


BMJ Open Assessing the impact of COVID-19 pandemic on the health of residents and the healthcare system in Alberta, Canada: an observational study – The Alberta POST-COVID Follow-up Study

Xueyi Chen ^{1,2}, Jeffrey Bakal,^{2,3} Tara Whitten,^{2,3} Barbara Waldie,² Chester Ho,^{2,3} Paul Wright,² Shahin Hassam,² Colleen Norris^{1,2}

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¹Faculty of Nursing, University of Alberta, Edmonton, Alberta, Canada

²Alberta Health Services, Edmonton, Alberta, Canada

³University of Alberta Faculty of Medicine & Dentistry, Edmonton, Alberta, Canada

Correspondence to

Colleen Norris;
cnorris@ualberta.ca

ABSTRACT

Introduction Very little is known about how the COVID-19 pandemic has affected the health of residents and the healthcare system in Alberta, Canada. The purpose of this study is to establish an observational study to characterise the health of residents in Alberta, Canada, over time, covering a population that tested negative or positive for COVID-19 during the pandemic. The primary outcome is to characterise ‘long COVID-19’ and the health status of residents during the COVID-19 pandemic. Secondary outcomes include the estimation of the risk of and risk factors associated with adverse health outcomes and healthcare utilisation and burdens.

Methods and analysis This is a population-level provincial observational study which will follow-up with Alberta residents who underwent testing for COVID-19 and completed surveys adapted from the ISARIC COVID-19 long-term follow-up survey. The survey data will be linked with medical records. Statistical analyses will be carried out to characterise ‘long COVID-19’ and the health status of residents during the pandemic. The outcomes of this study will inform strategies for primary care and rehabilitation services to prevent chronic consequences; contribute to healthcare management, interventional studies, rehabilitation and health management to reduce overall morbidity and improve long-term outcomes of COVID-19 and the COVID-19 pandemic and potentially guide a self-evaluation of a remote monitoring system to manage individuals’ health.

Ethics and dissemination This study was reviewed and approved by the University of Alberta ethics committee (Study ID: Pro00112053 & Pro00113039) on 13 August 2021 and adheres to the Alberta Health Services research information management policy. Study results will be used to manage clinical care, published in peer-reviewed journals and presented at local, national and international conferences.

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INTRODUCTION

Infection of SARS-CoV-2, COVID-19 has caused significant morbidity and mortality

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ The study surveys adult people across Alberta, Canada during the COVID-19 pandemic using standardised, comprehensive survey tools, providing a population-based view of the effect of the pandemic on adults in Alberta as well as the Alberta health systems.
- ⇒ The sampling frame includes those who tested negative for COVID-19, which will allow isolation of the outcomes arising from the COVID-19 illness and other societal changes during the COVID-19 pandemic.
- ⇒ The linkage between the patient-reported survey data and the clinical data will enable us to examine relationships and evaluate the health outcomes for people accounting for pre-morbid conditions.
- ⇒ A possible limitation is the potential for self-selection bias and low response rates in selected demographic groups.
- ⇒ Incorporating participants with antigen home tests with those who had nucleic acid tests may result in a potential rise in the rate of false positives and false negatives.

at an unexpected scale internationally.¹ Despite global efforts to contain the infection with preventive measures and the success of rapid vaccine development, the COVID-19 pandemic has continued to have a significant impact on society and the healthcare system.^{2 3} It has been established that COVID-19 can result in a multiorgan disease with a wide spectrum of disparate clinical manifestations, ranging from completely asymptomatic infection to a cluster of pneumonia, multiorgan failure and death, which is associated with direct SARS-CoV-2 attacks and indirect systemic inflammatory responses in multiorgan tissues such as the lung, the heart, kidneys, eyes and endothelium.⁴ Even after

recovering from the acute COVID-19 infection, growing reports have suggested residual effects of COVID-19, termed 'long COVID-19', on both the non-hospitalised and hospitalised COVID-19 survivors.^{5 6} Defined by the United Kingdom National Institute for Health and Care Excellence in December 2020 as the persistence of symptoms beyond 4 weeks following acute COVID-19 infection, 'long COVID-19' has affected 43% to 80% of COVID-19 survivors and involved multiple organ systems, displaying symptoms such as headache, chest pain, fatigue and muscle pain.⁷⁻⁹ However, without a universally accepted definition for 'long COVID-19', ongoing studies may struggle to provide a complete picture.¹⁰ Characterising the multidisciplinary sequelae and complications of 'long COVID-19' is critical for patient management.

