
Access to Essential Tuberculosis Medicines in Canada:

Insights from a National Survey
of Healthcare Providers



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01. GLOSSARY OF TERMS

TB Infection (TBI)	TBI is a bacterial infection caused by <i>Mycobacterium tuberculosis</i> acquired via an aerosol route. People with TBI do not feel sick and cannot spread TB bacteria to others, but have a lifetime risk of progressing to TB disease, especially if their immune system weakens.
TB Disease (TB)	TB is an infectious disease caused by <i>Mycobacterium tuberculosis</i> that is both preventable and curable with proper treatment. TB can affect any part of the body, including the glands, bones, and nervous system but mainly affects the lungs. A person with TB disease in their lungs can spread the infection to others in aerosols generated by things like coughing and sneezing.
Drug Susceptible TB (DS-TB)	People with DS-TB have disease that responds to TB treatments.
Drug Resistant TB (DR-TB)	People with DR-TB have disease that does not respond to some TB treatments.
Multi-drug Resistant TB (MDR-TB)	People with MDR-TB have disease that does not respond to many TB treatments.
Extensively Drug Resistant TB (XDR-TB)	People with XDR-TB have disease that does not respond to almost all TB treatments.
Non-Marketed Drugs	The term “non-marketed” is used in this report to describe drugs that are not yet licensed in Canada. This term underscores that this is a market failure as opposed to a lack of approval due to questions related to safety or effectiveness of the drugs.
Fixed Dose Combinations	A medicine that includes two or more active ingredients combined in a single dosage form.

02. REMARKS

A NOTE FROM OUR CO-CHAIRS



Stop TB Canada is a broad network of professionals, academics, and advocates who are committed to ensuring equitable access to healthcare for all. Together, we are working to end tuberculosis (TB) in Canada and abroad. With this report, Access to Essential Tuberculosis Medicines in Canada, we aim to inform policymakers about the significant barriers faced by healthcare providers and to highlight critical opportunities for improving access to high-quality TB care in Canada.

The findings of our survey show a concerning picture of access to TB medicines in Canada. Multiple essential TB drugs are not marketed in Canada, and the regulatory pathways for accessing these medicines are cumbersome, leading to significant delays. These barriers disproportionately affect Indigenous and newcomer populations, the two populations most affected by TB in Canada. Furthermore, the unavailability of child-friendly TB drug formulations severely complicates treatment for pediatric TB, creating undue hardship for families and healthcare providers alike. To make matters worse, ongoing shortages and stock-outs of critical TB medicines exacerbate these challenges, undermining the continuity of care that is vital for successful treatment outcomes.

Stop TB Canada urgently calls upon the Government of Canada to take immediate and decisive action to address these barriers. We cannot afford to delay progress towards Canada's TB elimination goals. These systemic inequities must be addressed to ensure that all people in Canada have access to the life-saving medications and care they need.

Tina Campbell and Petra Heitkamp

COMMENTS

It is a shame that in a wealthy country, like Canada, people are struggling to access essential tuberculosis medicines. This neglect must end.

The Canadian government and ITK [Inuit Tapiriit Kanatami] have a shared goal of eliminating TB among the Inuit by 2030. For this to happen, it is critical to ensure that all people with TB have easy access to the best TB treatments and formulations that we have today. The Stop TB Canada report offers clear recommendations on how to realize this.



Professor Madhukar Pai, MD, PhD, FRSC

Inaugural Chair, Department of Global & Public Health, McGill University
Canada Research Chair in Epidemiology & Global Health

The report provides actionable recommendations. I hope that these recommendations will be implemented to improve access to essential TB medicines for all people in Canada.

In addition to these solutions, I hope that more investments will be made to address the social determinants of health, such as housing, so that communities like Nunavummiut, that have the highest rates of TB infection in Canada do not contract this disease because of the lack of housing.

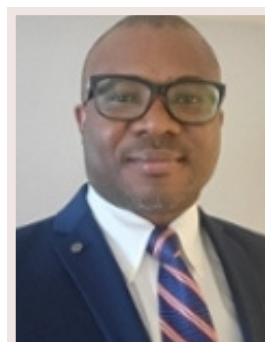


Lori Idlout

Member of Parliament, Nunavut

A recent study showed a rising number of pediatric TB cases across northern Saskatchewan. The lack of child-friendly TB formulations remains a significant challenge and impacts treatment outcomes. Access to these essential medications will save lives and contribute to TB elimination in Canada.

I support these recommendations from Stop TB Canada.



Dr. Nnamdi Ndubuka, MD, MPH, PhD, CCPE

Medical Health Officer, Northern Inter-Tribal Health Authority
Associate Professor, College of Medicine, University of Saskatchewan

Canada's support to international agencies like Unitaid has helped bring access to new and better TB prevention drugs to more than 11 million people, mainly in low- and middle-income countries.

It would be great to see this work being leveraged to support Canada's efforts to further scale up access to TB prevention domestically.



Robert Matiru

Director of Programmes, Unitaid

The Canadian and United States governments have played critical leadership roles in the 2001 founding and subsequent support of the Stop TB Partnership's Global Drug Facility (GDF). GDF's pooled procurement, unique set of tailored tools, and supplier incentives have resulted in the development of more than 100 optimized formulations, including fixed-dose combination products and child-friendly formulations for all TB medicines recommended by the World Health Organization. And while GDF supplies these formulations to more than 130 countries, a reverse inequity exists in most high-income countries where those in need cannot access these optimized TB formulations. Registering and supplying TB medicines in countries with low disease burdens and tiny markets is seen as a losing proposition with suppliers, with less than 5% of GDF's 100-plus TB formulations registered in North America. Several high-income countries, however, have successfully managed to procure TB medicines via GDF, including Australia, Spain, and Sweden; and GDF would be eager to collaborate and see how our procurement mechanism could benefit people in Canada directly.



Brenda Waning

Chief, Global Drug Facility

03. EXECUTIVE SUMMARY

Tuberculosis (TB) continues to pose a significant public health challenge in Canada, particularly for Indigenous communities and people born outside the country – the two populations that are disproportionately affected. Limited access to essential TB medicines, found on the World Health Organization’s Model List of Essential Medicines, is a critical issue that hinders effective treatment and undermines Canada’s ambitions to eliminate TB. This report, prepared by Stop TB Canada, presents the findings of a national survey conducted in 2024, capturing the experiences of healthcare providers regarding barriers to accessing essential TB medicines. The survey received 71 responses from 10 provinces and territories.

KEY FINDINGS

01 Limited access to essential TB medicines

People in Canada are not benefiting from the tremendous advancements in TB treatment over the past two decades, including the development of safer, shorter, and highly effective regimens. A key barrier is that these newer TB drugs – and several older ones that are integral to these innovative regimens – are not marketed in Canada. Access to non-marketed drugs is restricted to complex regulatory pathways like the Special Access Program (SAP) and the Access to Drugs in Exceptional Circumstances (ADEC) pathway. These mechanisms often result in substantial delays and administrative challenges for healthcare providers, impeding timely access for patients. Most survey respondents reported limited or no availability of the essential TB medicines delamanid (90%), pretomanid (88%), and bedaquiline (88%), while rifapentine was somewhat more accessible (49% reporting limited availability).

Recommendation:



Improve access to essential TB medicines by establishing appropriate obligations and incentives for the pharmaceutical industry to market essential TB medicines in Canada.



Reduce critical delays in patient care by simplifying and expediting approvals via existing mechanisms for accessing non-marketed TB drugs.

02 Lack of pediatric TB treatments

Canada lacks child-friendly TB drug formulations of both marketed and non-marketed drugs, resulting in sub-optimal treatment methods that are traumatic and burdensome for children, families, and healthcare workers alike. This contributes to poor adherence and missed doses, undermining the effectiveness of treatment. Only 55% of survey respondents were aware that child-friendly formulations were available in other countries. Most agreed that current treatment methods for children result in high attrition and poor outcomes.

Recommendation:



Improve pediatric TB treatment by ensuring that child-friendly formulations are readily available in Canada, as recommended on the World Health Organization's Model List of Essential Medicines for Children.

03 Drug shortages

There have been multiple shortages of essential TB medicines in Canada in recent years. These have included shortages of marketed drugs such as rifampin, and non-marketed drugs such as rifapentine. For non-marketed drugs, shortages compound existing access issues. Survey respondents reported that shortages of rifapentine are common across most provinces and territories. Inconsistent notification mechanisms further complicate treatment delivery and continuity of care.

Recommendation:



Ensure a stable supply of TB medicines by developing a national procurement strategy that includes a centralized stockpile and a standardized notification system to track and manage shortages, and by proactively preventing disruptions in access to both marketed and non-marketed essential TB medicines.

IMPACT

This survey shows that providers in Canada face remarkable challenges accessing the essential TB medicines and formulations that their patients require. Healthcare providers report that these access barriers result in treatment prolongations, increased hospitalizations, and poor patient outcomes.

