






# BMJ Open *Ku-gaa-gii pimitizi-win*, the COVID-19 cohort study of people experiencing homelessness in Toronto, Canada: a study protocol

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## ABSTRACT

**Introduction** Initial reports suggest people experiencing homelessness (PEH) are at high risk for SARS-CoV-2 infection and associated morbidity and mortality. However, there have been few longitudinal evaluations of the spread and impact of COVID-19 among PEH. This study will estimate the prevalence and incidence of COVID-19 infections in a cohort of PEH followed prospectively in Toronto, Canada. It will also examine associations between individual-level and shelter-level characteristics with COVID-19 infection, adverse health outcomes related to infection and vaccination. Finally, the data will be used to develop and parameterise a mathematical model to characterise SARS-CoV-2 transmission dynamics, and the transmission impact of interventions serving PEH.

**Design, methods and analysis** *Ku-gaa-gii pimitizi-win* will follow a random sample of PEH from across Toronto (Canada) for 12 months. 736 participants were enrolled between June and September 2021, and will be followed up at 3-month intervals. At each interval, specimens (saliva, capillary blood) will be collected to determine active SARS-CoV-2 infection and serologic evidence of past infection and/or vaccination, and a detailed survey will gather self-reported information, including a detailed housing history. To examine the association between individual-level and shelter-level characteristics on COVID-19-related infection, adverse outcomes, and vaccination, shelter and healthcare administrative data will be linked to participant study data. Healthcare administrative data will also be used to examine long-term (up to 5 years) COVID-19-related outcomes among participants.

**Ethics and dissemination** Ethical approval was obtained from the Unity Health Toronto and University of Toronto Health Sciences Research Ethics Boards (# 20-272). *Ku-gaa-gii pimitizi-win* was designed in collaboration with community and service provider partners and people having lived experience of homelessness. Findings will be reported to groups supporting *Ku-gaa-gii pimitizi-win*, Indigenous and other community partners and service providers, funding bodies, public health agencies and all levels of government to inform policy and public health programs.

## STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ *Ku-gaa-gii pimitizi-win* is a large, randomly sampled cohort of people experiencing homelessness (PEH) followed over 12-months during the COVID-19 pandemic.
- ⇒ Key variables such as infection and vaccination are collected using multiple sources (self-report, saliva and serological testing, linkage with administrative data sources) to minimise vulnerability to biases stemming from self-reported data.
- ⇒ Because recruitment was not possible at most encampments or on the street, and individuals in these locations represent about 10% of PEH in Toronto, our sample closely approximates, but is not fully representative of, the homeless population in Toronto.
- ⇒ Cultural safety and Indigenous-specific ethics and protocols were incorporated into the study after data collection and were more reactionary than embedded.
- ⇒ As anti-SARS-CoV-2 antibodies decline over time, we may underestimate true prevalence of past SARS-CoV-2 infection in our cohort at baseline.

## BACKGROUND AND RATIONALE

More than 235 000 people experience homelessness in Canada every year.<sup>1</sup> Homelessness places people at high risk of contracting SARS-CoV-2,<sup>2</sup> as shared living spaces, crowding, difficulty achieving physical distancing and high population turnover typical of homeless shelters all promote transmission.<sup>3 4</sup> Moreover, people experiencing homelessness (PEH) have disproportionate intersecting physical, mental and social burdens that greatly increase morbidity and mortality relative to the general population,<sup>5-8</sup> including physical and mental health conditions

associated with adverse outcomes following COVID-19 infection.<sup>8–12</sup>

To date, most studies describing incidence or prevalence of COVID-19 among PEH have been cross-sectional in design, many focussing on a convenience sample of shelters during the first or second waves (from March to December 2020). As a result, estimates from these studies vary widely depending on setting, timing and preventive measures in place,<sup>13–25</sup> with variability primarily determined by whether the settings, in most cases emergency shelters, were experiencing an outbreak.<sup>13 15 16 19 26</sup> One study using a longitudinal design estimated 6% prevalence in summer 2020, increasing to 18.9% within 90 days (coinciding with the early part of the second wave).<sup>27</sup> Generally, PEH are more likely to be infected than a reference general population.<sup>28 29</sup>

Specific settings, including emergency shelters and those with overcrowding or communal sleeping arrangements, are associated with increased risk of infection, presumably due to greater exposure during outbreaks compared with PEH living outdoors or in private and/or well distanced accommodations.<sup>15–18 24–27</sup> In Wales, where PEH were comprehensively housed in private settings during the pandemic, COVID-19 prevalence was lower than in the general population.<sup>30</sup> Similarly, shelters implementing physical distancing practices have been shown to have lower infection rates.<sup>15</sup> Evidence for other individual-level or shelter-level factors associated with COVID-19 infection remains to be established, and effectiveness of most interventions remain to be evaluated.

