see Appendix D). The purpose of these indicators is to trigger further investigation into whichever area(s) of programming needs adjustment. For example:

> *Over two years, a large community identifies 10 individuals with active TB. Four of these individuals took a long time to seek medical care after the appearance of symptoms. Seven did not complete treatment within a year. All contacts were fully investigated for each individual according to current recommendations. One individual was co-infected with HIV/AIDS. For this community, the primary level of analysis would suggest that further investigation is needed for* ***Treatment Completion*** *and likely also for* ***Diagnosis and Treatment Initiation****.*

Secondary Level of Analysis: If any of the indicators and/or data collected for each category through the primary level of analysis trigger concern, a more in-depth analysis is essential. The purpose of the secondary level of analysis is to identify questions (see Appendix E) that can pinpoint specific issues that may be contributing to high levels of TB in a community. Once these issues are identified, programming can be adjusted by implementing activities, approaches, strategies and/or policies to address these issues and, subsequently, break the cycle of transmission of TB within the community.

Building on the example above:

> *Further investigation into* ***Treatment Completion*** *determined that patients were not completing treatment due to issues around mental health and addictions. The TB program began partnering with FNIHB's National Native Alcohol and Drug Abuse Program. Further investigation of the delays in diagnosis (****Diagnosis and Treatment Initiation****)*

determined that patients were not aware of the symptoms of TB and, thus, did not seek health care in a timely fashion. The TB program started a community-based awareness campaign, enlisting the aid of community leadership and former TB patients, to increase community members' knowledge of TB and its symptoms.

Flexibility in approach: Sometimes issues underlying the continuing transmission of TB in high incidence communities may already be known or suspected by a TB program and may not be sufficiently captured by the high level indicators identified in the primary analysis. In this case, it is recommended that programs look to the secondary level of analysis to develop and add high level indicators to their primary level of analysis. For example:

*The TB program suspects that there may be an issue with **Treatment Completion** as annual monitoring shows that although there is a high treatment completion rate, there are several cases that have relapsed. In this case, the TB program may wish to add more detailed indicators on **Treatment Completion** to the primary level of analysis.*

Maintaining "no" incidence: One of the distinct features of TB as a disease is the fact that, when infected, people can develop either active TB or latent TB infection (LTBI). As a result, communities that experience an increased and/or sustained level of TB run a strong risk of developing a reservoir of LTBI. Since a reservoir of LTBI represents a potential source of active TB, communities with reservoirs need to remain highly vigilant after an outbreak and/or period of high incidence. Factors such as changing demographics (e.g., aging population) or increased cases of other diseases (e.g., HIV/AIDS) could lead to an increased risk of reactivation of TB from the LTBI reservoir in the community. Particular care needs to be taken to ensure that those who are newly infected are identified and provided with preventive therapy when relevant in order to help minimize the size of the LTBI reservoir within the community.

Anecdotally, regional programs report examples of communities that have successfully dealt with an outbreak, only to see a resurgence in cases of active TB a few years later. This is thought to be due to a decrease in vigilance and program activities, especially those related to prevention and community awareness that can occur when TB appears to be eliminated in a community. Similarly, it has been formally documented that a decrease in TB prevention and control activities due to low rates contributed to a large resurgence in cases of active TB in New York City in the 1990s.[12] Therefore, a lack of active TB does not necessarily mean "no TB."

In summary, TB programs need to recognize the risk a community carries for TB based on its history and resilience in coping with TB in the past and remain vigilant through consistent monitoring and proactive prevention efforts. It is strongly recommended that enhanced monitoring be maintained after communities are no longer considered to be in an outbreak or experiencing a period of high incidence. How long this enhanced monitoring continues should be negotiated with partners and reflect the community's risk for TB and the broader context of TB in the surrounding area.

D. Evaluation

The World Health Organization defines evaluation as the systematic and objective assessment of the relevance, adequacy, progress, efficiency, effectiveness and impact of a course of actions in relation to objectives, and taking into account the resources and facilities that have been deployed.[13] Evaluation analyzes why intended results were (or were not) achieved by assessing causal links between results and inputs or resources, by examining the implementation process and unintended results, and by providing highlights, lessons learned or recommendations for improvement.[14]

The Government of Canada's *Financial Administration Act* requires that each department complete evaluations for any programs involved in grants and contributions. Areas of focus for such evaluations are identified under Treasury Board's Policy on Evaluation.[15]

Program evaluations occur on a five-year cycle and are currently coordinated by Health Canada and the Public Health Agency of Canada's Portfolio Evaluation Services with input from relevant programs. The FNIHB TB Program is evaluated as part of the Communicable Disease Control and Management (CDCM) program evaluation.

In addition, special ad hoc studies/"evaluations" can be designed and completed for specific topics relevant to the TB program. For example, Health Canada undertook an evaluation of Bacille Calmette-Guérin vaccine (BCG) discontinuation in 2010[16] and determined that no unintended consequences (such as TB meningitis) have occurred due to this policy. This exemplifies how evaluation can play an important role in determining whether or not specific programmatic changes are successful. These ad hoc studies/"evaluations" can be initiated as required in collaboration with evaluation experts internal and/or external to Health Canada.

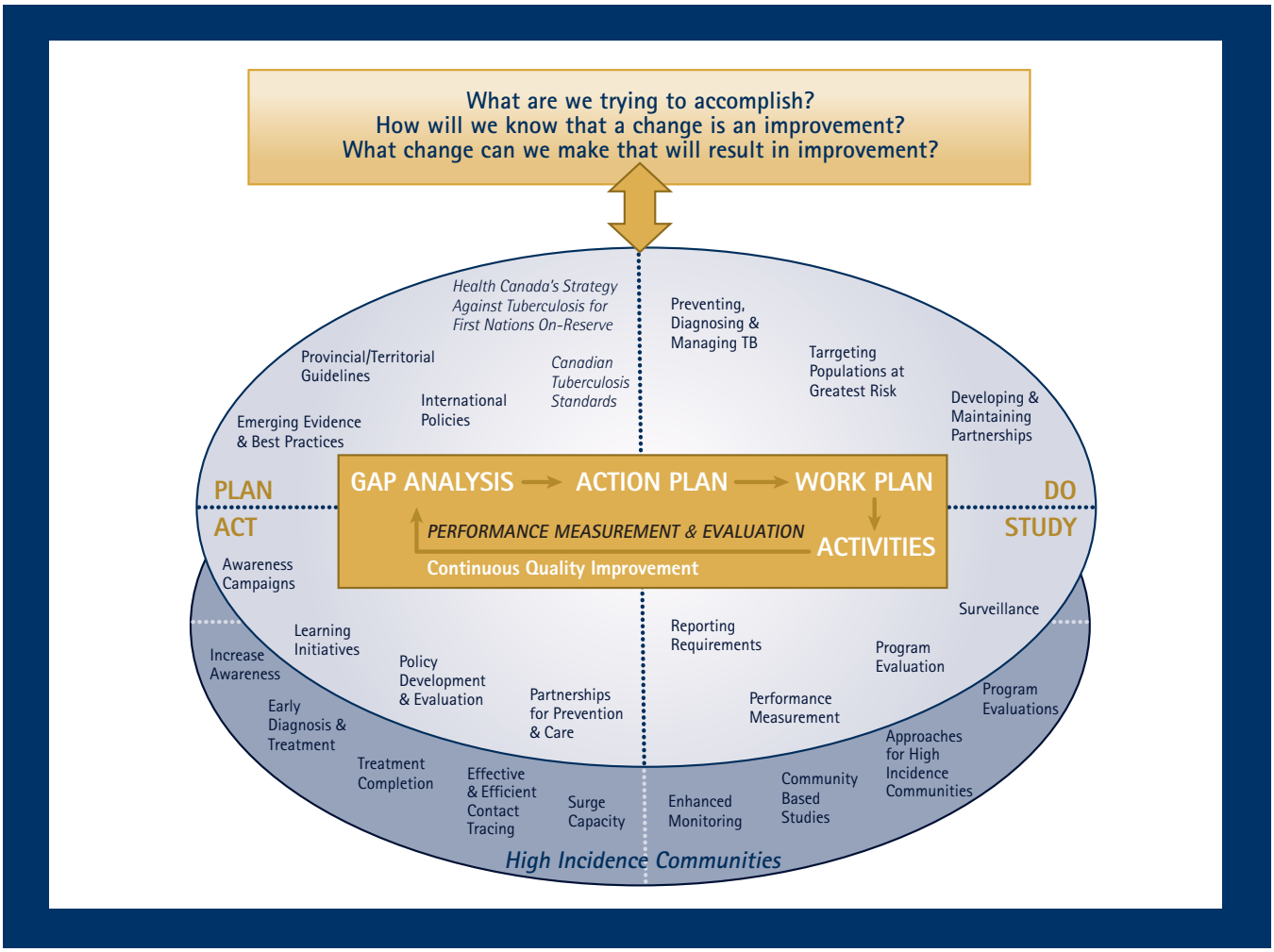
PART 3: Continuous Quality Improvement and FNIHB TB Programming

Generally speaking, the incidence and burden of TB in First Nation populations is higher than for non-Aboriginal populations in Canada. Health Canada's Strategy Against TB, 2012[8] outlined an approach to reduce this inequity, with a vision for sustainable, equitable and effective TB control.