In addition to delayed access, providers also report that their patients are hesitant to take drugs that are not approved by Health Canada and are instead accessed through alternative regulatory pathways designed for non-marketed drugs. Treatment hesitancy may negatively impact individual health outcomes and risk ongoing TB transmission.

Everyone, everywhere should have access to the safest, most effective TB treatment regimens. We urge Canadian decision makers to take decisive action to ensure essential TB medicines are accessible to those who need them, when they need them. Remedying the key challenges highlighted in this report will be necessary to achieve TB elimination in Canada.



“We do not have ready access to first-line drugs for MDR-TB [multidrug-resistant TB] in Canada – this is a national shame. Given TB’s disproportionate impact on Indigenous peoples, this is also a barrier in achieving the aims of the Truth and Reconciliation Commission.”

~ Physician, Ontario

04. BACKGROUND

TB IN CANADA

In 2018, the Government of Canada committed to eliminating TB by 2030 across Inuit Nunangat, and by 2035 across the country, with a targeted reduction in TB disease of at least 50% by 2025.¹

The 2024 WHO Global TB Report, however, highlights concerning trends: between 2015 and 2023, the WHO Region of the Americas experienced a +20% net increase in TB incidence, and Canada remains the only high-income country in the region with a reported increase of over 5%.² Canada is off track to meet its 2025 target by a significant and widening margin.

Over the past decade, the number of people in Canada diagnosed with TB has gradually risen, and publicly available data show that 1,971 people had TB in 2022.³ Indigenous peoples, who make up less than 10% of the Canadian population, account for nearly a quarter of all people affected by TB. Meanwhile, the remaining diagnoses of TB are predominantly among people born outside Canada. This latter fact underscores the country's connection to the global TB pandemic. In 2023, over 10 million people worldwide became sick with TB, and the disease claimed 1.25 million lives.²

Access to timely and effective TB medicines is critical to preventing and treating TB. Treatment challenges, however, are exacerbated by the growing burden of drug-resistant TB (DR-TB) globally. In Canada, approximately 11% of people affected by TB have strains resistant to at least one antibiotic. Treatment of DR-TB has historically been extraordinarily difficult, requiring multiple medicines to be taken for many months, with side effects as severe as permanent hearing loss and a treatment success rate of about 50%.

Global investments in TB research over the past two decades have transformed TB treatment options. Newly developed TB regimens are demonstrably shorter, safer, and more effective.⁴ These developments, for example, have led to once-a-month or once-weekly TB preventive treatment options compared to the previous standard of care which required 4 or 9 months of daily medicine. Similarly, a 4-month regimen to treat drug-susceptible TB disease (DS-TB) and a 6-month pill-only (no injections) regimen for DR-TB disease now exist as compared to the typical 6 and 18-to-24 months of treatment, respectively **(See Box 1)**.⁵

People in Canada are not yet benefiting from this tremendous expansion in safe and shorter-duration treatments for TBI and TB. This is due, in large part, to the fact that none of the new drugs, and a number of the older drugs, used in these novel treatment regimens are not currently marketed here.

BOX 1: STANDARD OF CARE IN CANADA VS. NEW, SHORTER WHO-ENDORSED REGIMENS

INDICATION	STANDARD OF CARE IN CANADA ⁶	REGIMENS ENDORSED BY THE WHO ⁷
TB Infection (Prevention)	• 3 months of weekly rifapentine and isoniazid (3HP), • 4 months of daily rifampin (4R)	• 1 month of daily isoniazid and rifapentine (1HP) • 3 months of weekly rifapentine and isoniazid (3HP), • 4 months of daily rifampin (4R)
Drug Susceptible TB	• 6-months of isoniazid, rifampin, with pyrazinamide and ethambutol for the first 2 months (6HRZE)	<u>Adults and adolescents:</u> • 4 months of isoniazid, rifapentine, moxifloxacin, and pyrazinamide for the first two months (4HPMZ). <u>Kids with nonsevere disease:</u> • 4 months of isoniazid and rifampicin, with pyrazinamide (and ethambutol in certain settings) for the first two months (4HRZE)
Multidrug-Resistant TB	• 18-24 months of levofloxacin or moxifloxacin, bedaquiline, linezolid, clofazimine and cycloserine	• 6 months of bedaquiline, pretomanid, linezolid with or without moxifloxacin (BPaL(M))

In addition to non-marketed drugs that shorten TB treatment, the past decade has seen great innovation in the quality of TB medicines for children.⁸ Appropriate formulations now exist for pediatric treatment of TBI, TB disease, and DR-TB. These formulations, dissolvable in water and flavoured, vastly improve on the previous standard of care, which required healthcare providers to crush bitter-tasting adult tablets for children too young to swallow pills **(see Box 2)**.

BOX 2: SPECIAL CHALLENGES FOR CHILDREN UNDERGOING TB TREATMENT

Administering TB treatment to young children typically requires using tablets designed for adults. This involves cutting approximate doses from adult tablets, crushing them, and mixing the resulting powder in a sweet food or liquid. Although liquid formulations of TB medication can be prepared by compounding pharmacists, such resources are usually only found in major cities. In rural and remote communities in Canada, including Indigenous communities, the TB treatment for children thus continues to require crushing adult tablets to mix with food. This reality presents several challenges for children, their providers, and caregivers:

- **Over- and under-dosing:** splitting and crushing pills and/or children vomiting or spitting out the bitter medication makes appropriate dosing challenging.
- **Burden for children and families:** even when mixed with food, the medications taste bitter causing discomfort to children and moral distress to caregivers for the duration of treatment.
- **Burden for healthcare providers:** medication for each patient must be crushed prior to administering the daily treatment, and getting the child to take the full dose may take hours each day.

Child-friendly formulations of TB medicines offer many benefits, including:

- accurate, weight-appropriate dosing
- improved palatability for children
- simplified administration and storage, and
- quality-assured treatment options.

Moreover, child-friendly formulations of TB drugs are prequalified by the WHO, included in its Model List of Essential Medicines for Children, and have been adopted in over 120 countries worldwide.^{8,9} Canada is not among them. These formulations now exist for both new and older TB medicines, but even for drugs that are currently marketed for adults in Canada, the equivalent child-friendly formulations remain unavailable.

As a result, children in Canada – who make up approximately 5% of those diagnosed with TB disease annually, half of whom are under 5 years old – are still treated with adult tablets.¹⁰ Children in Canada are not yet benefiting from the significant global advancements in pediatric TB care, and the country is falling short of providing the best and most effective treatments to the youngest and most vulnerable TB patients.

BARRIERS TO ACCESSING ESSENTIAL TB MEDICINES IN CANADA

UNJUST MARKET FORCES

The pharmaceutical regulatory system in Canada is designed to ensure that all drugs sold in the country are safe, effective, and quality-assured. It is, however, not designed to ensure that all safe and effective drugs are marketed in Canada, nor that once marketed, they remain available, let alone in sufficient quantities. Further to this, and most significantly, the initiation of the drug approval process is not dependent on an unmet need for the drug, but rather on the interest of companies in selling the drug in Canada.

Due to the relatively low number of people with TB in Canada, pharmaceutical companies view the market as insufficiently profitable. As a result, some TB drugs that were formerly marketed in Canada, such as cycloserine, have been discontinued for commercial reasons despite ongoing clinical need, while others, including all of the new drugs that have emerged in the 21st Century (bedaquiline, delamanid, pretomanid), have never been marketed in Canada. These issues also impact formulations of drugs such that even where a drug is available in Canada, it may not be offered in other forms including fixed-dose combinations and/or as a child-friendly formulation.

Paradoxically then, many TB drugs that are recommended in both domestic guidelines, such as the Canadian Tuberculosis Standards, and international guidelines from organizations like the WHO, are not marketed in Canada. Providers must, therefore, use existing but cumbersome mechanisms never designed as permanent solutions to ensure access to the standard of care.

INEFFECTIVE PATHWAYS FOR ACCESSING NON-MARKETED DRUGS AND FORMULATIONS

The fact that some important drugs for treating TB are not marketed in Canada does not mean that patients do not need access to them. There are two primary pathways for accessing non-marketed TB medicines.

For decades, the primary route of access has been via the Special Access Program (SAP). Under the SAP, a treating physician must request access to a particular non-marketed drug on an individual patient basis; if permission is granted, the physician is then permitted to acquire that non-marketed drug from the drug company (who is not obliged to provide the drug). Even when a SAP request is granted, and the company agrees to supply the drug, the process can impact treatment. The negative impacts of the SAP on TB treatment are so well known that they are explicitly highlighted in the Canadian Tuberculosis Standards (8th ed.).⁷

Broad reforms to the SAP in recent years have not fully removed these barriers. Some reforms, such as the ability to stockpile non-marketed medicines in anticipation of future patients, for example, have not been effectively realized for TB.

The burdensome nature of SAP underscores that it is meant to be a *temporary* access mechanism for medicines that have not yet received Health Canada approval. It was never intended to become a permanent solution for access to essential drugs, which are recognized domestically and internationally as the standard of care but have been left in limbo by market forces.