Moreover, many healthcare systems and governments imposed a wide range of preventative measures to contain the rapid spread of the virus during the COVID-19 pandemic, which included quarantine, contact tracing and isolation, school closure, adjusting working conditions, curfews and lockdowns. The COVID-19 pandemic context, compounded with the public health measures and the increased numbers of SARS-CoV-2 infections and fatalities, has shown an association with psychological disorders including depression, anxiety and sleeping disorders, disproportionately affecting women and people with low sociodemographic conditions.^{11 12} The societal changes during the COVID-19 pandemic have led to financial issues, lifestyle disruption and emotional and psychosocial distress.¹³ Increasing evidence has highlighted the negative impacts of the pandemic on lifestyle, mental and physical health.¹⁴⁻¹⁶ However, as current literature highlighted the effect of the early pandemic on population health, a comprehensive understanding of the impacts of the prolonged pandemic on physical and psychological health is essential.

While efforts have been made to better understand 'long COVID-19' and the influences of the COVID-19 pandemic on population health, many questions remain. First, the association between SARS-CoV-2 infection and 'long COVID-19' needs further investigation as much 'long COVID-19' research used no control groups, and the widely reported 'long COVID-19' symptoms, such as fatigue and sleep problems, are also commonly reported by the general population in the context of the pandemic.^{8 17} Second, while substantial efforts have focused on the emerging health needs and evaluated the public health measures during the acute phase of the pandemic,¹⁸ further studies are needed to assess the health needs and analyse the burden associated with 'living with COVID-19' and adverse health outcomes related to the pandemic in the near postpandemic phase. Furthermore, there is a need to comprehensively explore how 'long COVID-19' and societal changes during the pandemic have challenged specific vulnerable population groups: patients with specific pre-existing health conditions, ethnic minority people, people with socioeconomic deprivation and elderly people.

Early in the pandemic, we set out to create the Alberta POST-COVID Follow-up Study. The primary outcome is to characterise 'long COVID-19' and the health of residents during the COVID-19 pandemic, assessing the physical and psychosocial consequences over time of both those who contracted COVID-19 and those who did not in the Alberta population. Secondary outcomes include the estimation of the risk of and risk factors for adverse health outcomes and the healthcare utilisation and burdens associated with the adverse outcomes. The study's results not only apprise strategies to prevent long-term consequences associated with the pandemic but also inform clinical management and rehabilitation to better care for the population, and estimate the social economic cost related to the long-term consequences.

METHODS

This is an observational study which was reviewed and approved by the University of Alberta ethics committee (Study ID: Pro00112053 & Pro00113039) on 13 August 2021 and adhered to the Alberta Health Services research information management policy. The use of EQ-5D-5L in this study has been registered with EuroQol (EuroQol ID: 161015). Interim and final study results will be published in peer-reviewed journals and presented at local, national and international conferences.

Study design and population

Alberta residents aged 18 years and older, with a COVID-19 test, who are at least 28 days post-COVID-19 testing, and who consent to participate are eligible for the study. Anyone who fits the inclusion criteria, including the elderly, pregnant women, long-term care home residents and homeless population, is encouraged to participate. Participation is voluntary. Aiming to follow-up with participants serially over time for health condition changes, we will ask the participants who agreed to further follow-up studies to complete the survey again after 3–6 months.

Recruitment strategies

We intend to recruit as many participants as possible with an expectation of 9500 participants between September 2021 and May 2023. Three recruitment strategies will be used to maximise the sample size and to cover diverse population groups: (1) the targeted mail-out strategy, (2) a public campaign and (3) a senior outreach programme.