Finally, the few studies to date that have investigated vaccine coverage among PEH report low coverage compared with the general population. US-based estimates place coverage among PEH 11.0%–37.2% lower than the general US population.<sup>31 32</sup> Another recent Canadian study suggests vaccination rates among Ontario PEH who use healthcare are 25% lower than that of adult Ontarians.<sup>33</sup>

This prospective cohort study has five broad objectives:

1. Determine the incidence and prevalence of COVID-19 infection, related complications and vaccination status among PEH in Toronto over a 12-month observation period.
2. Examine the association between housing history and individual-level and shelter-level characteristics (including shelter-level interventions) with incident COVID-19 infection among PEH over a 12-month observation period.
3. Investigate associations between individual-level and shelter-level characteristics and adverse outcomes among PEH diagnosed with COVID-19 over a 12-month observation period and over long-term follow-up (up to 5 years after recruitment).
4. Assess vaccination uptake among PEH and factors associated with vaccination.
5. Develop a novel transmission model for COVID-19 among PEH living in urban settings.

*Ku-gaa-gii pimitizi-win*, formerly known as the COVENANT study, has two associated studies not described in this protocol: (1) a genomics study aiming to evaluate the phylogenetics of SARS-CoV-2-positive samples among PEH in Toronto, to determine the utility of viral sequencing in outbreak assignment and (2) a qualitative study focusing on the pandemic experiences of PEH and drivers of vaccine uptake and hesitancy, to develop strategies to reduce barriers and improve confidence in vaccination and other protective strategies.

## METHODS AND ANALYSIS

### Design and setting

To guide this work, a spirit name was given to the study in ceremony by Elder Dylan Courchene from Anishnawbe Health Toronto. *Ku-gaa-gii pimitizi-win*, which translates in English to *life is always/forever moving*, reflects and honours the movement of homeless individuals across the land, the spirit and growth of the land we are on, and the force that connects us all to the future.

*Ku-gaa-gii pimitizi-win* is an ongoing prospective, longitudinal study being conducted between June 2021 and approximately December 2022 in Toronto, a city on Treaty 13 territory in Canada. Toronto is the country's largest city, and has the largest group of PEH in Canada.<sup>34</sup> A recent point-in-time count estimated 7347 PEH were in Toronto on a single night, with approximately 90% staying indoors (eg, at shelters) and 10% staying outdoors on the street or in encampments.<sup>35</sup> Approximately 15% self-identified as Indigenous.<sup>35</sup> In Toronto, numerous community and service organisations, such as Anishnawbe Health Toronto and the Inner City Health Associates, provide PEH with targeted health and social services. The Shelter, Support & Shelter, Support & Housing Administration (SSHA) Division manages housing and homelessness services across the city, and policies and strategies related to containment and mitigation of COVID-19, including testing and vaccination, are guided by public health authorities at provincial and regional levels.<sup>36</sup>

Throughout the pandemic, PEH have been identified as being at higher risk for infection and related complications.<sup>37</sup> As a result, they received priority testing status when diagnostic tests were limited and prioritisation for vaccination, and funding has been made available to establish physical distancing hotels.<sup>38 39</sup>

Data from Indigenous participants in this study are possessed and owned by Anishnawbe Health Toronto (AHT), a fully accredited health centre, which serves Indigenous clients with a model of care based on Indigenous culture and traditions using both western and traditional approaches. Research focused on Indigenous study participants will be led by AHT and Waakebiness-Bryce Institute for Indigenous Health.

### Eligibility criteria

To be eligible, participants had to be aged 16 years or older, experiencing homelessness at the time of recruitment,<sup>40</sup>

able to provide informed consent, willing to provide a finger-prick blood sample at baseline and each follow-up encounter, and to be contacted for follow-up encounters.