Since 2017, a second mechanism, similar to the SAP, has been repurposed to provide ongoing access to essential medicines for TB even though it too was not designed as a de facto permanent mechanism for that purpose. The second mechanism – Access to Drugs in Exceptional Circumstances (ADEC) – was designed as an explicit response to the shortcomings of the SAP in facilitating access to medicines for public health responses.

ADEC allows temporary bulk access to an unlicensed drug by a requesting jurisdiction (such as a province) for a limited time, following its addition to the List of Drugs for an Urgent Public Health Need (UPHN List). It was originally designed in response to the overdose crisis, expanding access to both non-marketed drugs and formulations. However, the only drug currently eligible for the ADEC, and the only drug to be on the UPHN List without interruption since its inception, is rifapentine, which is used to treat TBI. The listed justification for its inclusion is the “tuberculosis crisis”.¹¹

While the ADEC has been reasonably effective in ensuring temporary access for treating TBI in Northern Canada, it has been less successful in ensuring access elsewhere, or for uses beyond TB preventive treatment (ie., treatment of active TB).

UNRELIABLE SUPPLY OF MARKETED DRUGS

Another issue facing TB care in Canada is the repeated shortages of drugs that are marketed in the country. In recent years, there have been significant shortages of first-line TB drugs like ethambutol and rifampin. In the case of rifampin, despite previous shortages, one of Canada’s two suppliers left the market in 2021. Although Health Canada has acknowledged shortages of drugs like rifampin to be Tier 3 shortages (those that have the greatest potential impact on Canada’s drug supply and health care system), and the government has the ability to permit temporary importation from alternative suppliers, the country currently lacks measures to effectively prevent and mitigate shortages in the long term.

05. METHODS

Stop TB Canada conducted a survey of healthcare providers and TB program staff using Google Forms, which was distributed via email and through Stop TB Canada's communication channels, including newsletters and social media, throughout 2024. The surveys were available in English and French.

Respondents were asked about the accessibility of TB drugs, challenges regarding administering pediatric TB treatment, and the occurrence of shortages of certain TB drugs. Likert scales and open-ended questions were used, allowing respondents to elaborate qualitatively on their experiences of drug access issues and the perceived impact on their patients. Quantitative responses, including Likert scale responses, are presented descriptively, with analyses conducted in R, version 4.1.2. Qualitative responses are presented either anonymously or with respondents' affiliation, where permission to do so was provided by the respondents.

On the survey's start page, participants were informed of its purpose, and assured that their individual identifying information would not be collected, unless they explicitly provided permission to have their name and/or affiliation quoted in qualitative responses. Quantitative responses are aggregated (e.g., by province/territory or federally) to preserve anonymity.

As the surveys were conducted to support Stop TB Canada's routine advocacy activities and the report is intended for advocacy purposes only, research ethics approval was not required or sought. Should secondary analyses be conducted with these data, the appropriate permissions and approvals will first be obtained.

06. FINDINGS

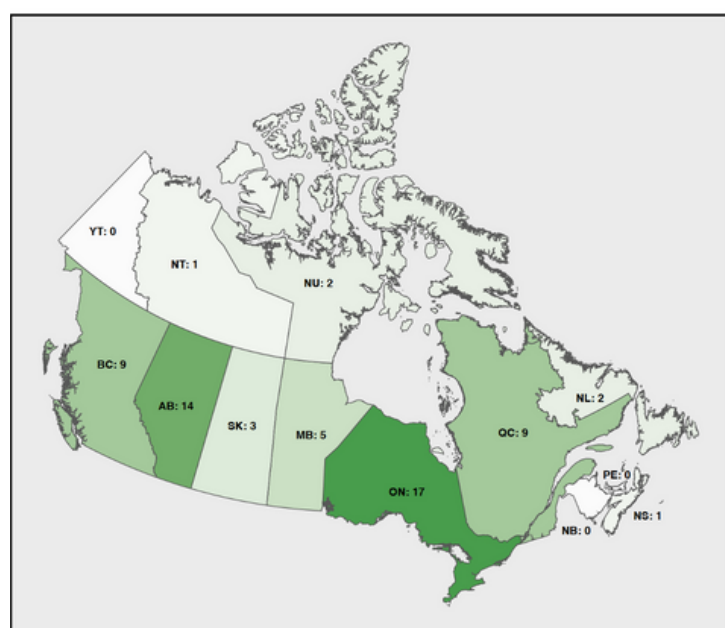
Considerable cross-Canada coverage was achieved among the 71 healthcare providers who participated in this survey, though the majority of responses came from Ontario (24%).

At least one provider responded from all other provinces and territories except New Brunswick, Prince Edward Island, and Yukon. Given the lower rate of TB in these three jurisdictions relative to the national average, response coverage should be sufficient to provide important insight into issues related to the access of essential TB medicines, particularly within jurisdictions where majority of TB affected persons reside.¹⁰

Responses by jurisdiction are shown in Figure 1, and by respondent role in Figure 2.

