

# TUBERCULOSIS AND MIGRATION *in Canada*



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# CCDR

## CANADA COMMUNICABLE DISEASE REPORT

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# Summary of the National Advisory Committee on Immunization (NACI) Statement: Recommendations on the use of pneumococcal vaccines in adults, including Pneu-C-21

Eva Wong<sup>1</sup>, Oliver Baclic<sup>1</sup>, Marina I Salvadori<sup>1,2</sup>, Kyla Hildebrand<sup>3</sup> on behalf of the National Advisory Committee on Immunization (NACI)\*

## Abstract

**Background:** Pneumococcal disease in adults includes invasive pneumococcal disease (IPD), an acute and serious communicable disease with manifestations such as meningitis, bacteremia and bacteremic pneumococcal pneumonia. There are more than 100 different serotypes, and the extent of protection provided by a pneumococcal vaccine depends on the vaccine formulation. In July 2024, Health Canada authorized a 21-valent pneumococcal conjugate vaccine (Pneu-C-21), which followed the recent introduction of a 20-valent vaccine (Pneu-C-20) authorized in 2022.

**Methods:** The National Advisory Committee on Immunization (NACI) reviewed evidence on the epidemiology of IPD in Canada, immunogenicity and safety of Pneu-C-21, and the cost-effectiveness of different pneumococcal vaccines in adult immunization programs. NACI has also considered additional factors, including ethics, equity, feasibility, and acceptability (EEFA).

**Results:** Differences in the distribution of serotypes causing IPD have been observed before and after the COVID-19 pandemic. The Pneu-C-21 demonstrated comparable immunogenicity to Pneu-C-20 for shared serotypes and higher responses for unique serotypes. The safety profiles of both vaccines are expected to be similar to other pneumococcal vaccines, and the cost-effectiveness of Pneu-C-21 and Pneu-C-20 will depend on regional serotype distribution. The overall impact of Pneu-C-21 compared to Pneu-C-20 is uncertain, but likely to vary over time with age, risk factors, and geography.

**Conclusion:** NACI now recommends including at least one of Pneu-C-20 or Pneu-C-21 in adult pneumococcal immunization programs. One dose should be given to adults 65 years and older and those 18 to under 65 years at increased IPD risk, regardless of previous pneumococcal vaccination history.

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**Keywords:** National Advisory Committee on Immunization, pneumococcal disease, conjugate pneumococcal vaccine, Canada, adult immunization program, vaccine guidance

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## Introduction

Invasive pneumococcal disease (IPD) in adults represents a significant global public health concern. The burden of disease is predominately attributable to a small number of serotypes

of the *Streptococcus pneumoniae* bacteria. The landscape of pneumococcal vaccination in Canada has evolved with the recent authorization of higher-valency pneumococcal conjugate



vaccines (Pneu-C), including Pneu-C-15 (Vaxneuvance®, Merck Canada), Pneu-C-20 (PREVNAR 20®, Pfizer Canada), and most recently, Pneu-C-21 (CAPVAXIVE™, Merck Canada).

Currently, all Canadian jurisdictions have publicly funded adult pneumococcal vaccination programs. While specific eligibility varies, the programs generally include adults 65 years of age and older and certain adults 18 to 64 years of age who are at increased risk for IPD. The current national coverage goal for adult pneumococcal vaccination is 80% of adults aged 65 and older receiving one dose by 2025 (1). However, this target remains unmet based on coverage estimates.

In 2023, the National Advisory Committee on Immunization (NACI) provided updated guidance recommending Pneu-C-20 for adult programs, with Pneu-C-15 and the 23-valent pneumococcal polysaccharide vaccine (Pneu-P-23) in series as an alternative. NACI has since reviewed additional evidence and provided guidance on the use of pneumococcal vaccines in adults, including Pneu-C-21 (2).

## Methods

NACI used a comprehensive, systematic approach for recommendation development, including an analysis of the IPD burden in Canada, and a systematic literature review of the efficacy, effectiveness, immunogenicity, and safety of Pneu-C-21. This included evidence from key clinical trials, published studies, and supplementary data from manufacturers. Evidence was evaluated using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology for studies comparing Pneu-C-21 and Pneu-C-20.

To inform policy recommendations in Canada, economic considerations were assessed through systematic reviews and a *de novo* model-based cost-utility analysis of higher valency pneumococcal conjugate vaccines in adults.

NACI used a published, peer-reviewed framework and evidence informed methodology to ensure that issues related to ethics, equity, feasibility and acceptability (EEFA) were systematically assessed and integrated into the guidance (3). The evidence and programmatic considerations were organized by the NACI Secretariat using a process informed by the GRADE framework, and all of the information was used to facilitate development of NACI guidance. Further information on NACI's evidence-based methods is available in *Evidence-based recommendations for immunization – Methods of the National Advisory Committee on Immunization* (4).

## Results

### Epidemiology of invasive pneumococcal disease in Canada

Between 2019 and 2023, Canada's National Microbiology Laboratory characterized 14,563 isolates of *S. pneumoniae* causing invasive disease in adults, with 39% identified from adults 65 years and older. The majority of IPD cases were caused by vaccine-contained serotypes, with serotypes 3, 4, 12F and 22F being the most common in adults overall during this period.

Age-specific analyses revealed varying serotype distributions. In adults 18 to 49 years, serotypes 4 and 12F were most common, while serotypes 3 and 4 were most common in the 50 to 64 age group. Among those 65 years and older, serotypes 3 and 22F were most frequently isolated. Notably, the proportion of cases caused by Pneu-C-21 serotypes remained relatively stable in adults 65 years and older between 2020 and 2023, while decreasing in younger age groups. There was an overall increasing trend observed in the proportion of Pneu-C-20/non-Pneu-C-21 serotypes across age groups, which was most prominent in the younger adults and less pronounced in adults 65 years and older.

In addition to age-based differences, trends in serotype distribution have also been observed to differ by geography (i.e., Northern Canada vs. the rest of Canada) and by other risk factors for IPD (e.g., individuals who are unhoused).

Additional details are available in the annual report for invasive pneumococcal disease in Canada (5).

### Clinical evidence

Clinical trials involving over 7,600 adults demonstrated the immunogenicity and safety of Pneu-C-21 (6). In the pivotal double-blind clinical trial, adults aged 18 years and older received either Pneu-C-20 or Pneu-C-21 (7). The Pneu-C-21 elicited comparable immune responses to Pneu-C-20 for shared serotypes and higher responses for unique serotypes across all age subgroups.

Generally, higher immune responses were observed in participants aged 18 to 49 years, compared to those 65 years and older. Similar immunogenicity was observed between study participants with and without risk factors for IPD. In vaccine-experienced adults, immune responses were generally comparable between intervention groups, though those previously receiving Pneu-P-23 showed somewhat lower responses.

Safety data from an integrated analysis of multiple trials, involving over 6,000 individuals, showed Pneu-C-21 was well-tolerated. The most common adverse reactions in younger



adults (18–49 years) included injection site pain (75%), fatigue (35%), and headache (30%). In adults 50 years and older, adverse events were less frequent, with injection site pain (40%), fatigue (20%), and headache (10%) being most common. The majority of reactions were mild and short-lived ( $\leq 3$  days), with severe events occurring in less than 1% of participants. The available evidence suggests that there are no meaningful differences in severe adverse events in individuals who received Pneu-C-21 compared to individuals who received Pneu-C-15, Pneu-C-20, or Pneu-P-23.

### Economic considerations

Two systematic reviews were conducted to identify economic evidence for the use of pneumococcal conjugate vaccines in adult populations (8,9). The first review, which did not include studies on Pneu-C-21, found that conjugate vaccines (Pneu-C-13 alone or in combination with Pneu-P-23 or Pneu-C-20) may be cost-effective compared to no vaccination for adults aged less than 65 years at higher risk of IPD, at a threshold of \$50,000 per quality-adjusted life year (QALY) gained (8). A second review identified five economic evaluations assessing the cost-effectiveness of Pneu-C-21 in adults and found that Pneu-C-21 is likely cost-effective in adults within specific age and risk groups; however, the applicability of these evaluations to the Canadian context is limited, as findings are sensitive to the region- and age-specific serotype distribution of pneumococcal disease cases and vaccine price (9).

A *de novo* model-based cost-utility analysis (10) was conducted by updating a model previously used to assess the cost-effectiveness of Pneu-C-15 and Pneu-C-20 in Canadian adults (11). The use of one of the higher valency conjugate vaccines is expected to be a cost-effective strategy (using a \$50,000 per QALY threshold) in all population groups considered, with the choice of vaccine being highly dependent on serotype distribution in the target population. These results held even with conservative assumptions about indirect effects and serotype replacement.

### Ethics, equity, feasibility and acceptability considerations

The COVID-19 pandemic has broadly impacted the uptake of routine vaccines, particularly among children. Because paediatric pneumococcal immunization offers indirect protection to adults, it is uncertain how IPD serotype epidemiology will evolve with improved paediatric vaccination, along with the use of higher valency pneumococcal vaccines in both children and adults. While regional epidemiology can better inform the choice of product(s) to use in adult programs, jurisdictions do not necessarily collect and/or have equal access to detailed data, and there may be variability in how or when updated pneumococcal vaccine recommendations are adopted. It is anticipated that program- and individual-level acceptability of the high valency conjugate vaccines will depend on the complexity of the recommendations, and will need to be clearly communicated if

programs are recommended to use multiple products, given that Pneu-C-15 and Pneu-C-20 have been recently recommended for use in paediatric and adult immunization programs.

## Discussion

### NACI recommendations on adult pneumococcal vaccines for public health program-level decision-making

The following are recommendations for provinces/territories making decisions for publicly funded immunization programs:

- NACI recommends that adult pneumococcal immunization programs should include at least one of Pneu-C-20 or Pneu-C-21 (**Strong NACI recommendation**)
- NACI recommends that one dose of either Pneu-C-20 or Pneu-C-21 should be given to adults 65 years of age and older, and adults under 65 years at increased risk of IPD (**List 1**), regardless of pneumococcal vaccination history (**Strong NACI recommendation**)
- For hematopoietic stem cell transplant recipients, both Pneu-C-20 and Pneu-C-21 should be offered after consultation with a transplant specialist. A primary series of three doses should be administered starting 3–9 months post-transplant at four-week intervals, followed by a booster dose at 12–18 months post-transplant (**Strong NACI recommendation**)

### Additional guidance on pneumococcal vaccines

- The aim of the pneumococcal vaccine program is to protect adults at high risk for infection and medical complications. With the uncertainty around ongoing IPD epidemiology and as vaccine effectiveness data accrues, simplicity and flexibility in the recommendations are needed to allow jurisdictions the ability to consider how to best achieve the highest possible benefit in the targeted populations.
- The choice of the vaccine(s) used will depend on determining the most suitable vaccine(s) based on regional epidemiology, vaccine eligibility (including prior immunization with a pneumococcal vaccine), and programmatic considerations.
- For adults who have previously received pneumococcal vaccination, the choice of vaccine and interval from the last dose will depend on the type of vaccine previously received and time since vaccination. Based on expert opinion, the recommended interval between Pneu-P-23 and either Pneu-C-20 or Pneu-C-21 is now one year; however, an interval as short as eight weeks may be considered in those who might be anticipating initiation of immunosuppressive treatments or who have diseases that might lead to immunodeficiency.



## List 1: Adult risk factors for invasive pneumococcal disease

### Medical conditions:

- Hematopoietic stem cell transplant recipients
- Chronic cerebrospinal fluid (CSF) leak
- Cochlear implants, including those who are to receive implants
- Congenital immunodeficiencies involving any part of the immune system, including B-lymphocyte (humoral) immunity, T-lymphocyte (cell) mediated immunity, complement system (properdin, or factor D deficiencies), or phagocytic functions
- Immunocompromising conditions or immunosuppressive therapy within the past two years, including use of long-term corticosteroids, chemotherapy, radiation therapy, and immunosuppressive biologics
- Active malignant neoplasms<sup>a</sup>, including leukemia and lymphoma
- Candidates and recipients of solid organ or islet transplants
- Chronic kidney disease, particularly those individuals with stage 4 and 5 chronic kidney disease, and those with nephrotic syndrome, on dialysis or renal transplant recipients
- Chronic liver disease, including cirrhosis, biliary atresia and chronic hepatitis
- HIV infection
- Functional or anatomic asplenia (congenital or acquired) or splenic dysfunction, including sickle cell disease and other hemoglobinopathies
- Chronic neurologic conditions that may impair clearance of oral secretions
- Chronic heart disease requiring regular medication and follow up for ischemic heart disease, congenital heart disease, chronic heart failure, or hypertension with cardiac complications
- Diabetes mellitus, particularly in those over 50 years of age
- Chronic lung disease (particularly chronic obstructive pulmonary disease, emphysema, bronchiectasis, interstitial lung fibrosis, and cystic fibrosis), including asthma that required medical care in the preceding 12 months

### Social, behavioural, and environmental factors:

- Individuals who are unhoused
- Individuals living in communities or settings experiencing sustained high IPD rates, including those who are in residential care<sup>b,c</sup>
- Smoking, particularly in those over 50 years of age
- Substance use (i.e., alcohol misuse, cocaine use, and injection drug use)
- Occupational risk with long-term continuous exposure to metal fumes (i.e., welders)

Abbreviation: IPD, invasive pneumococcal disease

<sup>a</sup> Immune compromised status can vary over time depending upon the disease state, which may or may not involve immunosuppressive medication

<sup>b</sup> Including long-term care homes

<sup>c</sup> Individuals should be vaccinated with a vaccine that covers serotypes circulating in the community

Note: It should be noted that some conditions listed above carry higher risk than others. In adults, risk increases at a population level with advancing age (beginning at age 50). In addition, having multiple risk factors at once may also increase risk for an individual. Program-level recommendations may focus on the populations particularly at risk

- At the individual level, it should also be noted that adults 18 years of age and older who are not included for higher valency pneumococcal vaccine in publicly funded programs may opt to receive higher valency pneumococcal vaccination in consultation with their healthcare providers.

## Conclusion

NACI now recommends that adult pneumococcal vaccination programs use at least one of Pneu-C-20 or Pneu-C-21. The impact of the recent changes to Canadian pneumococcal vaccine programs may not be evident in the short-term, as it can take several years to observe notable changes to IPD serotype epidemiology. NACI will continue to monitor the epidemiology of pneumococcal disease, including IPD, and will update the recommendations on the use of pneumococcal vaccines as needed.

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None.

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# Evaluating Canada's initiative of enhanced screening for tuberculosis infection in migrants: Implementation lessons from Alberta

Courtney Heffernan<sup>1</sup>, Abdul Jamro<sup>2</sup>, Mary Lou Egedahl<sup>1</sup>, Richard Long<sup>1,2\*</sup>

## Abstract

**Background:** The domestic tuberculosis (TB) disease burden in high-income, low TB-incidence countries is largely driven by the reactivation of remotely acquired TB infections (TBIs) in people born outside the country (PBOC). In Canada, PBOC now accounts for more than three quarters of annual active TB diagnoses. To prevent some of this disease experience, Immigration, Refugees and Citizenship Canada (IRCC) rolled out a new TBI screening initiative in 2019.

**Objective:** An evaluation of TB outcomes among individuals referred through this initiative between May 2019 and May 2023 in Alberta, Canada.

**Methods:** Inclusion criteria for this initiative are migrants who are required to undergo an immigration medical exam with at least one of HIV/AIDS, solid organ transplant, end-stage renal disease, recent close TB contact (within five years), and past head and neck cancer. Those with a positive screening test for TBI are referred directly to TB services in the stated province/territory of landing for assessment and treatment.

**Results:** Over four years, 179 referrals were made to Alberta. No one referred through the program and offered treatment developed active TB. Overall, 95 individuals were considered suitable candidates for prevention, among whom 87% accepted. Completion was high at nearly 95%. Inefficiencies included 113 individuals undergoing repeated TBI testing locally, 39 (21.8%) referrals not meeting the inclusion criteria, and 61 (34.1%) individuals being rereferred despite being past patients of Alberta TB services.

**Conclusion:** Our findings highlight that, in Alberta, IRCC's new TBI screening initiative was highly successful in connecting referred individuals to TB services. The initiative experienced some inefficiencies and we describe areas where it could be improved.

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**Keywords:** tuberculosis, surveillance, incidence rate, migrants, screening, evaluation, implementation

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## Introduction

Despite being preventable and curable, in 2023, 10.8 million people fell ill with tuberculosis (TB) disease worldwide and 1.25 million succumbed to its effects (1). Tuberculosis has traditionally been conceived as existing in a binary of TB infection (TBI) and TB disease (TBD), with the former being neither contagious nor symptomatic but requisite to developing TBD (2). The global prevalence of TBI is estimated at 25%, but

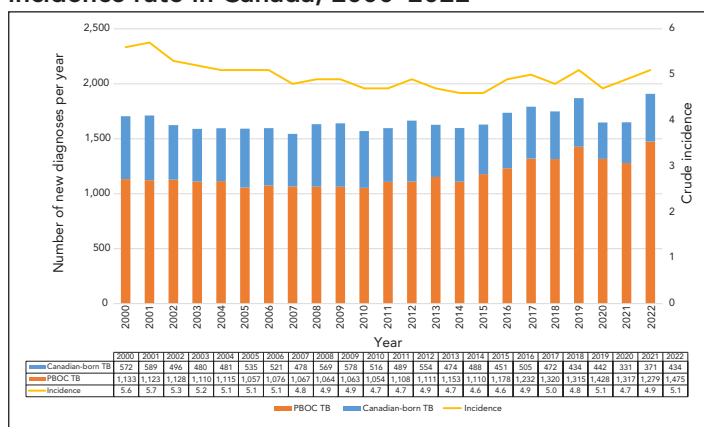
only 5%–10% of those infected will progress to disease (3). Progression risk is highest among people who have been recently infected, have immune compromising conditions, or are in poor general health, including from undernutrition (4). As a result, TBD proliferates in places where the health and social welfare needs of most citizens are largely unmet, as in low- and middle-income countries. Meanwhile, in high-income countries,



the majority of TBD is experienced by people born outside the country (PBOC), with most resulting from reactivation of remotely acquired infections (5).

Canada has a rate of TBD that is among the lowest in the world, but which has hovered at approximately five per 100,000 population from 2000 to present (6). In part, this may be because in 2016, the decades long shift from people arriving from countries of Western Europe with a low TB burden to people arriving from countries of Asia, Africa, and Latin America with intermediate and high TB incidence was at a nearly 30/70 split, while the absolute number of migrants have been increasing rapidly since (7–10). By 2019, PBOC made up 74% of all people affected by TB nationally, see **Figure 1**. Such considerations imply that the immigration pathways are ideal settings for TBI screening with positive impacts to both the individual and public.

**Figure 1: Annual count of individuals with tuberculosis disease who are Canadian-born and people born outside the country along with the overall tuberculosis incidence rate in Canada, 2000–2022**

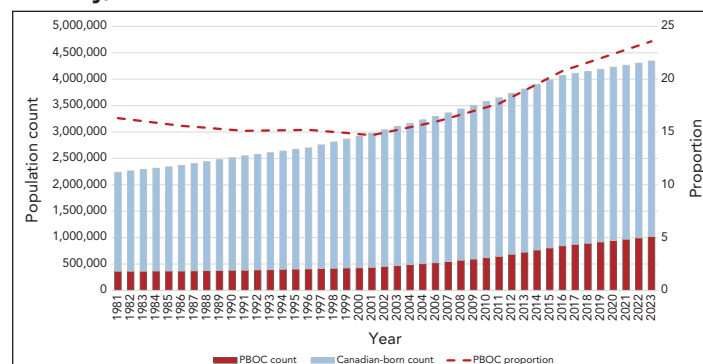


Abbreviations: PBOC, people born outside the country; TB, tuberculosis

Canada has high levels of immigration, having welcomed 437,000 new permanent residents in 2022 (11). In light of the ostensible TB prevention gap among PBOC to Canada, Immigration, Refugees and Citizenship Canada (IRCC) introduced a federal program of enhanced screening for TBI in 2019 as an add-on to their existing medical surveillance program for TBD. Prior to the introduction of this initiative, the immigration focus was on finding active TBD, including domestic post-landing medical surveillance for TB among those with abnormal chest X-rays or past history of TB (12). This article describes TB outcomes among individuals referred by this new, systematic TBI screening initiative between May 2019 and May 2023 to the province of Alberta, where net international migration is a major component of population growth and the majority of TBD is diagnosed among PBOC (13,14). The top three countries of birth of newcomers to Alberta are Philippines, India, and Nigeria, with corresponding rates of TB ranging from 199 to 638 cases

per 100,000 people (**Figure 2**) (15). In 2021, 241 people in Alberta had TBD, with a corresponding crude rate of 5.4 per 100,000 population (6).