### Recruitment and consent

We obtained a representative sample of PEH living in emergency and provisionally sheltered settings using field-tested methods used successfully in two previous studies.<sup>41 42</sup> Recruitment, data collection and follow-up were conducted by the Survey Research Unit of the MAP Centre for Urban Health Solutions, which has extensive expertise in research involving PEH. Recruitment occurred from June 2021 to September 2021 at 61 physical distancing hotels and shelter sites for youth (16–24 years), adults and families experiencing homelessness in Toronto. Recruitment at major encampment sites was planned; however, because municipal authorities enforced a series of encampment clearances during the recruitment period,<sup>43–45</sup> only one encampment recruitment visit could be completed. Due to prohibitive logistical considerations, we were unable to recruit individuals living on the street.

A random number schedule was assigned to randomly select beds or rooms at each shelter or hotel site. Staff approached each potential participant from eligible beds/rooms to confirm study eligibility. Once confirmed, staff explained the purpose, process, risks and benefits of the study. Participants chose to participate by providing written informed consent (online supplemental file 1). For encampments, research staff worked with outreach workers to approach and invite encampment residents to participate. Due to the small number of encampment residents, all residents were approached and invited, if eligible.

Most potential participants were able to understand and participate fully in the consent process. Where doubts existed, an Additional Consent Measures Checklist (online supplemental file 2) was used to confirm understanding of key aspects of the letter of information and consent form. Additionally, we offered access to an on-the-spot interpretation service to prevent language barriers to participation.

Participants can withdraw from the study at any time. If a participant withdraws, research staff will cease further data collection, and will not recontact the participant. Because interim analyses will be performed throughout the follow-up period, participants are unable to retroactively withdraw data that have already been collected.

### Sample size

We used the exact Clopper-Pearson CI formula to calculate the sample size required to estimate a 95% CI with half width (precision) of 5% or less for the primary outcome (incidence of SARS-CoV-2 infection over 12 months). A sample size of 402 achieves this goal under incidence scenarios between 10% and 90%. Assuming a follow-up rate of 80% at the end of the 12-month period, the initial sample size required is 503. This sample size is further

inflated to account for participants with past infection at baseline who must be excluded from the calculation of incidence. Assuming 75% of participants are uninfected at baseline, the sample size required is  $503/0.75=670$ . Thus, we conservatively planned for a sample size of 700, achieved by sampling among a fraction (20%) of beds available at each participating site.

We recruited a total of 736 participants between June and September 2021.

### Promotion of continued participation

Longitudinal studies with PEH face special challenges with follow-up. To minimise attrition, we will be using methods effective in tracking and retaining study participants living in homeless or marginalised housing situations.<sup>46–50</sup> At each interval and during recruitment, interviewers endeavour to establish trust and rapport with participants. Participants will receive a \$C40 honorarium at each interview as compensation for their time. Participants will also be asked to provide detailed contact information as well as contact information of family, friends and other service providers who we may contact if research staff are unable to reach the participant. Finally, participants will be asked to call research staff at a toll-free study number between interviews to provide updates about contact information and location. Participants who do this will receive an additional \$C10 honorarium at the next follow-up encounter.

### Data collection

#### Baseline

At the time of recruitment, research staff conducted a 60–90 min baseline interview (online supplemental file 3). Telephone interpretation service was used as needed. The interview asked participants about their sociodemographic information (age, sex, gender identity, race, Indigenous identity, immigration/refugee status, education, weight, height and duration of current period of homelessness), health information, housing history, prior COVID-19 infection history, current COVID-19 symptoms, vaccination history and activities and behaviours related to COVID-19.

Participants also provided two self-collected saliva samples and one finger-prick blood sample at baseline. Saliva specimens for the detection of SARS-CoV-2 have been shown to be sensitive, safe and less invasive to obtain compared with nasopharyngeal specimens.<sup>51 52</sup> One saliva sample was obtained using the mouth swish-and-gargle technique.<sup>53</sup> The second saliva sample, used for parallel detection of antibodies against SARS-CoV-2, was collected using Salivette tubes, for which participants kept a swab in their cheek for 2 min or until the swab was saturated.<sup>51</sup> Approximately 250  $\mu$ L of capillary blood was collected into a plasma tube (BD365985). If collection of blood into a plasma tube was unsuccessful, blood was blotted onto filter paper (Whatman 903) as a dried blood spot.