Through performance measurement, TB programs can ensure that they are delivering sustainable, equitable and effective TB programming—including confirming that all components of a quality TB program are in place and working effectively. The latter is essential to reaching the goal of reducing the incidence and burden of TB in First Nations on-reserve. Achieving this goal will only happen over time, pointing to the need for programs to remain vigilant to changing circumstances, to the needs of their population and in their health care delivery system.

Continuous quality improvement uses surveillance, performance measurement and evaluation to obtain information that can improve the quality of a program and allow it to adapt effectively to changing needs and circumstances. A depiction of how performance measurement and evaluation for FNIHB TB programming fit into the cycle of continuous quality improvement (specifically, into the Plan-Do-Study-Act (PDSA) Model for Improvement) is set out below (see Figure 6).[17,18,19]

Figure 6: Continuous Quality Improvement for FNIHB TB Programming



Progress can be tracked only when programs are measured against a starting point or baseline. Typically, "baseline data" are data that are measured prior to an intervention, initiative or event that is expected to cause change. Ongoing, data collected and analyzed for FNIHB TB programming will not only contribute to efforts in continuous quality improvement, they will also help track the impact of Health Canada's Strategy Against TB.[8]

Targets are also important for determining the progress of a program. Targets should be based on epidemiology, trends, evidence and best practices, while keeping in mind any limitations and challenges. In the case of First Nations on-reserve, targets must be set in collaboration with partners, especially when partners are directly involved in the delivery of TB prevention and control programs in First Nation communities. It is expected that although all programs will consider targets recommended in the *Canadian Tuberculosis Standards*[1] and *Guidance for Tuberculosis Prevention and Control Programs in Canada*[7], there will be some variation as regions align and work with partners.

Ongoing assessment of all aspects of TB prevention and control programs, including the instruments of assessment themselves, is what will ensure continuous quality improvement over time. In alignment with Health Canada's Strategy Against TB[8], FNIHB's TB programs will continue to place a high priority on performance measurement and evaluation while working toward reducing the incidence and burden of TB in First Nations on-reserve.

APPENDIX A: Overview of Health Canada's Strategy Against Tuberculosis for First Nations On-Reserve

To address the continuing high rates of TB in First Nations on-reserve, Health Canada released *Health Canada's Strategy Against Tuberculosis for First Nations On-Reserve*[8] (the Strategy) on March 21, 2012. The Strategy was developed in collaboration with First Nation organizations, TB experts and provincial and federal partners, the latter of which included the Public Health Agency of Canada and Aboriginal Affairs and Northern Development Canada.

Health Canada's Strategy Against TB, 2012:[8]

- Aims to reduce the incidence and burden of TB in First Nations on-reserve through the application of current evidence, best practices and lessons learned.
- Enables Health Canada's regional TB programs to apply key elements that will address their population's unique circumstances and needs.
- Provides targeted approaches for populations at higher risk for TB in First Nation communities.
- Promotes partnerships to address complex issues such as integrated access to care and social determinants of health.
- Emphasizes continuous quality improvement as a key element in effective and efficient TB programming.

The Strategy's three themes are:

- ***Preventing, Diagnosing, and Managing TB:*** focuses on high quality, effective TB programming at community and regional levels. Includes: primary prevention; latent TB infection (LTBI) identification and management; early case finding; contact identification; treatment compliance; surveillance; targeted screening; education/training; and community awareness.
- ***Targeting Populations at Greatest Risk for TB:*** takes into account issues relevant to First Nations that are recognized as increasing the risk of TB. Includes: outbreaks and high incidence; remoteness and isolation; TB-HIV co-infection; pediatric population; chronic medical conditions; mental health and addictions; and untreated LTBI and aging.
- ***Developing and Maintaining Partnerships:*** focuses on the necessity of effective partnerships at all levels to prevent and control TB and to strengthen alignment with federal, provincial and community health systems. Important for: populations moving on- and off-reserve; integrated care; data sharing; and social determinants of health.

A copy of *Health Canada's Strategy Against Tuberculosis for First Nations On-Reserve* can be accessed at: publications@hc-sc.gc.ca.

APPENDIX B: National Performance Measurement and Health Data Indicators for TB Programming

As reporting at Health Canada evolves, data collection and reporting mechanisms change over time with the general aim of reducing the burden of reporting for programs and communities. However, the topics upon which programs report performance measurement data largely remain unchanged. Outlined below are the topics that are typically used for performance measurement of FNIHB's TB programming and how they align with the Strategy's themes and this Framework's logic model. In addition, current indicators, data sources and reporting requirements are highlighted. Tuberculosis health data indicators relevant to TB are also presented below.

Please Note: The indicators below are reflective of the 2013–2014 reporting period (performance measurement indicators are reported for the fiscal year [2013–2014]; program data indicators are reported for the calendar year [2013]) and may undergo revision in future reporting periods.

PERFORMANCE MEASUREMENT INDICATORS—FNIHB NATIONAL TB PROGRAM, 2013–2014 FISCAL YEAR

Strategic Themes	Short-Term Outcomes	Topics for Performance Measurement	Indicators up to 2013–2014	Data Source(s)	Information Reported In
THEME 1: Prevention, Diagnosing and Managing TB	Improved access to TB prevention and control programming	Policies, guidelines, strategies, frameworks Research and evaluation reports Partnerships	• Number and brief description of TB-related Inter-Departmental Letter(s) of Agreement, and Memoranda of Understanding in place with other federal and/or provincial government entities • Number and brief description of key TB working groups and committees being led or participated in • Number and description of regional policies, procedures, publications, guidelines, strategies and/or frameworks developed or adapted as required relating to TB	National Regional Provincial Regional Health Authority(ies) Community	Annual Performance Measurement Reports PMF
	Improved staff retention and knowledge	Training/ education Knowledge transfer Partnerships	• Number of TB knowledge transfer materials produced and/or activities engaged in (e.g., poster presentations, conference presentations, publications); include a brief description of the activity including when and where it took place	National Regional Community	Annual Performance Measurement Reports PMF CBRT

Strategic Themes	Short-Term Outcomes	Topics for Performance Measurement	Indicators up to 2013–2014	Data Source(s)	Information Reported In
THEME 2: Targeting Populations at Greatest Risk	Increased focus on populations at greatest risk for TB	TB testing/ screening of at-risk groups Policies, guidelines, strategies, frameworks	• Description of TB screening programs/ policies • Please specify the group(s) screened, method(s) of screening, etc.	Regional Provincial Regional Health Authority(ies) Community	Annual Performance Measurement Reports CBRT
THEME 3: Developing and Maintaining Partnerships	Expanded community capacity, involvement and awareness	Training/ education Awareness Partnerships Policies, guidelines, strategies, frameworks Community-based project	• Number of communities conducting TB-related social marketing/public education/awareness activities and a brief description of these activities	National Regional Provincial Regional Health Authority(ies) Community	Annual Performance Measurement Reports PMF CBRT

CBRT—Community Based Reporting Template

PMF—Performance Measurement Framework

HEALTH DATA INDICATORS—FNIHB NATIONAL TB PROGRAM, 2013 CALENDAR YEAR, RELEVANT FOR ALL STRATEGIC THEMES

Category	Indicators	Data Source(s)	Data Reported In	Notes
Incidence	Number of newly reported cases of active TB (new and re-treatment cases) by age and sex	CTBRS Regional Province Community	Annual Program Data Reports PMF	
	Number of newly reported cases of respiratory TB by age and sex; by primary, pulmonary or other respiratory	CTBRS Regional Province Community	Annual Program Data Reports	
	Number of newly reported cases of non-respiratory TB by age and sex	CTBRS Regional Province Community	Annual Program Data Reports	

Category	Indicators	Data Source(s)	Data Reported In	Notes
Incidence Continued	Number of newly reported cases of drug-resistant TB by age and sex	CTBRS Regional Province Community	Annual Program Data Reports	
	Number of newly reported cases of active TB (new and re-treatment cases) who were also co-infected with HIV by age and sex	Regional Province Community	Annual Program Data Reports	
Treatment Outcome	Number of TB cases (active and re-treatment) diagnosed in [year]	CTBRS Regional Province Community	Annual Program Data Reports	Treatment completion rate is reported in: PMF PMS
	Number of TB cases (active and re-treatment) diagnosed in [year] who completed treatment (including cured) within one year of treatment start date	CTBRS Regional Province Community	Annual Program Data Reports PMF	
	Number of TB cases diagnosed in [year] who died before or during treatment within one year of treatment start date	CTBRS Regional Province Community	Annual Program Data Reports	
	Number of TB cases diagnosed in [year] who transferred out before treatment completion within one year of treatment start date	CTBRS Regional Province Community	Annual Program Data Reports	
Deaths (among active TB cases)	Number of deaths—TB was direct cause	CTBRS Regional Province Community	Annual Program Data Reports	
	• Number of deaths—TB contributed but was not cause of death	CTBRS Regional Province Community	Annual Program Data Reports	
	• Number of deaths—had TB, but TB did not contribute to death	CTBRS Regional Province Community	Annual Program Data Reports	