**Figure 2: Alberta population count by group along with the proportion who are people born outside the country, 1981–2023**



Abbreviation: PBOC, people born outside the country

Source: Population estimates from Statistics Canada (<https://www.statcan.gc.ca/>)

**Table 1** shows the top countries of origin of new arrivals to Alberta from 2016–2021. **Table 2** shows the top five countries of origin and five-year average TB incidence in those countries for PBOC diagnosed with TB in Alberta from 2016–2021 during which time a total of 1,248 people were diagnosed with TB.

**Table 1: Top 5 countries of origin of new arrivals in Alberta, 2016–2021**

Country	n (%)
Philippines	47,605 (24.6)
India	31,810 (16.5)
Nigeria	9,840 (5.1)
China	9,495 (4.9)
Syria	7,300 (3.8)
Total in Alberta	193,130 (100.0)

**Table 2: Top 5 countries of origin for people born outside the country diagnosed with tuberculosis in Alberta, 2016–2021**

Country	n (%)	Average five year incidence
Philippines	414 (33.2)	577/100,000
India	255 (20.4)	201/100,000
Ethiopia	79 (6.9)	133/100,000
Somalia	74 (5.3)	254/100,000
Vietnam	31 (2.5)	174/100,000



## Methods

The enhanced TBI screening initiative for migrants focuses on TBI-test-positive individuals at high risk of reactivation who would benefit from TB preventive therapy (TPT). Individuals coming from select countries are required to complete an immigration medical exam (IME) to evaluate their health in order to be admissible to Canada (16). All permanent residents and some temporary resident applicants are required to complete an IME. After screening, applicants who can be part of this intervention must have a complete IME with at least one high-risk medical condition for TB reactivation (HIV/AIDS and have a solid organ transplant, end-stage renal disease, recent close TB contact within five years, and head and neck cancer) together with either a positive interferon-gamma release assay (IGRA) or Tuberculin Skin Test (TST) (17). The IRCC notifies provincial or territorial public health authorities of these individuals so that they can arrange assessment for TPT. A letter is also provided at the port of entry to applicants whose IME was performed overseas directing them to follow up with TB services in their intended province/territory of residence within 30 days. As a result, health system contact can be initiated either by provincial/territorial TB services or by the individual. Assessment by a clinician or public health designated specialist is

a condition of entry that can affect future eligibility of Canadian citizenship (12). For this reason, TB services and individual migrants assume mutual responsibility for medical surveillance of TB in Canada, and compliance is high.

Other high-income countries with low rates of TB in the general population, such as the United Kingdom (18), Australia (19,20), and the United States (21), run varied TB screening programs for inbound migrants to reduce imported prevalent TB infection and disease, as shown in **Table 3**. Compared to Canada, the governments of the United Kingdom, Australia, and especially the United States have more comprehensive TB screening programs for PBOC that emphasize prevention and involve more robust testing of persons arriving from high incidence countries. The initiative evaluated in this article is intended to lessen existing TB prevention gaps between Canada and other high-income countries.

## Implementation and effectiveness

Between 2019 and 2023, IRCC made 9,887 referrals to TB services in Alberta and between May 2019 and May 2023, with 179 or fewer than 2%, resulting from the enhanced TBI screening initiative. To describe the effectiveness of this initiative (i.e., its ability to connect eligible individuals to

**Table 3: Basic characteristics of screening programs for migrants in Canada, the United Kingdom, Australia and the United States<sup>a</sup>**

Characteristics	Canada	United Kingdom	Australia	United States
Target population	Individuals applying for permanent resident status and select temporary residents who require an IME (7).	Visa applicants aged ≥11 years, coming from countries with a TB rate of >40 per 100,000 and staying for ≥6 months (18).	Individuals applying for permanent resident status and select non-permanent residents who require an IME (19,20).	Immigrants, refugees, or other legal permanent residents (21).
Screening tests	Tests include physical examination, medical history, chest X-ray, and sputum for acid-fast bacilli smear and culture if indicated (7).	Tests include chest X-ray and symptom inquiry. Sputum for acid-fast bacilli smear and culture is required for those with a suggestive chest radiograph.	Tests include chest X-ray and symptom inquiry. Children aged >2 but <11 years coming from high-TB-incidence countries, which includes all those not categorized by WHO as low-TB risk, are required to complete an IGRA or TST.	Tests include physical examination, medical history, chest X-ray and sputum for acid-fast bacilli smear and culture if indicated. IGRA test for those aged ≥2–15 years, expanding in fall of 2024 to those aged >15 years, who come from high-TB-burden countries (defined by an incidence of ≥20 cases per 100,000).
Medical surveillance requirement	Past history of TB or abnormal chest X-ray, but no microbiological confirmation of disease which are required to report to a public health authority within 30 days of arrival.	Migrants arriving by unofficial routes are screened for active TB at the first point of contact with healthcare services.	Past history of TB or an abnormal chest X-ray but not microbiological confirmation of disease, which are required to report to public health within 28 days of arrival.	Panel physicians assign applicants into one of seven TB classifications with varying travel clearances: Those classified as A or B are referred to their local state health department for follow-up within 90 days of arrival.
Other screening	Selective TBI testing predates the 2019 enhanced program, and applies to individuals who intend to work, study or train in certain areas, including medicine and allied health (16).	TBI testing and treatment for recently arrived (within 5 years) PBOC aged 16–35 from countries with an incidence rate of 150 per 100,000 or greater (18).	Selective TBI testing of individuals aged ≥15 years, arriving from high TB-incidence countries who intend to work, study, or train in health care, aged care or disability care.	Refugees undergo domestic screening within 90 days of arrival to find TB disease that may have developed between an overseas IME and arrival to the United States.

Abbreviations: IGRA, interferon-gamma release assay; IME, immigration medical exam; TB, tuberculosis; TBI, tuberculosis infection; TST, tuberculin skin test; WHO, World Health Organization

<sup>a</sup> Individuals diagnosed with active tuberculosis disease during their immigration medical exam are required to submit proof of treatment completion before being permitted to enter any of the four countries or else have visa conditions lifted





TB services for domestically delivered prevention), this study focused on TB outcomes. Data were extracted in a retrospective review of public health records to establish care cascades. Every referred individual had a one-year follow up to assess for development of TBD. The characteristics of individuals referred through this initiative are described in this article. Thereafter, to identify implementation challenges, the entire process is explored in detail, from application of screening inclusion to referral and subsequent stages of TB care in Alberta.

## Results

Alberta TB services received 179 referrals through IRCC's enhanced screening initiative, relating to 177 unique individuals over four years. Characteristics of individuals referred are shown in **Table 4**. The majority of IMEs were performed overseas compared to Canada (71.8% and 28.2%, respectively). Recent close contact of a TB case was the top reason for referral, followed by HIV/AIDS (46.9% and 35.6%, respectively). The majority of referred individuals were applying for permanent residence status (67.2%). Approximately 40% of the individuals referred through the program were coming from the Philippines. Overall, 87.6% of referred individuals came from the World Health Organization (WHO) designated, high-TB-burden countries (22). The IGRA was used to screen the majority of individuals, compared to TST (81.4% and 15.2%, respectively). Close to one-quarter of the results of the screening test were reported in the IME qualitatively.

No one referred through the program and offered treatment developed active TB, whether they accepted and completed treatment, declined, or discontinued, but one individual had prevalent active TBD diagnosed at their surveillance appointment, which occurred within two weeks of landing in Canada.

Attendance at the surveillance and assessment appointments was high, at 94.3% and 92.7%, respectively (defined in **Table 5**). The median time between surveillance and assessment appointments was 28 days (interquartile range [IQR]: 9, 101), and 10% of all referrals were associated with a wait time of >6 months between referral and assessment. From 177 unique individuals referred, only 95 (53.6%) were ultimately determined to be candidates for prevention, 86 (90.5%) of whom were offered treatment. Just over 87% of individuals who were offered accepted treatment and completion was high at 94.6% (**Figure 3**). Out of 95 individuals referred through this initiative, 71 successfully progressed through the TBI cascade of care while attrition at some step or another affected 24. Individuals who had a successful cascade were slightly younger than those who did not (average 36 years vs. 52.8 years), and less likely to have had their IME in-country (32.4% vs. 58.3%); data not shown.

**Table 4: Characteristics of the 177 unique individuals referred by Immigration, Refugees and Citizenship Canada to Alberta tuberculosis services, May 2019–May 2023<sup>a</sup>**

Characteristics	n (%)
<b>Location of IME</b>	
Overseas	127 (71.8)
Canada	50 (28.2)
<b>Screening inclusion group</b>	
Recent close TB contact (within five years)	83 (46.9)
HIV/AIDS	63 (35.6)
End-stage renal disease	22 (12.4)
Previous head/neck cancer	6 (3.4)
Previous organ/transplant recipient	3 (1.7)
<b>IME screening tool</b>	
IGRA	144 (81.4)
TST	27 (15.2)
No test	6 (3.4)
<b>Reporting of results in IME (n=171)</b>	
Quantitatively	128 (74.9)
Qualitatively	43 (25.1)
<b>Gender</b>	
Male	90 (50.8)
Female	87 (49.2)
<b>Age group (years)</b>	
5–14	12 (6.8)
15–35	73 (41.2)
36–60	63 (35.6)
60+	29 (16.4)
<b>Immigration type<sup>b</sup></b>	
Permanent resident	119 (67.2)
Temporary resident	57 (32.2)
<b>Country of birth</b>	
Philippines	71 (40.1)
Ethiopia	15 (8.5)
India	15 (8.5)
Nigeria	11 (6.2)
Other	65 (36.7)
<b>WHO region</b>	
Western Pacific	78 (44.1)
African	59 (33.3)
South-Eastern Asia	16 (9.0)
Eastern Mediterranean	15 (8.5)
Region of the Americas	8 (4.5)
European	1 (0.6)
<b>WHO high-burden country<sup>c</sup></b>	
Yes	155 (87.6)
No	22 (12.4)

Abbreviations: IGRA, interferon-gamma release assay; IME, immigration medical exam;

TB, tuberculosis; TST, tuberculin skin test; WHO, World Health Organization

<sup>a</sup> Two individuals were referred twice through this initiative

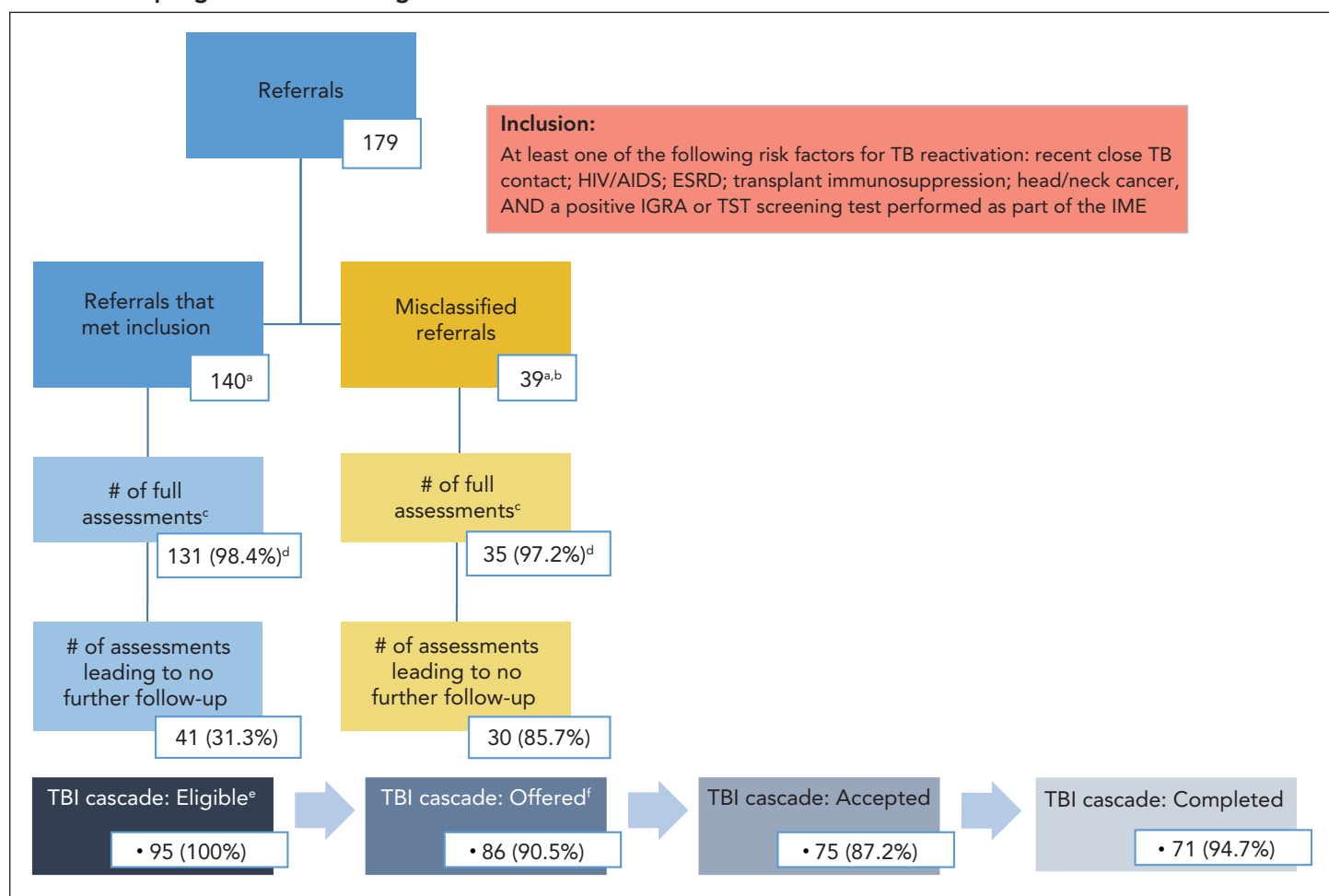
<sup>b</sup> Immigration type of one individual was unknown

<sup>c</sup> List of 30 countries created by WHO, which is valid until 2025 (22)

**Table 5: Metrics of performance for the enhanced screening initiative showing the cascade of care and redundancies**

Performance metrics	n (%)
<b>Total unique individuals referred</b>	<b>177 (100.0)</b>
Individuals who attended a surveillance appointment <sup>a</sup>	167 (94.3)
Individuals who completed an assessment appointment <sup>b</sup>	164 (92.7)
Individuals who had TBI testing repeated	113 (63.8)
<b>Total unique individuals who attended surveillance</b>	<b>167 (100.0)</b>
Individuals with a surveillance appointment that preceded referral	60 (35.9)
Individuals whose surveillance appointment occurred within 6 months of referral	89 (53.2)
Individuals whose surveillance appointment occurred >6 months from referral	18 (10.7)
<b>Total unique individuals who completed physician assessment</b>	<b>164 (100.0)</b>
Individuals recommended TPT	86 (52.4)
Individuals who initiated TPT	75 (87.2)
Individuals who completed TPT	71 (94.7)

Abbreviations: TBI, tuberculosis infection; TPT, tuberculosis preventive therapy

<sup>a</sup> Surveillance appointment is the first point of contact between the referred individual and the TB program, where an individual may be required to undergo additional testing for TBI<sup>b</sup> At an assessment appointment, which follows surveillance, a physician goes through the test results to determine whether an individual would benefit from treatment**Figure 3: Flow chart illustrating how the 179 referrals moved through the various stages of care in the Alberta tuberculosis program and resulting tuberculosis infection cascades of care for individuals<sup>a,b,c,d,e,f</sup>**

Abbreviations: ESRD, end-stage renal disease; IGRA, interferon-gamma release assay; IME, immigration medical exam; TB, tuberculosis; TBI, tuberculosis infection; TST, tuberculin skin test

<sup>a</sup> Each referral group includes one individual who had two distinct IMEs during the review period and was hence referred twice<sup>b</sup> 33 negative test results on file; 6 missing test results<sup>c</sup> Of the 166 full assessment appointments, 61 were for individuals who had contact with provincial TB services that pre-dated the referral, of which 72.1% resulted from an IME performed in Canada and 27.9% were from those whose IME was done overseas<sup>d</sup> Of surveillance appointments (n=133 in the "met inclusion" group; n=36 in the misclassified group)<sup>e</sup> Sum of individuals who were fully assessed but not put to no further follow up<sup>f</sup> Nine individuals were not offered treatment for miscellaneous reasons (did not have insurance, died incidentally, moved or left Canada)



Notably, 60 (35.9%) individuals had contact with TB services prior to notification to the province by IRCC of their referral through this initiative, with the median number of days between those events being 148 days (IQR: 67, 364) (see Table 5). For 53 (88.3%) of those individuals, their prior contact occurred more than 30 days before the province receiving their referral, and majority was observed in individuals whose IME was performed in-country (83%). In addition, TBI screening tests were repeated in Alberta for 113 (63.1%) of all individuals referred. Among those, 39 had a negative test result or else no evidence of a prior test having been performed as part of the IME; see Figure 3. From the remaining 140 referrals, after excluding those 39 with negative or no test result in their IME, were two individuals each referred twice. In other words, of the 179 total referrals made, 138 unique individuals were seen from referrals to Alberta TB services that met all inclusion criteria of this enhanced screening initiative over the review period.

## Discussion

This enhanced TBI screening initiative has been nationally administered by IRCC since 2019 but, given its restrictive screening inclusion, applies to very few of all newcomers to Canada (17,23). Outcomes of individuals referred through it have heretofore not been reported, a knowledge gap that this evaluation contributes to closing. Local data showed that this initiative was highly effective at connecting referred individuals to TB services in the province in a timely fashion, including for one individual who had prevalent disease at their surveillance appointment who was rapidly provided TBD treatment. Despite this success, only about half of those referred for prevention were considered suitable candidates for TPT after in-country assessment. Those who were offered treatment had high rates of acceptance and completion. The conclusion drawn is that the program was limited by certain inefficiencies, but future evaluations should be undertaken in other high immigrant receiving provinces to determine unique and common obstacles to its implementation and effectiveness with respect to TB control in Canada. From the limited vantage point of this study, cautious, but generalizable takeaways are presented.

First, redundant patient referrals were observed. About one-third of individuals referred by this initiative had already been seen by TB prevention and care services in Alberta prior to the referral being made. This may be due to an administrative delay, whereby individuals initiate their surveillance appointment prior to TB services being notified of the referral. It may also result from in-country applicants, who are likelier to have prior health system contact to manage their high-risk medical condition that satisfies the requirement for screening during the IME. Across Canada, it is the standard of care to screen for TBI among patients provided care for HIV/AIDS, end-stage renal disease, solid organ transplant, and head and neck cancers and this may account for much of the duplication (9,24).

Second, a substantial number of individuals referred, who did not meet the screening or test result inclusion criteria, were observed. Such misclassification occurs in the events prior to referrals being made by IRCC, so its rate is likely countrywide. As a result, a high volume of individuals who are not suitable candidates for TPT are referred nationally contributing to increased workload, unnecessary testing, and reduced yield of the intervention.

Third, information management pitfalls and resource waste were observed. For example, in Alberta, nearly two-thirds of individuals referred underwent local repeat screening. On the one hand, this may be due to test results being hard to find. On the other hand, it may be due to misalignment between panel physician member guidance and the local standard of care. For instance, the instructions guide physicians to report test results qualitatively, which conflicts with the standard of care in Alberta to base a TBI diagnosis on quantitative test results (17).

Although it is recognized that this initiative is a step in the right direction to close prevention gaps for migrants to Canada, more expansive screening for PBOC especially designed to reach migrants not identified by current methods should be considered. For example, the latest edition (8<sup>th</sup>) of the Canadian Tuberculosis Standards recommends TB screening within five years of arrival for PBOC originating from countries with a TB incidence of >200/100,000, who have low to moderate risk of TB reactivation, and are aged ≤65 years; the TBI screening infrastructure now in place for the IME would ideally support implementation of this recommendation. This strategy would elevate weighting of exposure and infection risk in addition to, or instead of, underlying reactivation risks (7). Relatedly, it was noted that individuals whose IME was performed in-country as opposed to overseas were less likely to be considered eligible for prevention at assessment, and more likely to have an inferior TBI care cascade. As a result, cost savings may be achieved by restricting TBI screening to those undertaking an IME overseas.