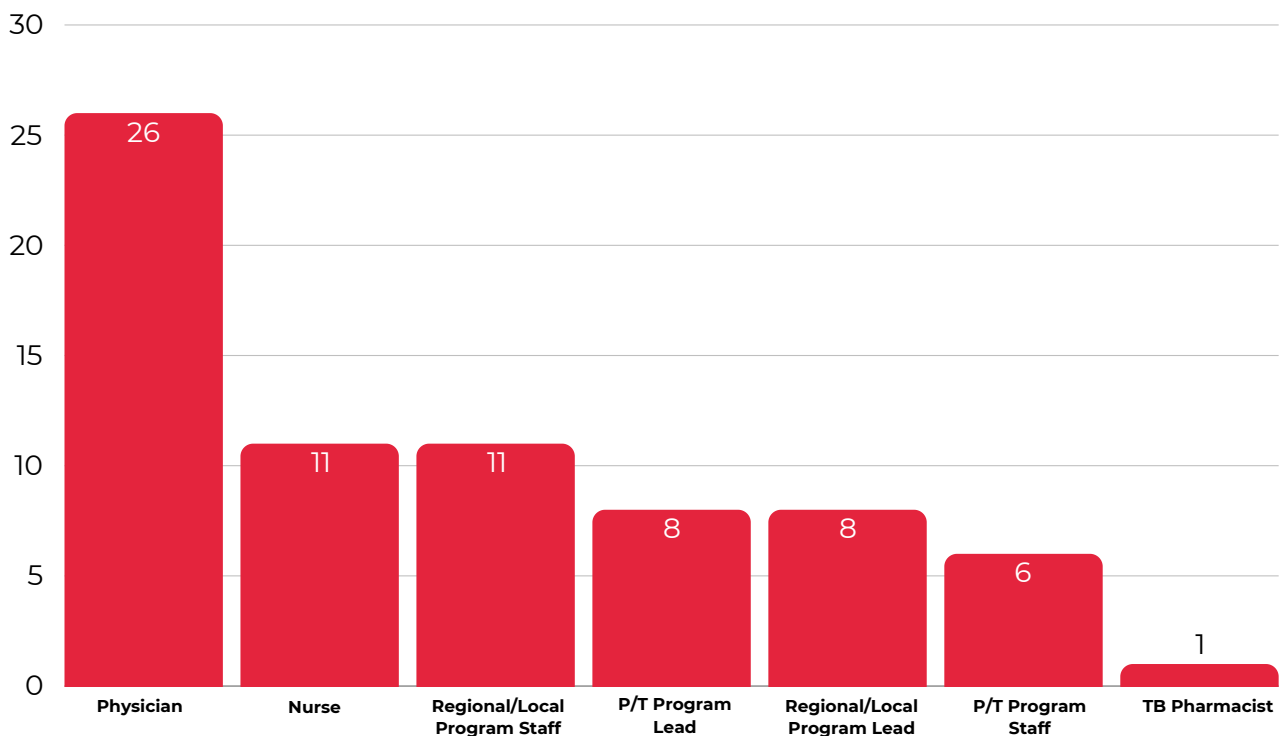
RESPONDENT SUMMARY

FIGURE 1: RESPONSES BY LOCATION



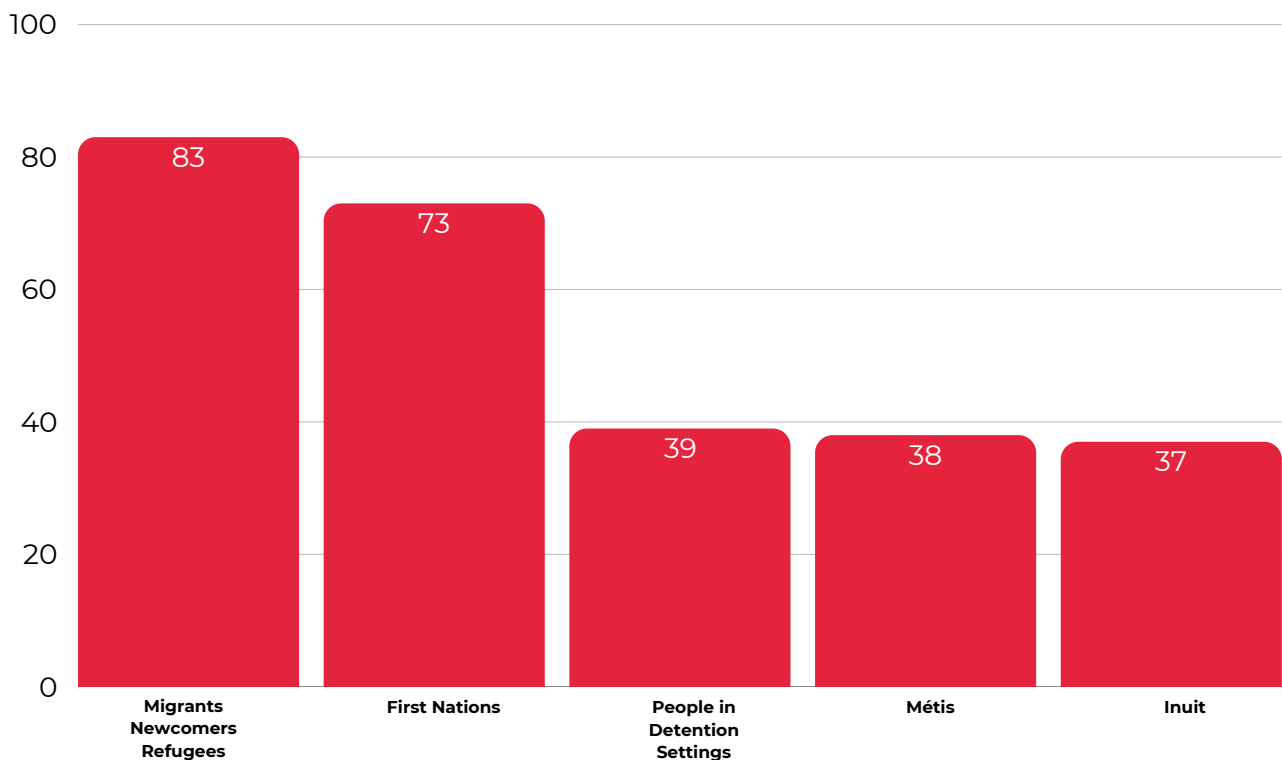
- 8 respondents indicated having worked in more than one province/territory and are therefore not shown on this map. They reported working in: AB, NU, ON (n=1); AB, ON (n=1); BC, MB, NT, NS, NU, ON (n=1); MB, NU, ON, QC (n=1); NT, NU (n=1); NU, ON (n=1); MB, ON (n=2).
- Administrative Boundary Source: Statistics Canada 2016 census boundary files (<https://www12.statcan.gc.ca/census-recensement/2011/geo/bound-limit/bound-limit-2016-eng.cfm>)

FIGURE 2: NUMBER OF RESPONDENTS BY ROLE



- Only primary TB specific role is shown in graph

FIGURE 3: NUMBER OF RESPONDENTS WORKING WITH KEY POPULATION GROUPS



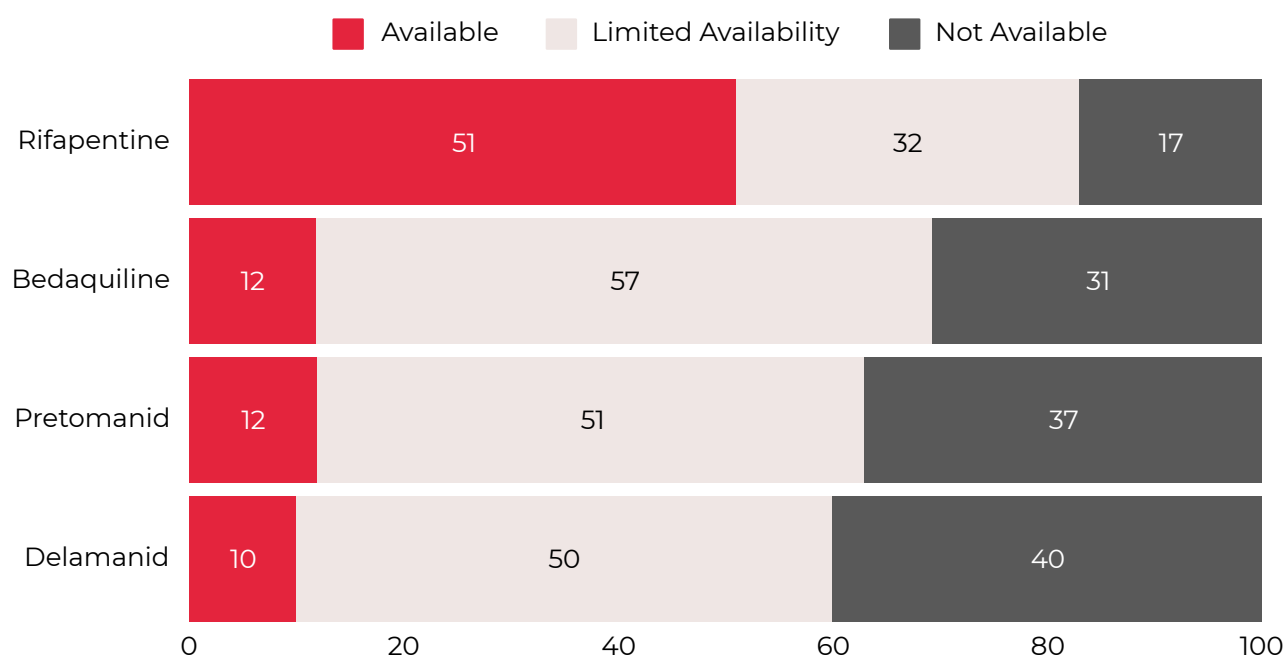
- Respondents could indicate serving more than one key population group

ACCESS ISSUES

AVAILABILITY OF NON-MARKETED DRUGS

Figure 4 indicates the extent of availability (percentage of respondents reporting availability, by province/territory) of bedaquiline, rifapentine, pretomanid, and delamanid, four key drugs that remain non-marketed in Canada and are accessible solely via special regulatory pathways, such as SAP and ADEC. Responses suggest low availability of bedaquiline, pretomanid and delamanid. Availability of rifapentine was generally higher. It is important to note that multiple respondents elaborated that, although the drugs are technically “available”, the process of accessing them is challenging, requires effort, and incurs delays (see **Critical Comments**). This suggests that the true accessibility of these drugs may be even lower than the “availability” metrics below indicate.

FIGURE 4: PERCEIVED AVAILABILITY OF NON-MARKETED TB DRUGS IN CANADA



- The graph shows the percent (%), or proportion of respondents who indicated availability out of all those who answered the question for the specified drug. Out of 71 total respondents, missing values (those who did not answer the question) for each drug are: bedaquiline n=12, rifapentine n=6, pretomanid n=14, delamanid n = 13.

In addition to the four drugs explicitly asked about in the survey, respondents were invited to mention other drugs that were a challenge to access for their program. Multiple respondents identified clofazimine, ethionamide, and intravenous isoniazid and rifampin as difficult to access. Pediatric formulations was also reported as inaccessible, which is covered in more detail below. In addition, beyond access to TB drugs, one respondent highlighted that the BCG vaccine for TB also requires an onerous SAP process (although not covered in this report).

CRITICAL COMMENTS



All SAP and ADEC drugs are difficult to obtain and unavailable unless we refer clients out of our health unit to specialists in [large urban centre].

~ Survey respondent (anonymous)

Although the above are "available" it is not without effort and delay; access needs to change.

~ Survey respondent (anonymous)

CHALLENGES ACCESSING NON-MARKETED DRUGS

To assess the extent of challenges related to timely access to drugs via special regulatory pathways (**Figure 5, annex page 31**), respondents were asked whether current access mechanisms hinder the provision of treatments to patients when needed, whether these delays contribute to unfavourable treatment outcomes, and whether patients are hesitant to take drugs that are not officially approved by Health Canada despite being approved by regulatory authorities elsewhere.

The majority of respondents agreed or strongly agreed that current access pathways are insufficient to provide patients with timely access to:

- bedaquiline (74%)
- delamanid (74%)
- pretomanid (75%), and
- rifapentine (56%).

Similarly, most respondents agreed or strongly agreed that delays in accessing bedaquiline, delamanid, and pretomanid contributed to unfavourable treatment outcomes for patients (70%, 60%, and 70%, respectively), with slightly less than half indicating this to be the case for rifapentine (44%). Lastly, approximately half of the respondents indicated hesitancy among patients to take drugs that are unapproved by Health Canada.

Beyond the challenges with access to the four drugs highlighted above, over three-quarters of respondents also agreed that the special regulatory pathways currently in place hinder the use of drugs in other appropriate regimens, including the implementation of newer, shorter TB regimens. For example, the current access mechanism for rifapentine only allows its use for preventive therapy in patients with TB infection, limiting its potential as part of a newer 4-month regimen for DS-TB.