**Table 1** Summary of intervals and associated domains and specific instruments/methods for data collected

Interval	Domain	Method/instrument	Purpose	
Baseline	Sociodemographics		To describe the participant	
	Health		To describe the participant	
	Prior COVID-19		To describe the participant	
	Activities and behaviours related to COVID-19		To describe the participant	
	Housing		To describe the participant	
	Biological samples		Saliva sample (Swish and gargle method)	Detection of current SARS-CoV-2 infection
			Saliva sample (Salivette tube method)	Detection of past antibodies against SARS-CoV-2
		Finger-prick capillary blood sample (500 µL) and/or dried blood spot	Detection of past antibodies against SARS-CoV-2	
Follow-up (3, 6, 9 and 12 months)	Health		To describe the participant since last interview	
	Prior COVID-19		To describe the participant since last interview	
	Activities and behaviours related to COVID-19		To describe the participant since last interview	
	Housing		To describe the participant	
	Biological samples		Saliva sample (Swish and gargle method)	Detection of current SARS-CoV-2 infection since last interview
			Finger-prick capillary blood sample (500 µL) and/or dried blood spot	Detection of past antibodies against SARS-CoV-2 since last interview

### Follow-up

Follow-up interviews will occur approximately every 3 months after the baseline interview, and must occur between 45 and 135 days after the previous interview. If this time window is missed, the interview will be skipped and participants will be contacted for the subsequent interview. If the research team cannot recontact the participant, they will contact the shelter programme where the participant is currently registered according to Shelter, Support & Housing Administration (SSHA) databases, or their last known location if not registered in the databases, to locate them.

Follow-up interviews will take approximately 30 min, and may take place at the site of recruitment, another shelter programme, or another location in the community convenient to the participant. One saliva sample (swish and gargle method) and one finger-prick blood sample will be acquired, and updated information regarding housing history, prior COVID-19, vaccination history and behaviours related to COVID-19 will be recorded.

Research staff will use personal protective equipment during all interviews, including face masks, face shields, gowns and gloves, and participants will be required to wear face masks during the interviews. Table 1 shows the full schedule of interviews and biological specimens collected each interval.

### Data recording and processing

Survey information will be entered onto tablets during the interview, removing the need for secondary data entry. An original copy of the data will be kept separate from a master copy, which will undergo quality control assessments by two research team members independently to

identify invalid or suspect data. Any inconsistent information will undergo further evaluation, and the team will collaboratively decide if and how to correct the master dataset. Decisions about corrections will be recorded.

Current COVID-19 infection will be determined by quantitative reverse transcription PCR (RT-qPCR) for SARS-CoV-2 in saliva. Samples will be processed in a clinical microbiology lab with standard methods.<sup>51,54</sup> Evidence of past COVID-19 infection and/or response to vaccination will be determined by ELISA for anti-SARS-CoV-2 IgG antibodies against the spike protein trimer, the spike protein receptor-binding domain, and the nucleocapsid antigen in capillary blood, or in dried blood spot samples obtained when capillary blood cannot be obtained. These assays are validated; details of the assays are reported elsewhere.<sup>55</sup>

### Linkage

Participants having provincial healthcare coverage will have their data linked to Ontario health administrative data holdings at ICES<sup>56</sup> (formerly known as the Institute for Clinical Evaluative Sciences) to access historical (up to 10 years back) and on going (up to 5 years forward) information on COVID-19 testing, health conditions relevant to COVID-19, emergency department visits, hospitalisations and deaths. This linkage will be accomplished using name, date of birth and health card number (a unique identifier permanently assigned to each individual covered by Ontario's single-payer universal health insurance system). ICES is an independent, not-for-profit research institute that hosts Ontario's health administrative data, and has provided extensive reporting related to COVID-19 in Ontario.<sup>57</sup>

In addition, aggregate shelter-level data and participant use of physical distancing hotels or shelter programmes in Toronto, as well as site-specific information (eg, gender mix, bed capacity, shelter layout, documented COVID-19 infections among residents and staff) will be obtained from the SSHA Division of the City of Toronto for 1 year prior to the start of recruitment, and up to 2 years following recruitment.

### Outcomes

The main outcomes of interest will be incidence of COVID-19 infection over 12 months, and prevalence of COVID-19 infection at 12-month follow-up. At each time point, incident infection will be defined as: (1) positive saliva PCR test in an individual without previously positive saliva PCR or blood serology tests or (2) positive blood serology test in an individual without previously positive serology. As certain antibodies are present with both vaccination and infection,<sup>58</sup> final infection and vaccination statuses will be adjudicated following a decision tree (online supplemental file 4), which uses biological sample results and self-reported infection and vaccination information.