## Limitations

Although the enhanced TBI screening initiative for migrants is a nationally administered initiative, it was only evaluated in one province and the review period overlapped with the COVID-19 pandemic, which contributed to a sharp decline in global movement and thus reduced expected referral volume. It is noted that while some implementation challenges are related to pre-referral events in administering and reporting of tests in the IME, others may be unique to the organization of TB services by jurisdiction, thereby limiting the generalizability of our reported data. Alberta TB services are highly centralized, with one point of contact for IRCC referrals that get distributed to its three public health TB clinics based on the referred individual's residence (25). Other areas with decentralized TB control efforts may see distinct and more diffuse challenges. The retrospective nature of data collection for this study, and a lack of qualitative data, limit this article to a description of that but not why events occurred.



Nevertheless, an evaluation of this initiative is important for detailing implementation lessons that can be used to optimize both its administration, nationally, and corollary patient care, provincially/territorially.

## Conclusion

In low TB-incidence settings like Canada, reactivation of imported infection is a significant driver of the epidemic. Immigration pathways are good places to implement screening as they reflect a major pipeline through which infection flows into Canada. That said, targeting screening, so as not to overwhelm the resources of local TB programs to deliver a treatment response, is crucial; IRCC has implemented one such targeted effort cross-country (10,26,27). Compared to its peers, TBI screening has been less robust in Canada. This new initiative, however, is a good step toward expanding TBI screening among PBOC, but we note areas where its administration and local prevention responses can be improved. A lot of work remains if Canada is serious about meeting its TB elimination targets.

## Authors' statement

CH — Conceptualization, methodology, project administration, writing—original draft

AJ — Formal analysis, writing—original draft

MLE — Data curation, writing—review & editing

RL — Supervision, funding acquisition, writing—review & editing

The content and view expressed in this article are those of the authors and do not necessarily reflect those of the Government of Canada.

## Competing interests

None declared.

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# Treatment of tuberculosis infection among immigrants in southern New Brunswick, Canada: A cross-sectional study

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## Abstract

**Background:** Treating individuals with tuberculosis (TB) infection (TBI) is an important aspect of the global strategy to eliminate TB as a public health problem, as it would help reduce the pool of individuals with TBI who are at risk of developing TB disease (TBD). Understanding factors that impact effective management of patients with TBI is helpful in informing policy.

**Objective:** To assess the proportion of immigrants with TBI accepting and completing TB preventive treatment (TPT), variables potentially related to accepting and completing TPT were examined and healthcare provider (HCP)-related factors that impact TBI management were identified.

**Methods:** Tuberculosis preventive treatment was offered to TBI-positive immigrants without a history or treatment of TBD from a pilot TBI screening study conducted in southern New Brunswick, Canada between November 2021 and November 2023. Tuberculosis preventive treatment acceptance and completion rates were calculated, and the HCP completed a questionnaire to identify factors that affected TBI management. Participant characteristics were summarized using descriptive statistics, while Fisher's exact tests were conducted to test for independence between demographics and treatment acceptance and completion. The HCP questionnaire data were analyzed using thematic analysis.

**Results:** Of the 49 participants who screened positive for TBI, 11 (22.4%) were lost to follow-up prior to being assessed and offered TPT and 38 (77.6%) were offered TPT, of whom 3 (7.9%) declined, 35 (92.1%) accepted and initiated TPT, and 30 (85.7%) completed treatment. Treatment acceptance and completion were found to be independent from the participant demographics examined. Thematic analysis revealed five emerging themes regarding the management of TBI participants (i.e., supports, collaboration, communication, time, and satisfaction).

**Conclusion:** This study demonstrates the feasibility of treating TBI in immigrants and highlights HCP-related factors that impact the management of TBI among immigrants in southern New Brunswick. Our findings may assist programs aimed at improving TBI screening and treatment.

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**Keywords:** tuberculosis infection, treatment, management factors, immigrants, southern New Brunswick

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## Introduction

Tuberculosis (TB) is the leading cause of death from a single infectious agent, with 10.8 million reported cases and 1.25 million fatalities globally in 2023 (1). A major concern is that approximately one-quarter of the world's population is estimated to have TB infection (TBI) (2), an asymptomatic condition that can lead to TB disease (TBD) in 5%–10% of those infected (3).

In 2001, Canada adopted the Stop TB Partnership goal of eliminating TB as a public health threat by 2030 (4). In 2014, Canada signed the World Health Organization (WHO)'s *Towards tuberculosis elimination: an action framework for low-incidence countries*, which set a pre-elimination target of fewer than one TBD case per 100,000 people by 2035 and full elimination, defined as fewer than 0.1 cases per 100,000 people per year, by 2050 (5). Although Canada reported a low TBD incidence rate of 5.1 cases per 100,000 people in 2022 (6), to achieve the full TB elimination target by 2050, the country needs to reduce its annual TBD incidence by more than 10% (5). The TBD incidence in Canada decreased from the 1990s to the early 2000s, was maintained at that lower rate for over a decade, and then started rising steadily from 2014 onward (6,7).

In New Brunswick (NB), an Atlantic Canadian province, the incidence of TBD has consistently remained below the national average, though it has shown a slight upward trend, rising from 0.4 cases per 100,000 people in 2013 to two cases per 100,000 population in 2022 (6).

This increase parallels the province's population growth, which is largely driven by immigration (8), and is widely believed to stem from the reactivation of TBI acquired before arriving in Canada (9,10). To counter this more recent trend, it is essential to adopt innovative strategies, such as providing routine screening and treatment of TBI among at-risk populations, as this could help lower the number of people at risk of developing TBD and help with the country's commitment to meeting the WHO's goal of reaching less than one TBD case per 100,000 population by 2035 (5). Individuals immigrating to Canada are required to undergo immigration medical examinations (IMEs) pre-arrival. These examinations include a chest X-ray to screen for TBD in everyone aged 11 and older, along with TBI screening for specific high-risk populations (11). In 2022, 76.2% of TBD cases in Canada (6) as well as all TBD cases in NB in 2022 (n=17) and 2023 (n=14) were among immigrants (*personal communication, Public Health Agency of Canada Tuberculosis Task Force meeting, November 26–27, 2024*), yet routine screening and treatment for TBI among immigrants is not widely available (9).

There is a dearth of data on rates of acceptance and completion of TBI treatment in Canada, as well as factors that affect the management of individuals with TBI. Previous studies on TBI screening and treatment in Canada were conducted among

refugees at refugee health centres (12–18). Two of these studies also examined healthcare worker-related factors associated with TBI management (12,13).

This study seeks to contribute to the body of knowledge by determining the acceptance and completion rates of TBI treatment among eligible immigrants of all immigration streams in southern NB, Canada, a region with a rising number of immigrants from TB-endemic areas, albeit without an immigrant health clinic. Furthermore, this study seeks to examine variables potentially related to accepting and completing TB preventive treatment (TPT) and examine healthcare provider (HCP)-related factors that impact the management of individuals with TBI. This study was part of a pilot TBI screening program for immigrants residing in southern NB, which offered TPT following clinical assessment among those who screened positive (19).

## Methods

Study participants, recruited consecutively, were  $\geq 19$  years of age, resided in southern NB, Canada, and born in a country with a TB incidence of  $\geq 40$  cases per 100,000 people or were considered at high risk of TBI by an HCP and were referred for TBI screening in a study conducted between November 2021 and November 2023 (19). The study was conducted in southern NB partly because there is no dedicated refugee or immigrant health clinic in the area. This setting is of further importance, given the increased number of immigrants arriving in the area from TB-endemic countries. Tuberculosis infection screening was performed using the interferon-gamma release assay (IGRA), (QuantiFERON-TB Gold Plus, Qiagen, Germantown, Maryland, United States). To be eligible for this study, participants were required to have screened positive for TBI without prior TPT and have no history or treatment for TBD upon clinical assessment.

## Tuberculosis infection treatment procedures

Upon clinical assessment, participants diagnosed with TBI who consented to TPT and were without contra-indications were offered first-line TBI treatment regimens by the treating HCP, as recommended by the Canadian Tuberculosis Standards: 1) rifampicin (4R) – four-month duration with self-administered daily dosing; or 2) isoniazid/rifapentine (3HP) – three-month duration with 12 once per weekly doses observed and monitored at the participant's community pharmacy (20). All medications provided to participants were covered under the provincial health plan and were dispensed by community pharmacies. Treatment was initiated and was accompanied by routine monitoring blood work to assess for adverse effects, as per Canadian Tuberculosis Standards recommendations (20). The decision to move forward with TPT was made in consultation



with the patient following counselling on the natural history of TB and individualized risk for reactivation to TBD. Patients were counselled by the treating HCP. If the patient expressed interest in moving forward with TPT, they were offered options for treatment with a focus on 4R and 3HP. Risks and benefits were discussed. In each case, if English was not the primary language of the patient or if there was a preference to use an alternate language, a translator was used to allow for back-and-forth dialogue in real-time to ensure the patient was able to receive the needed information and ask all desired questions to ensure understanding around the risks and benefits of TPT. Interpreters were also available for follow-up. The infectious disease physician, public health nurses, community nurses, local pharmacies, and community organizations provided screening and treatment support based on participants' needs.

Treatment was considered complete when participants reported taking all prescribed doses within the designated timeframe. Treatment adherence was corroborated by reviewing the dispensing history of the community pharmacy. Dropout rates and the reasons for dropping out at each stage were recorded. Participants who declined treatment were counselled on the natural history of TB by the HCPs and were encouraged to undergo annual chest X-rays for two years from their arrival date in Canada. Local immigrant-serving organizations, namely the YMCA of Greater Saint John and the Saint John Newcomer Centre, provided substantial support to study participants and HCPs throughout the treatment process. This support included assistance with navigating the healthcare system through the clinical encounters, diagnostic imaging, and scheduled phlebotomy, as well as community guidance with pharmacy services and refills when needed. The organizations also served as a communication conduit between the patient and the healthcare team and public health. This was critical in navigating a multitude of logistical challenges and assisting with scheduling and rescheduling appointments.

## Data collection and analyses

### Treatment acceptance and completion

Demographic data and treatment variables of participants, including age, sex, gender, year of arrival to Canada, type of visa used on the participants' initial entry to Canada, country of birth, and TB incidence in the country of birth were collected during the recruitment process (19). In addition, a history of the country of repatriation prior to arrival in Canada was obtained. Other countries and regions where the participants had lived were also noted. As a component of the clinical history, details pertaining to the precise region of the countries where study participants

had lived in addition to a timeline of migration were gathered and documented. Country of birth was categorized into one of six WHO regions (21). TBI positivity was reported using defined WHO incidence rate categories (22). The type of treatment each participant received, reasons for loss to follow-up, and not initiating or completing TPT were documented. Proportions for each step of the treatment cascade were calculated and reasons for loss to follow-up and not initiating or completing treatment were recorded. Participant demographic variables were summarized using descriptive statistics. To test for independence between each of the demographic variables listed in **Table 1** and the acceptance and completion variables, the dataset was imported into RStudio (version 2024.12.0.467). To account for the small sample size and expected cell counts in the contingency tables being less than five, in some cases, Fisher's exact tests were used. Analyses were conducted using the 'fisher.test()' command in RStudio (version 2024.12.0.467). To address the potential issue of multiple comparisons, a more stringent alpha criterion of 0.01 was applied.

### Healthcare provider survey

At study completion, the HCP completed a pilot-tested survey regarding their experiences in managing TBI positive participants (23), **Appendix Table A1**. The survey was developed by the research team and pilot-tested with four HCPs to evaluate clarity, coherence, and completion time. The survey was revised based on feedback received, which addressed the wording and sequencing of both the initial and follow-up questions. The survey consisted of 10 dichotomous questions, nine of which had open-ended follow-up questions to gather additional clarification if the HCP answered "yes" to any of the dichotomous questions. The questions aimed to collect information about the HCPs' role, the adequacy of tools needed to support and care for patients during both initial and follow-up visits, barriers in arranging follow-up tests, and the helpful aspects of the care process throughout the pilot screening program. The survey also sought to determine the average time spent per patient visit, the total time dedicated to patient management (including administrative tasks) and any final comments the HCPs wished to provide. The survey was completed virtually through an email containing an attachment sent by a research team member. The HCP survey data were analyzed using thematic analysis to identify recurring patterns and emerging themes to gain a better understanding of the HCP's views, opinions, and experiences (24).

### Ethical approval

The main component of this sub-study was approved by the Horizon Health Network (file #: RS 2021-3046) and the University of New Brunswick (file #: 033-2021) Research Ethics Boards.





Table 1: Demographics and tuberculosis infection treatment acceptance and completion with Fisher's exact test

Demographic characteristics	Treatment acceptance (n)		p-value	Treatment completion (n)		p-value
	Yes	No		Completed	Not completed	
Sex						
Male	14	1	-	12	2	-
Female	21	2	-	18	3	-
Total	35	3	1.00	30	5	1.00
Year of arrival in Canada						
2001	1	0	-	1	0	-
2014	1	0	-	1	0	-
2016	0	1	-	0	0	-
2018	1	0	-	1	0	-
2019	3	0	-	3	0	-
2021	5	0	-	4	1	-
2022	8	2	-	7	1	-
2023	16	0	-	13	3	-
Total	35	3	0.084	30	5	1.00
Visa type on initial entry to Canada						
Family reunion	1	0	-	1	0	-
Visitor	1	0	-	1	0	-
Permanent resident	4	1	-	3	1	-
Study	7	0	-	7	0	-
Government-assisted refugee	22	2	-	18	4	-
Total	35	3	0.531	30	5	0.610
Country of birth by WHO region						
Western Pacific	5	0	-	5	0	-
Americas	3	1	-	2	1	-
Africa	10	1	-	8	2	-
South-East Asia	2	0	-	2	0	-
Eastern Mediterranean	15	1	-	13	2	-
Total	35	3	0.635	30	5	0.746
TB incidence by country of birth (per 100,000 population) <sup>a</sup>						
Lower–moderate (10–9)	3	1	-	3	0	-
Upper–moderate (50–99)	9	0	-	6	3	-
Endemic (100–299)	15	1	-	13	2	-
Highly endemic (300–499)	4	1	-	4	0	-
Severely endemic (≥500)	4	0	-	4	0	-
Total	35	3	0.331	30	5	0.528
Age range, years						
19–24	3	0	-	3	0	-
25–34	7	0	-	4	3	-
35–44	18	1	-	16	2	-
45–54	5	0	-	5	0	-
55–64	2	1	-	2	0	-
65 and older	0	1	-	0	0	-
Total	35	3	0.108	30	5	0.382
Treatment regimen <sup>b</sup>						
Rifampicin (4 months)	-	-	-	23	4	-
Isoniazid and rifapentine (3 months)	-	-	-	6	1	-
Intermittent isoniazid (9 months)	-	-	-	1	0	-
Total	-	-	-	30	5	1.00

Abbreviations: TB, tuberculosis; WHO, World Health Organization; -, not applicable

<sup>a</sup> World Health Organization. WHO global lists of countries for tuberculosis (TB), TB/HIV and multidrug/rifampicin-resistant TB (MDR/RR-TB), 2021–2025: Background document. Geneva, CH: WHO; 2021. (22)<sup>b</sup> Adapted from Alvarez GG, Pease C, Menzies D. Chapter 6: Tuberculosis preventive treatment in adults. Can J Respir Crit Care Sleep Med 2022;6(sup1):77–86. (20)



## Results

### Participant characteristics

This study included 49 participants who screened positive for TBI (16). Participants consisted of 21 males and 28 females, with a mean age of 40.2 years (range: 19–67). Most participants (85.7%,  $n=42$ ) arrived in Canada between 2021 and 2023 and were predominantly government-assisted refugees (71.4%,  $n=35$ ) from the Eastern Mediterranean (53.1%,  $n=26$ ) WHO region. Other participants held permanent resident ( $n=5$ ) and study ( $n=7$ ) visas. Additionally, two participants held a family reunion and visitor visas, respectively, when they first arrived in the country. Approximately half (51%,  $n=25$ ) of participants were born in a TB-endemic country, defined as TB incidence of 100–299 cases per 100,000 people. A detailed list of participant characteristics is presented in **Table 2**. Two HCPs on the research team, consisting of an infectious disease physician and a nurse practitioner, managed participants throughout their treatment process.

### Tuberculosis infection treatment outcome

Of the 49 participants who screened positive, 11 were lost to follow-up prior to the clinical assessment. Of these, three were lost to follow-up in the local setting, while eight moved out of province before they could be assessed and offered TPT. The remaining 38 participants (77.6%), who underwent clinical assessment, were offered TPT after ruling out TBD and confirming TBI with no prior TPT. Among these 38 participants, following counselling on the natural history of TB and the risks and benefits of treatment, 35 (92.1%) accepted TPT, of whom 30 (85.7%) completed treatment and five (14.3%) did not complete TPT. Notably, while the treatment completion rate across most defined age groups was generally high (88.9%–100%), only four out of seven (57.1%) participants in the 25–34 age group completed their treatment. Of the five (14.3%) participants who did not complete treatment, three discontinued due to dyspepsia, perceived side effects such as facial and extremity paresthesias, and concerns about rifampicin causing discoloration of teeth and facial hair, respectively. The reasons for treatment discontinuation in the remaining two participants are unknown. A more detailed account of the participants included in this study is provided in **Figure 1** and Table 1.

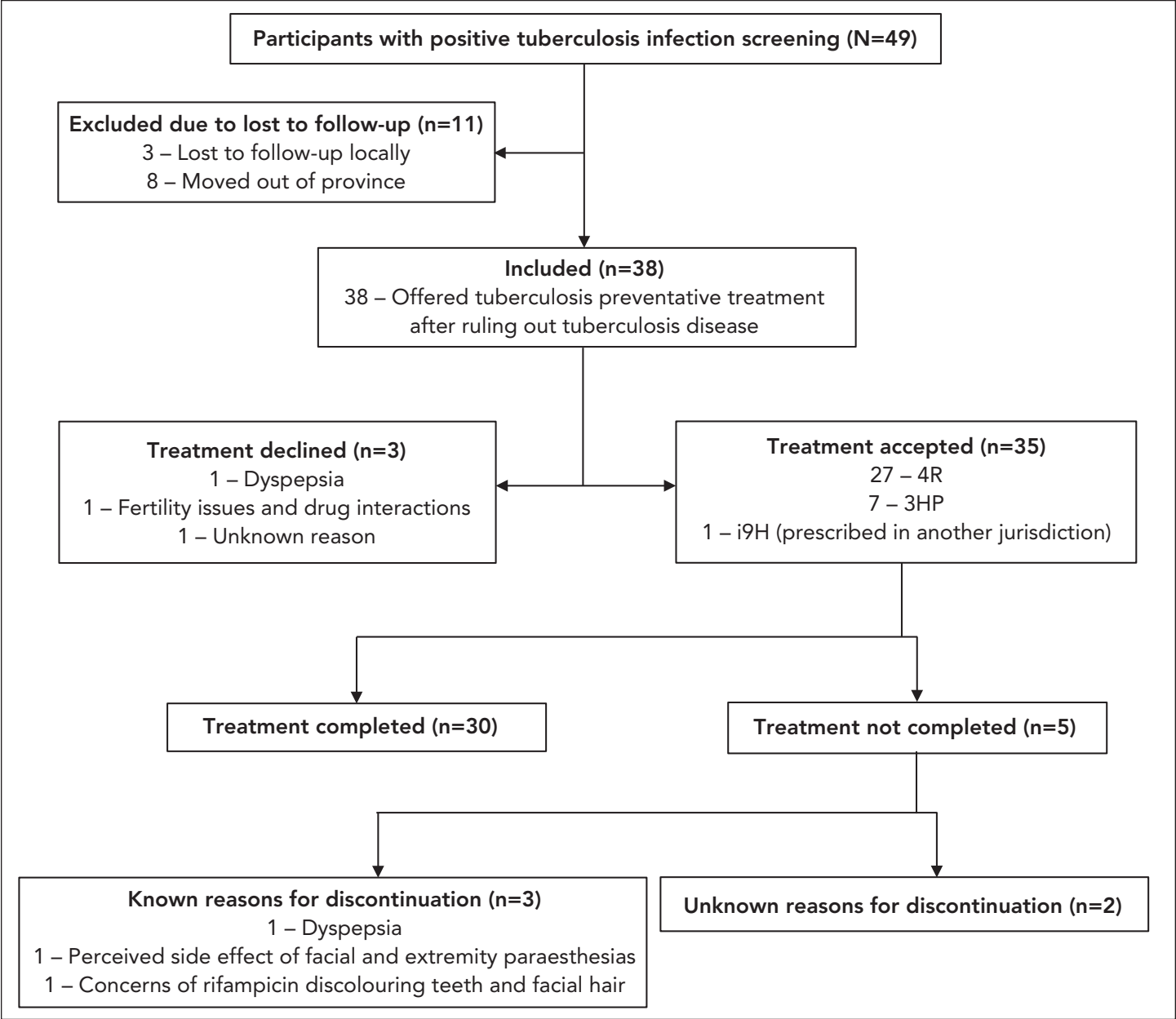
The infectious disease physician oversaw the care of all but two participants—one was cared for by the nurse practitioner, and another was managed by an HCP in a province/territory where they had relocated following the clinical assessment. The participant ( $n=1$ , 2.9%) who relocated to another province/territory following initial clinical assessment and before initiating TPT was prescribed twice weekly intermittent isoniazid treatment for nine months by the provincial/territorial public health program in the new location; this patient remained in contact with the study physician throughout the duration of the study and was included in this study analysis (Figure 1, Table 1).