Category	Indicators	Data Source(s)	Data Reported In	Notes
LTBI	Total number of reported contacts of active TB cases diagnosed in [year]	Regional Province Community	Annual Program Data Reports	Contacts and LTBI as defined in CTS
	• Number of close contacts of active TB cases diagnosed in [year]	Regional Province Community	Annual Program Data Reports	
	• Number of Other Contacts (not close) of Active TB Cases diagnosed in [year]	Regional Province Community	Annual Program Data Reports	
	Of the total number of reported contacts of active TB cases diagnosed in [year], the number having no known past history of TB or LTBI (positive TST/IGRA), who were screened for LTBI	Regional Province Community	Annual Program Data Reports	
	Of the number of contacts screened for LTBI above, the number with a new positive TST/IGRA or TST/IGRA conversion (i.e., number of newly identified LTBI)	Regional Province Community	Annual Program Data Reports	
	Of the number of contacts with a new positive TST/IGRA or TST/IGRA conversion above, the number recommended for treatment of LTBI	Regional Province Community	Annual Program Data Reports	
	Of the number of contacts recommended for treatment of LTBI above, the number who accepted treatment for LTBI	Regional Province Community	Annual Program Data Reports	
	Of the number of contacts accepting treatment of LTBI above, the number who started treatment	Regional Province Community	Annual Program Data Reports	
	Of the number of contacts accepting treatment of LTBI above, the number (without contraindications to INH or RMP) who started treatment	Regional Province Community	Annual Program Data Reports	
	Of the number of contacts starting treatment of LTBI above (and without contraindications to INH or RMP), the number completing treatment within 12 months of treatment initiation	Regional Province Community	Annual Program Data Reports	
	Of the number of contacts starting treatment of LTBI above (and without contraindications to INH or RMP), the number completing treatment at the time of reporting (irrespective of length of treatment)	Regional Province Community	Annual Program Data Reports	

Category	Indicators	Data Source(s)	Data Reported In	Notes
BCG Vaccination	Number of communities using BCG vaccination	Regional Community	Annual Program Data Reports	Only relevant for regions where BCG is still in use
	Number of BCG vaccinations administered	Regional Community	Annual Program Data Reports	
	Number of births eligible to receive BCG vaccination during reporting period	Community	Annual Program Data Reports	
	Number of reported adverse reactions from BCG	Regional Community	Annual Program Data Reports	
	Adverse reactions from BCG: line list of type of reaction(s) for each adverse event	Regional Community	Annual Program Data Reports	
Outbreaks	Number of new outbreaks (new in the reporting period)	Regional Province Community	Annual Program Data Reports	Based on CTS definition for outbreak
	Number of outbreaks in [year] that were ongoing from previous year	Regional Province Community	Annual Program Data Reports	
	Number of active TB cases per new outbreak	Regional Province Community	Annual Program Data Reports	
	Number of active TB cases per outbreak ongoing from previous year(s)	Regional Province Community	Annual Program Data Reports	

BCG—Bacille Calmette-Guérin vaccine
CTBRS—Canadian Tuberculosis Report System
CTS—*Canadian Tuberculosis Standards*[1]
IGRA—interferon-gamma release assay
INH—isonicotinylhydrazine
LTBI—latent tuberculosis infection
PMF—Performance Measurement Framework
PMS—Performance Measurement Strategy
RMP—rifampin
TST—tuberculin skin test

APPENDIX C: Background on Outbreak and High Incidence Definitions

For outbreaks of TB, a standard definition has not been used consistently by Health Canada for First Nations communities across Canada. As a result, TB outbreaks in First Nations communities have not been consistently reported and neither meaningful analysis nor roll-up of national data have been possible. Similarly, while many regions can already identify high incidence communities, no standardized definition exists for surveillance purposes, meaning aggregation of data at a national level and the analysis of trends over time is not possible.

Health Canada's Strategy Against Tuberculosis in First Nations On-Reserve[8] identified outbreaks and high incidence communities as two key issues to be addressed in order to reduce rates of TB in First Nations on-reserve. However, without consistent use of standardized definitions, it will be difficult to achieve this goal.

As part of the early implementation of the Strategy, a discussion group of Health Canada TB program staff, policy analysts, and epidemiologists from both national and regional levels, as well as external TB experts, collaborated in reviewing the outbreak definition from the *Canadian Tuberculosis Standards, 6th Edition*[11] (CTS 6th) for its use in First Nations communities and in developing a definition of high incidence for surveillance purposes.

Outbreak Definition

In 2010, a report was developed for Health Canada to determine whether the outbreak definition presented in the CTS 6th[11] was relevant in the context of First Nations communities.[20] TB experts across Canada were surveyed and the majority believed that the CTS 6th[11] definition was relevant as long as the unique demographic, social and structural circumstances that impact ongoing TB transmission in First Nations communities were also considered when applying the definition for program purposes.

In reviewing this report and historical outbreak data previously collected via regional programs, the discussion group determined, in agreement with the Health Canada report,[20] that the CTS outbreak definition, if used in a consistent manner, is relevant for identifying outbreaks of TB in First Nations communities for surveillance purposes. For program use, the First Nations context must be considered when applying the CTS outbreak definition.

High Incidence Definition

A "high incidence" community is a community that is experiencing a current or recently elevated burden of TB disease. A designation of "high incidence" for a reporting year is a cue to the regional and/or community level TB program to assess whether there are program factors that require adjustment to address the current or recent burden of TB. A designation of high incidence may or may not result in changes to programming but, most importantly, it signals that a closer look at the community's TB situation is needed.

A quantitative surveillance definition allows programs to summarize in a meaningful way, and at a regional or national level, the number of high incidence communities. Therefore, a surveillance definition of high incidence was developed to facilitate regional and national monitoring of the number of high incidence communities and any related trends.

Using quantitative data (i.e., case numbers and rates) to determine whether a community is high incidence increases the objectivity of the designation. From a practical perspective, understanding a community that is deemed high incidence is usually the result of a composite of qualitative and quantitative information. In other words, from a TB programming perspective, the number of cases in the current year, the number of cases in previous years, or the five-year average are only part of a community's TB story. This information should be considered in the context of the community's resources, capacities and experiences when assessing TB risk and burden/high incidence of TB from a programming perspective.

Based on a literature review of domestic and international research and surveillance methods, the discussion group developed an initial approach for identifying high incidence. This approach was discussed and refined by the discussion group before being sent to TB experts in Canada for feedback. Resulting from this process was a set of definitions, as well as a list of considerations for use and interpretation. These definitions were tested with simulated and actual data by national and regional program representatives. The definitions were further simplified to facilitate their use in the field (see Table 1 and Figure 1, below).

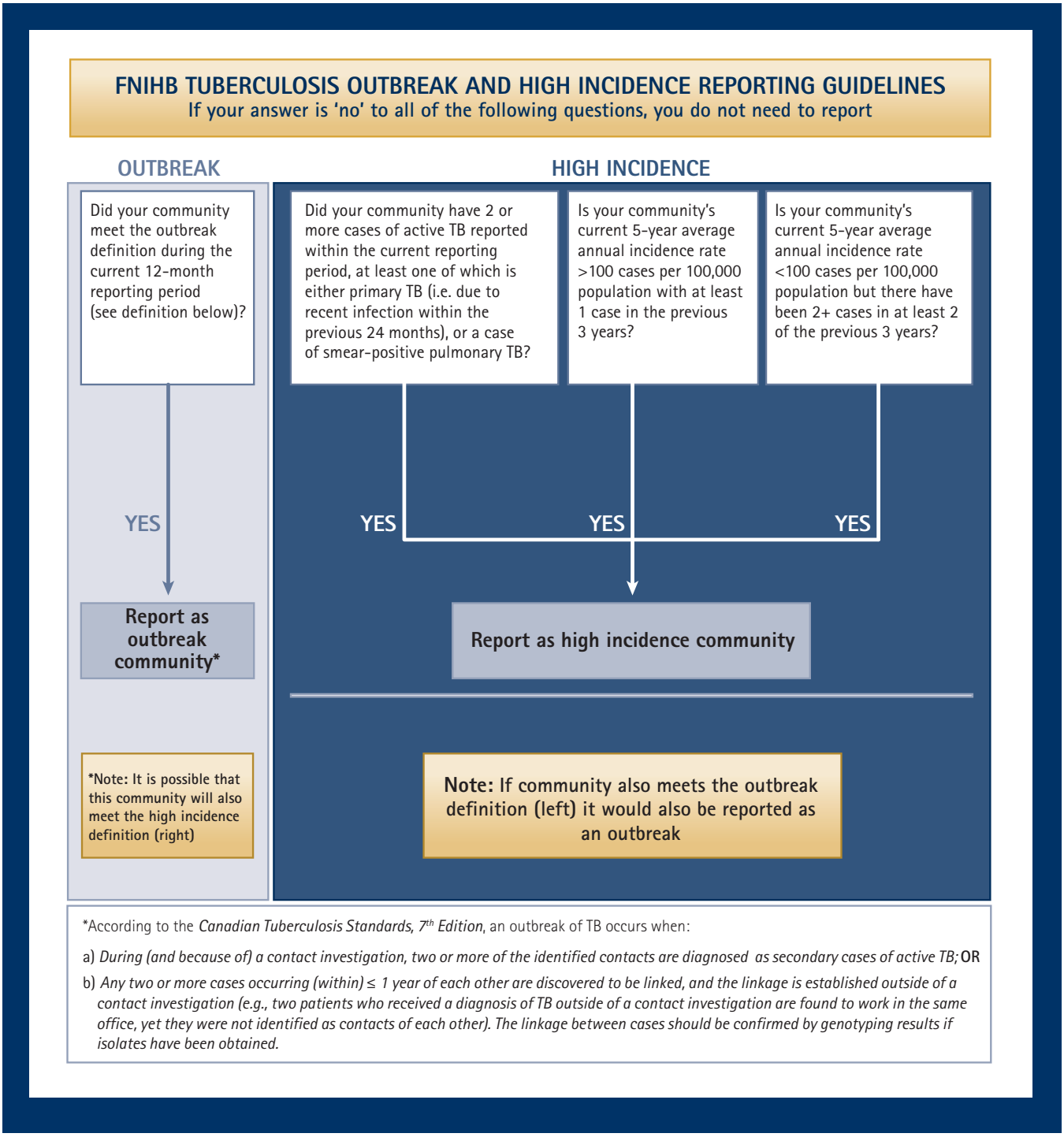
A community can be considered high incidence under the three following scenarios:

1. *Two or more cases of active TB in the current (reporting) year, of which at least one is primary TB or smear-positive pulmonary TB;* ***OR***
2. *A five-year average incidence of TB that is* ***greater*** *than 100 cases per 100,000 population with at least one case of active TB in the previous three years;* ***OR***
3. *A five-year average incidence of TB that is* ***less*** *than 100 cases per 100,000 population but with two or more cases of active TB per year in at least two of the previous three years.*

Table 1: Definitions for High Incidence

	Year 1 Current year	Year 2 1 year ago	Year 3 2 years ago	Year 4 3 years ago	Year 5 4 years ago	Report as:
Number of new cases of active TB	≥2 cases at least one of which is primary TB or smear-positive pulmonary TB					High incidence
		5-year average incidence rate **>100 cases per 100,000** with at least 1 case in previous 3 years				High incidence
		5-year average incidence rate **<100 cases per 100,000** but ≥2 cases in at least 2 of the previous 3 years				High incidence

Figure 1: FNIHB Tuberculosis Outbreak[1] and High Incidence Reporting Guidelines Flow Chart



Note that a community may meet more than one of the criteria above. In addition, a community may meet the definition of a TB outbreak as well as being designated as high incidence. The criteria for a TB outbreak are described in the *Canadian Tuberculosis Standards, 7th Edition*,[1] which are available on the Canadian Thoracic Society website at: www.respiratoryguidelines.ca/tb-standards-2013

Considerations for Surveillance

1. In isolation, these definitions are primarily intended for annual surveillance purposes, namely to track the number of First Nations communities that meet the definition in a standardized manner. Before using the data collected from these definitions for program planning and evaluation, it is imperative to recognize and account for the complexity of TB in First Nations communities.
2. The CTS[1] outbreak definition is sensitive such that events that meet the CTS definition may or may not be officially declared as an outbreak by the local or FNIHB regional medical officer of health. Often, small clusters are contained and are not officially declared as an outbreak despite meeting the definition outlined in the CTS.
3. In regions in which TB rates are relatively low, the CTS definition may be well-suited for identifying distinct outbreaks of active TB. However, it may be less suitable for identification of outbreaks in regions and/or communities with existing higher rates of active TB, as transmission events and secondary cases merge together to create an epidemiological continuum, often over time.
4. Application of the CTS definition is challenging because the identification of source cases, as well as linkages between the source case and secondary cases, requires data that are not always timely. For example, the time that may elapse between infection, development of active TB disease, and diagnosis of a case can result in difficulties in linking the source case to secondary cases, meaning an outbreak might be only identified retrospectively.
5. According to the U.S. Centers for Disease Control and Prevention,[21] TB genotyping in combination with epidemiological data can play an important role in: a) identifying linkages between cases; b) identifying cases resulting from reactivation of TB infection that was acquired in the past; and c) ruling out TB when culture results are false-positive. Genotyping data for TB cases are available to varying degrees across Health Canada regions.

Considerations for Interpretation and Use

1. Health Canada's involvement in TB prevention and control varies across regions and communities. This variation may create challenges in terms of accessing data for surveillance, such as genotyping results to confirm linkages among cases.
2. Surveillance data collected in the context of an outbreak or condition of high incidence may not necessarily reflect the workload in a First Nations community during a TB outbreak. For example, a single case of active TB in some First Nation communities may require an intensive response and additional resources. Usually, the level of response would be based on the TB program's structure within the community and/or the presence of additional risk factors such as diabetes, HIV/AIDS, substance abuse, and social determinants of health.[22]
3. TB transmission can cross geographic boundaries. For this reason, identifying the number of communities with cases linked to a particular outbreak or period of high incidence will provide important information about the geographic spread of TB.
4. Many First Nation communities across Canada have had no active TB cases for many years. When traditionally low incidence communities do experience active TB, focused TB prevention and control activities are often required. However, these activities are not necessarily the same as those required in communities already experiencing high incidence.
5. It is important to note that although the high incidence definition was developed to help programs identify First Nation communities needing enhanced TB prevention and control programming, communities not classified as high incidence are still recognized as being important. Efforts aimed at TB prevention and control in low incidence areas are required in order to ensure that TB remains low in these communities.

Step-by-Step Process for Applying the Surveillance Definition for High Incidence Communities

Please note that the following is based on fictional data.

Assemble Materials:

- FNIHB Tuberculosis Outbreak and High Incidence Reporting Guidelines Flow Chart (Figure 1).
- Community TB data, specifically: number of active TB cases diagnosed in each community for the previous five years and corresponding community population numbers. Cases are counted in the year they were diagnosed. Note that you may also need specific details about the cases, such as disease site(s) and laboratory results.

Steps to Follow:

1. Organize your data. You will need at least five years of data (including the current/reporting year) to perform these analyses. You may find it useful to enter the data into a spreadsheet (e.g., MS Excel) in the following format. To keep a running tally, case counts and population can be added each year.

Community	2006		2007		2008	
	TB Cases	Population	TB Cases	Population	TB Cases	Population
A						
B						
C						

2. Calculate the five-year average incidence rate of new active TB cases for each community. To do this, add up the total number of cases in the previous five years (current year and four prior)—this becomes the numerator. Then add up the total population of the community for each of the previous five years—this becomes the denominator. Divide the numerator by the denominator and then multiply by 100,000 to give the average five-year incidence rate per 100,000 population. See the example below:

Community G

Year	2006	2007	2008	2009	2010	Sum
Cases	0	2	1	3	2	8
Population	4,114	4,218	4,352	4,446	4,526	21,656

Average five-year incidence rate = 8/21,656 x 100 000
= 37.0 cases per 100,000

3. Perform these calculations for all communities. When complete, you should have a data table similar to the one below.

Active TB Cases, Community Population, and Five-Year Average TB Incidence, by Community, 2006–2010

Community	2006		2007		2008		2009		2010		Five-Year Average (2006–2010)
	TB Case Count	Pop.	TB Case Count	Pop.	TB Case Count	Pop.	TB Case Count	Pop.	TB Case Count	Pop.	
A	1	957	0	963	0	989	0	997	0	1,004	20.4
B	0	387	0	396	0	408	0	415	1	426	49.2
C	0	339	0	347	0	351	0	356	0	365	0.0
D	0	331	3	332	0	335	2	344	2	354	408.8
E	1	300	0	325	0	333	0	321	0	314	62.8
F	3	128	0	132	0	135	0	144	0	148	436.7
G	0	4,114	2	4,218	1	4,352	3	4,446	2	4,526	37.0

4. Identify all communities with a five-year average incidence greater than 100 cases per 100,000 population. ***In the table above, these would be communities D and F.*** Of these, determine which communities had at least one case in the previous three years. ***In the table above, this would be Community D only.*** Any communities with at least one case in the previous three years, and a five-year average incidence of greater than 100 cases per 100,000 population, should be designated as "high incidence," in this case, Community D.
5. Next, identify all the communities that have had two or more cases per year in at least two of the previous three years, even if the five-year averages are not greater than 100 per 100,000 population. ***In addition to Community D, this also implicates Community G.*** These two communities should be designated as "high incidence."
6. Identify any communities that have cases in the current/reporting year. For any communities with two or more cases, determine if one or more of the cases were primary TB or smear-positive pulmonary TB. Any community with two or more cases, at least one of which was primary TB or smear-positive pulmonary TB, should be designated as "high incidence." ***This may also implicate Communities D and G; however, they have already been designated as high incidence under previous criteria. Communities with two or more cases detected within one year of each other may also meet the definition of a TB outbreak and should be assessed for this potential.***

In summary, the high incidence communities identified through this exercise are Communities D and G.

APPENDIX D: Enhanced Monitoring for High Incidence—PRIMARY ANALYSIS

For the primary level of analysis, the following indicators are recommended as a starting point for determining the underlying factors contributing to a high incidence of TB in a community. Particular attention is given to cases with the potential to transmit TB—i.e., adolescents or adults with culture-positive pulmonary TB. Data sources, frequency of data collection and thresholds for each calculation should be determined with all partners involved in the delivery and uptake of TB services. Indicators are grouped according to what can be collected at a community level and what can be collected at the regional level. Indicators are further grouped into the five categories (Diagnosis and Treatment Initiation; Treatment Completion; Contact Tracing/Investigation; Populations at Greatest Risk; Capacity and Awareness) outlined in the main document.