In the targeted mail-out strategy, eligible study subjects who received a COVID-19 PCR/nucleic acid test between 1 March 2020 and 31 May 2022 are not living in Long Term Care (LTC)/Designative Support Living (DSL) facilities and have a valid residential address, they will be mailed an invitation letter. Specifically, 80 000 letters of invitation will be sent to residents with a positive COVID-19 test, and 20 000 letters will be sent to individuals who tested negative for COVID-19 and did not have a subsequent positive test on record. The invitation letter contains study information and instructions on how to participate.

Participants interested in the study can either complete the survey online or call the toll-free phone number to access the interactive voice response (IVR) survey service. The later survey mode provides an opportunity for individuals without access to the internet to respond vocally to survey questions through a prerecorded automated phone survey.

A public campaign will be launched to invite eligible individuals to complete the survey online. A study poster with the survey link will be created and shared in local meetings and via emails. In addition, the online survey link will be posted on websites, social media and news media. Sufficient study information will be given and consent to participate is required at the beginning of the survey. With consent, we will then be able to link the data from the public survey responses to confirm testing dates and other components of their healthcare utilisation.

Finally, to efficiently make this study project accessible to the LTC/DSL residents who suffered considerably from COVID-19 and the restrictions implemented during the pandemic, a senior outreach programme will be carried out to distribute the study information to the residents of assisted living and LTC facilities and their family members. Specifically, invitation letters will be sent to residents living in LTC/DSL facilities across Alberta, inviting them to participate in the online survey. In addition, communications and meetings with the LTC/DSL facility operators will take place for assistance in participant recruitment. With LTC/DSL facility operators'

support, the study information will be shared with the LTC/DSL residents' families, gaining support from residents' family members.

Survey data collection and entry

The positive and negative surveys have been adapted from the ISARIC COVID-19 long-term follow-up survey, which is a standardised, international, prospective, observational study aiming to assess the risk of and risk factors for long COVID-19.¹⁹ The original survey tools of the ISARIC-developed COVID-19 follow-up study are available on isaric.org website.

Two participation methods have been developed—the online survey and an IVR survey. The surveys are anonymous to maintain the privacy of the participants. The customised online survey tool will be managed by professional web developers and housed on a University of Alberta server (figure 1). The online surveys are available in English and French. Individuals responding to the targeted mail-out strategy will take part in the survey using an assigned File Number enclosed in the invitation letter, while participants from other recruitment strategies will be directed to the REDCap consent platform to provide study consent before accessing the survey. All participants will be asked to provide their COVID-19 test information to be appropriately directed to the negative or the positive survey.

Targeted mail-out participants also have the option to participate in the study via an IVR platform developed by

AHS/SCN Adapted ISARIC Tool English ▾

1. About you and your COVID-19 illness

Have you been vaccinated against influenza within the last 12 months?
 Yes No Not sure

Have you had a pneumococcal vaccination within the last 5 years?
 Yes No Not sure

Have you been vaccinated against COVID-19?
 Yes No Not sure

Roughly what day did you first experience symptoms like COVID-19?

Were you admitted to hospital due to COVID-19?
 Yes No

If ever admitted to a hospital / health facility for COVID-19, were you admitted to intensive care (ICU/ITU)?
 Yes No Not sure

Go Back Pause Reset Save and Continue

Figure 1 Online survey form displaying the first question for COVID-19-positive participants. AHS, Alberta Health Services; SCN, Strategic Clinical Networks; ICU, Intensive Care Unit; ITU, Intensive Therapy Units.

Ivrrnet. Using artificial intelligence-driven technologies, the IVR systems understand human speech and automatically convert participants' responses to the text. This technology allows participants to complete the survey vocally without pressing any buttons on the phone keypads and eliminates the need for a live interviewer. This survey method will be more inclusive of individuals with lower literacy levels, without access to the internet and/or with visual impairment.