**Table 2: Descriptive statistics of participants who were eligible for tuberculosis preventive treatment, (N=49)**

Variables	Male (n=21)	Female (n=28)	N=49
<b>Age range, years</b>			
19–24	1	2	3
25–34	3	8	11
35–44	11	11	22
45–54	4	4	8
55–64	1	3	4
65 and older	1	0	1
<b>Year of arrival in Canada</b>			
2001	1	0	1
2014	0	1	1
2016	0	1	1
2018	1	0	1
2019	3	0	3
2021	1	4	5
2022	8	10	18
2023	7	12	19
<b>Visa type on initial entry to Canada</b>			
Family reunion	0	1	1
Visitor	1	0	1
Permanent resident	1	4	5
Study	2	5	7
Government-assisted refugee	17	18	35
<b>Country of birth by WHO region</b>			
Western Pacific	3	3	6
Americas	1	3	4
Africa	2	9	11
South-East Asia	0	2	2
Europe	0	0	0
Eastern Mediterranean	15	11	26
<b>TB incidence by country of birth (per 100,000 population)<sup>a</sup></b>			
Low (<5)	0	0	0
Lower-moderate (10–49)	2	4	6
Upper-moderate (50–99)	4	5	9
Endemic (100–299)	14	11	25
Highly endemic (300–499)	0	5	5
Severely endemic (≥500)	1	3	4
<b>Primary healthcare provider (doctor/nurse practitioner) in Canada</b>			
No	20	27	47
Yes	1	1	2

Abbreviations: TB, tuberculosis; WHO, World Health Organization  
<sup>a</sup> World Health Organization incidence

Figure 1: Flow chart of immigrants with tuberculosis infection eligible for tuberculosis preventive treatment in southern New Brunswick, Canada, (N=49)



Abbreviations: 3HP, isoniazid/rifapentine; 4R, rifampicin; i9H, intermittent isoniazid

Treatment adherence was assessed through patient reports and follow-up by the treating physician who tracked patient-reported adherence in combination with dispensing history from the community pharmacy to ensure reported adherence correlated with the timing of refill dispensing.

Assistance from immigrant-serving organizations was helpful in establishing and maintaining successful contact for several participants before and during treatment, including three participants who needed to restart treatment after an interruption. Among the eight participants who moved out of the province before clinical assessment and initiating treatment, four (50%) were from the same family. One participant obtained

a new HCP in their new province, and a letter was dictated to their new HCP detailing the positive IGRA.

Fisher’s exact tests were run to determine whether treatment acceptance and completion were dependent on sex, arrival year, visa type, country and TB incidence of the country of birth by WHO region, and age. An assessment was also conducted on whether treatment completion was dependent on treatment regimen. None of the Fisher’s exact tests for independence yielded statistically significant results, indicating that treatment acceptance and completion were independent of the examined variables. The p-values for each test are provided in Table 1.



Thematic analysis

Thematic analysis was used to analyze qualitative survey data. The infectious disease physician completed the HCP survey, and thematic analysis of the feedback revealed five emerging themes that affected the management of TBI among immigrants in southern NB. Themes and supporting statements are listed in **Table 3** and below:

- 1) Support systems for participants: During the study, it was reported that resource adequacy impacted participant care, highlighting factors such as availability of support and need for participant navigators.
- 2) Collaboration and support mechanisms: This theme revealed the invaluable support provided by immigrant-serving organizations and community pharmacy partnerships in caring for immigrants with TBI. As well, clear national TPT guidelines and objective diagnostic tools allowed the HCP to work efficiently and effectively.
- 3) Communication and follow-up challenges: The HCP experienced challenges when trying to reach participants and when communicating during the cascade of care. Due to a lack of multilingual resources at certain points in the cascade of care, the HCP took extra precaution to help ensure participants understood the follow-up procedures, with particular reference to bloodwork coordination.
- 4) Time allocation in participant care: It was identified that more time during appointments were required for newcomer

participants, due to, for example, language barriers, assisting with healthcare navigation, answering questions and educating participants regarding treatment procedures, side effects.

- 5) Satisfaction with care: Finally, the HCP reported that participants generally responded positively to TPT and care. For example, participants expressed appreciation with regards to receiving information pertaining to TBI and clinical support and follow-up during the course of TPT. Participants also expressed feeling positive upon completion of treatment.

Discussion

This study is the first to assess TPT acceptance and completion rates in Atlantic Canada and the third in the country to investigate HCP-related factors affecting the management of individuals on TPT (12,13). The 92.1% TBI treatment acceptance and 85.7% treatment completion rates reported in this study are concordant with rates reported in Canada, which range from 75.0% to 93.4%, and 49.0% to 100%, respectively. The HCP’s feedback identified key factors that could enhance TBI management for immigrants. The rates reported herein are promising, especially considering adherence to TPT is often low (25,26). Treatment acceptance or completion was not found to be associated with any of the examined demographic and treatment variables. Although we had an additional variable (TB incidence category) and one variable (age) was categorized

Table 3: Themes and supporting statements

Themes	Illustrative quotes
Support system for participants	"Overall, the patient support required was available."
	"The YMCA health liaison and the local newcomer associations were very supportive."
	"For those newcomers who had recently arrived in New Brunswick, a navigator to assist with moving through the medical system would be very helpful."
Collaboration and support mechanisms	"The YMCA and newcomers associations were a big help."
	"Community pharmacy partners were also incredibly valuable."
	"Clear Canadian guidelines were instrumental."
	"The use of the IGRA allowed for clear documentation of objective results in all cases."
Communication and follow-up challenges	"Follow-up was challenging as some individuals were hard to reach."
	"Many individuals did not understand the concept of a refill."
	"Setting up the recommended one-month bloodwork was sometimes challenging."
	"Having written or typed information on TB and treatment in various languages would have helped with the first visit in many cases."
	"Patient information in various languages would improve care."
Time allocation in participant care	"I spent one hour for the initial visit."
	"Roughly 15 minutes per follow-up visit."
	"I spent an average of approximately two hours per patient overall."
Overall satisfaction with care	"The preventive treatment was also well received, overall."

Abbreviations: IGRA, interferon-gamma release assay; TB, tuberculosis





differently, our results were largely consistent with the findings of Harwood-Johnson *et al.* (14) but differed in one respect. Whereas age was found to have been associated with acceptance in their study, here it was not. Harwood-Johnson *et al.* (14) reasoned that the association found in their study was likely due to the dichotomous age categories of those older than 18 years and those younger than 18 years, where those less than the age of majority would have decisions made for them by a legal guardian. Participants in the current study were all above the age of majority. The findings of this study, together with those of Harwood-Johnson *et al.*, suggest that age might only be a factor in treatment acceptance when also considering those under the age of majority.

The TPT acceptance and completion rates in this study surpass those reported in a recent global systematic review and meta-analysis of migrants, which indicated TPT initiation and completion rates of 69% and 74%, respectively (27), but within rates reported in Canada (12–18). Individualizing treatment options in the current study was seen as an opportunity to enhance completion rates. Participants were given the option to choose either the 4R or 3HP regimens or consider no medical therapy with clinical and radiological follow-up offered for up to two years. The majority of participants preferred to move forward with the 4R regimen. Although this treatment option is longer in duration, it enabled participants to dose daily in their own setting. In contrast, the shorter 3HP regimen required observed dosing at their community pharmacy once per week.

Consistent with reports from prior studies (12,25,28), barriers such as missed appointments, difficulties rescheduling, and geographic mobility significantly contributed to attrition throughout the treatment cascade in the current study. Missed appointments remain a persistent challenge, particularly among new arrivals who may struggle with navigating the healthcare system and adhering to scheduled appointments. Immigrant-serving organizations helped minimize barriers by providing essential information and support to assist individuals manage healthcare appointments more effectively. However, these organizations remain with limited resources and a lack of stable funding.

In this study, moving out of province primarily impacted government-assisted refugees recruited shortly after their arrival during their post-arrival health assessment (PAHA). Intentions to relocate to other provinces were often not communicated to their navigators or study investigators until after the fact. To assist in diminishing this concern, it may be beneficial to inquire about potential medium- to long-term settlement plans during the PAHA. Alternatively, delaying invitations for several weeks could allow for better assessment of stability. However, this latter approach may lead to even greater attrition with loss of access to language translation services necessary for many government-assisted refugees who often only had temporary residences and

frequently no cell phones or email addresses for communication. A third option would be to wait until participants have access to primary HCPs before conducting assessments. However, this could present additional challenges considering only two of the participants in this study had access to primary HCPs. The time it takes for individuals to be assigned a primary HCP can vary significantly in our context. Furthermore, routine treatment of TBI through primary HCPs is not generally offered in this setting.

While relocating out of province has often been linked to disruptions in care, effective collaboration among HCPs across provincial/territorial lines can help maintain continuity of care. This was demonstrated in the current study with two participants. In one case, the HCP coordinated with the participant's new HCP in the other province, ensuring a smooth transition for the participant's treatment. In another instance, the HCP provided a detailed note to the receiving HCP in another province, which ensured seamless transfer of care for the participant.

Although medication side effects have been noted in other studies as a significant reason for participants discontinuing treatment (29–32), their impact in this study was minimal, as only three participants cited this as the plausible reason for discontinuing treatment. Close follow-up to assist with managing minor adverse effects and enhanced education of participants on the importance of completing treatment may help address this limitation.

In this study, coordination between HCPs, community organizations, and public health entities was essential for effective TBI management. This finding aligns with current public health strategies that emphasize a multidisciplinary approach to TB care, promoting better health outcomes through shared responsibility among various stakeholders (33). There were several participants who appeared to not fully understand the need of adhering to treatment or the potential consequences of non-compliance. Conducting participant education initiatives, offering culturally sensitive materials in the predominant languages spoken by immigrants, and follow-up reminders may help mitigate these challenges.

Limited access to HCPs noted in other studies was not a concern in this study, thanks to dedicated HCPs involved in the research, even though nearly all participants were primarily cared for by one HCP (13). Although it is unlikely to represent the situation in regular clinical settings, the use of a single HCP resulted in less variability in patient management, a more comprehensive understanding of each patient's needs, and improved data accuracy. Feedback from the HCP suggested that some participants required more time to be provided with adequate care. Increased staffing levels throughout the cascade of care and continuous quality improvement measures that focus on enhancing the participant experience may improve TBI treatment acceptance and completion.



## Limitations

This study has some limitations. First, the high treatment acceptance and completion rates reported in this study should be interpreted with caution, as participation was voluntary. This may have resulted in the inclusion of participants who were concerned about TB and motivated to take action. Furthermore, the treatment completion rates are largely based on self-reported data and corroborating community pharmacy data. As treatment was not always administered through directly observed therapy, there is potential for some inaccuracy in reported treatment completion. Second, while this study was designed to capture insights from immigrants across all immigration streams, most of the participants were refugees. As a result, we were unable to gather enough data from non-refugee immigrant groups, as initially intended. Future studies could consider using a stratified sampling design to overcome this limitation. Finally, the authors of this study acknowledge that the low sample size means that caution is required when interpreting the results and before any attempts to generalize to the population. The 49 individuals included here were captured from a larger sample of 264 screened individuals, making up 18.6% of that initial sample. Future studies should attempt to replicate these results using a larger sample size.

## Conclusion

In conclusion, this study achieved a treatment acceptance rate of 92.1% and a treatment completion rate of 85.7%, demonstrating the feasibility of addressing TBI in immigrants when healthcare teams work in partnership with local immigrant-serving organizations. Additionally, the study highlights several key factors that impact the management of TBI among immigrants in southern NB.

## Authors' statement

ICS — Conceptualization, methodology, acquired the financial support, investigation, data curation, software, validation, formal analysis, writing—original draft, writing—review & editing  
DTKN — Conceptualization, methodology, validation, acquired the financial support, writing—original draft, writing—review & editing  
HM — Writing—review and editing, supervision  
DJG — Validation, data curation, software, formal analysis, writing—original draft, writing—review & editing  
AH — Investigation, writing—review & editing  
KB — Conceptualization, supervision, acquired the financial support, writing—review & editing  
DW — Conceptualization, investigation, validation, acquired the financial support, supervision, data development, writing—review & editing

The content and view expressed in this article are those of the authors and do not necessarily reflect those of the Government of Canada.

## Competing interests

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## Appendix

**Table A1: Healthcare practitioner survey**

1. What was your role in this study?	1. NP	2. ID Physician
2. Did you feel the patients were appropriately supported?	1. Yes	2. No
<b>Please explain:</b>		
3. Were there any barriers in supporting the patients during the initial visit?	1. Yes	2. No
<b>If yes, what were the barriers and how could they have been prevented?</b>		
4. Were there any barriers in supporting the patients during the subsequent visit?	1. Yes	2. No
<b>If yes, what were the barriers and how could they have been prevented?</b>		
5. Did you feel you had all the tools to care for the patients in your role?	1. Yes	2. No
<b>If no, what tools were missing?</b>		
6. Were there any barriers in arranging follow-up tests or visits?	1. Yes	2. No
<b>If yes, what were the barriers and how could they have been prevented?</b>		
7. What was helpful in caring for the patients?		
<b>Please state them below:</b>		
8. On average how long did you spend with each patient per visit (in hours)?		
<b>Please state them below:</b>		
9. How much time did you spend on patient management in total including administration, diagnostics, and arrangements?		
<b>Please state them below:</b>		
10. Do you have any final comments?	1. Yes	2. No
<b>If yes, please state them below:</b>		

Abbreviations: ID, infectious disease; NP, nurse practitioner

# Surveillance of laboratory exposures to human pathogens and toxins, Canada, 2024

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## Abstract

**Background:** Exposure incidents to human pathogens and toxins (HPTs) in licensed facilities in Canada are monitored by Laboratory Incident Notification Canada (LINC), a surveillance system that describes and identifies trends among exposure incidents in Canada using quantitative and qualitative data.

**Methods:** Confirmed exposure incidents reported to LINC in 2024 were analyzed. The exposure incident rate was calculated and compared to previous years. A seasonality analysis compared monthly trends. Exposure incidents were described by sector, implicated HPTs, main activity, occurrence types, root causes, affected individuals and reporting delay. Text-based descriptions of exposure incidents underwent qualitative analysis.

**Results:** In 2024, there were 71 confirmed exposure incidents affecting 132 individuals. There were 67.5 incidents per 1,000 active licences. Bacteria was the most commonly implicated HPT (64%). Microbiology (67.6%) was the primary activity during confirmed exposures. The public health sector had the highest incident rate and mean number of affected persons per active licence. The most frequently reported occurrence type and root cause was procedure-related (21.4%) and human factors (62%), respectively. Most affected individuals were technicians/technologists (76.5%). The median time between incident and reporting was five days.

**Conclusion:** The exposure incident rate was higher in 2024 compared to the previous year. The public health sector had the highest incident rate between 2016–2024. Qualitative analysis revealed that working with cultures outside the biological safety cabinet and insufficient face-related personal protective equipment were common factors involved in confirmed exposure incidents.

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**Keywords:** Centre for Biosecurity, human pathogens and toxins, laboratory-acquired infections, laboratory exposures, laboratory incidents, Laboratory Incident Notification Canada, surveillance

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## Introduction

Research involving human pathogens and toxins (HPTs), such as bacteria, viruses and fungi, can provide valuable insight into developing protective measures against harmful biological agents. However, work involving HPTs carries numerous risks, including potential exposure incidents that may lead to laboratory-acquired infections (LAIs) or intoxications (1,2). In rare cases, these incidents can extend beyond the facility and affect public health (2,3).

In Canada, more than 1,000 licensed facilities conduct activities involving HPTs. These facilities are regulated by the Public Health Agency of Canada (PHAC) under the *Human Pathogens and Toxins Act* (HPTA) (4) and its associated *Human Pathogens and Toxins Regulations* (HPTR) (5), which mandate the reporting of exposure incidents involving Risk Group (RG) 2 or higher pathogens. The RG classification is assigned based on inherent characteristics and describes the risk of a pathogen at the



individual-level and population-level. To monitor exposures to RG2, RG3 and RG4 HPTs in licensed facilities throughout Canada and support licensed facilities with mitigation of recurrence, a federal surveillance system, Laboratory Incident Notification Canada (LINC), was launched by PHAC in December 2015.

Since its inception, LINC has published annual reports summarizing exposure incidents in Canada and provided data on a number of variables associated with these exposure incidents (6–13). These reports have often found that confirmed exposures occurred particularly during microbiology or *in vivo* animal research activities (9–13). Common occurrence types involved issues with procedures, sharps and personal protective equipment (PPE) (6–13). Frequent root causes are issues with standard operating procedures (SOPs) and human factors-related issues (6–13). Most affected individuals worked as laboratory technicians or technologists (8–13). The most commonly implicated biological agents are RG2 bacteria and viruses (6–11,13).

Canada remains one of the few countries with a dedicated surveillance system focused on exposures to biological agents. Some countries (Australia, the United States and Singapore) have their own surveillance programs that focus on specific risk groups or elements of biosafety (14–17). In Australia, Security Sensitive Biological Agents (SSBAs), a subset of pathogens posing higher biosecurity risks due to their potential to be used for biological weapons, are monitored (14,18). In the United States, the possession, use and transfer of biological select agents and toxins are monitored under the Federal Select Agent Program (FSAP) (15). In Singapore, infections, illnesses, adverse events and incidents involving certain agents or toxins must be reported to the Ministry of Health (16,17). Comparative analyses between LINC's incident reports and those from other countries remain limited due to differences in data collection and availability, particularly regarding exposure incident characteristics. However, LAIs reported in the literature from other countries align with LINC's data. Globally, procedural errors and sharps-related incidents are common sources of LAIs (1,2,19–22), with most incidents occurring during microbiology activities (1,2,20) and laboratory technicians as the most frequently affected personnel in these incidents (1,20).

With the overall goal of enhancing biosafety awareness and improving laboratory practices in Canada, LINC's annual reports have provided insights to help minimize exposure incidents. The objective of this report is to analyze exposure incidents reported to LINC in 2024. These findings will further enhance the understanding of factors contributing to exposure incidents and inform targeted areas for biosafety training and best practices.

## Methods

### Data source and collection

Under the HPTA and HPTR, in the event of an HPT-related incident, all licensed Canadian facilities must report specific details to PHAC without delay. The Agency's web-based Biosecurity Portal, which uses Microsoft Dynamics' Customer Relationship Management (CRM) software, provides standardized forms for licensed facilities to report laboratory exposures, non-exposures and other incidents. These forms contain data validation rules to prevent missing mandatory data. Each report is monitored and processed by LINC in the Integrated Suite of Tools for Operational Processes (iSTOP) and undergoes manual verification by LINC to ensure completeness. A biocontainment review is conducted following receipt of incident reports. For each exposure report, a subsequent follow-up report providing updates and additional incident investigation details, such as root causes and corrective actions, is required and analyzed. If a follow-up report was not submitted, information from the initial exposure report is used.

Incident data from January 1, 2024, to December 31, 2024, were collected through the Biosecurity Portal and extracted from iSTOP on January 10, 2025, and analyzed for this article. The total number of active licences per sector was extracted from iSTOP on January 29, 2025. The analysis included reports that did not have a specific incident date, in which case the submission date was used.

### Report variables

Several variables were used to describe the confirmed exposure incident reports in 2024, including exposure report type, activity being performed during the incident, occurrence types, root causes, reporting delay, licence sector, number of active licences, type of HPTs involved, and description of the incident. Definitions for the main activities and occurrence types are provided in the **Appendix, Table A1 and Table A2**. Information on affected individuals, such as their role, highest level of education and years of laboratory experience, was also collected. Other demographic data, such as gender, age and income, are not collected by LINC.

### Analysis

The analysis was performed in R 4.2.2. Plots and tables were generated in R and Microsoft Excel, which was also used for data validation. This study also reviewed data from 2016–2023 to incorporate any updates to previously submitted reports.