DELAYS ACCESSING NON-MARKETED DRUGS

Figure 6 (annex page 32) shows providers' estimations of delays accessing drugs for use via existing regulatory pathways, from initial request to initiating treatment for a patient, by jurisdiction.

The majority of respondents reported delays of 3-4 weeks or more for all drugs except rifapentine, where delays were closer to 1-2 weeks in most areas. Alarming, in some provinces/territories delays of 4 months or more were reported for delamanid, pretomanid and rifapentine. In particular, 50% of respondents from Manitoba and 40% of respondents from Quebec indicated delays of 4 months or more for pretomanid.

Qualitative responses regarding reasons for these delays are summarized below the figure on page 36, and the consequences of the resulting lengthy treatment delays for people affected by TB are highlighted in **Box 3**.

When asked whether these delays in access to drugs resulted in loss to follow-up of patients before treatment can be started, of those who answered this question (n=57), n=1 respondent (2%) indicated "always", n=5 (9%) indicated "often", and n=17 (30%) indicated "sometimes" (with the remaining respondents indicating that this rarely or never occurs).

BOX 3: REASONS GIVEN BY PROVIDERS FOR DELAYS ACCESSING NON-MARKETED DRUGS



“Getting a response from Health Canada has been delayed up to a week, and then they require additional information which adds additional weeks before we can even start the process of shipping the drug over. Accessing bedaquiline **requires the approval from the manufacturer first, and then Health Canada and there can be delays from either side.**”

~ Survey respondent (anonymous)

“Rifapentine ordered from [manufacturer] has taken **more than 4 months to confirm availability from the manufacturer** and then receive the actual lot. It has been delayed on numerous occasions by Sanofi and we have also been told on more than one occasion that we would receive an order, only to receive an email months later stating there was no availability of the drug.”

~ Survey respondent (anonymous)

“It used to be an issue to access [rifapentine] without a **lengthy explanation as to why a client would greatly benefit.** In one specific case, the client ended up with active TB in the waiting period.”

~ TB Program staff & nurse, Saskatchewan

“The **process for each drug is different** since each manufacturer has their own requirements and paperwork. They also **differ in how much drug they will supply at once.** This not only adds a considerable burden on treating physicians but also greatly adds to the complexity of managing these patients and keeping track of the quantities of drugs that are available to them. It is **not unusual for patients to run out of at least one drug during treatment,** creating treatment interruptions.”

~ Survey respondent (anonymous)

“Pretomanid supply was delayed an extra month because the...company said we had not paid an earlier invoice[,] so they refused to ship the drug. In the end, we provided documentation they HAD been paid and it was their own **poor record keeping** that lead to an extra delay. During this extra time the patient was on **IV Amikacin** [drug given by injection which can cause permanent hearing loss].”

~ Survey respondent (anonymous)

“Drugs through special access mechanisms require clinicians to complete **significant paperwork** and **most are unfamiliar with the process,** which makes them less likely to choose these treatments. If a client requires [MDR-TB] treatment or special medications, they will usually be referred to a specialist in [urban centre], leading to treatment pauses and delays before they can even be assessed...then further delays accessing the medications.”

~ Survey respondent (anonymous)

As detailed above, some respondents elaborated on the reasons behind delays in accessing essential TB drugs, noting significant administrative delays with manufacturers, as well as delays in requests to Health Canada. For example, one respondent noted that access to bedaquiline requires approval from the manufacturer, and subsequently from Health Canada, and that delays occur at both stages. Another respondent noted it took 4 months just to confirm the availability of rifapentine with a manufacturer, with additional delays occurring when an order was confirmed but later found to be unavailable. Someone else highlighted that part of the challenge is that access processes vary for each drug, as manufacturers have different requirements and documentation, including differing quantities they will supply at once. This suggests that while access to these drugs may fall under the same mechanism, each presents unique challenges. Apart from increasing the burden on healthcare providers, this also makes it difficult to ensure an adequate supply of each drug, which can result in treatment interruptions for patients.

Importantly, some respondents also noted that the current administrative challenges in accessing these drugs and being unfamiliar with the processes dissuades providers from prescribing them at all. Therefore, even if mechanisms for accessing these drugs were improved, raising awareness of these improvements among healthcare providers would be critical to ensure the drugs are used (further discussion of lack of awareness of existing access mechanisms follows).

EXPERIENCES AND CONSEQUENCES ACCESSING NON-MARKETED TB DRUGS IN CANADA

Respondents shared their experiences regarding the impact of accessibility issues for drugs available via existing access pathways **(Box 4)**.

Key points include that the lack of access to these drugs results not only in higher administrative workloads for healthcare providers, but also unnecessary treatment prolongations, hospitalizations, and increased adverse side effects for people with TB. This, in turn, increases costs to the system and directly leads to more unfavourable treatment outcomes. In addition, loss to follow-up (as patients wait for delayed medicines or deal with increased side effects from sub-optimal treatment alternatives) not only worsens treatment outcomes, but also heightens the risk of TB transmission.

As one respondent points out, the lack of timely access to essential TB medications in Canada, particularly within Indigenous communities disproportionately affected by TB, represents a failure to honour the calls to action of the Truth and Reconciliation Commission (TRC) and hinders the achievement of health equity in Canada.¹²

BOX 4: EXPERIENCES AND CONSEQUENCES OF ATTEMPTING TO ACCESS NON-MARKETED DRUGS VIA EXISTING MECHANISMS



“We do not have ready access to first-line drugs for MDR-TB [multidrug-resistant TB] in Canada – this is a national shame. Given TB’s disproportionate impact on Indigenous peoples, this is also a barrier in achieving the aims of the Truth and Reconciliation Commission.”

~ Physician, Ontario

“Recent case of MDR-TB in [a] young [person] from [country with high MDR-TB burden]. Multiple SAP forms had to be submitted [resulting in] delays (initial declines for access to bedaquiline and pretomanid). This left [the] patient on multi-drug therapy with side effects, and [resulted in] a prolonged admission that was otherwise unnecessary. **High cost to system, greater adverse effects** (which could have been avoidable), and **poorer patient experience.**”

~ Survey respondent (anonymous)

“Drugs through special access mechanisms require clinicians to complete significant paperwork. If a client requires MDR treatment or special medications, they will usually be referred to a specialist... leading to **treatment pauses and delays** before they can even be assessed... then **further delays** accessing the medications. Additionally, this places a significant burden on clients to travel out of region... **some simply stop going to appointments**, causing treatment interruptions or making it difficult to assess for side effects...”

~ Survey respondent (anonymous)

“Delays mean that MDR-TB patients **continue to get sicker for weeks while awaiting treatment** and/or **face considerable toxicity** from regimens cobbled together from available drugs. [This] also [increases the time in which they can] transmit the infection[,] **increasing the risk to household members.**”

~ Survey respondent (anonymous)

“We have patients continuing on regimens that are much less tolerable for many months as we wait for the drug and **suffering through side effects**, etc...We need easier access to the medications.”

~ Regional/local TB program lead (multiple provinces/territories)