Secondary outcomes of interest will include: (1) COVID-19 vaccination status, determined by self-report, serology tests or ICES confirmation in its provincial vaccination database (COVAXON) and (2) health complications arising from COVID-19 infection, as determined by self-report and health administrative databases at ICES, both over the shorter (within 1 year) and longer term (within 5 years).

### Statistical analyses

Unless otherwise indicated in the manuscript, we will estimate prevalence of past COVID-19 infection as the proportion of participants who had a positive PCR or adjudicated serology result at any point during the 12-month observation period.<sup>59</sup> Incidence will be calculated as incidence proportion (number of participants with incident COVID-19 infection during a time point divided by uninfected participants at baseline) and incidence rate (number of participants with incident COVID-19 infection during a time point divided by total person-months of observation) at all time points. Where infection date information is unavailable, it will be imputed assuming that new infections occur at a random time between the last negative and first positive PCR or adjudicated serology result available.<sup>60</sup>

To explore factors associated with infection incidence, we will fit Poisson regression models to estimate rate ratios and 95% CIs, or time-to-event models to estimate HRs and 95% CIs, as appropriate. Infection incidence will be the dependent variable, and individual-level and shelter-level characteristics will be independent variables (either summarised for the period or as time-varying covariates). To explore factors associated with adverse outcomes and vaccination status, we will construct logistic regression models to estimate ORs and 95% CIs for COVID-19 hospitalisation, COVID-19 intensive care unit admission, COVID-19 death and

COVID-19 vaccination, respectively. Housing state history and individual-level and shelter-level characteristics will be selected as covariates, as appropriate (either inferentially or where unadjusted associations are statistically significant).

Data may be missing for specific variables if participants decline to answer, or for entire intervals if participants are not found within the specific time frame for that interval. In these cases, we will perform multiple imputations, either for the main analysis or as sensitivity analyses as the situation dictates.<sup>61</sup> Individuals who cease participation or who die during follow-up may not be missing at random; as such, these individuals may be analysed separately if their model trajectories are found to differ substantially from the cohort as a whole.

For objective 5, we will simulate SARS-CoV-2 transmission using a modified, compartmental, Susceptible–Exposed–Infectious–Recovered mathematical model.<sup>62–64</sup> The model will include asymptomatic and presymptomatic states and strata for temporary housing, infection control, masking and vaccination. The network structure of the model will be specified as a patch (or meta-population) model, where shelters represent facility patches and surrounding neighbourhoods represent community patches. PEH, staff and volunteers will connect shelter patches. We will use *Ku-gaa-gii pimitizi-win* baseline COVID-19 prevalence with anonymised person-level characteristics (including contact rates and mixing (who contacts whom)), external COVID-19 surveillance data (person-level and outbreak data by shelter), shelter-level characteristics and data from the literature to parameterise and calibrate the transmission model.

We will use the transmission model to estimate SARS-CoV-2 incidence trends and the probability and size of future outbreaks and to conduct counterfactual modelling experiments. The latter will be used to evaluate the transmission impact of population-specific intervention strategies and programmes that were implemented in Toronto during the pandemic (such as physical distancing efforts at shelters and physical distancing hotels; COVID-19 isolation strategies; vaccination programmes; housing interventions; and to estimate the potential impact of future population-specific interventions and preparedness strategies focused on the needs of PEH).

Statistical analyses will be conducted using R, STATA and SAS Enterprise Guide v 7.1; the transmission model will be coded in R and C++. All statistical tests will be two sided and a p value of 0.05 or less will indicate statistical significance. Reporting will adhere to the Strengthening the Reporting of Observational Studies in Epidemiology guidelines<sup>65</sup>; transmission modelling reporting will follow the ISPOR Best Practices in Transmission Dynamics Modeling.<sup>66</sup>

### Study limitations

The *Ku-gaa-gii pimitizi-win* study has several limitations to consider. First, this study is being conducted in a single city (Toronto, Canada). Findings may not be generalisable to other settings with different policies, social or healthcare settings or contexts, or homeless populations with markedly different characteristics. Second, due to logistical

constraints, our study recruited no participants living on the street, and very few participants at encampments. The 2021 Street Needs Assessment indicates that, during a time of the year with moderate climatic conditions (spring), approximately 10% of PEH in Toronto were staying in settings not sampled.<sup>35</sup> Therefore, our sample will be close to, but not entirely representative of, the homeless population in Toronto. Third, many recent studies have found evidence that anti-SARS-CoV-2 antibodies decline over time.<sup>67–69</sup> This is an inherent limitation of all serological studies, and may lead us to underestimate the true SARS-CoV-2 prevalence in our cohort. Fourth, Indigenous ethics and protocols were incorporated into the study after data collection and were more reactionary than embedded. Ongoing research will include Indigenous community partnership as a framework for any Indigenous data sets.