Quantitative data analysis

Follow-up reports were reviewed to classify exposure incidents reported to LINC in 2024 as either confirmed exposures, including LAIs, or ruled out. Ruled out exposure incidents, which were excluded from the main analysis, include those ruled out after investigation, exposures involving RG1 pathogens (which are unregulated), and exposures that are not mandated under the HPTA and HPTR, such as incidents involving primary specimens or unlicensed laboratories. The incident rate of exposures to HPTs was calculated by dividing the number of reported exposure incidents by the total number of active licences during the surveillance period. The 2024 exposure incident rate was compared to rates from previous years and the baseline incident rate from 2016 to 2023. The baseline incident rate was calculated by dividing the total number of exposure incidents between 2016–2023 by the total number of active licences between 2016–2023. Descriptive statistics were obtained for continuous and categorical quantitative variables. Wilcoxon signed rank tests were used to compare exposure incident rates per sector in 2024 with those of 2016–2023. The t-tests were used to compare the monthly incident rates in 2024 with those of 2016–2023.

Qualitative data analysis

The text-based variables extracted from iSTOP followed an unstructured format, similar to journal entries. To transform the text into structured data, the variables underwent text preprocessing, including the removal of stop words, punctuation and whitespace. Through tokenization, the text was broken down into individual words, which were then analyzed for frequency and visualized in a plot. A manual revision of the text-based variables was also conducted for cross-validation.

Results

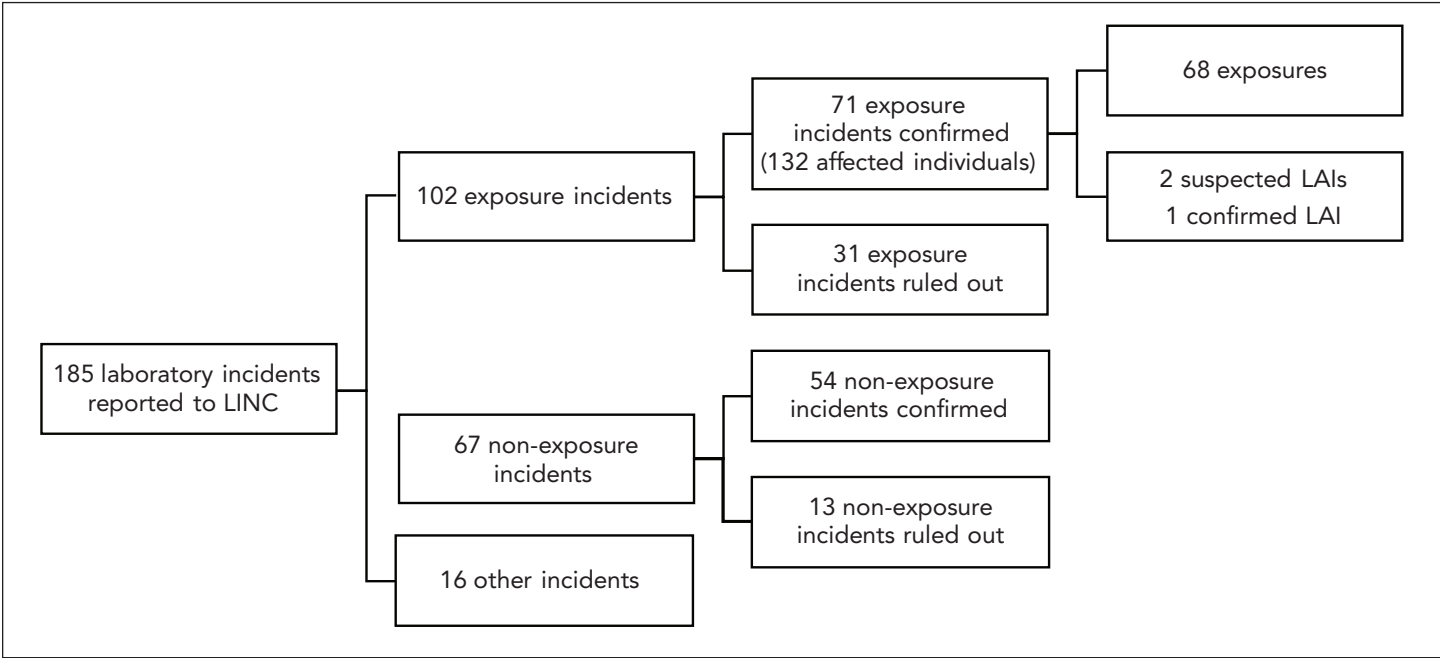
Between January 1, 2024 and December 31, 2024, LINC received 185 laboratory incident reports (Figure 1). Of these, 102 (55.1%) were exposure incidents, 67 (36.2%) were non-exposure incidents, and 16 (8.6%) were other incidents. The exposure incidents included 71 confirmed exposure incidents and 31 ruled out exposure incidents. The 71 confirmed exposure incidents, which involved 132 affected individuals, were further categorized into 68 (95.8%) confirmed exposures, two (2.8%) suspected LAIs, and one (1.4%) confirmed LAI.

Annual and monthly exposure incident rate trends

In 2024, there were 1,052 active licences, of which 975 (92.7%) were for RG2 HPTs, 71 (6.7%) for RG3 HPTs, two (0.2%) for RG4 HPTs, and four (0.4%) for SSBAAs (data not shown). The exposure incident rate, calculated as the number of confirmed exposure incidents per 1,000 active licences, was 67.5 in 2024. This represented a slight increase from 61.5 in 2023 (Figure 2). The annual baseline incident rate from 2016 to 2023 was 55.5 confirmed exposure incidents per 1,000 active licences (95% confidence interval [CI]: 43.2–67.9), an increase from the 2016 to 2022 baseline of 54.6 in the 2023 surveillance report (13). Although the 2024 exposure incident rate was higher than the annual baseline incident rate, the difference was not statistically significant ( $p=0.099$ ).

An average of 5.9 (95% CI: 4.7–7.1) confirmed exposure incidents per month was observed in 2024, which did not differ significantly from the monthly average of 4.5 (95% CI: 4.0–5.1)

Figure 1: Incidents reported to Laboratory Incident Notification Canada, 2024

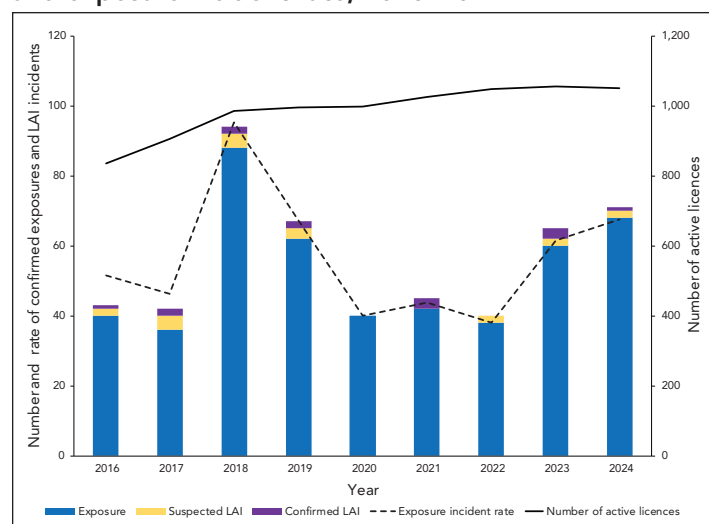


Abbreviations: LAIs, laboratory-acquired infections; LINC, Laboratory Incident Notification Canada





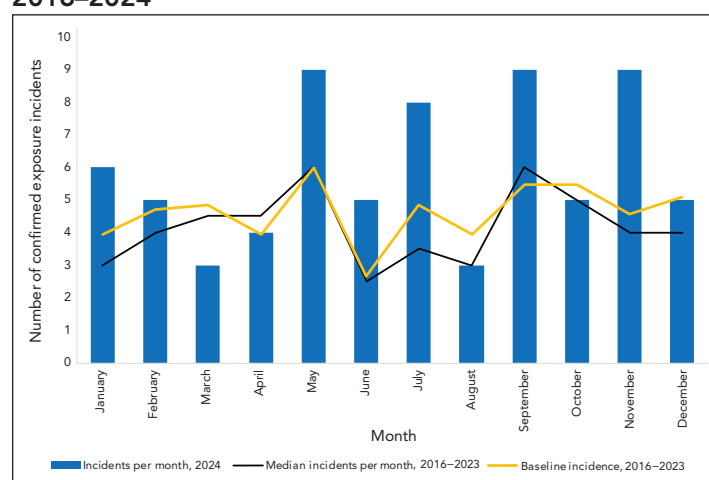
**Figure 2: Confirmed exposure incidents, suspected and confirmed laboratory-acquired infections, active licences and exposure incident rate, 2016–2024**



Abbreviation: LAI, laboratory-acquired infection

from 2016 to 2023 ( $p=0.07$ ). The seasonality trend differed slightly in 2024 compared to the 2016–2023 median incidents per month and the baseline incidence, with the number of confirmed exposure incidents in 2024 peaking in May, September and November ( $n=9$ ; 12.7% each) (Figure 3). Compared to the 2016–2023 median number of incidents per month, the frequency of incidents in 2024 was lower than expected in March ( $n=3$ ; 4.2%) and nearly doubled in January ( $n=6$ ; 8.5%), June ( $n=5$ ; 7.0%), July ( $n=8$ ; 11.3%) and November ( $n=9$ ; 12.7%).

**Figure 3: Seasonality analysis using median confirmed exposure incidents per month and baseline incidence, 2016–2024**



## Implicated human pathogens and toxins

Of the 75 known implicated HPTs, 64% ( $n=48$ ) were RG2 pathogens and 36% ( $n=27$ ) were RG3 pathogens (Table 1). There was one unknown pathogen, not included in Table 1. All

**Table 1: Known human pathogens and toxins implicated in reported exposure incidents by risk group level and the biological agent's security sensitive status, 2024 ( $n=75$ )**

Biological agent type by risk group	Non-SSBA		SSBA		Total	
	n	%	n	%	n	%
<b>RG2</b>	<b>48</b>	<b>64.0</b>	<b>0</b>	<b>0</b>	<b>48</b>	<b>64.0</b>
Bacteria	34	45.3	0	0	34	45.3
Fungus	3	4.0	0	0	3	4.0
Parasite	0	0	0	0	0	0
Prion	2	2.7	0	0	2	2.7
Toxin	3	4.0	0	0	3	4.0
Virus	6	8.0	0	0	6	8.0
Cell line	0	0.0	0	0	0	0
<b>RG3</b>	<b>9</b>	<b>12.0</b>	<b>18</b>	<b>24.0</b>	<b>27</b>	<b>36.0</b>
Bacteria	1	1.3	13	17.3	14	18.7
Fungus	3	4.0	2	2.7	5	6.7
Parasite	0	0	0	0	0	0
Prion	1	1.3	0	0	1	1.3
Toxin	0	0	0	0	0	0
Virus	4	5.3	3	4.0	7	9.3
Cell line	0	0	0	0	0	0
<b>Total</b>	<b>57</b>	<b>76.0</b>	<b>18</b>	<b>24.0</b>	<b>75</b>	<b>100</b>

Abbreviations: RG2, Risk Group 2; RG3, Risk Group 3; SSBA, Security Sensitive Biological Agent

of the RG2 pathogens implicated were non-SSBAs, with bacteria being the most frequently reported ( $n=34$ ; 45.3%). In contrast, only 12% of implicated RG3 pathogens were non-SSBAs, with viruses being most commonly reported ( $n=4$ ; 5.3%). All implicated SSBA were RG3 pathogens and accounted for 24% of all HPTs, with bacteria being the most frequently involved pathogen ( $n=13$ ; 17.3%).

Overall, bacteria and viruses were the leading HPTs implicated in exposure incidents involving both RG2 and RG3 pathogens. Except for parasites and cell lines, which were not implicated in any exposures, prions were the least commonly involved pathogens (2.7% for RG2; 1.3% for RG3). The confirmed LAI in 2024 was associated with *Staphylococcus aureus*, while the two suspected LAIs were linked to *Mycobacterium tuberculosis* and *S. aureus*. The top three most implicated HPTs in 2024 were *Neisseria meningitidis* ( $n=8$ ; 10.7%), *Brucella melitensis* ( $n=6$ ; 8.0%), and *S. aureus* ( $n=6$ ; 8.0%).

## Main activity

Reporters could select from 11 possible main activity types performed during the exposure incident: animal care, autopsy/necropsy, cell culture, education/training, *in vivo* animal research, maintenance, microbiology, microscopy, molecular investigations, serology or "other" (Appendix, Table A1). Microbiology and *in vivo* animal research were the most commonly reported



activities in 2024, accounting for 67.6% and 8.5% of confirmed exposure incidents, respectively. The remaining activities were less frequently reported, each accounting for 1.4% to 5.6% of confirmed exposure incidents (data not shown).

Sector

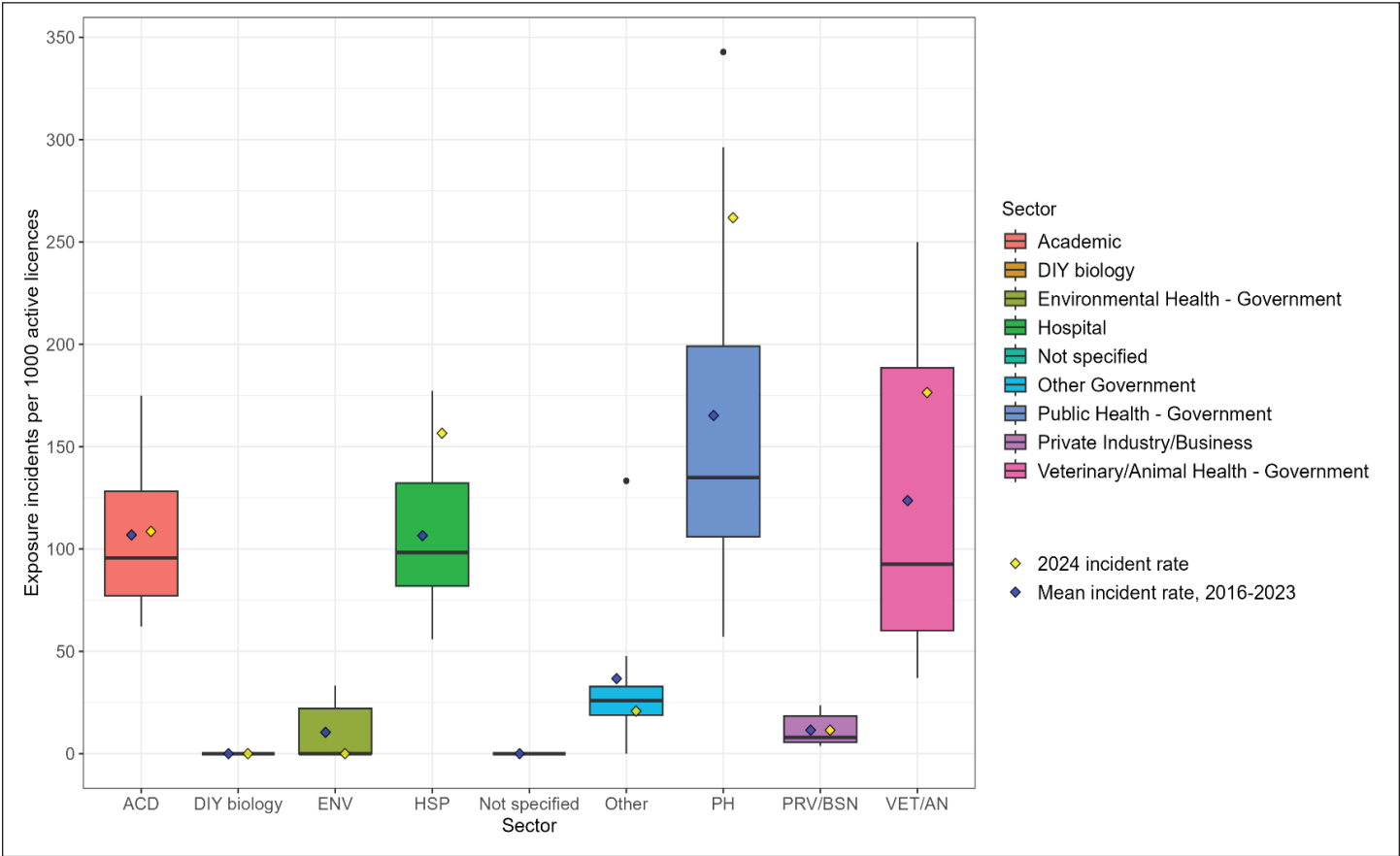
Licensed facilities could belong to one of eight sectors: academic, do-it-yourself (DIY) biology, environmental health – government (environmental health), hospital, other government, public health – government (public health), private industry/business, or veterinary/animal health – government (veterinary/animal health). The other government sector includes facilities that handle HPTs at the federal, provincial/territorial and municipal levels, but are not classified under environmental health, public health or veterinary/animal health. The DIY biology sector, whose data was first analyzed and presented in 2024 (13), includes any individual conducting their own experiments who is not working within an institutionalized facility. Data for the “not specified” sector was also first analyzed in 2024 (13).

Between 2016 and 2023, the mean and median exposure incident rates were highest in the public health sector (mean=165.3, median=135.0), followed by

veterinary/animal health (mean=123.7, median=92.6), academic (mean=106.9, median=95.7), and hospital sectors (mean=106.5, median=98.3) (Figure 4). Excluding the DIY biology sector and cases where the sector was not specified, the environmental health sector (mean=10.5, median=0) and private industry/business sector (mean=11.5, median=7.9) had the lowest incidence rates. The greatest variation in exposure incident rates was observed in the veterinary/animal health sector (interquartile range [IQR]: 128.3), while the private industry/business sector had the least variation (IQR: 12.9), excluding the DIY biology sector.

The 2024 exposure incident rate patterns mirrored trends observed between 2016 and 2023; however, incident rates in the hospital (incidence=156.6) and public health (incidence=261.9) sectors were statistically significantly higher ( $p<0.05$ ) (Figure 4) in 2024 than trends from previous years. While exposure incident rates in the environmental health (incidence=0) and other government (incidence=20.8) sectors were visibly lower than those between 2016 and 2023, the differences were not statistically significant ( $p>0.35$ ). Among the LAIs reported in 2024, one confirmed and one suspected case occurred in

Figure 4: Exposure incidents per 1,000 active licences (exposure incident rates) by sector, 2016–2024<sup>a</sup>



Abbreviations: ACD, academic; DIY biology, do-it-yourself biology; ENV, environmental health – government; HSP, hospital; Other, other government; PH, public health – government; PRV/BSN, private industry/business; VET/AN, veterinary/animal health – government  
<sup>a</sup> The boxplots summarize the exposure incidents per 1,000 active licences between 2016 and 2023. For each sector, the yellow diamond corresponds to the 2024 exposure incident rate, and the blue diamond corresponds to the mean exposure incident rate from 2016 to 2023. The black dot corresponds to an outlier. There is no yellow diamond for the incidents with no specified sector because there were no licences associated with these cases in 2024; the exposure incident rate for the cases with no specified sector reflects data from 2023 only

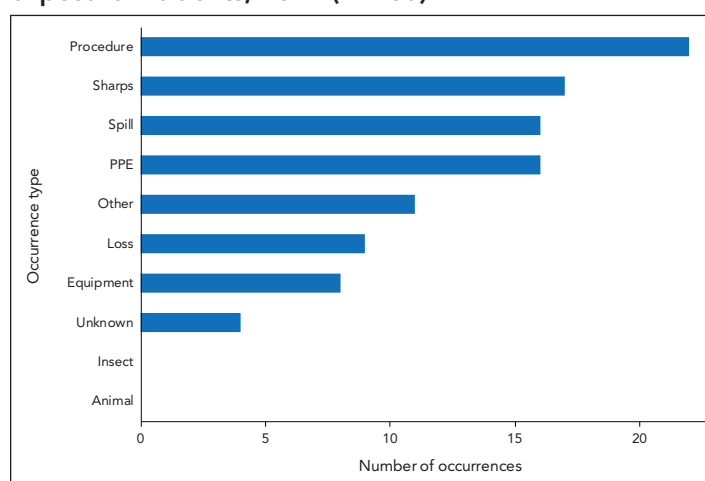


the hospital sector, while one suspected LAI occurred in the academic sector.