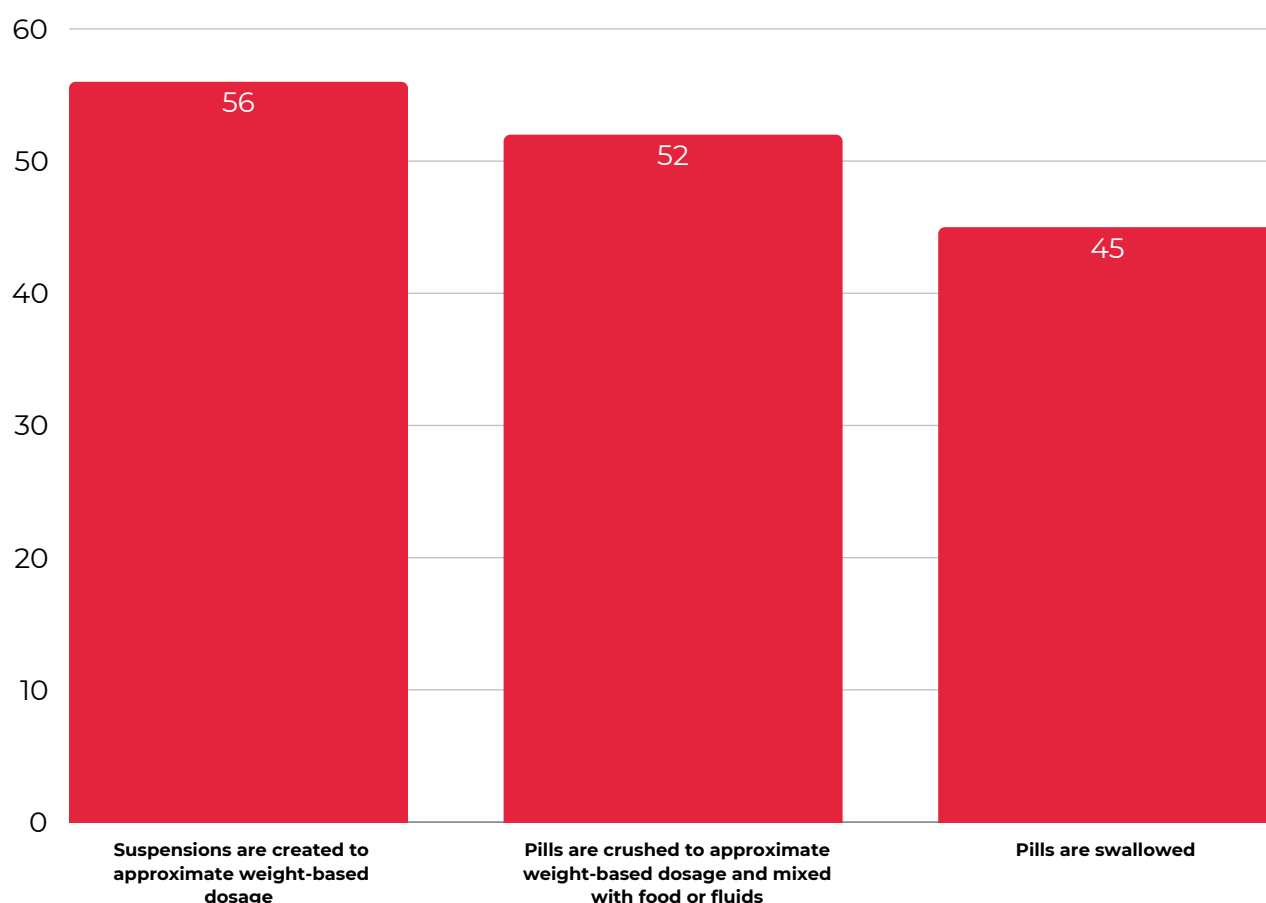
BARRIERS TO PROVIDING PERSON-CENTRED PEDIATRIC TB CARE

DELIVERY OF PEDIATRIC TB TREATMENT

Child-friendly formulations of TB medications are widely used globally but remain unavailable in Canada. In the absence of these child-friendly formulations, TB programs continue to rely on inefficient and often ineffective methods of pediatric TB treatment delivery, including crushing pills to approximate weight-appropriate doses for children, and mixing pills with food to render them more palatable.

Modes of delivery of pediatric TB treatment are shown in **Figure 7**, by province/territory, suggesting widespread use of suboptimal and challenging treatment delivery methods.

FIGURE 7: NUMBER OF RESPONDENTS INDICATING MODES OF PEDIATRIC TB TREATMENT DELIVERY IN CANADA



- Respondents could select multiple modes of delivery used

AWARENESS OF AVAILABILITY OF CHILD-FRIENDLY FORMULATIONS OF TB DRUGS

Just over half of respondents indicated they were aware of child-friendly formulations being available in other countries (n=28, 55% of n=51 answering the question). Some respondents specifically expressed that they were shocked to learn that these formulations are widely available elsewhere but not in Canada, especially considering the significant burden and trauma that the lack of suitable pediatric regimens represents for children, families and caregivers (**Box 6**).

BOX 6: AWARENESS OF CHILD-FRIENDLY FORMULATIONS OF TB DRUGS AMONG PROVIDERS

“I recently learned about this, and I was completely appalled... The taste and volume of the medicine are major factors in noncompliance – **many hours are spent trying to convince/force children to take their meds**, often unnecessarily traumatic events.”

~ Survey respondent (anonymous)

“It is shocking that this formulation is not available! I have tirelessly tried different alternatives for kids to take their TB medication. It is a **huge burden and traumatising to kids** and their families.”

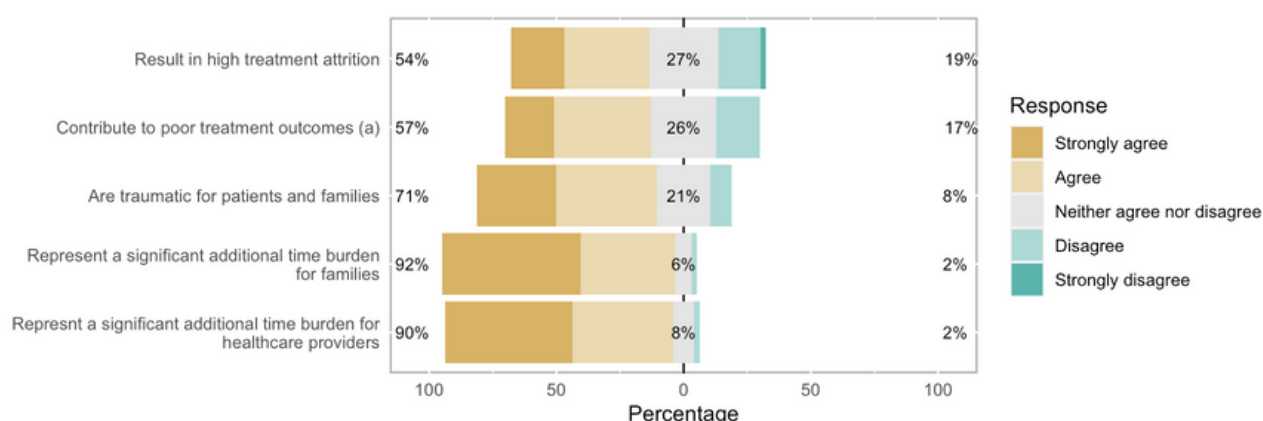
~ Survey respondent (anonymous)

CONSEQUENCES OF A LACK OF ACCESS TO CHILD-FRIENDLY TB DRUG FORMULATIONS IN CANADA

Given the unavailability of child-friendly formulations in Canada, prevailing methods of administering treatment for pediatric TB are challenging for children and caregivers, and can lead to suboptimal treatment. **Figure 8** indicates to what extent healthcare providers find that certain challenges are associated with current treatment administration methods.

Most respondents agreed or strongly agreed that these methods result in high treatment attrition, and that they contribute to poor treatment outcomes, for example due to inaccuracies in dosing (54% and 57%, respectively). Almost three quarters of healthcare providers agreed or strongly agreed that these methods are traumatic for children affected by TB and their families (71%). Lastly, almost all respondents agreed that these methods are associated with a significant additional time burden for families (92%) and healthcare providers (90%).

FIGURE 8: IMPACTS OF USING SUB-OPTIMAL TREATMENT FORMULATIONS IN CANADA



- Percentages refer to percentages of respondents indicating a particular challenge, out of those who answered the question for the specified challenge. Of 71 total respondents, missing values (those who did not answer the question) for each challenge are: Treatment attrition n=23, Traumatic for patients and families n=23, Poor outcomes n=24, Time burden for providers n=23, Time burden for families n=23.

Given the challenges highlighted above regarding current methods of administering pediatric TB treatment, unsurprisingly, almost all healthcare providers indicated that they would like child-friendly formulations to be available in Canada (n=50, 96% of the n=52 responding to this question).

When describing the challenges administering pediatric TB treatment (**Box 7**), respondents generally highlighted the inadequacies of available treatment modalities and their consequences for children affected by TB, including treatment attrition and missed doses or incorrect dosing, all of which contribute to unfavourable treatment outcomes.

Respondents also highlighted the long and often traumatic processes required to get children to take their treatment – sometimes including hospitalizations, or distraught family members having to give their child the medications by force. Access to child-friendly formulations would mitigate these challenges and – as one respondent underlined – is critical to achieving domestic TB elimination goals.

BOX 7: PROVIDER EXPERIENCES WITH CURRENT METHODS OF ADMINISTERING PEDIATRIC TB TREATMENT



“Administering pediatric TB treatment is a **daily challenge**, as much for families as for healthcare providers, even being a limiting factor in treatment completion... any improvement in access to child-friendly formulations is welcome.”

~ Survey respondent (anonymous). Translated from French.

“I have countless stories of my pediatric patients having challenges in taking their TB medications. Many children are simply not able to take all their [medications] and end up **missing many doses**. Caregivers are not able to do it alone and **many end up giving up**. It is a huge problem. We need these fixed dose combinations to be available in Canada. I think it is an issue of equity.”

~ Regional/local TB program lead (multiple provinces/territories)

“Collectively, my colleagues and I (8 nurses total) spent the entirety of the allowable 16 weeks trying to convince an 8-year-old to take 3HP. We tried mixing it with all typical foods...and tried crushed pills as well as liquid [medications] – in the end, she would flat out refuse, and her grandma would try to pin her down and force it in her mouth. **Each encounter took hours, and left all parties involved in tears...** Something [has] to change.”

~ Survey respondent (anonymous)

“Having [child-friendly formulations] available in Canada is **the least we could do to make things easier on families** and to have people fully treated in the shortest amount of time. Especially if the goal is to eliminate TB by 2030.”