COMMUNITY-LEVEL DATA

DIAGNOSIS AND TREATMENT INITIATION*

Indicator	Definition	Purpose	Calculation
At diagnosis, proportion of cases that are:			
Smear-positive	Presence of at least one acid-fast bacilli (AFB) smear-positive (semi-quantitative smear 1+ or greater) airway secretion specimen (spontaneously expectorated sputum, induced sputum, bronchial wash, broncho alveolar lavage, tracheal tube or endotracheal tube suctioning or gastric aspirate), collected on or before the start date of treatment or date of death in the event the patient died before treatment could begin	Infectiousness of cases	= (# of smear-positive pulmonary cases) / (total # of cases)
Re-treatment	1. a) Documented evidence or adequate history of previously active TB which was declared cured or treatment completed by current standards b) At least a six-month interval since the last day of previous treatment c) Diagnosis of a subsequent episode of TB that meets the active TB case definition ***OR*** 2. a) Documented evidence or adequate history of previously active TB which cannot be declared cured or treatment completed by current standards b) Inactive disease for six months or longer after the last day of previous treatment c) Diagnosis of a subsequent episode of TB that meets the active TB case definition[1]	Effectiveness of treatment; persistence of bacteria	= (# of re-treatment cases) / (total # of cases)

Indicator	Definition	Purpose	Calculation
Drug-resistant	A strain of TB that is resistant to one or more of the four first-line drugs (isoniazid, rifampin, pyrazinamide, ethambutol)[1] Primary resistance (PR): previously untreated patients found to have drug-resistant isolates before beginning treatment Acquired resistance (AR): initially drug susceptible but develop resistance during treatment or cases where pre-treatment isolate is drug-resistant and who give a history of having been treated in the past	Presence of drug-resistant TB in community, whether primary or acquired	PR = (# of primary drug-resistant cases) / (total # of culture-positive cases) AR = (# of initially drug susceptible cases that became drug resistant during treatment) / (total # of cases with initially susceptible isolates)
Average time between:			
Symptom(s) onset and date of diagnosis**	Symptom onset is based on when client first notices symptoms attributable to TB, such as cough or change in existing cough	Delays in diagnosis Also look at range: a small range may suggest a specific underlying factor while a large range may relate to several underlying factors	= (sum of time between symptom onset and date of diagnosis) / (total # of cases)
Date of diagnosis** and treatment initiation	Treatment initiation is when client is provided with treatment specifically for TB	Delays in treatment initiation, i.e., delay from positive smear or culture report Also look at range: a small range may suggest a specific underlying factor while a large range may relate to several underlying factors	= (sum of time between date of diagnosis and treatment initiation) / (total # of cases)
Proportion of cases:			
Starting treatment within 48 hours of receipt of laboratory confirmation	Treatment must be specifically for TB	Starting treatment only when TB is lab confirmed	= (# of cases starting treatment within 48 hours of receipt of lab confirmation) / (total # of lab confirmed cases)

*For cases of active TB unless otherwise specified.

**Date of diagnosis is defined as start date of treatment.

AFB—acid-fast bacilli

AR—acquired resistancePR—primary resistance

TREATMENT COMPLETION*

Indicator	Definition	Purpose	Calculation
Proportion of cases for which adequate treatment was completed	Adequate treatment is defined based on the *Canadian Tuberculosis Standards*,[1] as well as any additional policies required by the TB program providing treatment	Effectiveness of treatment	= (# of cases completing adequate treatment) / (total # of cases)
Average time to complete treatment (adult [age >14 years] drug susceptible culture-positive and culture-negative pulmonary cases only)**	Treatment completion of active disease is defined as treatment completed without submission of an end of treatment specimen for AFB smear and culture Cure of active disease is defined as treatment completion with submission of an end of treatment specimen for AFB smear and culture with a negative result for both	Treatment adherence and/or complications	= (sum of time to complete treatment for all cases) / (total # of cases)

*For cases of active TB unless otherwise specified.

**Does not include TB deaths within one year of start date of treatment, those that transferred out and those that were co-morbid with CNS TB, disseminated or miliary TB, or bone and joint TB.

AFB—acid-fast bacilli

CNS TB—central nervous system tuberculosis

CONTACT TRACING/INVESTIGATION*

Indicator	Definition	Purpose	Calculation
Proportion of high and medium priority contacts** of adult smear-positive pulmonary cases assessed within 30 days (one month)	Prioritization of contacts is as follows: High: close contacts (household or non-household) that are young (<5 years) and/or immunocompromised (across the lifespan) Medium: all other close contacts (household or non-household) and all casual contacts that are young (<5 years) and/or immunocompromised (across the lifespan) Low: all other casual contacts Close household contacts are those who regularly sleep in the same household as the infectious case on an ongoing basis (e.g., three or more times per week)[1] Close non-household contacts are those who have regular, extensive contact with the index case and share breathing space daily or almost daily, but do not sleep in the same household most of the time[1] Casual: those who spend time regularly but less frequently with the infectious case[1]	Effectiveness of contact investigation Efficiency in reducing transmission	= (sum of # of high and medium priority contacts per case assessed within 30 days) / (sum of total # of high and medium priority contacts per case)

Indicator	Definition	Purpose	Calculation
Proportion of contacts completely assessed: • Of the number of contacts that required an 8–12 week TST, how many completed? • Of the number of contacts that had a positive TST, how many had a chest X-ray?	All available experimental and epidemiologic evidence consistently shows that TST conversion (increase in size of a TST reaction on repeated testing that reflects new TB infection) occurs within eight weeks of exposure[1]	To determine whether contacts are being completely assessed	• For contacts that required an 8–12 week TST: = (sum of number of contacts that completed an 8–12 week TST) / (sum of total number of contacts that were required/ recommended to have an 8–12 week post-exposure TST) • For contacts that had a positive TST: = (sum of the number of contacts with a positive TST that had a chest X-ray) / (sum of total number of contacts that had a positive TST)
Average number of contacts per adult (age >14 years) smear-positive pulmonary case (close, casual, community)	In addition to close household and non-household contacts, other contact categories include: • Casual contacts are those who spend time less frequently with the infectious case[1] • Community contacts are those living in the same community or attending the same school or workplace but in a different classroom or area of workplace[1]	Depth of exposure of community to TB Idea of possible extent of transmission Also look at range: a small range may suggest a specific underlying factor while a large range may relate to several underlying factors	For close, casual and community: = (sum of contacts for all cases) / (total # of cases)
TST conversion among contacts of adult smear-positive pulmonary TB cases	Tuberculin conversion: an increase in size of a TST reaction on repeated testing that reflects new TB infection***[1]	Possible recent exposure Change in immune status	For each contact investigation: = (# of contacts with TST conversion) / (total # of contacts completely assessed)
Proportion of contacts of adult smear-positive pulmonary TB cases that were reported to be secondary cases when assessed during contact investigation	A secondary case is any case that was infected by a source case whose contacts were being assessed	Extent of transmission Infectiousness	= (sum of # of secondary cases among completely assessed contacts of each case) / (sum of total # of completely assessed contacts per case)

*For cases of active TB unless otherwise specified.

**Programs will want to especially focus on assessing the investigation of close contacts, young persons (<5 years old) and other high risk contacts. The highest priority contacts are those with the most exposure and those with the highest risk of progression to active disease, if infected.[1] See *Canadian Tuberculosis Standards, 7th Edition* (CTS 7th), chapter 12, for definition of "highest priority" contacts.[1]

***See the Glossary in the CTS 7th[1] for induration parameters associated with tuberculin conversion.

TST—tuberculin skin test

POPULATIONS AT GREATEST RISK

Indicator	Definition	Purpose	Calculation
Presence of risk factors[1] in community: High risk: • HIV/AIDS • Transplantation (related to immune suppressive therapy) • Silicosis • Chronic renal failure requiring hemodialysis • Carcinoma of head and neck • Recent TB infection (≤2 years) • Abnormal chest X-ray (fibronodular disease) Moderate risk: • Diabetes mellitis (all types) • Tumour necrosis factor alpha inhibitors • Treatment with glucocorticoids (≥15mg/d prednisone) • Young age when infected (0–4 years) Slightly increased risk: • Heavy alcohol consumption (≥3 drinks per day) • Underweight (<90% ideal body weight) • Cigarette smoker (one pack/day) • Abnormal chest X-ray—granuloma Other known risk factors for TB:[8] • Mental health and addictions • Malnutrition • Known reservoir of LTBI • Homeless/inadequate housing	Identified as high or increased risk in the *Canadian Tuberculosis Standards*[1] and/or in *Health Canada's Strategy Against Tuberculosis for First Nations On-Reserve*[8]	Individuals at risk of developing active TB if infected with LTBI Areas for possible concern, extra vigilance, etc. Identifies possible need for enhanced screening, case management policies, partnerships, etc. High/moderate risk are most important	Use of checklist to determine frequency of each risk factor among cases