## Occurrence types

Confirmed exposure incidents could have one or more of ten occurrence types (Appendix, Table A2). There were 103 occurrence types cited in 2024. Procedure-related occurrences (n=22; 21.4%) were the most common, followed by sharps (n=17; 16.5%), spill (n=16; 15.5%) and PPE (n=16; 15.5%) (Figure 5). The least cited occurrence types were unknown (n=4; 3.9%) and animal and insect occurrences, which were not cited in any confirmed exposure incidents.

**Figure 5: Occurrence types involved in confirmed exposure incidents, 2024 (n=103)**



Abbreviation: PPE, personal protective equipment

## Root causes

There are six main root causes that can be associated with an exposure incident: human factors, SOPs, training, management/oversight, equipment, and communication. Examples of areas of concern for each of these categories are presented in Table 2. Most confirmed exposure incidents cited multiple root causes (n=167), averaging 2.35 root causes per confirmed exposure (Table 2). Human factors were the most common root cause (n=44; 62%), followed by SOP (n=27, 38%).

## Affected individuals

A total of 132 individuals were affected in the confirmed exposure incidents, averaging 1.86 affected persons per incident. The three sectors with the highest mean number of affected persons per confirmed exposure incident were private industry/business (mean=4.00), hospital (mean=2.42) and public health (mean=2.00), while the lowest mean was in academic sector (mean=0.79) (Figure 6). The public health and hospital sectors also had the highest mean number of affected persons per active licence (mean=0.52 and mean=0.38, respectively), while the other government sector had the lowest (mean=0.02) (Figure 6).

The majority of affected individuals were technicians/technologists (n=101; 76.5%) with a median of 8.5 years of laboratory experience (Figure 7). Students (n=13; 9.8%) were the second most affected individuals and had the least laboratory experience (median=0 years). Among the roles with the lowest number of affected individuals (n=2; 1.5% each)

**Table 2: Root causes reported in follow-up reports of confirmed exposure incidents, 2024 (n=167)**

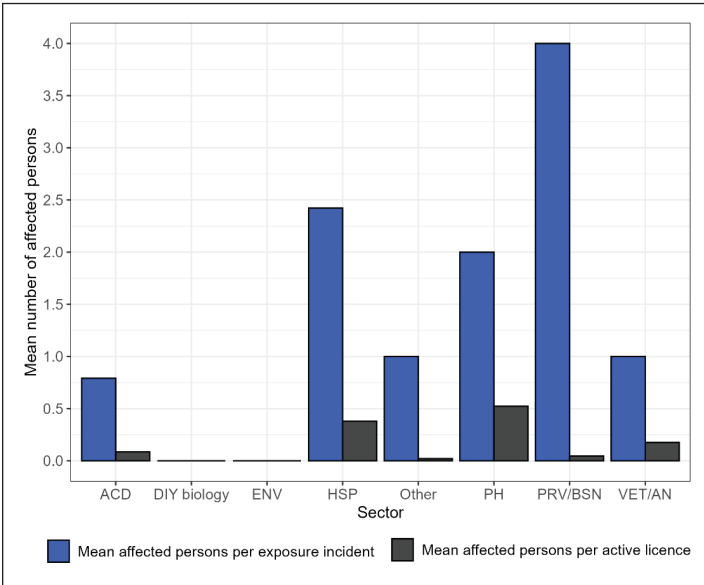
Root cause	Examples of areas of concern	Citations	
		n	% <sup>a</sup>
Human factors	A violation (cutting a corner, not following correct procedure, deviating from SOP)	44	62.0
	An error (a mistake, lapse of concentration, or slip of any kind)		
SOP	Documents were followed as written but not correct for activity/task	27	38.0
	Procedures that should have been in place were not in place		
	Documents were not followed correctly		
Training	Training was not in place but should have been in place	23	32.4
	Training was not appropriate for the task/activity		
	Staff were not qualified or proficient in performing task		
Management and oversight	Supervision needed improvement	20	28.2
	Lack of auditing of standards, policies and procedures		
	Risk assessment needed improvement		
Equipment	Equipment quality control needed improvement	24	33.8
	Equipment failed		
	Equipment was not appropriate for purpose		
Communication	Communication did not occur but should have	18	25.4
	Communication was unclear, ambiguous, etc.		
Other	Root causes not captured elsewhere	11	15.5
	Unpredictable/random movement by research animal		

Abbreviation: SOP, standard operating procedure

<sup>a</sup> Percentage of exposure incidents associated with this root cause

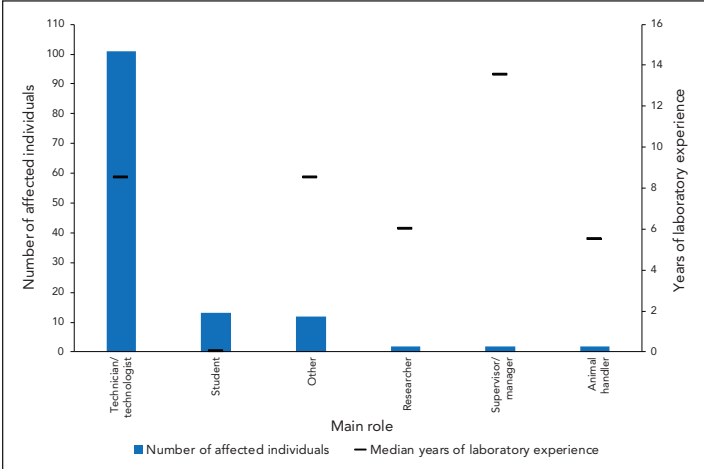


Figure 6: Mean number of affected persons per exposure incident and per active licence by sector, 2024



Abbreviations: ACD, academic; DIY biology, do-it-yourself biology; ENV, environmental health – government; HSP, hospital; Other, other government; PH, public health –government; PRV/BSN, private industry/business; VET/AN, veterinary/animal health – government

Figure 7: Affected individuals in confirmed exposure incidents reported by number of years of laboratory experience and main role, 2024 (n=132)

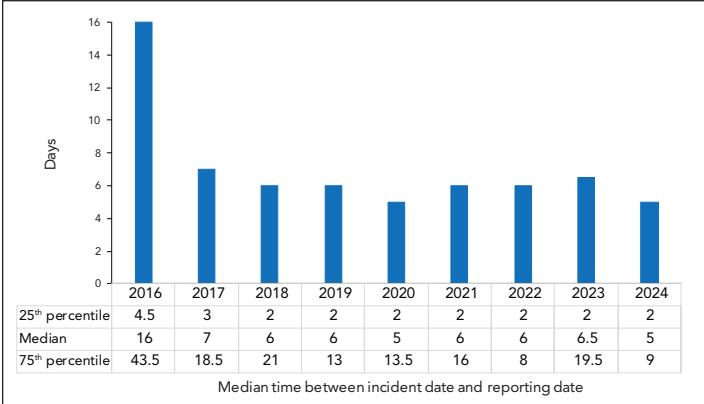


were supervisors/managers, who had the most laboratory experience (median=13.5 years), researchers (median=6 years), and animal handlers (median=5.5 years).

### Reporting delay

Reporting delay refers to the time between when the exposure incident actually happened and when it was reported to PHAC through LINC. The median time between incident date and reporting date in 2024 was five days, the shortest duration since 2020 (Figure 8). Compared to previous years, with the exception

Figure 8: Time between when the confirmed exposure incident happened and when it was reported to Laboratory Incident Notification Canada, 2016–2024



of 2022, there was also less variation in the reporting delay in 2024, with an IQR of seven days, approximately 50% less than in most past years.

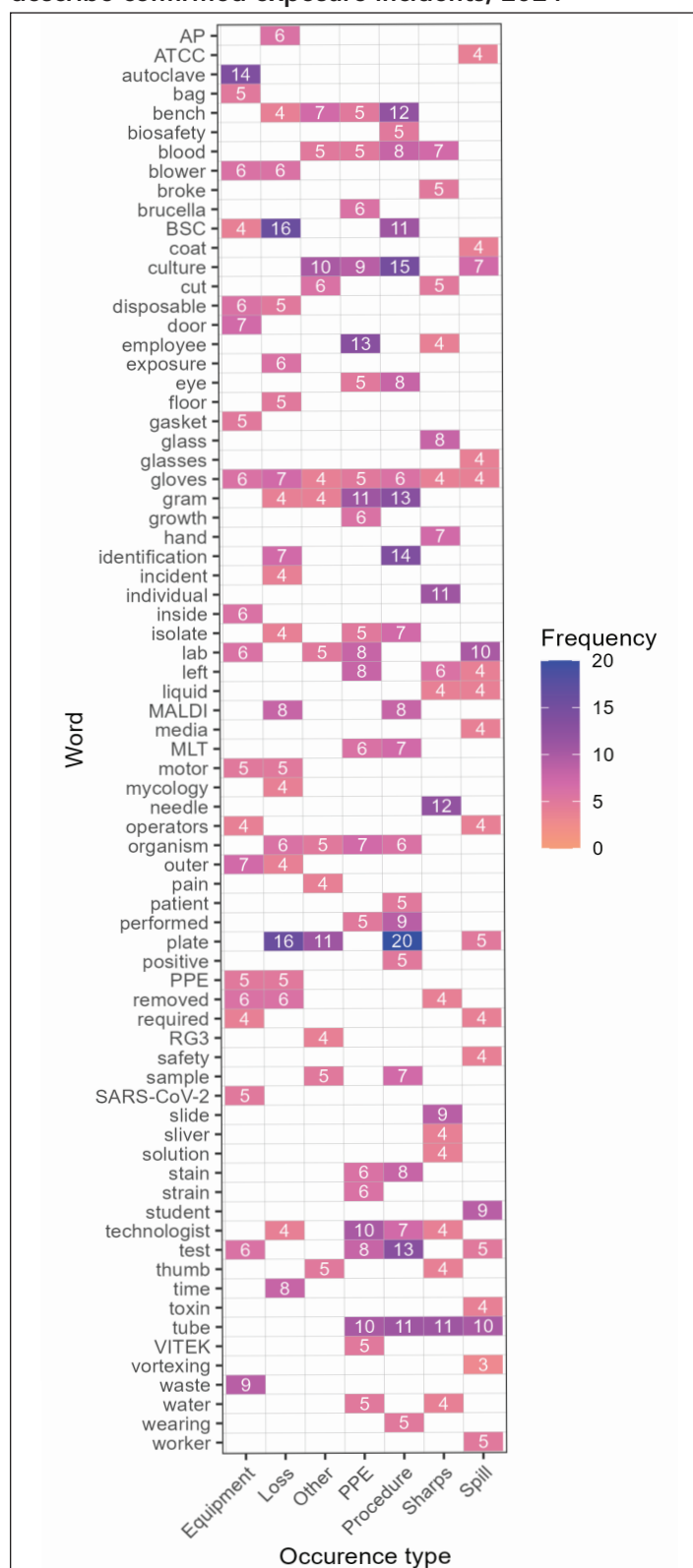
### Qualitative analysis

Seventy of the 71 confirmed exposure incidents provided text-based descriptions of the incidents. The frequencies of the most commonly used words to describe exposure incidents by occurrence type are presented in Figure 9. Overall, the most frequent words were “plate” (n=52; 5.7%), “biological safety cabinet” (BSC) and “tube” (each n=42; 4.6%), “culture” (n=41; 4.5%), “gloves” (n=36; 4.0%), “gram” (n=32; 3.5%), “lab” (n=29; 3.2%), “bench” (n=28; 3.0%), “test” (n=26; 2.8%), “blood” and “technologist” (each n=25; 2.8%) and “organism” (n=24; 2.6%). All of these words were mentioned in at least four occurrence types.

The word “plate,” primarily referring to petri dishes/culture plates, appeared across four occurrence types: most frequently in procedure, then loss of containment, “other,” and spill. It was used frequently along with “culture,” which also appeared most often in procedure-related occurrences, “BSC,” and “gram” (referring to gram stain tests for bacteria). Manual examination of the descriptions found that exposures often resulted during identification of HPTs in plates or while working in proximity to cultures or colonies in the plates, particularly on an open bench. The word “tube,” mentioned in occurrences related to PPE, procedure, sharps, and spills, was commonly used to describe liquid spills, issues with vortexing and broken glass from tubes breaking. The word “gloves” was the only one to appear across all occurrence types, mostly used to state that they were being worn during the incident.



**Figure 9: Heatmap of most frequently used words to describe confirmed exposure incidents, 2024<sup>a</sup>**



Abbreviations: AP, affected person; ATCC, American Type Culture Collection; BSC, Biological Safety Cabinet; gram, gram stain test/gram smear; MALDI, matrix-assisted laser desorption/ionization; MLT, medical lab technologist; PPE, personal protective equipment; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2; VITEK, VITEK 2 system (BioMérieux)

<sup>a</sup> Coloured tiles refer to the frequency of the word. Blank tiles do not indicate absence of word usage in the occurrence type, but that it was not used frequently enough to be considered among the most used words

## Discussion

An increase in the exposure incident rate was observed in 2024, continuing the upward trend since 2022 (13). While this rise may be due in part to a return to pre-COVID-19 working conditions, other factors could have also contributed, including increased familiarity with the incident reporting process. For example, over the past few years, PHAC engaged with stakeholders through conferences, webinars (23,24), information bulletins (25), e-learning courses (26) and inspections to enhance awareness of the surveillance program and reinforce appropriate reporting practices. These actions may have contributed to increased reporting and a reduction in reporting delays in 2024.

Consistent with previous years, microbiology and *in vivo* animal research remained the most frequently reported activities being conducted at the time of the confirmed exposure incident (9–13). Primary occurrence types remained procedure-related and sharps-related (9–13), while human factors and SOPs continued to be the most commonly cited root causes (8–13). Technicians and technologists represented the majority of affected individuals (8–13), and non-SSBAs, RG2 and bacteria remain the most implicated HPTs (9–13). For the second consecutive year, the bacteria *B. melitensis*, emerged as a leading SSBA (12,13), a trend also observed in the FSAP (15). No RG4 HPTs were implicated in exposure incidents in 2024.

## Public health sector had the highest exposure incident rate

Analysis of the data revealed that the public health sector had the highest exposure incident rate in 2024, and the highest mean exposure incident rate from 2016 to 2023. While no studies indicate that public sector facilities have distinct laboratory practices leading to greater risks, the relatively small number of licences in this sector may contribute to an overrepresentation of incidents in the data. The veterinary/animal health sector had the second-highest exposure incident rate, which could be due to the larger number of possible exposure routes when working with animals (i.e., biting, scratching) compared to *in vitro* settings (27) and more risks working with animals. These sectors also had larger IQRs, potentially because of variation of research activity from year-to-year and disruption in activity in 2020 and 2021 due to the COVID-19 pandemic (11,12,28,29).

## Increase in affected individuals, differences between sectors

A higher average number of affected persons per confirmed exposure incident was noted in 2024 compared to the last few years, with the exception of 2022 (10–13). While an average of 1.57 persons were affected per confirmed exposure incident in 2023, this average rose to 1.86 in 2024. This was due to the greater number of confirmed exposure incidents involving more than five individuals compared to the previous year. Differences





in affected persons by sector were also observed in 2024. The private industry/business sector, which historically has had fewer confirmed exposure incidents (Figure 4), had the highest mean number of affected individuals per confirmed exposure. This could indicate that a larger number of individuals were working on the task or were nearby during the confirmed exposure incident. The higher number of affected individuals per licence in the public health and hospital sectors could be attributable to contact with cultured biohazardous samples (i.e., blood cultures) (29) and higher risk HPTs. The majority of licensed facilities are containment level 2, where hand-to-face contact transmission might be a significant risk to workers (30).

## A qualitative analysis provides more insight about exposure incidents

A qualitative analysis of the confirmed exposure incidents revealed occurrence type-specific trends and overall areas to improve. Procedure-related occurrences frequently involved exposures from working with HPT cultures on an open work bench, instead of working in a BSC, without knowing the cultures consisted of higher risk pathogens (e.g., when opening/examining plates, identifying the organism). This situation was also described in loss of containment-related occurrences. This suggests that stronger emphasis on handling cultures in a BSC is needed to prevent aerosol releases or transmission, even if it may not necessarily be the current common practice (31,32). For sharps-related occurrences, finger-pricking from needles (e.g., during re-capping, injection, obtaining samples) or cuts by glass shards from broken tubes/slides were the main sources of exposure, while cuts by scalpels/blades were less common. This could be due to the greater number of tasks involving needles. The increased risk of occupational injuries related to needles and glass shards has been documented in other studies (33–36). There should, therefore, be increased caution when performing certain high-risk procedures. Equipment-related occurrences most commonly involved the malfunctioning of the BSC blower motor and tubing issues. Although the word “autoclave” was used most frequently for equipment-related occurrences, it was usually to confirm that it had been used for sterilization. However, there was one incident involving exposure to waste that had not been properly autoclaved. Further, while most of the exposure incident descriptions mentioned that gloves and laboratory coats were worn as PPE, face masks and eye protection equipment tended not to be worn as consistently and partially explained the reason for some of the confirmed exposures.

## Limitations

The use of standardized reporting forms during the incident reporting process over the past nine years remains a strength. It has allowed for the collection of consistent data and enhanced the reliability of trend analysis and identification of biosafety challenges.

Lack of facility-specific details (e.g., size of workforce, breakdown of roles, years of experience of each employee, etc.) remains a limitation. Access to such data could enable more detailed analyses using inferential statistics and hypothesis-driven studies to explore potential factors associated with laboratory exposure incidents. Second, there is a relatively small sample size of confirmed exposure incidents each year, potentially leading to higher variability in the results and challenges in detecting trends. The possibility of underreporting remains, though its scale cannot be estimated. Licence holders can only self-identify in one sector, which does not take into consideration the fact that a facility can operate in more than one sector. As the number of active licences each year is recorded by LINC at the beginning of each year, inaccuracies may occur when conducting analyses retrospectively, since the number can vary slightly throughout the year. Finally, a lack of comparable national incident reporting surveillance systems outside Canada remains a limitation that affects our ability to contextualize these findings and trends internationally (37).

## Conclusion

The exposure incident rate continued to increase in 2024 and surpassed all pre-pandemic levels, except for 2018. Most of the confirmed exposure incident characteristics in 2024 were consistent with previous years. Sector-specific analyses found that the public health sector had both the highest exposure incident rate between 2016 and 2024, and the highest number of affected persons per active licence between 2016 and 2024. The qualitative analysis of confirmed exposure incident reports identified that not working with cultures in a BSC and a lack of face-related PPE were common factors in confirmed exposure incidents. The insights from this report can inform enhancements to biosafety guidelines and practices, thereby helping to reduce exposure incidents in licensed Canadian facilities.

## Authors' statement

EFT — Methodology, data analysis, data validation, writing—original draft, writing—review & editing

AG — Conceptualization, incident monitoring, methodology, data analysis, data validation, writing—original draft, writing—review & editing

AND — Conceptualization, writing—original draft, writing—review & editing, supervision

CA — Incident monitoring, writing—original draft, writing—review & editing

SBA — Writing—review & editing

## Competing interests

There are no competing interests to declare.



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## Appendix

**Table A1: Definitions of main activity**

Main activity	Definition
Animal care	Activities such as attending to the daily care of animals and providing animals with treatment
Autopsy or necropsy	Post-mortem surgical examinations for purposes such as determining cause of death or to evaluate disease or injury for research or educational purposes
Cell culture	The process of growing cells under controlled conditions—it can also involve the removal of cells from an animal or plant
Education or training	Education or training of students and/or personnel on laboratory techniques and procedures
<i>In vivo</i> animal research	Experimentation with live, non-human animals
Maintenance	The upkeep, repair and/or routine and general cleaning of equipment and facilities
Microbiology	Activities involving the manipulation, isolation or analysis of microorganisms in their viable or infectious state
Molecular investigations	Activities involving the manipulation of genetic material from microorganisms or other infectious material for further analysis
Serology	Diagnostic examination and/or scientific study of immunological reactions and properties of blood serum
Hematology	Scientific study of the physiology of blood
Other	Other types of activity not captured elsewhere

**Table A2: Definitions of occurrence types**

Occurrence type	Definition
Spill	Any unintended release of an agent from its container
Loss of containment	Includes malfunction or misuse of containment devices or equipment and other types of failures that result in the agent being spilled outside of, or released from, containment
Sharps-related	Includes needle stick, cut with scalpel, blade or other sharps injury (i.e., broken glass)
Animal-related	Includes animal bites or scratches, as well as other exposure incidents resulting from animal behaviour (i.e., animal movement resulting in a needle stick)
Insect-related	Includes insect bites
PPE-related	Includes either inadequate PPE for the activity or failure of the PPE in some way
Equipment-related	Includes failure of equipment, incorrect equipment for the activity or misuse of equipment
Procedure-related	Includes instances when written procedures were not followed, were incorrect for the activity or were inadequate or absent

Abbreviation: PPE, personal protective equipment



# Trust in community as a predictor of public health measure adherence: Insights from a national Canadian survey

Neil Seeman<sup>1\*</sup>, Justin Trent<sup>2</sup>, Kumar Murty<sup>2,3</sup>

## Abstract

**Background:** Public health models often lack comprehensive behavioural data, leading to inaccurate predictions about the spread of disease and insufficient information about how to effectively build and sustain adherence to changing public health protocols.