The surveys are designed to enable self-completion. Using the COVID-19 test date as an index date, the surveys will assess participants' health conditions before and after the index date. Moreover, using a 6-point Likert scaling system, the negative survey also inquires about participants' belief in having had COVID-19 despite the negative test result, while the positive survey assesses their recovery status following the COVID-19 illness. Both surveys collect a wide range of data on initial illness and subsequent COVID-19 test information, vaccinations, hospitalisation and readmissions, specific post-COVID-19 test morbidities, recent febrile illness, new or persistent symptoms, quality of life measured by EQ-5D-5L, dyspnoea through Medical Research Council (MRC) dyspnoea scale, difficulties in functioning by Washington disability score, lifestyle changes, demographics and socioeconomic data.

An electronic form of survey data will be stored in the REDCap platform, which provides a secure environment to store highly sensitive data.²⁰

Linking with medical records

Participants will be asked on the REDCap consent platform for permission to link the survey records with their medical records. With participants' consent and the use of a unique identifier, the personal health number, the collected survey data will be linked with Alberta health-care databases such as the Physician Billing Claims, the Discharge Abstract Database, the National Ambulatory Care Reporting System, Pharmaceutical Information Network and the provincial registry/vital statistics. The module will collect data on demographics, hospital stay and readmissions, comorbidities and previous diagnosis and clinical presentation and diagnosis during the study periods. The participants' comorbidities will be considered as present using a cut-off of 2 years prior to the time of the COVID-19 positive/negative test.

We will also look at the association of dissemination area (DA)-level socioeconomic factors in the study. Using the Pampalon deprivation index, we will assign material and social deprivation scores to each person in the cohort. The validated index assigns quintiles ranging from Q1 to Q5 representing least deprived (Q1) to most deprived (Q5) DAs, respectively. Participants' postal codes will be used to link the DA with the material and social deprivation score obtained from the 2016 Pampalon Deprivation Index database.

The date of the COVID-19 positive/negative swab will be used as the index date for all linkages as well as the creation of a time from COVID variable that will

be calculated based on the time from positive/negative testing to survey completion. This will allow the examination of the association between time from COVID-19 testing to reported post-COVID symptoms/clinical manifestations of outcomes.

Analysis plan

Health outcomes will be compared between groups: (1) the COVID-19-negative participants and the COVID-19-positive individuals, (2) COVID-19 waves in Alberta according to the timing of the COVID-19 test result (wave 1: March 2020 to October 2020; wave 2: November 2020 to January 2021; wave 3: February 2021 to June 2021; wave 4: July 2021 to November 2021; wave 5: December 2021 to April 2022), (3) the seniors dwelling in the communities and the LTC/DSL residents, (4) important demographic and other groups (such as age categories, sex, ethnicity, socioeconomic deprivation, comorbidities, self-belief in having had COVID-19 and the recovery status from the COVID-19 disease, specific exposures such as cancer and heart failure, COVID-19 severity and hospitalisation). As the study progresses, new questions outside this protocol may arise. Where this occurs, analysis plans will be developed prior to undertaking analyses.

Collected data will be summarised using simple summary statistics. First, the baseline characteristics of the participants recruited by the mailing strategy will be compared with the non-respondents. Second, the crude prevalence of health outcomes will be calculated for groups of participants, and differences in baseline characteristics and outcomes between groups will be explored. In addition, the COVID test date will be used as the index date to examine time-to-event outcomes.

Statistical models will be used to analyse the association between COVID-19 infection and health outcomes. Specifically, logistic regressions will be used for binary outcomes. For all-cause mortality, Cox proportional hazard model will be used. Non-death time-to-event outcomes will be examined using competing risk analysis. All aforementioned models will be adjusted for baseline characteristics, including age, sex, educational level, occupation, comorbidity, etc. We will estimate the risks and burdens of health outcomes across the study groups. Several subgroup analyses will be performed by participants' age, ethnicity, sex and specific comorbidity.

$p < 0.05$ will be considered statistically significance. The analysis will be conducted in R (R Foundation for Statistical Computing, Vienna, Austria) or SAS Enterprise Guide (SAS Institute).