Indicator	Definition	Purpose	Calculation
Proportion based on age groups:			
Pediatric (<15 years)	TB in those less than 15 years of age[20]	At risk due to still developing immune system Indicator of recent transmission	= (population under 15 years) / (total population)
Older (>64 years)	TB in those 65 years or older is becoming a growing issue in low prevalence countries[23]	At risk due to failing immune system, higher co-morbidity with other conditions Possibly a large reservoir of LTBI Can show atypical clinical features	= (population over 64 years) / (total population)
Proportion of individuals with one or more high or moderate risk factors that were screened and identified as having LTBI: • Identified through focused screening practices unrelated to contact investigations	Screening refers to a process that attempts to discover conditions suitable for early preventive or curative intervention[1]	At risk for developing active TB; reservoir of LTBI in the community Assess outcome of focused screening to inform future screening practices	= (# screened with one or more high or moderate risk factors who are identified as having LTBI) / (total # screened)
Proportion of clients in the community with:			
Active TB and risk factor(s)	Risk factors of interest are identified in the *Canadian Tuberculosis Standards*[1] and *Health Canada's Strategy Against Tuberculosis for First Nations On-Reserve*[8]	Possible complications for treatment Compromised immune system	= (# of active cases with risk factors) / (total # of active cases)
Known LTBI and risk factor(s)		Cases at high/ increased risk for conversion	= (# of known LTBI with risk factors) / (total # of known LTBI)

LTBI—latent tuberculosis infection

REGIONAL LEVEL DATA

HIGH INCIDENCE

Indicator	Definition	Purpose	Calculation
Proportion of communities that are high incidence	High incidence is defined under "Definition of TB Outbreak and High Incidence for Surveillance" in Section 2 of this document	Prevalence of high incidence	= (# of high incidence communities) / (total # of communities)
Average number of cases per high incidence community		Extent of high incidence within communities Also look at range	= (sum of # of cases per high incidence community) / (total # of high incidence communities)

POPULATIONS AT GREATEST RISK

Indicator	Definition	Purpose	Calculation
Proportion of high incidence communities with:			
Drug-resistant case(s)	A strain of TB that is resistant to one or more of the four first-line drugs (isoniazid, rifampin, pyrazinamide, ethambutol)[1]	Existence and possible transmission of drug-resistant TB	= (# of high incidence communities with drug-resistant case(s)) / (total # of high incidence communities)
Case(s) of HIV-TB co-infection within the high incidence communities	Number of confirmed cases of HIV-TB co-infection within each high incidence community	Potential for other HIV-TB co-infected cases	= (# of high incidence communities with case(s) of HIV/TB co-infection) / (total # of high incidence communities)
Known reservoir of LTBI	A reservoir of LTBI—when people with untreated LTBI are known to be present in the community	Increased risk for more active TB Need for policy to prevent reactivation	= (# of high incidence communities with known reservoir of untreated LTBI) / (total # of high incidence communities)
Proportion of high incidence communities:			
Screening at-risk groups	Screening refers to a process that attempts to discover conditions suitable for early preventive or curative intervention[1] Groups are identified as high, moderate or slightly increased risk in the *Canadian Tuberculosis Standards*[1] and/or in *Health Canada's Strategy Against Tuberculosis for First Nations On-Reserve*[8]	Vigilance of at-risk groups Assess outcome of screening program(s) for high risk groups to inform future screening practices	= (# of high incidence communities with screening program for at-risk groups) / (total # of high incidence communities)
Partnering with other programs/organizations for TB case management	Partners would include any program/organization that contributes to case management	Access to information/expertise for co-morbid conditions Evidence of integrated care	= (# of high incidence communities with partnerships with other programs/organizations) / (total # of high incidence communities)

LTBI—latent tuberculosis infection

CAPACITY AND AWARENESS

Indicator	Definition	Purpose	Calculation
Proportion of high incidence communities with:			
Access to family physician clinics/ services	Access is defined as having access to family physician clinics/services in the community or within 100 km	Presence and scope of services available within or near community Scope of diagnostic and treatment options within or near community	= (# of high incidence communities with in-community family physician clinics/ services) / (total # of high incidence communities)
			= (sum of kilometers between each high incidence community and closest physician clinic) / (total # of high incidence communities)
Easy access to TB expertise	Easy access is defined as having an identified TB expert with whom to communicate on a regular basis		= (# of high incidence communities with easy access to TB expertise) / (total # of high incidence communities)
Access to X-ray capabilities within community or within 100 km of community			= (# of high incidence communities with X-ray in community) / (total # of high incidence communities)
			= (# of high incidence communities with access within 100 km of community to X-ray) / (total # of high incidence communities)
Proportion of communities where TB is a recognized priority		Community priorities/ engagement	= (# of high incidence communities where TB is a recognized priority (e.g., in their respective community health plan) / (total # of high incidence communities)
Proportion of cases in high incidence communities:			
Diagnosed when CHN was employed in community			= (# of cases of active TB diagnosed when a CHN was employed in the high incidence community) / (total # of cases of active TB in high incidence community)
Treatment is directly observed by trained DOT worker, CHN or other community health staff			= (# of cases of active TB in high incidence community whose treatment is directly observed by trained DOT worker, CHN or other community health staff) / (total # of cases of active TB in high incidence community)
Isolated within 48 hours of diagnosis if airway secretions are smear-positive	Whether at home, in airborne isolation room or other hospital room Isolation is defined in the *Canadian Tuberculosis Standards*[1]		= (# of cases of smear-positive active TB isolated within 48 hours of diagnosis in high incidence community) / (total # of cases of airway secretion smear-positive active TB in high incidence community)

Indicator	Definition	Purpose	Calculation
Proportion of high incidence communities with:			
Publicly available TB awareness material	Any TB awareness materials that are provided or available to the public (e.g., pamphlets, posters)	Community awareness	= (# of high incidence communities with publicly available TB awareness material) / (total # of high incidence communities)
Identified TB champion(s)	An individual who can speak to increasing awareness on TB and/or mobilize leadership and community members to address TB in their area		= (# of high incidence communities with a TB champion) / (total # of high incidence communities)

CHN—Community Health Nurse

DOT—Directly Observed Therapy

APPENDIX E: Enhanced Monitoring for High Incidence—SECONDARY ANALYSIS

The purpose of the secondary level of analysis is to begin an in-depth investigation of areas of concern identified through the primary level of analysis. Essentially, the main point of the secondary level of analysis is to "know your community" and to "know the impact of TB in your community" so that appropriate measures can be put into place to reduce TB. To begin that exercise, a set of follow-up questions related to each category and its primary level indicators are outlined below. This list of questions is by no means exhaustive and will be updated over time as programs begin to use this enhanced approach for high incidence communities. Some questions are easily answered while others will need the development of additional indicators and identification of relevant data. In regard to the latter, programs should work with partners as detailed data will be needed for this level of analysis.

Based on results from the secondary level of analysis, appropriate and effective approaches, activities, tools and/or resources can be identified to address the problem(s). For example, if most cases are smear-positive because there is a delay in diagnosis because community members are not aware of the signs and symptoms of TB, an enhanced, intensive community-based TB awareness campaign could be implemented.

COMMUNITY LEVEL DATA

DIAGNOSIS AND TREATMENT INITIATION*

Indicator	Purpose	Follow-Up Questions
At diagnosis, proportion of cases that are:		

Smear-positive	Infectiousness of cases	• Was cavitation present on chest X-ray?
		  ◦ Was the diagnosis thought to have been delayed? If so, what is the nature of the delay?
		  ◦ Why is there a delay? (see below)
		• Could cases have been prevented?
		  ◦ Did they have a history of TB (e.g., previous positive TST, contact of another case, etc.)?
		  ◦ Were they identified as belonging to a high risk population, either currently or in the past?
		• What kind of TB was diagnosed?
		  ◦ How far has the disease progressed? And why?

Indicator	Purpose	Follow-Up Questions
Re-treatment	Effectiveness of treatment Persistence of bacteria	• How many completed treatment before being diagnosed for re-treatment? • Were they deemed "cured" after the previous round of treatment? • Are they being re-treated for the same strain of bacteria or are they infected with a new strain? • Has the strain of bacteria been identified as especially infectious/persistent?
Recently converted	Possible recent exposure Change in immune status	• Were cases recently exposed to TB? • Did cases recently experience a change in their immune system (e.g., identified as high risk)?

Drug-resistant	Presence of drug-resistant TB in community
	Resistance developed during treatment (acquired resistance)
		• Was drug resistance acquired?
		• What is the extent of drug resistance?
		  ◦ Mono, poly, multi or extensively drug-resistant?
		• Are there known drug-resistant cases in the community?
		  ◦ If so, how did it enter the community: acquired or imported?

Average time between:		

Symptom(s) onset and diagnosis	Delays in diagnosis
	Also look at range
		• What is the patient's behaviour in accessing health care?
		  ◦ Are there barriers to accessing health services in the community?
		  ◦ Were patients reluctant to seek care (e.g., stigma associated with TB)?
		  ◦ Were patients aware of the symptoms of TB?
		  ◦ Is this a highly mobile population?
		  ◦ Was substance abuse or mental health thought to contribute to diagnosis delay?
		• Are health care professionals working in/with the community familiar with TB?
		  ◦ Is there education/training available for health care professionals on TB?
		  ◦ Are health care professionals working in the community aware and "thinking" TB?
		  ◦ Are there mechanisms/plans in place to address staff turnover (e.g., is there orientation related to TB for new staff)?
		• Are there barriers to accessing TB expertise?
		  ◦ Are there challenges in accessing TB expertise when needed? What are they?
		  ◦ Is there reluctance to access TB expertise? Why?

