

Study Protocol of the COVID-HIV Evaluation of Serology and Health Services (CHES) Study

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Background




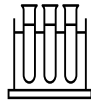

There are concerns that people living with HIV (PLWH) may experience more adverse impacts than the general public from circulating SARS-CoV-2, the virus that causes COVID-19, and pandemic restrictions on health care¹. To date, studies evaluating the impact of the pandemic on PLWH have reported conflicting results²⁻⁵ and significant knowledge gaps remain, especially within the Canadian context. Here, **we describe the design of the CHES Study** that will assess the burden of COVID-19 among people living with HIV in Ontario.

CHES Study Aims

- AIM 1:** To estimate **SARS-CoV-2 sero-prevalence** among people living with HIV (PLWH) in Ontario
- AIM 2:** Using administrative health data linkages:
- ❖ To measure rates of and identify risk factors for **COVID-19 testing, diagnosis and COVID-19-related outcomes** among PLWH compared to HIV-negative individuals
 - ❖ To estimate **vaccine effectiveness** against laboratory-confirmed infection with SARS-CoV-2
 - ❖ To assess the impact of the pandemic on **HIV care engagement**

References
¹Shiau et al, 2020; ²Tesoriero et al, 2021; ³D'Souza et al, 2020; ⁴Ho et al, 2020; ⁵Xu et al, 2020; ⁶Rourke et al, 2013.

AIM 1 Methods

Participant Recruitment	Study Procedures	Analysis	Progress to Date
 Up to 1,000 active participants of the Ontario HIV Treatment Network Cohort Study (OCS) ⁶ , an established clinical cohort, will be invited to participate in the CHES study.	 1) Brief COVID-19 Questionnaire Questions include: COVID-19 symptoms, testing, diagnosis, and vaccine history. Completed via online or paper-based survey.  2) Dried Blood Spot (DBS) Sample Self-collected, one-time DBS sample collected using at-home collection kits for SARS-CoV-2 serology.	 Enzyme-linked immunoassays (ELISAs) will be used to screen DBS for seropositivity based on IgG, IgM and IgA antibody levels for 3 viral antigens: Spike (S) protein, the receptor binding domain (RBD) of the S1 domain of the S protein, viral nucleoprotein (N). Neutralizing assays, which measure the ability of antibodies to block virus infection, will be performed on seropositive samples.	Participant recruitment began in February 2022 at St-Michael's Hospital, Unity Health Toronto (expanding to 9 Ontario sites by summer 2022)  38 participants have consented to participate to date

AIM 2 Methods

Data Source: Health administrative databases at ICES. Analyses will be conducted using three cohorts:

- The linked OCS cohort of individuals aged ≥16 years living with HIV in Ontario. All OCS participants have consented to linkage of their data at ICES. (~4,300 PLWH)
- A validated, ICES-derived HIV cohort representing all adults aged ≥19 years living with HIV in Ontario who access health services (~21,000 PLWH)
- A matched cohort of HIV-negative individuals

Outcomes: We will ascertain COVID-19-related outcomes (vaccine uptake, testing, diagnosis, hospitalization, ICU admission, mortality) and changes in health service utilization including HIV care engagement prior to and during the pandemic.

Significance and Impact

The COVID-19 pandemic remains a constantly evolving public health emergency. Results will provide reliable, efficient, and comprehensive information on the burden of COVID-19 among people living with HIV in Ontario. Findings will fill a knowledge gap in immunocompromised populations that can inform health policy, health services planning, immunization and clinical guidelines for PLWH.



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