Finally, and as with most other cohort studies, we rely on the collection of self-reported data from participants, which suffers from potential biases including social desirability and recall bias. We have, however, minimised the impact of these biases by also collecting key variables (eg, infection and vaccination) through saliva and blood samples, and will also cross-reference against information in health administrative data.

## ETHICS AND DISSEMINATION

### Ethics approval

The *Ku-gaa-gii pimitizi-win* study has been approved by the Unity Health Toronto Research Ethics Board (REB # 20-272). All changes to the protocol will be communicated to and receive approval from the REB before implementation. COVID-19 infection events will be obtained for modelling from the Case and Contact Management database made available from the Ontario Ministry of Health and Ontario COVID-19 Modelling Consensus Table, with approval from the University of Toronto Health Sciences REB. Ethical approval from the community partner (AHT) will be incorporated in an ongoing manner and they will continue to be consulted through the life of the project.

### Participant safety

The main benefit to participants will be detection of active COVID-19 infection through RT-qPCR testing. Because the saliva test used in this study is not currently approved for clinical use, participants cannot be formally diagnosed with COVID-19 unless they subsequently undergo confirmatory testing. Until January 2022, we attempted to contact participants who had positive test results to assist with referral and transportation to a COVID-19 assessment centre for confirmatory testing. Beginning in January 2022, when confirmatory testing was no longer advised by provincial guidelines, we will continue to notify Toronto Public Health of positive test results and contact participants who test positive to ask them to self-isolate following their shelter or residence's usual procedure.

The main risk to participants will be the possibility that some may find certain interview questions challenging or uncomfortable. To mitigate this risk, the interview guide

was pilot tested with several people having lived experience of homelessness and reviewed by partners at AHT before recruitment. Participants will also be told they may choose to not answer specific questions or stop the interview at any time. Also, cultural safety was identified as a potential issue for participants subsequent to data collection and has since been addressed by the incorporation of culturally safe Indigenous researchers to the research team.

A second, minor risk for participants will be the transient pain or discomfort caused by finger-prick blood sampling at each encounter.

### Dissemination

With the help of the Canadian Alliance to End Homelessness, we will disseminate interim and final results through brief reports, presentations and meetings to our extensive network of researchers, clinicians, public health professionals, and community and political leaders in cities across North America. The transmission model code from objective 5 will also be shared as open-access code and thus comprise a tool for future use in Toronto, and for adaptation in other settings.

Anishnawbe Health will lead the dissemination plan for Indigenous data and results to ensure the minimisation of harm and to maximise benefits for Indigenous peoples.

### Data protection and retention

The research team will make every effort to keep data confidential in accordance with all current local and provincial privacy legislation. Indigenous data will be possessed and owned by AHT according to OCAP principles.<sup>70</sup> Information and biological samples will only be linkable through a unique study identifier. Personally identifying information will be stored in a Master Linking Log, which will only be used by designated team members to contact participants and for administrative data linkage with participant consent. Contact information will be stored separately in a password-protected database. All study data will be stored at St. Michael's Hospital on a secure and password-protected computer server. Saliva samples for RT-qPCR, blood samples for ELISA and salivettes will be stored at Mount Sinai Hospital and the University of Toronto.

All study information and samples will be kept for a period of at least 10 years from the end of the study and then destroyed.

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**Contributors** SHW conceived of the study. SHW, RN, ML, SM, A-CG, JLG and SB assisted with study design. RN, ML, CP, OS and JH designed the survey instrument. CP, OS, RS, JH, RN and LR helped with data collection and/or processing. RN and LR provided statistical expertise and LR is writing the statistical analysis plans, conducted the primary statistical analyses and drafting study manuscripts. SM and SB designed and are leading the transmission modelling. All authors contributed to refinement of the study protocol. LR drafted the manuscript, and all authors reviewed and approved the final manuscript.

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**Patient and public involvement** Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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