~ Survey respondent (anonymous)

“...We often find that not all of a dose is administered because the child resists and some is lost. Additionally, we have had **errors with dosing** when pharmacies change the concentrations of their suspensions without families noticing. Clients with active TB disease do not stop their treatment, but a very high percentage of **preventative treatment is stopped before completion due to challenges with administration of medication.**”

~ Survey respondent (anonymous)

“The management of pediatric TB cases in remote First Nations is most challenging. In a recent cluster of cases in a remote community, the burden of pill crushing and literally forcing little children to swallow a medication that tastes awful seems **inhumane and may traumatize kids** who already have ongoing colonial trauma to deal with.”

~ Survey respondent (anonymous)



“We have many [children] who have had [lots of] trouble taking TB meds and it delays treatment, makes it harder for the client, family and [providers], which overall seems to **impact the therapeutic relationship**, especially when we are working in very small and remote communities with limited access and a lot of TB stigma.”

~ Survey respondent (anonymous)

“I have had **children needing nasogastric tubes** inserted so that we could administer life-saving medications (which usually is done in hospital, and warrants hospitalizations that otherwise would not have been necessary). I have had other children needing to be **admitted to the hospital for prolonged periods of time (months)**, away from their home communities... This creates significant burdens for families, medical trauma for kids, and is time consuming.”

~ Physician, Saskatchewan

“...Children who are high risk for active and **we have tried every last thing to give them [TB preventive therapy] and failed.**”

~ Provincial/territorial TB program staff & nurse, Saskatchewan

“We have ongoing significant challenges providing standard of care treatment to children in the communities we serve with the current therapies we have available. We have very recently had months of struggle providing therapy to a family with multiple children with active TB who have all on a regular basis refused their medications due to taste. This has resulted in...**significant trauma** for the children to the extent they will not go near our staff, **high burn out** from both the family and our staff...**unnecessary treatment prolongation...missed doses**, and concern about the possibility of breeding resistance... Furthermore, we have had to come up with delivery methods for the medications which involve mixing them with sugary or rich foods which may **compromise the efficacy of the medications**. The challenges we have faced in providing treatment to this family has been truly exemplary in the absolute need for more pediatric-friendly formulations to be available to our children in Canada.”

~ Physician, Ontario

SHORTAGES OF ESSENTIAL TB DRUGS

Shortages of rifampin (also referred to as rifampicin) and rifapentine have been an ongoing challenge in Canada. In the current survey, no respondents reported current shortages of rifampin across provinces / territories, except in Ontario, where 7% of respondents reported a current shortage (**Table 1, annex page 33**). Respondents across all provinces, however, reported having had past shortages of the drug (between 64% and 100% of respondents across provinces/territories), except for Newfoundland and Labrador. In comparison to rifampin, both current and regular shortages were more commonly reported for rifapentine (with 27% of respondents from Ontario indicating a current shortage, as well as 50% of respondents from Quebec and British Columbia, and 100% of respondents from Newfoundland and Labrador). It should be noted that as rifapentine is non-marketed in Canada, shortages exacerbate other access issues; however, in interpreting this section, it is possible that respondent perceptions of shortages have been impacted by other access barriers and delays.

Timely notification regarding shortages of rifapentine and rifampin was generally poor across all provinces. Mechanisms for programs and healthcare providers to receive notification of shortages were inconsistent and varied. Respondents reported receiving notifications through the Ministry of Health, provincial health authorities, drug distribution centres, pharmacies, or informally via the Canadian TB Elimination Network (CTBEN).

Notification processes, however, are not always reliable nor standardized. One respondent mentioned learning of drug shortages via word of mouth, while others noted that the shortages only became apparent after a drug has already been prescribed, or when patients could not pick up their medications at pharmacies. Additionally, a respondent noted that even where notification processes are generally in place, notification occurs without sufficient time for supply planning, resulting in the need to revert to older, longer treatment regimens with more adverse side effects.

In addition to shortages of rifampin and rifapentine covered in Table 1, respondents were also asked if their program had experienced shortages of drugs other than rifampin and rifapentine, with respondents indicating that quinolones, ethambutol, cycloserine and intravenous isoniazid were also affected by shortages.

07. DISCUSSION

Canada's commitment to eliminating TB nationally by 2035 – and by 2030 in Inuit Nunangat – requires urgent action to address critical barriers to accessing the essential medicines that underpin modern TB care. Despite the existence of groundbreaking innovations, including shorter, safer, and more effective TB regimens, as well as child-friendly drug formulations, systemic issues in Canada's healthcare and regulatory frameworks have left these advancements largely out of reach. The reliance on restrictive regulatory pathways, such as SAP and ADEC, results in substantial delays and administrative burdens, leaving patients in limbo and providers without timely access to the tools they need to deliver effective care.

The limited availability of child-friendly TB formulations is particularly troubling. These formulations, designed to ensure weight-appropriate dosing, ease of administration, and improved treatment adherence, are now standard in over 120 countries worldwide. Yet, children in Canada continue to rely on outdated practices that lead to suboptimal outcomes. Compounding the issue is the relatively low awareness of these formulations among healthcare providers in Canada, as revealed in this report. This lack of awareness has likely hindered advocacy efforts to make these medications accessible, perpetuating the status quo.

The absence of these advancements in Canada's healthcare system is a glaring injustice, particularly for a high-income country committed to universal health care and health equity. Canada should be a global leader in TB care but instead risks falling further behind other nations that have prioritized access to modern TB treatments. Without decisive leadership and comprehensive reforms, these barriers will continue to jeopardize the health and well-being of Indigenous peoples, newcomers, children, and other populations affected by TB in Canada.

Addressing these challenges demands meaningful action on multiple fronts. Ensuring access to all essential TB medicines requires Health Canada to simplify regulatory pathways, establish appropriate obligations and incentives for pharmaceutical companies to market TB drugs domestically, and explore international procurement mechanisms such as the Stop TB Partnership's Global Drug Facility (GDF). While most high-burden countries procure TB medicines through the GDF, Canada has yet to embrace this cost-effective and efficient mechanism, as other low-burden countries like Spain and Australia have successfully done. Health Canada should publicly clarify any specific regulatory barriers to procuring medicines via the GDF and take immediate steps to remove them, prioritizing the health of people over market-driven considerations.

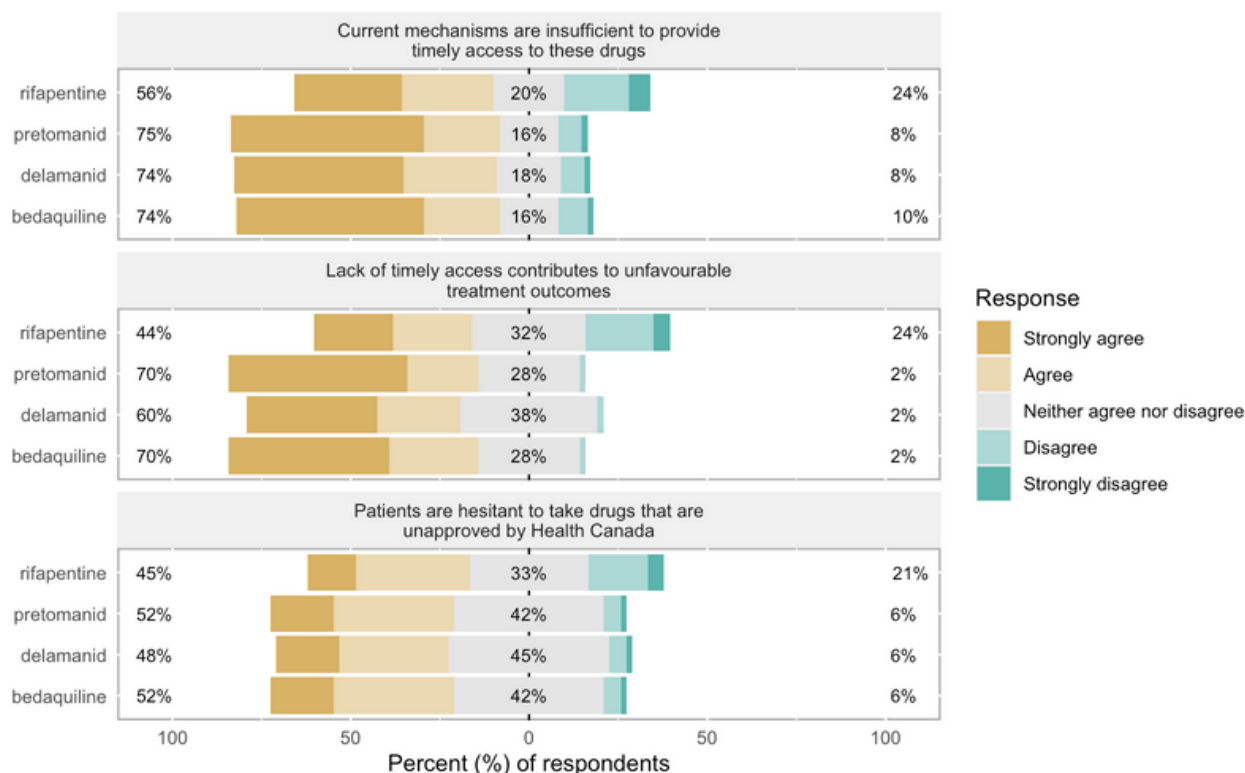
Improving access to TB medicines must be a cornerstone of a broader, comprehensive National TB Elimination Strategy for Canada. Stop TB Canada continues to call for a national strategy that improves access to TB medicines, while also: improving TB screening strategies among high-priority groups, addressing the social determinants of health, optimizing TB surveillance and reporting, and adopting accountability, monitoring and evaluation measures for TB programs.