Patient and public involvement

This protocol and the surveys have been presented to Alberta residents living under the COVID-19 pandemic, including patients with 'long COVID-19' and from diverse groups. The feedback was incorporated into the final version, which included suggestions on survey questions and dissemination plans of the study information.

Data protection and sharing

Data protection regulations will be coordinated with the University of Alberta ethics committee, Alberta Health Services and Alberta Health. Data containing identifiable information will not be shared due to the privacy of the participants and ethical reasons. These data will be accessible only to personnel involved in the research project. In line with the university policy for storing research data, electronic copies of the data will be encrypted and stored on a password-protected computer within the University of Alberta for a minimum of 5 years.

The deidentified data can be shared on a reasonable and formal request to the corresponding author with ethical approval obtained and following Alberta Health and Alberta Health Services guidelines. This data set can be used to identify subsets of patients experiencing specific symptomatology or syndromes for specific studies. Moreover, it can be used in combination with biological sampling, radiologic studies and other medical examinations for immunology, pathophysiology or other studies.

DISCUSSION

The Alberta POST-COVID Follow-up Study aims to collect quality data for analyses to inform health policy and to benefit patient care, which will contribute to increasing knowledge on 'long COVID-19' and the COVID-19 pandemic-associated effects in the Alberta population. This includes, for example, identifying the prevalence of 'long COVID-19', evaluating the health status and health problems experienced by Alberta residents during the pandemic, characterising the frequency of and risk factors for long-term sequelae in the Alberta Population and assessing how 'long COVID-19' and the pandemic affect specific population groups including women and elderly people. We expect that the outcomes of the study will inform strategies to use rehabilitation resources to prevent chronic consequences; contribute to clinical management, interventional studies, rehabilitation and health management to reduce overall morbidity and improve long-term outcomes of COVID-19 and the COVID-19 pandemic and potentially guide a self-evaluation of a remote monitoring system to manage individuals' health. By studying the impact of the COVID-19 pandemic on the seniors living in congregate care facilities, the study will also contribute to guiding the best strategies to prevent COVID-19-associated and COVID-19 pandemic-associated adverse outcomes in congregate care facilities.

The strengths of this project are first, the adaptation of the standardised protocol developed by ISARIC enables the standardised collection of high-quality data in a globally harmonised manner.¹⁹ The study contributes to the international collaboration on understanding many angles and perspectives of COVID-19 and the COVID-19 pandemic. Second, our study links different health data sets with individual survey responses. Prior studies have highlighted significant limitations in the

acquisition of health information from either health surveys or electronic health records alone.^{21–23} By linking survey and health record data, we can carry out comprehensive analyses of the overall research objectives. Third, a combination of different recruitment methods and a mixed survey mode in the study maximise the efficiency of representative population sampling and may mitigate some limitations of using a single strategy. Detailed evidence supports the adoption of comprehensive recruitment strategies to succeed in efficiently recruiting people from diverse sociodemographic backgrounds.^{24–26} Finally, by recruiting residents who tested negative or positive for COVID-19, the collected data have great potential to answer multiple research questions, increasing our understanding of post-COVID-19 illness and post-COVID-19 pandemic effects.

The Alberta POST-COVID Follow-up Study will provide original information on (1) the impact of the COVID-19 pandemic on emotional, functional and physical health; (2) the new or persistent physical and psychological symptoms following SARS-CoV-2 infection ('long COVID-19') and (3) effects on the health status of people with sociodemographic diversity.

First, the study will help better understand the impact of the COVID-19 pandemic on Alberta residents' health and identify the risk factors associated with the self-report and clinical presentation and outcomes. The growing stress levels and behavioural health issues (eg, mental health, substance use conditions, physical activity and diet) associated with the pandemic have increased concern about developing adverse health outcomes.^{27–29} As the pandemic has tightened the link between lifestyle, mental health and physical health,^{15 30–32} a rigorous, evidence-based approach to identify the needs and to access the risk factors for the health changes is critical for the population's health and well-being.