Diagnosis and treatment initiation	Delays in treatment initiation
	Also look at range
		• When are cases started on treatment?
		  ◦ Within 48 hours of laboratory confirmation?
		  ◦ Over 48 hours after laboratory confirmation?
		• Are cases being started on the appropriate treatment, as per the *Canadian Tuberculosis Standards*[1] and provincial/regional/community policies?
		• Is there a delay in reporting results?
		  ◦ Do specimens arrive at the lab intact?
		  ◦ Are there undue delays in getting results from smear and/or culture samples?
		• Is treatment immediately available (within 48 hours)?
		• Is treatment easily accessible?

*For cases of active TB unless otherwise specified.

TST—tuberculin skin test

TREATMENT COMPLETION*

Indicator	Purpose	Follow-Up Questions

Proportion of cases for which adequate treatment** was completed	Effectiveness of treatment	• How is "treatment completion" being determined?
		  ◦ Percentage of expected doses taken?
		  ◦ Percentage completing within 9 months for a 6-month regimen; 12 months for a 9-month regimen; and 15 months for a 12-month regimen?
		  ◦ Percentage of drug-susceptible cases completing in one year?
		• Were cases compliant throughout treatment?
		  ◦ Were at least 80% of the recommended doses taken?
		  ◦ What was the rate of default (treatment interruption of ≥2 months) or loss to follow-up?
		  ◦ What were the barriers to treatment completion?
		  ◦ Is the population highly mobile?
		• What are the provincial protocols in place?
		  ◦ Are they being followed?
		  ◦ Are there several protocols being used to determine treatment regimen?
		• Are co-morbidities/co-infections creating issues?
		  ◦ Are additional treatment regimens for other conditions creating the need to adjust treatment for TB?
		  ◦ Are issues related to mental health/addictions affecting treatment compliance?
		• What drugs were initially prescribed?
		  ◦ Was there a change in the drug regimen during the course of treatment?
		  ◦ If yes, why?
		• Was DOT recommended?
		  ◦ Were there any modifications to DOT over the course of treatment?
		  ◦ Were all doses delivered via DOT?
		  ◦ Were incentives/enablers used/available?
		• Were cases isolated until non-infectious?
		• Did any complications or adverse events occur during treatment?
		  ◦ Did these lengthen the course of treatment?
		  ◦ Did these change which drugs were given to the patient?
		  ◦ Who is managing treatment of cases? Was additional expertise needed?
		  ◦ Was additional expertise accessed when complications arose?

*For cases of active TB unless otherwise specified.

**Adequate treatment is defined based on the *Canadian Tuberculosis Standards*[1] as well as any additional policies required by the TB program providing treatment.

DOT—Directly Observed Therapy

CONTACT TRACING/INVESTIGATION*

Indicator	Purpose	Follow-Up Questions

Proportion of high and medium priority contacts of adult smear-positive pulmonary cases completely assessed within 30 days (one month)	Effectiveness of contact investigation
	Efficiency in reducing transmission
	Prioritization of contacts is as follows:
	High: close contacts (household or non-household) that are young (<5 years) and/or immunocompromised (across the lifespan)
	Medium: all other close contacts (household or non-household) and all casual contacts that are young (<5 years) and/or immunocompromised (across the lifespan)
	Low: all other casual contacts
		• Are close contacts and contacts at greatest risk (young children [<5 years] and the immunocompromised) being prioritized?
		  ◦ Are these contacts being fully assessed and followed?
		• Why are contact investigations taking longer than planned?
		  ◦ Lack of resources and/or capacity?
		  ◦ Mobile population?
		  ◦ At six months, are contacts still being found?
		• Are there issues related to jurisdiction?
		  ◦ Do contacts span more than one community/area/region/province?
		  ◦ Are there information-sharing agreements in place across jurisdictions?
		• Is there a wide range in the time it takes to complete contact investigations?
		  ◦ Is this due to variations in the number of contacts?
		  ◦ What other factors may contribute to variation?

Proportion of individuals screened who have LTBI	At risk for developing active TB
	Reservoir of LTBI in the community
		• What is the estimated prevalence of untreated LTBI within the community?
		  ◦ Is this historical or recent LTBI?
		  ◦ Can the source case(s) for LTBI be identified?
		• Why were individuals being screened for LTBI?
		• Regarding the treatment of LTBI:
		  ◦ How many were offered treatment and refused? If refused, why?
		  ◦ How many contacts accepted and initiated treatment?
		  ◦ Of those that started, how many completed treatment?
		  ◦ Of those that did not complete, what was the reason?

Average number of contacts per case	Depth of exposure of community to TB
	Idea of possible extent of transmission
	Also look at range
		• Is there a wide range in the number of contacts per case?
		  ◦ Are cases easily able to name/find contacts?
		• Are there trends in contacts?
		  ◦ Close versus casual?
		  ◦ Household versus non-household?
		• What is the mobility of the source case?
		  ◦ Complex social network?
		  ◦ Homelessness and/or couch surfing?
		• What methods are being used to trace contacts?
		  ◦ Social network analysis?
		  ◦ Location-based investigation?
		  ◦ Genomic analysis?

Indicator	Purpose	Follow-Up Questions

Proportion of high and medium priority contacts determined to be secondary cases when assessed	Extent of transmission
	Infectiousness; timeliness of contact investigation
		• ALSO SEE POSSIBLE FOLLOW-UP QUESTIONS UNDER DIAGNOSIS AND TREATMENT INITIATION
		• What is the time between identifying a contact and completely assessing him/her?
		• How infectious was the source case?
		• How was contact tracing prioritized?
		• Is location of exposure important?
		• What proportion of contacts is at greater risk for TB?
		  ◦ How many have a history with TB?
		  ◦ How many have a history of prior exposure?
		  ◦ How many are <5 years of age?
		  ◦ How many are immune-suppressed and/or have other conditions?
		  ◦ How are at-risk contacts being managed and/or followed?
		• What were the criteria used for recommending treatment to contacts?
		  ◦ How many contacts that were recommended treatment of LTBI accepted/refused?
		  ◦ What were the treatment completion rates for contacts accepting treatment?
		  ◦ When refused, why did contacts recommended for treatment refuse treatment?

*For cases of active TB unless otherwise specified.

LTBI—latent tuberculosis infection

POPULATIONS AT GREATEST RISK

Indicator	Purpose	Follow-Up Questions

Presence of risk factors in community:
• HIV/AIDS
• Diabetes
• End-stage renal disease
• On immuno-suppressive treatment
• Long-term corticosteroid use
• Mental health and addictions
• Malnutrition
• Known reservoir of LTBI
• Homeless/ inadequate housing
	Individuals with higher risk of contracting TB if infected
	Areas for possible concern, extra vigilance, etc.
	Identifies possible need for enhanced screening, case management policies, partnerships, etc.
		• Does the community have accessible data on these groups?
		  ◦ Are these groups being monitored?
		• When accessible, is available data being used to inform TB prevention and control programming and practices (e.g., screening, case management, etc.)?
		• Are these risk factors increasing the risk of developing TB and/or the risk of transmitting TB in the community?
		• Are these risk factors complicating diagnosis, treatment and/or case management in the community?
		• What are the trends in these groups for other indicators?
		  ◦ See indicators in DIAGNOSIS AND TREATMENT INITIATION; TREATMENT COMPLETION; CONTACT TRACING/INVESTIGATION
		  ◦ Do these trends differ from cases without risk factors?
		• Are there screening programs in place for these groups?
		  ◦ Are those deemed at risk being followed and are they educated about TB?
		• What does the access to health care look like for these groups?
		  ◦ Which sectors/programs are involved?
		  ◦ Is the system integrated?
		• What proportion of cases of TB in a community has more than one risk factor?
		  ◦ Are additional factors further complicating diagnosis, treatment and/or case management?
		• Is drug resistance an issue for those from these groups who develop TB in the community?
		• Are social determinants of health contributing to the transmission of TB in the community?
		  ◦ Are data available on the social determinants of health in the community?
		  ◦ Are the social determinants of health of concern to the community?
		  ◦ Are there trends in the social determinants of health of individuals with active TB in the community?

Proportion based on age groups:		
Pediatric (<15 years)	At risk due to still developing immune system	• Is there any evidence that this age group is at greater risk for TB in the community? • Are there screening programs in place for this group in the community?
Older (>64 years)	At risk due to failing immune system, higher co-morbidity with other conditions Possible reservoir of LTBI	• Is there any evidence that this age group is at greater risk for TB? ◦ Higher rates of co-morbidities? Co-infections? • Are there screening programs in place for this group?

Indicator	Purpose	Follow-Up Questions
Proportion of cases of:		
Active TB with risk factor(s)	Possible complications for treatment Compromised immune system	See first indicator in this category (presence of risk factors in community)
Known LTBI with risk factor(s)	Cases at high/increased risk for reactivation	See first indicator in this category (presence of risk factors in community)

LTBI—latent tuberculosis infection

REGIONAL LEVEL DATA

HIGH INCIDENCE

Indicator	Purpose	Follow-Up Questions

Proportion of communities that are high incidence	Prevalence of high incidence	• Are there links among high incidence communities?
		  ◦ Are there common trends in epidemiology?
		  ◦ Is the population linked via social networks and/or events?
		  ◦ Are there links via the health care system?
		• Are communities also:[24]
		  ◦ Remote?
		  ◦ Isolated?
		  ◦ Remote and isolated?
		• What does health care access look like in these communities?