**Objective:** The current study addresses this lack of comprehensive behavioural data by examining the role of trust as a predictor of adherence to public health measures.

**Methods:** Data were collected from an online Web intercept survey of 3,021 randomly engaged Canadians aged 16 years and older, analyzing factors such as gender, education and sources of COVID-19 information in relation to adherence to public health guidelines.

**Results:** Trust, respecting someone's expertise sufficiently to be willing to accept their counsel, emerged as a potent predictor of adherence to public health measures, highlighting the significance of trust in shaping community engagement; further, community-level adherence was found to predict anticipated future adherence.

**Conclusion:** This study emphasizes the critical role of trust, especially at the community level, in the success of public health measures, and proposes integrating trust measurement into public health models of compliance and resistance.

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**Keywords:** public health measures, trust in community, adherence to guidelines, predictive modelling, community resilience

## Introduction

The COVID-19 pandemic underscored the critical importance of public adherence to health measures in managing public health crises. Understanding the factors that influence this adherence is essential for developing effective strategies to address future health emergencies. This study aims to explore the relationship between trust in the community, healthcare providers and political communications and adherence to public health and social measures (PHSMs) in Canada.

Previous research has highlighted the role of trust in government and health authorities in promoting adherence to public health guidelines (1–4); however, less attention has been directed toward understanding the role of community trust in this context.

This study seeks to fill this gap by examining how trust affects both past and future adherence to PHSMs.

The primary objective of this study was to improve the identification of factors such as age, education, region, information sources and community engagement, that affect adherence to health measures, providing public health authorities a clearer picture of the underlying drivers of compliance at both individual and community levels. Additionally, it aimed to gather data to assist in predicting instances of low adherence to PHSMs in future public health crises by considering community-specific influences. Using predictive modelling techniques, the study sought to generate reliable models that





can help forecast non-adherence scenarios within different community contexts, allowing public health authorities to design targeted interventions that mitigate risk in critical areas and strengthen community resilience.

## Methods

An online survey was conducted of 3,021 randomly selected participants across Canada, all aged 16 years and older. This survey formed part of a broader international study that included 10 additional countries, resulting in a total sample size of 22,015 respondents.

Regression and classification models were utilized to estimate the impact of trust, location and demographic variables on individual and community adherence to PHSMs in Canada. Statistical analysis was employed to identify outliers within specific sub-groups. To model the relationship between trust and adherence, response survey scales were transformed into numeric values, and trust and adherence scores were calculated for each respondent. Average scores were then computed across demographic groups, such as gender, age, region, city and a combination thereof, provided each group included at least 50 respondents. This was initially analyzed using simple linear regression, which revealed a surprisingly strong relationship between trust and adherence ( $R^2 > 0.84$ ). Predicting individual adherence proved more complex. However, the analysis indicated that individual adherence can be effectively predicted as a binary outcome using a gradient-boosted decision tree classification model using dimensionality reduction of metadata and with further data engineering to refine urban-rural classifications and city size variables. Moreover, this approach appears particularly adept at forecasting shifts in adherence behaviour, such as high past adherence followed by low anticipated future adherence, and vice versa.

The survey instrument was designed to assess the following: 1) trust in community; 2) trust in healthcare providers; 3) trust in political communications; 4) past adherence to PHSMs; 5) anticipated future adherence to PHSMs; and 6) demographic information, including age, gender, education level and primary information sources.

The analysis began with a review of Organisation for Economic Co-operation and Development and Statistics Canada reports on trust, then scanned both grey literature and peer-reviewed publications from the previous three years that mentioned “public trust” in the abstracts. This process helped in the identification of key elements of institutional trust (public trust in institutions) and interpersonal trust (public trust in community) (5,6).

Sample questions were developed based on the literature review. These questions were refined using principles of

construct validity, reliability, objectivity and credibility (7), and by drawing on relevant experience from previous COVID-19-related surveys deployed in Ontario and the United States with the same sampling methodology (8,9).

These questions were further refined through feedback from a network of researchers and infectious disease modelers from the Mathematics for Public Health Network of the Fields Institute for Research in Mathematical Sciences. This network represents over a dozen Canadian universities and includes international collaborators from institutes in France, the United Kingdom, Brazil, the United States, Japan and China. Although the survey instrument was deployed in 11 countries, the findings presented here are restricted to Canada, as the literature review could not conclusively establish cross-national transferability of the selected trust elements (10).

A pilot study, involving 500 completed surveys, was conducted during the week of September 20, 2022. The regional meta-data, as well as self-reported data on age and gender, were cross-validated with Statistics Canada data (11). No changes to the collection process or the question set were made following the pilot. The full data collection proceeded in two waves: from October 5 to 21, 2022 and from November 16 to December 11, 2022.

As expected with a survey of this nature, where anonymous potential respondents encounter the survey while searching for other information, a modest percentage of participants (19.2%) who opted in to the survey completed all questions. Despite this relatively low completion rate as compared to some incentive-based surveys, it is contended that this method offers data quality advantages over other online non-probability sampling techniques involving actively recruited and/or compensated respondents. Under the sampling approach used, no incentives were offered (eliminating incentive bias), and participants were able to exit the survey at any time. Since the survey sites did not have ad tracking pixels, ad block technology did not reduce the size or diversity of the sample. These techniques seek to reduce self-selection bias, recruitment bias, social desirability bias, acquiescence bias and online coverage bias (9). Further details on survey completion rates, regional, gender and age breakdowns are available in **Appendix** and upon request.

## Results

The findings revealed several key insights into the relationship between trust and adherence to PHSMs.

### Outsized impact of trust in community

The survey indicated that 88.4% of respondents who strongly believed that their community members were diligently following PHSMs reported adhering to these measures themselves (89.7% when adjusted for age, gender and province/territory).



In stark contrast, only 30.1% of respondents who perceived their community as rarely following PHSMs reported similar adherence (28.5%, when similarly reweighted). This pattern demonstrates a clear, proportional decline in adherence as trust in community compliance decreases. Similar trends were observed in the respondents' trust in healthcare providers and political communications.

### Low education, low adherence

Across age groups, regions and information sources, those reporting primary school (or below) as their highest level of formal educational attainment were consistently among the least likely to adhere to PHSMs.

### Complex interplay of age, region and gender

Overall, Canadian seniors (aged 65 years and older) were among the most likely to adhere to PHSMs; however, in certain provinces, adherence among seniors was below both the national and provincial averages. Generally, young males were among the least likely to adhere. Yet, in select urban areas, this demographic reported adherence levels well above the municipal average.

### Role of information sources

Respondents who reported podcasts or radio as their primary source for COVID-19 information showed consistently, and often significantly, lower adherence to PHSMs across almost all age groups and regions. The impact on PHSM adherence among those relying on other information sources varied in both direction (positive or negative) and magnitude, depending on age group, education level and region.

### Trust data can facilitate predictive modelling

Results suggest that knowledge of trust in community, healthcare practitioners and political communications was sufficient to make reasonably accurate group-level predictions of adherence levels across a wide range of age, region and gender combinations. Further analysis indicates that individual adherence could be predicted with reasonable accuracy as a binary outcome, using the higher-dimensional data collected along with additional feature engineering.

## Discussion

These findings highlight the complex relationship between trust and adherence to PHSMs, with community trust emerging as the most influential predictor of adherence. This finding has significant implications for public health strategies, suggesting that efforts to build and maintain trust at the community-level are critical for ensuring compliance during health crises.

The variations in trust and adherence based on geography, age, education and information sources emphasize that a one-size-fits-all approach to public health messaging is unlikely to be effective. Instead, strategies that are tailored to local contexts

and community dynamics, such as engaging local leaders and partnering with trusted community figures may prove more successful in promoting adherence to PHSMs (aligning with results seen in Barrett *et al.*) (9). The strong correlation between trust and adherence highlights the importance of understanding trust dynamics to pinpoint areas where adherence may be low, allowing public health authorities to target their efforts more effectively.

Furthermore, the nuanced demographic variations observed in the study indicate that simply attributing non-adherence to factors like the negative influence of social media or demographic stereotypes (e.g., the "angry young male") is counterproductive. Public health authorities must work to understand the complex interplay of age, location, gender and information sources.

The success of the predictive model deployed across a range of demographics and communities highlights the potential value of measuring trust as a tool for anticipating PHSMs adherence. This could enable public health authorities to identify areas or groups where compliance is likely to be low and implement targeted interventions designed to address specific trust deficits, ultimately improving public health outcomes during future crises.

### Limitations

This study has several limitations that should be considered when interpreting the results: 1) self-reported data: a reliance on self-reported adherence may be subject to social desirability bias; 2) cross-sectional design: this study provides a snapshot of trust and adherence but cannot establish causal relationships or track changes over time; 3) generalizability: while this survey was deployed in multiple countries, the findings here may not be universally applicable to all public health crises or cultural contexts; and 4) this survey did not include questions related to race/ethnicity or income-level.

While other studies have suggested that race/ethnicity or income-level play a role in adherence, these were not included as the study's goal was to use a single question set across all 11 countries covered by this survey (translated to the local languages where applicable) and the income brackets as well as ethnic make-up shifted considerably from country to country.

### Future research

Future research could address these limitations through 1) longitudinal studies to track changes in trust and adherence over time, 2) experimental designs to explore causal relationships between trust and adherence, 3) in-depth qualitative studies to assess the nuances of community trust in different contexts; 4) studies focusing on specific demographic groups or regions to develop more targeted interventions; and 5) comparing and contrasting results in Canada with those of other countries surveyed, sensitive to the challenges in the cross-national transferability of the survey questions.



## Conclusion

Trust was found to be closely tied to adherence, with community trust emerging as a particularly strong predictor. This pattern persisted across multiple demographic groups and regions, suggesting that local trust plays an even more critical role in compliance than trust in healthcare providers or political figures.

This study improved the identification of factors influencing adherence by highlighting the significance of demographic variables such as education, age, gender and region, as well as preferred information sources. Lower education levels and reliance on certain media (e.g., podcasts and radio) were associated with reduced adherence. These findings point to the need for targeted public health messaging that addresses the specific concerns and trust deficits within different population subgroups.

Finally, the data collected proved effective for predicting instances of low adherence. The models used, which incorporated trust data along with demographic variables, enabled accurate group-level predictions, offering a potential tool for public health authorities to anticipate and address areas of low compliance in future crises.

In conclusion, trust, particularly at the community-level, is a critical lever for ensuring public health compliance. To maximize adherence in future health emergencies, public health strategies should prioritize building and maintaining trust within local communities, measuring trust at the community-level and tailoring communications to address the demographic and regional variations in both trust and behaviour. To serve these goals, trust measurement can be embedded in public health models of compliance and resistance. By doing so, authorities can better predict and mitigate areas of low adherence, enhancing the overall effectiveness of public health interventions.

## Authors' statement

NS — Survey design, conceptualization, writing, project administration

JT — Statistical analysis, software, methodology

KM — Conceptualization, formal analysis (hypothesis review)

## Competing interests

Neil Seeman is the inventor of the sampling technology used in this study, and a non-executive member of the board of RIWI Corp., which owns the technology.

Justin Trent has no competing interests.

Kumar Murty has no competing interests.

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## Appendix

**Table A1: Completion rates and demographic characteristics of survey respondents<sup>a,b,c</sup>**

Characteristic	Completion rate	Population	Surveys
Total study group	19.2%	100%	3,021
<b>Gender (at age 16 years)</b>			
Female	19.9%	50.9%	30.6%
Male	20.0%	48.9%	59.0%
Prefer not to answer	14.6%	0.2%	10.4%
<b>Age group (years) (for participants aged 16 years and older)</b>			
16–24	19.4%	14.2%	25.5%
25–34	16.6%	17.4%	17.8%
35–44	17.6%	16.2%	16.3%
45–54	18.2%	14.4%	12.3%
55–64	21.7%	15.4%	12.0%
65 and older	24.5%	22.3%	16.1%
<b>Region</b>			
Alberta	18.1%	11.5%	10.3%
British Columbia	16.7%	13.5%	12.1%
Manitoba	22.2%	3.6%	3.6%

**Table A1: Completion rates and demographic characteristics of survey respondents<sup>a,b,c</sup> (continued)**

Characteristic	Completion rate	Population	Surveys
<b>Region (continued)</b>			
New Brunswick	21.9%	2.1%	1.9%
NFL and Labrador	26.8%	1.4%	1.4%
Nova Scotia	20.8%	2.6%	2.8%
Ontario	19.5%	38.5%	42.8%
PEI	15.5%	0.4%	0.4%
Québec	19.7%	23.0%	22.2%
Saskatchewan	19.7%	3.1%	2.4%
Territories	21.7%	0.3%	0.2%

Abbreviations: NFL, Newfoundland and Labrador; PEI, Prince Edward Island

<sup>a</sup> Both unweighted and reweighted (by age group, gender and province/territory as outlined below) data have been included in the aggregate figures

<sup>b</sup> Completion rate was significantly lower among respondents who preferred not to provide their gender and notably higher among those whose self-reported age was over 65. As other demographic information was collected at the end of the survey, we cannot comment on the impact of those characteristics on completion

<sup>c</sup> The proportion of surveys completed by self-reported females and respondents aged 65 and older was significantly lower than population estimates provided by Statistics Canada. Respondents aged 16 to 25 constituted a notably higher proportion of completed surveys compared to their population representation. Representation among other groups aligned with population estimates



## Appendix 2: Questionnaire

This survey is being carried out by the Fields Institute for Research in Mathematical Sciences for the purposes of research. You will not be asked for any personal identifying information. There is no risk to you in filling out this survey and you will not benefit from taking part. If you would like more information about this study you can contact the Fields Institute. This survey has been reviewed by the Human Research Ethics Program at the University of Toronto. By continuing with this survey, you agree to participate in this research study and acknowledge that you are over the age of 15.

Questions	Possible answers
Age	16 to 75+
Are you	Male Female Prefer Not to Answer
Please Select Your Region	[Provinces/Territories in Canada]
<b>In this survey, we would like to know how you feel about public health policies and the guidelines used to deal with COVID-19.</b>	
Would most people in your local community follow public health guidelines during a public health crisis?	Yes, almost everyone would follow the guidelines Yes, many would follow the guidelines Maybe half of the population would follow the guidelines No, many would not follow the guidelines No, almost no one would follow the guidelines
Do you feel that <b>doctors and other health professionals</b> have communicated useful and reliable information to meet your needs during the COVID public health crisis?	Yes, the information has been completely useful and reliable Yes, the information has been quite useful and reliable The information has been somewhat useful and reliable No, the information has not been useful and reliable No, the information has been wrong and misleading
Do you feel that <b>political leaders</b> have communicated useful and reliable information during the COVID-19 public health crisis?	Yes, the information has been completely useful and reliable Yes, the information has been quite useful and reliable The information has been somewhat useful and reliable No, the information has not been useful and reliable No, the information has been wrong and misleading
How much did you follow the health guidelines given <b>over the past two years</b> to prevent the spread of the pandemic?	I was very careful to follow all the guidelines I followed most of the guidelines I followed some of the guidelines I did not follow the guidelines
If there is a new health emergency <b>in the future</b> , how much would you follow any new health guidelines?	I would follow all the guidelines I would follow most of the guidelines I would follow some of the guidelines I would not follow the guidelines
In the event of a <b>future disease outbreak</b> , whose information would you find most useful and believable?	World Health Organization Red Cross/Red Crescent Doctors and Nurses Other Public Health Officials National Government/Health Minister Local Government Military/Police I don't believe any of the above would provide use useful and believable information
Where do you live?	Rural area/village/small town Medium town/small city Medium city Large city





## Appendix 2: Questionnaire (*continued*)

Questions ( <i>continued</i> )	Possible answers ( <i>continued</i> )
Which of the below is your <b>primary source</b> of information about COVID-19?	International media National media Government Briefings World Health Organization Directly from Friends and Family Social Media (Facebook, Twitter, Instagram, Tik Tok, etc.) Social messengers (e.g. WhatsApp groups, Telegraph, etc.) Radio Podcasts and Blogs TV News
How much schooling have you completed?	No formal education Primary school Secondary school/High school Post-secondary/Vocational training Bachelor's Degree Master's Degree or Higher

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 Canada



# Detection of non-travel-associated, ceftriaxone non-susceptible *Neisseria gonorrhoeae* FC428-like harbouring the mosaic *penA60* allele in Ontario, Canada

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## Abstract

**Background:** This case report describes a young male with multidrug-resistant *Neisseria gonorrhoeae* infection acquired in Ontario, Canada with no travel history.

**Methods:** Case follow-up was conducted following routine public health practice in Ontario. Antimicrobial susceptibility testing of the isolate was done by agar dilution. Strain typing and other molecular characterization was done by whole genome sequencing.

**Results:** The patient was treated successfully with intramuscular ceftriaxone and oral azithromycin. Agar dilution testing demonstrated reduced susceptibility to all tested agents, except for azithromycin and spectinomycin, including non-susceptibility to ceftriaxone (minimum inhibitory concentration [MIC]=0.5 mg/L) and cefixime (MIC=2 mg/L), resistance to tetracycline (MIC=2 mg/mL) and ciprofloxacin (MIC=32 mg/L), and testing intermediate to penicillin (MIC=1 mg/L). Whole-genome sequencing revealed the isolate was closely related to the FC428 clone, which harbours the mosaic *penA60* allele responsible for elevated MICs to extended-spectrum cephalosporins, such as ceftriaxone or cefixime, both currently recommended as first-line or alternative treatment options for uncomplicated anogenital gonorrhea infections in Ontario.

**Conclusion:** Identification of this case suggests previously unrecognized local transmission of this multidrug-resistant *N. gonorrhoeae* strain is occurring in Ontario and highlights the need for ongoing surveillance to monitor trends and inform treatment recommendations.

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**Keywords:** gonorrhea, *Neisseria gonorrhoeae*, sexually transmitted diseases, drug resistance, public health surveillance

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## Introduction

*Neisseria gonorrhoeae* (*N. gonorrhoeae*) is the second most commonly reported sexually transmitted infection in Canada (1), with 92.34 cases per 100,000 population in 2022, representing an increase of 175.9% since 2010 (2,3). Infection rates among both males and females have increased over time, though

more rapidly in males (2). While the highest rate of gonorrhea infections remains in the 20–29 age group in Canada, the greatest relative increases between 2010–2019 were identified in those 30–39 years old and 40–59 years old (2).



*Neisseria gonorrhoeae* antimicrobial resistance has increased over the past 20 years and is a public health concern, as untreated, and untreatable, gonorrhea poses a significant risk of reproductive morbidity and can increase susceptibility to HIV transmission and acquisition (4,5). The ability of *N. gonorrhoeae* to develop resistance to antimicrobials is due to a combination of transferrable plasmid-borne resistance determinants, as well as chromosomal genes that result in antimicrobial destruction, target modification, decreased membrane permeability to antimicrobials, or drug efflux (6).

*Neisseria gonorrhoeae* FC428 has been implicated in multiple clonal outbreaks of gonorrhea infection in Asia, Europe, and the United Kingdom (7–12). This article reports the first known case of ceftriaxone non-susceptible *N. gonorrhoeae* FC428 infection with the mosaic *penA60* allele identified in an Ontario patient. Notably, the patient lacked a compatible travel history typically associated with FC428 infection, suggesting under-recognized local transmission.

Methods

Case presentation

A young adult male who reported a risk factor of having condomless sex with the opposite sex, presented to a walk-in clinic in Ontario with a one-week history of dysuria and urethral discharge. The patient denied any urinary urgency, persistent sore throat, or neck swelling. He had a history of one episode of unprotected insertive vaginal intercourse with a female partner (not disclosed to be a sex professional) two weeks prior to symptom onset. He was unable to recall whether insertive oral intercourse also occurred. The patient denied any recent travel outside of Ontario.