With regards to the evaluation of 'long COVID-19' in Alberta, the Alberta POST-COVID Follow-up Study will systematically characterise the physical and psychological conditions experienced by COVID-19 survivors compared with those who tested negative for COVID-19. As most of the available studies did not include a control group and reported widely varying prevalence levels,⁸ the symptoms and signs of 'long COVID-19' require further investigation. Some of the identified symptoms were similar to the symptomatology of adverse mental health outcomes including stress, anxiety, depression and post-traumatic stress disorder developed during an unprecedented challenge such as negative life events, pandemics and epidemics.^{8 33–35} Moreover, the study will recognise factors heralding 'long COVID-19' development and a more severe disease progression as the reason why some patients experience the long-term symptoms is still unknown. Studies on cancer patients have shown the negative impact of antitumour therapy and surgery on COVID-19 disease outcomes.³⁶ An internationally online survey study found that physical or mental activity might trigger 'long COVID-19' relapses.³⁷ Further studies



on such variables will guide better decisions on disease management.

Finally, this project will assess how the impacts of the pandemic and COVID-19 are different across different population groups. The sex differences underlying post-acute COVID-19 outcomes and behaviour changes responding to the COVID-19 pandemic have been reported, but conflicting results exist.^{38–41} Moreover, ‘long COVID-19’ has been reported to have a negative association with COVID-19 severity, age and deprivation, while vaccination has demonstrated some protection on symptom presentation.^{42–44} In addition, the SARS-CoV-2 infection and the COVID-19 pandemic took a heavy toll on older adults physically and mentally.^{45–49} The uniqueness and transient nature of the LTC/DSL residents warrants a thorough assessment of their health conditions and the ‘long COVID-19’ situation. Containing a diverse population, Alberta needs a throughout study to better prepare the health system combating the aftermath of the COVID-19 pandemic.

This study has several limitations. First, despite the use of a mixed-mode approach and multiple recruitment methods, the participants who agreed to take part may not completely represent the sociodemographic distributions of the population of interest. Second, as with any survey data, response bias and social desirability bias may cause concerns despite the option of taking the survey anonymously. Third, with the wide distribution of the rapid antigen home test kits, participants who tested for COVID-19 with antigen home tests are eligible to participate, which may result in a potential rise in the rate of false positives and false negatives. Finally, the study variables are selected based on available resources during the early phase of the COVID-19 pandemic, and, therefore, there is the possibility that essential outcomes are not reported despite open-ended options for question responses being included.

The results of the Alberta POST-COVID Follow-up Study will provide important insights not just for clinicians but also for healthcare systems and societies, contributing to the development of new evidence-based approaches to prevent and manage the adverse health outcomes associated with the COVID-19 pandemic and following the recovery of the acute COVID-19 disease. Evidence emerging from the study will inform the clinical management of ‘long COVID-19’ and the growing healthcare needs of individuals in the postpandemic stage by guiding the allocation of healthcare resources and possibly informing the development of remote health monitoring systems. Despite the thought that the end of the COVID-19 pandemic is near,⁵⁰ information and possible solutions from the study will go beyond and will increase the readiness of the healthcare systems to cope with likely future crises without disrupting basic healthcare needs.

Ethics and dissemination

This study was reviewed and approved by the University of Alberta ethics committee (Study ID: Pro00112053

& Pro00113039) on 13 August 2021 and adheres to the Alberta Health Services research information management policy. Study results will be used to manage clinical care, published in peer-reviewed journals and presented at local, national and international conferences.

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Contributors XC, CN, JB and CH lead the development of the follow-up protocol and tools (surveys, consent forms, study information sheet, and study invitation letters) in collaboration with TW, BW, PW and SH. JB, XC and TW developed the statistical analysis plan and data element list. XC and BW managed the consent data set up on REDCap and individual websites set up. XC, CN and JB lead on drafting the protocol and manuscript, with contributions from CH, TW, BW, PW and SH. All authors reviewed and approved the final manuscript.

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Competing interests None declared.

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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ORCID iD

Xueyi Chen <http://orcid.org/0000-0001-9869-6701>

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