Average number of cases per high incidence community	Extent of high incidence within communities	• Are there commonalities among cases within the respective high incidence community? • Do cases that are linked span more than one community? • Do cases that are linked span more than one health care jurisdiction?

POPULATIONS AT GREATEST RISK

Indicator	Purpose	Follow-Up Questions
Proportion of high incidence communities with:		

Drug-resistant case(s)	Existence and possible transmission of drug-resistant TB	• Are drug-resistant cases confined to a limited number of communities?
		• How are drug-resistant cases entering communities?
		  ◦ Acquired by community member?
		  ◦ Visitor from outside community?
		• Is drug-resistant TB being transmitted?
		• What is the nature of the drug resistance?

Indicator	Purpose	Follow-Up Questions

Case(s) of HIV/AIDS	At-risk population
	High risk of disease if co-infected
		• Is the presence of HIV/AIDS contributing to the TB case load?
		• Are programs working together to assess and address the issue of co-infection?
		• Is treatment for co-infection adequate?
		  ◦ Is expertise available for both conditions?
		  ◦ Has additional expertise been accessed?
		• Are patients with HIV/AIDS being screened for TB?
		  ◦ Are those with LTBI being treated and monitored?
		• Are patients with TB being screened for HIV/AIDS?
		• Is active TB in co-infected patients being detected early?
		• Are there common trends in diagnosis, treatment and/or case management of co-infected patients?
		  ◦ Are there common complications/challenges?

Known reservoir of LTBI	Increased risk for more active TB
	Need for policy to prevent reactivation
		• Can estimates be made about the true prevalence of LTBI in the community?
		  ◦ How many of those with LTBI are at greater risk of developing active TB?
		• What are the community's policies for dealing with LTBI?
		  ◦ For screening?
		  ◦ For follow-up and monitoring?
		  ◦ For treatment?

Proportion of high incidence communities:		

Screening at-risk groups	Vigilance of at-risk groups	• Is information on at-risk groups being shared across different programs?
		  ◦ Are programs that collect data on TB status sharing this information with the TB program?
		• Do screening policies adequately reflect the epidemiology of the community?
		• Are there barriers to completing planned screening?
		  ◦ Resources?
		  ◦ Capacity?
		  ◦ Unwillingness of public?

Partnering with other programs for case management	Access to information/ expertise for co-morbid conditions	• Is the TB program partnering with other programs for case management?
		  ◦ Do partnerships reflect the epidemiology of TB in the community?
		  ◦ Do partnerships reflect the needs of the community and its members?

LTBI—latent tuberculosis infection

CAPACITY AND AWARENESS

Indicator	Purpose	Follow-Up Questions
Proportion of high incidence communities with:		

In-community family physician clinics
Uninterrupted service by trained CHN
Trained DOT workers
Easy access* to TB expertise
	Presence and scope of services available within community	• Is there a centralized program in the region?
		  ◦ How are communities supported?
		  ◦ Is there an enhanced plan/policy/strategy for high incidence communities?
		• Is there access to primary care and/or public health in the community?
		  ◦ Is there TB expertise in the community?
		• Are programs consistently fully staffed?
		  ◦ If not, what are barriers to hiring and retaining staff?
		• Do staff have access to opportunities for professional development?
		  ◦ Have staff received training on TB?
		  ◦ Have staff received cultural competency training?
		• Do region/community programs have policies and procedures for including TB in community health planning?

X-ray capabilities Isolation facilities	Scope of diagnostic and treatment options within community	• If diagnostic and treatment options are not available in the community, are they easily accessible elsewhere? • Is the need to leave the community to access health care services a barrier to people seeking care?

Proportion of communities where TB is a recognized priority	Community priorities/ engagement	• Is community leadership being updated on TB in their community?
		  ◦ Are epidemiological data being provided?
		• Is stigma an issue?
		• Are there competing priorities?
		  ◦ Can these be leveraged to increase awareness on TB?
		  ◦ Is the TB program working with other programs?
		• Do communities have capacity to increase awareness?

Proportion of high incidence communities with:		

Publicly available TB awareness material
Identified TB champion(s)
	Community awareness	• Are community members aware of the signs and symptoms of TB?
		  ◦ Is information being shared?
		  ◦ Are individuals aware of their own history with and risks for TB?
		• Is awareness material easily understood?
		  ◦ Are materials provided in more than one language?
		  ◦ Is health literacy an issue?
		• Do communities have a plan to maintain awareness during periods of low incidence?
		  ◦ Awareness of symptoms/signs?
		  ◦ Awareness of risks of LTBI?
		  ◦ Awareness of risk factors?
		  ◦ Awareness of screening practices and policies?

*Easy access is defined as having an identified TB expert with whom program is able to communicate on a regular basis if necessary.

CHN—Community Health Nurse

DOT—Directly Observed Therapy

LTBI—latent tuberculosis infection

APPENDIX F: Potential TB Program Objectives and Performance Targets

(from the Guidance for Tuberculosis Prevention and Control Programs in Canada)

The following potential program objectives and performance targets from the *Guidance for Tuberculosis Prevention and Control Programs in Canada*[7] were reproduced with permission from the Public Health Network Council.

This list of program objectives and performance targets is based upon review of existing provincial/territorial/local objectives and targets, U.S. Centers for Disease Control and Prevention National TB Program Objectives and Performance Targets for 2015 (see: www.cdc.gov/tb/programs/evaluation/indicators/default.htm) and the following standards and guidelines:

- *Canadian Tuberculosis Standards, 6th Edition.*[11] Accessed November 22, 2010, from publications.gc.ca/collections/collection_2011/aspc-phac/HP40-18-2007-eng.pdf
- Tuberculosis Coalition for Technical Assistance. (2006). International Standards for Tuberculosis Care. The Hague: Tuberculosis Coalition for Technical Assistance. Accessed November 22, 2010, from www.who.int/tb/publications/2006/istc_report.pdf
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POTENTIAL TB PROGRAM OBJECTIVES AND PERFORMANCE TARGETS

	Program Objective	Performance Target/Turnaround Time to Completion or Report for Laboratory Procedures
Microbiological diagnosis of active TB disease	Specimen collection and arrival at the laboratory	24 hours
	AFB smear microscopy	24 hours from specimen receipt
	Nucleic acid amplification testing for *M. tuberculosis* complex detection	24 hours from smear result
	Bacteriological diagnosis—culture	Up to 6 weeks for broth cultures and 8 weeks for solid media cultures from specimen receipt
	Identification of mycobacterial species	21 days from specimen receipt
	Primary susceptibility testing	7–14 days from a positive culture
	Reporting all test results (electronically)	24 hours from test completion
	Reporting of all test results (hard copy by fax or hand delivery)	48 hours from test completion
HIV serologic testing	HIV status known and reported on PHAC Active TB Case Report Form	>90% of cases by 2015
Treatment of active TB disease	Started on anti-TB drugs within 48 hours of diagnosis	≥95% of cases
	Treated by standard or enhanced directly observed therapy	≥90% of cases
	Treatment started with four or more anti-TB drugs until drug sensitivity test results are available, unless there are current local drug sensitivity data showing that resistance is not a risk	≥90% of cases
	Sputum culture conversion in culture-positive, drug-sensitive respiratory cases	≥80% have three consecutive negative sputum cultures within 60 days of treatment initiation
	Treatment success (cure of completion) within 12 months of treatment initiation for patients who did not die or transfer out during treatment	≥90% of cases
	Re-treatment rate within two years after the end of previous treatment in Canada	≤3%
	Acquired drug resistance rate	0%
Contact follow-up	Initial list of contacts for each infectious TB case is completed within seven calendar days	100%
	Assessment of close contacts completed and LTBI treatment started, if indicated and not contraindicated or refused, within 28 calendar days	100%
	Proportion of contacts with a diagnosis of LTBI who begin treatment	≥80%
	Proportion of contacts beginning treatment for LTBI who complete treatment	≥80%
	Proportion of contacts completing treatment who show active TB disease within two years after completion	<0.5%
	Proportion of contacts with LTBI at high risk of progression to active TB disease, but unable or unwilling to be treated for LTBI who have chest radiography and sputum smear plus culture at 6, 12 and 24 months	≥90%

	Program Objective	Performance Target/Turnaround Time to Completion or Report for Laboratory Procedures
Targeted screening for active TB disease and LTBI	HIV-positive individuals	100%
	End-stage renal disease	100%
	Transplant-related immunosuppression	100%
	Tumour necrosis factor alpha inhibitor use	100%
	Long-term (≥1 month) corticosteroid use (prednisone ≥15 mg/day or equivalent)	≥75%
Immigration medical surveillance	Proportion of individuals referred for immigration medical surveillance who: 1) keep the first appointment with the clinic/physician or who have been evaluated by public health; and 2) the relevant provincial/territorial authorities have reported such information to Citizenship and Immigration Canada	≥90%

AFB—acid-fast bacilli

LTBI—latent tuberculosis infection

PHAC—Public Health Agency of Canada

APPENDIX G: Acknowledgements

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- FNIHB TB Outbreak and High Incidence Definitions Discussion Group
- FNIHB Communicable Disease Working Group
- FNIHB TB Network
- All other partners that contributed throughout the development process

APPENDIX H: References

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