Canada has a unique opportunity to lead by example, demonstrating how a low-burden, high-income country can overcome systemic barriers to provide equitable access to life-saving TB medicines. This leadership would not only advance Canada's domestic TB elimination goals but also serve as a model for other countries grappling with similar challenges.

Everyone, everywhere deserves the right to benefit from scientific innovations like modern medicine. Canada must act now to fulfill this fundamental responsibility, bridging the gap between innovation and implementation and ensuring that no one is left behind in the fight against TB. Stop TB Canada calls on the Government of Canada to make these issues a priority and take the decisive steps needed to achieve TB elimination.

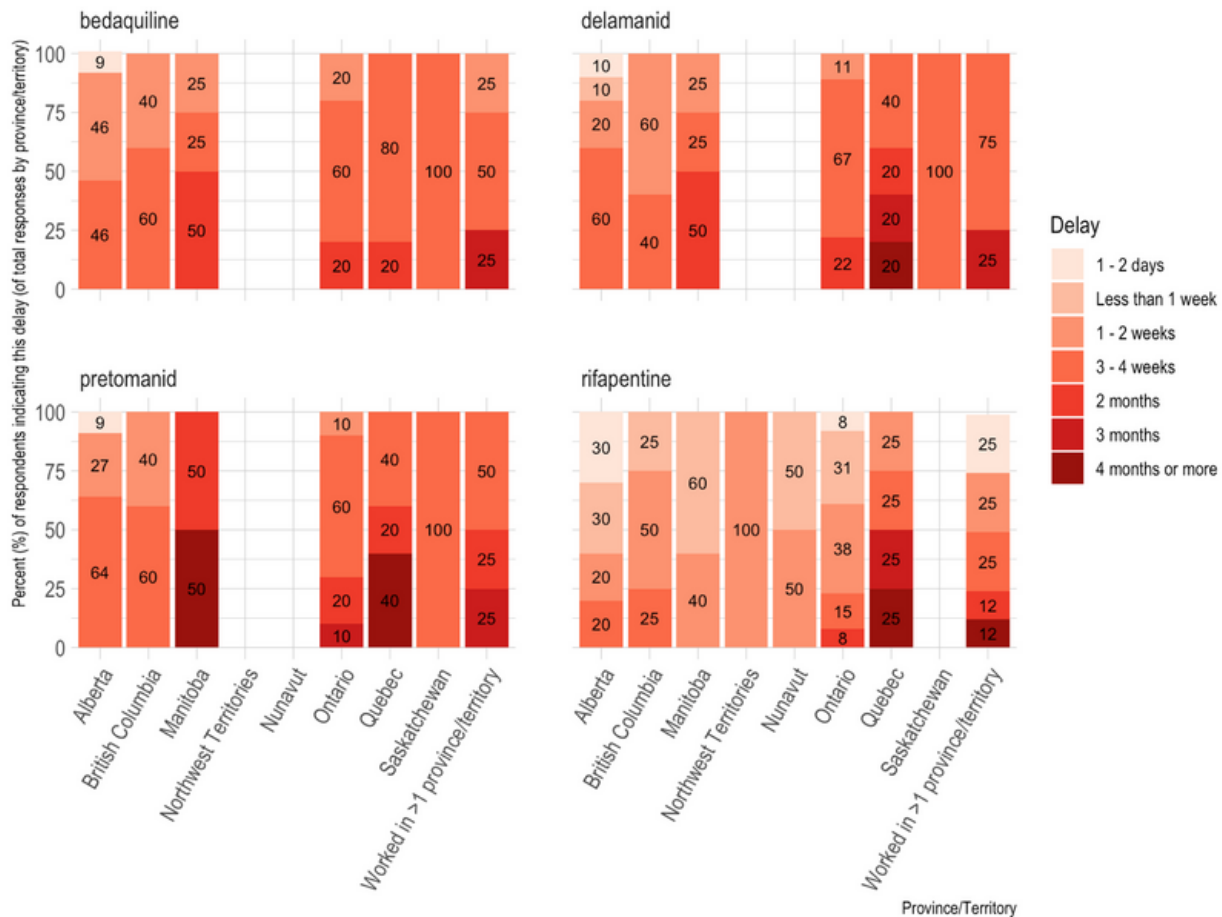
08. ANNEX

FIGURE 5: CONSEQUENCES OF CHALLENGES IN ACCESSING DRUGS VIA SPECIAL ACCESS PROGRAMS



- Percent (%) refers to the proportion of respondents indicating each challenge out of everyone who answered the question for the specified challenge. Of 71 total respondents, missing values (those who did not answer the question) for each challenge and drug are: Mechanisms insufficient for timely access: n=10 for bedaquiline, delamanid, and pretomanid, n=5 for rifapentine. Unfavourable treatment outcomes: n=11 for bedaquiline, delamanid, and pretomanid, n=8 for rifapentine. Hesitancy to take drugs: n=9 for bedaquiline, delamanid, and pretomanid, n=5 for rifapentine.

FIGURE 6: APPROXIMATE DELAYS BETWEEN REQUESTING TB DRUGS VIA EXISTING MECHANISMS AND INITIATING TREATMENT, BY PROVINCE/TERRITORY (A), AS ESTIMATED BY RESPONDENTS (B)



- 8 respondents indicated having worked in more than one province/territory. These are grouped separately from single-province/territory responses so that the remaining responses correspond to the experiences of specific provinces/territories.
- Percentages refer to percentages of respondents indicating delays for a particular drug, out of those who answered the question for the specified drug. Of 71 total respondents, missing values (those who did not answer the question) for each drug are: bedaquiline n=31, delamanid n=33, pretomanid n=33, rifapentine n=24.
- Missing bar for a province/territory = no responses from that province/territory regarding delays for that particular drug.

TABLE 1: SHORTAGES (A) OF ESSENTIAL TB DRUGS, BY PROVINCE/TERRITORY (B) (% OF RESPONDENTS)

	AB, N = 14	BC, N = 9	MB, N = 5	NFLD, N = 2	NWT, N = 1	NS, N = 1	NU, N = 2	ON, N = 17	QC, N = 9	SK, N = 3	Worked in >1 jurisdiction, N = 8
Rifampin											
Current shortage (%)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	7.1	0.0	0.0	0.0
Missing responses (n)	3	5	1	0	0	0	0	3	3	0	0
Regular shortages (%)	9.1	0.0	0.0	0.0	0.0	0.0	0.0	7.1	16.7	0.0	0.0
Missing responses (n)	3	5	1	0	0	0	0	3	3	0	0
Past shortage (%)	63.6	100.0	100.0	0.0	100.0	100.0	100.0	78.6	66.7	100.0	50.0
Missing responses (n)	3	5	1	0	0	0	0	3	3	0	0
Timely shortage notification (%)	36.4	0.0	0.0	100.0	0.0	0.0	0.0	50.0	16.7	33.3	50.0
Missing responses (n)	3	5	1	0	0	0	0	3	3	0	0
Rifapentine											
Current shortage (%)	0.0	50.0	0.0	100.0	0.0	0.0	0.0	27.3	50.0	0.0	0.0
Missing responses (n)	5	5	3	1	0	0	0	6	7	0	1
Regular shortages (%)	33.3	25.0	0.0	0.0	0.0	100.0	0.0	9.1	0.0	0.0	14.3
Missing responses (n)	5	5	3	1	0	0	0	6	7	0	1
Past shortage (%)	44.4	25.0	100.0	0.0	100.0	0.0	100.0	54.5	0.0	100.0	42.9
Missing responses (n)	5	5	3	1	0	0	0	6	7	0	1
Timely shortage notification (%)	33.3	25.0	0.0	0.0	0.0	0.0	0.0	36.4	50.0	33.3	42.9
Missing responses (n)	5	5	3	1	0	0	0	6	7	0	1
% Of respondents indicating:											
<i>Shortages:</i>						<i>Timely notification of shortages</i>					
0.0	20.0	40.0	60.0	80.0	100.0	0.0	20.0	40.0	60.0	80.0	100.0

- Respondents could select multiple options, e.g., both current and past shortages.
- 8 respondents indicated having worked in more than one province/territory. These are grouped separately from single-province/territory responses so that the remaining responses correspond to the experiences of specific provinces/territories.

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Stop TB Canada is a network committed to raising awareness, mobilizing communities, and generating the political will to end tuberculosis in Canada and abroad.

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