Following counselling, a first-void urine specimen and a urethral swab were aseptically obtained, the latter being placed into Amies with charcoal transport media. The patient was treated empirically with ceftriaxone 250 mg given as a single intramuscular dose in the gluteal muscle, as well as azithromycin 1g given as a single oral dose. Nucleic Acid Amplification Test (NAAT) by strand displacement amplification on the urine specimen was performed using the BD Viper™ (Becton, Dickinson and Company), which was positive for *N. gonorrhoeae* and negative for *Chlamydia trachomatis*. The positive *N. gonorrhoeae* was confirmed by polymerase chain reaction (PCR) using the BD MAX™ platform.

A presumptive isolate of *N. gonorrhoeae* from the urethral swab was submitted to Public Health Ontario (PHO), which is a provincial public health reference laboratory, for confirmatory and antimicrobial susceptibility testing. The laboratory performed *N. gonorrhoeae* culture by plating specimens on New York City agar and incubating at 35–37°C in 5% carbon dioxide for 48 hours. Matrix-Assisted Laser Desorption/Ionization Time of

Flight Mass Spectrometry (MALDI-TOF MS) was used to confirm the identity of any oxidase-positive colonies, alongside cysteine trypticase agar carbohydrate utilization and O-Nitrophenyl-β-D-galactopyranoside (ONPG) testing. The isolate was oxidase positive, ONPG negative, and utilized dextrose but not maltose or sucrose, consistent with *N. gonorrhoeae*. Susceptibility testing was performed on the *N. gonorrhoeae* isolate using the agar dilution method recommended by the Clinical and Laboratory Standards Institute (CLSI) and interpreted using the CLSI breakpoints (13,14). The isolate was sent to Canada’s National Microbiology Laboratory (NML) for confirmatory agar dilution testing. Minimum inhibitory concentrations (MICs) of the clinical isolate are shown in Table 1.

Table 1: Antimicrobial susceptibility testing results for *Neisseria gonorrhoeae* patient isolate

Antimicrobial tested	Minimum inhibitory concentration (MIC), mg/L	Interpretation <sup>a</sup>
Penicillin	1	Intermediate
Ceftriaxone	0.5	Non-susceptible
Cefixime	2	Non-susceptible
Ertapenem	0.06	N/A
Azithromycin	0.25	Susceptible
Gentamicin	8	N/A
Tetracycline	2	Resistant
Ciprofloxacin	32	Resistant
Spectinomycin	16	Susceptible

Abbreviation: N/A, no breakpoint available  
<sup>a</sup> Clinical Laboratory Standards Institute, MIC breakpoint interpretations as per Clinical and Laboratory Standards Institute (CLSI) M100, 33<sup>rd</sup> edition. Note that the MICs for ceftriaxone and cefixime are considered resistant using the European Committee on Antimicrobial Susceptibility Testing (EUCAST) breakpoints (Version 14.0)

The patient returned to the walk-in clinic 18 days after completion of treatment for follow-up and reported no symptoms indicative of treatment failure. A urethral swab was obtained for test-of-cure by culture and tested negative. The patient was discharged from follow-up. The patient did not disclose his sexual contact for public health follow-up; he was advised to let the contact know to seek testing and treatment for suspected gonorrhea.

Results

Whole-genome sequencing and molecular typing

Whole-genome sequencing was used to elucidate the genetic markers responsible for the resistance profile of the patient’s isolate. Genomic DNA was extracted using the EMAG® system (bioMérieux SA, Marcy-l’Étoile, France) and performed sequencing on the MiSeq instrument (Illumina Inc., San Diego, United States). Raw FASTQ files were assembled using

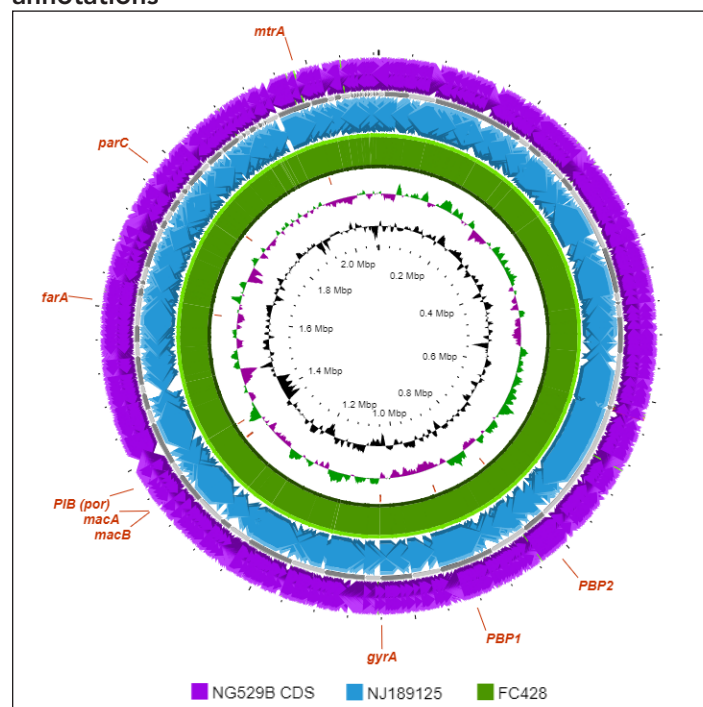


CLCGenomics Workbench version 8.5.3 (CLC bio, Germantown, Maryland, United States), and the assembled genome was submitted to the Bacterial and Viral Bioinformatics Resource Centre (BV-BRC) (15) for genome annotation and comparison. The assembled genome was of good quality overall, with 88 contigs, a total length of 2.129 Mb, an average guanine-cytosine content of 52.37%, and an average coverage of 641x. **Figure 1** shows a graphical display of the genome annotation.

Antimicrobial resistance determinants were identified in the genome using the Comprehensive Antibiotic Resistance Database (CARD) (16) to assign a functional annotation and broad mechanism of resistance, where possible. The resistance determinants identified are listed in **Table 2**, and include genes responsible for target alteration, target protection, reduction of cell wall permeability, and the production of efflux pumps. Of note, the patient's isolate harbours the mosaic *penA60* allele, which has the *penA* A311V mutation and is associated with increased MICs to cephalosporins (17). In silico analysis was largely concordant with antimicrobial susceptibility testing.

*Neisseria gonorrhoeae* multilocus sequence typing (MLST), multi-antigen sequence typing (NG-MAST), and *N. gonorrhoeae* Sequence Typing for Antimicrobial Resistance (NG-STAR) were confirmed using contigs obtained by *de novo* assembly via pubMLST. The isolate was assigned a sequence type of ST13943 using MLST, and clonal complex 233 in NG-STAR.

**Figure 1: Graphical display of distribution of genome annotations**



Legend: Circular map showing a comparison of the genome of *Neisseria gonorrhoeae* strain NG 529B together with closely related genomes using Proksee. The outermost ring represents the NG 529B chromosome position, the grey-coloured ring represents the genome backbone (in contigs), the blue ring represents strain NJ189125, and the green ring represents strain FC428 (NZ\_AP018377.1). The GC Skew (purple/green) is represented as the second innermost ring. The GC content is represented as the innermost ring (black). This whole genome shotgun project has been deposited at DDBJ/ENA/GenBank under the accession JBFHAD010000000. The version described in this paper is version JBFHAD010000000.

**Table 2: Antimicrobial resistance genes identified from sequenced *Neisseria gonorrhoeae* patient isolate according to the Comprehensive Antibiotic Resistance Database**

RGI criteria	Antimicrobial resistance gene	Single nucleotide polymorphism(s)	Antimicrobial classes affected	Resistance mechanism	% Identity of matching region	% Length of reference sequence
Perfect	<i>mtrA</i>	<i>mtrR</i> -promoter:g.-57_-57del, and <i>mtrR</i> -promoter:p.H105Y	Macrolide antibiotic, penam	Efflux	100	100
Strict	PBP1 ( <i>ponA</i> )	L421P	Cephalosporin, cephameycin, penam	Target alteration	97.24	100
Strict	PBP2 ( <i>penA</i> ) mosaic	A311V, V316T, I312M, T483S, F504L, A510V, N512Y, H541N, I515V, G545S, I566V	Cephalosporin, cephameycin, penam	Target alteration	91.58	100.17
Strict	<i>rpsJ</i>	V57M	Tetracyclines	Target protection	99.03	100
Strict	porin PIB ( <i>porB</i> )	G120K, A121D, I218M, A323V, M18T, Q143K, M257T, G259V, S258R, N297D	Monobactam, carbapenem, cephalosporin, cephameycin, penam, tetracycline antibiotic, penam	Reduced permeability	96.26	100
Strict	<i>parC</i>	S87R, V596I	Fluoroquinolone antibiotic	Target alteration	99.74	100
Strict	<i>gyrA</i>	S91F/D95A	Fluoroquinolone antibiotic	Target alteration	99.67	100
Strict	<i>mtrC</i>	<i>mtrC</i> -promoter:p.G29R and S163G	Macrolide antibiotic, penam	Efflux	95.63	100
N/A	<i>folP</i> <sup>a</sup>	P68S, R228S	N/A	N/A	N/A	N/A
N/A	<i>rpoB</i> <sup>a</sup>	H552N	N/A	N/A	N/A	N/A

Abbreviations: N/A, not applicable; RGI, resistance gene identifier

<sup>a</sup> Insufficient data were present in the Comprehensive Antibiotic Resistance Database (CARD) database to assign interpretations to the single nucleotide polymorphisms identified for this antimicrobial gene

Note: The CARD database was accessed March 2023

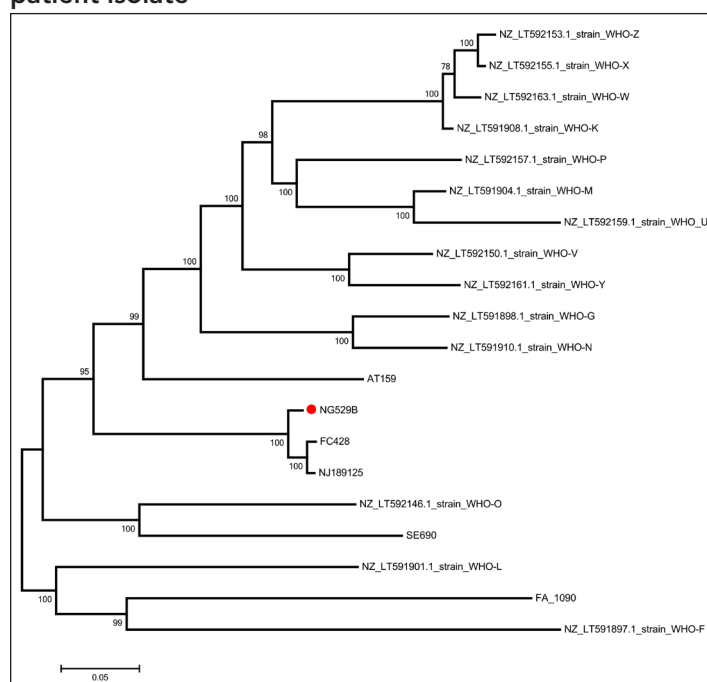




This patient's isolate contained a novel *porB*-2035 and *tbpB*-21 allele combination, which was assigned as ST-21711 by NG-MAST v.2.0.

Finally, to examine the relatedness of the Ontario isolate to other resistant strains, phylogenetic analysis was performed and a maximum-likelihood phylogenetic tree was created using 9,116 core-genome single nucleotide polymorphisms (SNPs) across *N. gonorrhoeae* World Health Organization (WHO) strains and strains reported to harbour the mosaic *penA60* allele (Figure 2). The phylogenetic tree illustrates the similarity of the patient isolate's genome to that of clone FC428.

**Figure 2: Phylogenetic tree of *Neisseria gonorrhoeae* patient isolate**



Legend: Maximum likelihood phylogenetic tree based on core-genome single nucleotide polymorphisms (SNPs) across World Health Organization strains and recently reported strains harbouring the mosaic *penA60.001* gene and the strain from this study (red dot, 'NG529B'). The tree was constructed using 9116 SNPs and drawn to scale, with branch lengths measured in the number of substitutions per site

## Discussion

*Neisseria gonorrhoeae* infection is an important cause of morbidity and is transmitted via mucosal contact during oral, vaginal, or anal intercourse, as well as vertically during childbirth (6). It is an important cause of cervicitis in females and urethritis in males, though upwards of 50% of females remain asymptomatic (6). In Canada, gay, bisexual, and other men who have sex with men (GBMSM) are a key population at risk of infection (2). Ascending, untreated infection can be a cause of infertility and other urogenital complications. Over the past decade, gonorrhea infection and resistance rates have increased at an alarming pace (2). However, because only a small percentage of gonorrhea cases are identified with

culture, prevalence estimates of multidrug resistance may be underreported. Combating the spread of *N. gonorrhoeae*, in the absence of effective vaccination and poor uptake of chemoprophylaxis, requires a multifaceted approach consisting of sexual health education, use of barrier protection, adequate surveillance infrastructure, timely access to testing and treatment, and an effective contact notification strategy (6).

This case report describes the first known ceftriaxone non-susceptible *N. gonorrhoeae* FC428-like isolate harbouring the mosaic *penA60* allele in Ontario, Canada, that was not linked to travel. This was the third ceftriaxone-non-susceptible strain of *N. gonorrhoeae* identified in Ontario and the first detected since 2018. Single nucleotide polymorphism (SNP) analysis demonstrated that the patient's isolate was most closely related to *N. gonorrhoeae* clone FC428, a strain first recognized in Nanjing, China in 2018. Similar to our patient's isolate, clone FC428 harbours the mosaic *penA60* gene and has elevated MICs to ceftriaxone and cefixime. While the mosaic *penA60* allele has been previously identified in patients from the Canadian provinces of Québec and Alberta and may be associated with an increased risk of treatment failure (18,19), this is the first instance of its identification in Ontario—this allele is a growing concern worldwide, having been isolated in Asia, Australia, Europe, and North America (7,10,18–23). Of note, although the first two cases in Ontario did not have the *penA60* allele, they did have the *penA* A311V mutation of interest. Interestingly, this case had clinical resolution despite phenotypic non-susceptibility to cephalosporins; however, as the proportion of resistant isolates increases over time, it may be worthwhile to consider use of a higher dose of ceftriaxone as standard of care for uncomplicated gonorrhea infections. Of note, in December 2024, the Public Health Agency of Canada updated its treatment guideline to recommend 500 mg ceftriaxone monotherapy as the preferred treatment of uncomplicated gonorrhea infections for adults (24). Although some mutations associated with elevated macrolide MICs were detected, it was not enough to confer azithromycin resistance (the isolate was phenotypically susceptible), since resistance is mediated through additive effects of multiple mutations within the multidrug efflux pump system (*mtrCDE*) operon. Clinical cure in this patient's case may have been related to azithromycin administration.

## Limitations

Identification of this isolate suggests that transmission of ceftriaxone non-susceptible *N. gonorrhoeae* is occurring in Ontario. As of the time of publication, four additional ceftriaxone non-susceptible *N. gonorrhoeae* isolates have been identified in the province that bore different MLST and NG-MAST types than the case described. As *N. gonorrhoeae* case numbers and antimicrobial resistance rapidly increase, there is an urgent need for renewed public health messaging and guidance to help reduce the transmission rate in Canada.





An increasing incidence of multidrug-resistant gonorrhea infection in Canada should incentivize public health laboratories to create new strategies to rapidly identify whether treatment failures or suspected outbreaks may be clonal in nature. This approach has been adopted by the NML (25,26) and the United Kingdom's Health Security Agency, with the implementation of a mosaic *penA60* allele PCR test, specifically designed to detect the *penA* A311V mutation (19,20). Another recent protocol developed in China uses a multiplex high-resolution melting assay to genetic markers of resistance to cephalosporins and azithromycin (27). In a cross-sectional study, when compared to phenotypic testing, this assay was shown to have a specificity of 96.29% (95% CI: 94.57–97.50) for cefixime and 99.52% (95% CI: 98.68–99.85) for azithromycin (28). Of note, the assay's sensitivity was significantly lower for both ceftriaxone (79.10%, 95% CI: 63.52–89.42) and azithromycin (31.34%, 95% CI: 20.87–43.97) (28). The identification of this case also highlights the continued relevance of culture-based diagnostics at local laboratories in Canada, in the absence of widespread NAAT that includes predominant genetic markers of resistance. As treatment becomes more challenging for gonorrhea, enhanced uptake of emerging preventive interventions, such as doxycycline post-exposure prophylaxis, may need to be considered.

## Conclusion

This case highlights the growing threat of multidrug-resistant *N. gonorrhoeae* infections, which are being increasingly identified in Canada (18,19). It underscores that laboratory surveillance programs should include a combination of genotypic and phenotypic testing methods to help investigate isolates with multidrug resistance and treatment failures and highlights the continued relevance of culture-based diagnostics. However, as diagnostics continue to shift from culture-based to molecular-based methods, it is important to continue exploring direct testing of NAAT specimens for antimicrobial resistance prediction. Healthcare professionals should screen for gonorrhea as per national guidelines (29) and test individuals with compatible signs and symptoms in order to identify and treat those with gonorrhea and reduce *N. gonorrhoeae* transmission in Canada. With increasing gonorrhea resistance, emerging preventive interventions, such as doxycycline post-exposure prophylaxis, may need to be considered and universal use of higher doses of ceftriaxone for empiric treatment may become necessary.

## Authors' statement

ASK — Writing, original draft, writing, review & editing  
 AE — Formal analysis, visualization, writing, review & editing  
 JB — Writing, review & editing  
 KJ — Review & editing  
 AS — Review & editing  
 AZ — Review & editing  
 MH — Review & editing  
 HA — Review & editing

IM — Review & editing  
 SNP — Project administration, review & editing  
 VT — Project administration, supervision, writing, review & editing

## Competing interests

None.

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## Appendix

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# ZOONOSSES

## Research



### Prioritization of zoonoses for health professional knowledge building: focus on a collaborative approach

The prioritization project identified high priority zoonoses for knowledge building for health professionals in Canada in collaboration with **CEHPZCC**<sup>1</sup> and **PHAC**<sup>2</sup> experts in zoonoses and prioritization. These partners ensured that perspectives from diverse disciplines, covering multiple areas of practice and expertise were included throughout the project.

#### One Health lens

Collaborators were chosen mindfully with the goal of obtaining a One Health perspective.

#### Collaborators

**Disciplines**<sup>3</sup>: Nursing, Medicine, Veterinary Medicine, Epidemiology, Entomology

**Areas of practice and expertise**<sup>3</sup>: Family Medicine, Public Health, Paediatrics, Community Health, Infectious Disease, Travel Health, Indigenous Health

#### Modes of engagement

- 1 Collective discussion through a virtual meeting
- 2 Sub-working group with subject matter experts from the CEHPZCC to work on a specific project objective
- 3 Request and obtain feedback through consultation and survey
- 4 Inform collaborators of key project update

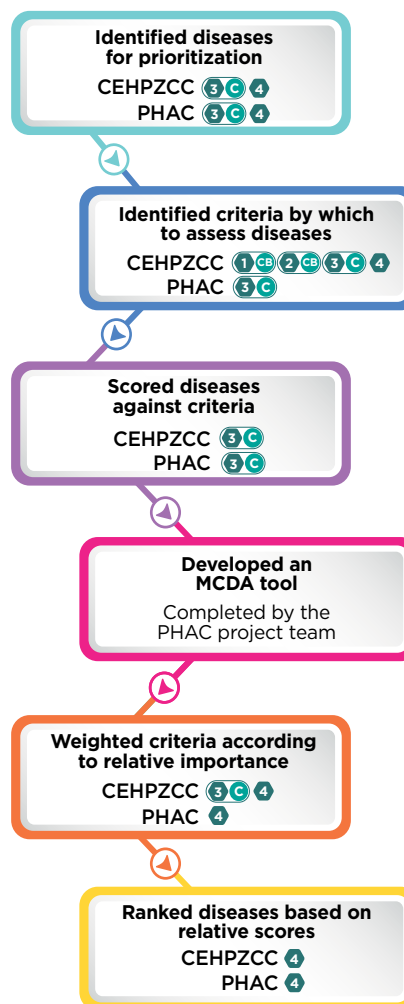
#### Decision-making model

- CB Consensus-based approach
- C Consolidation of input

#### Footnotes

1. Committee for the Education of Health Professionals on Zoonoses and Climate Change
2. Public Health Agency of Canada
3. This list is not exhaustive.
4. Method adapted from O'Brien, E. C., Taft, R., Geary, K., Ciotti, M., & Suk, J. E. (2016). Best practices in ranking communicable disease threats: a literature review, 2015. *Eurosurveillance*, 21(17). <https://doi.org/10.2807/1560-7917.es.2016.21.17.30212>

#### Multi-criteria decision analysis<sup>4</sup> (MCDA) process







# CCDR

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