Vaccine Registry PROTOCOL

Canadian COVID-19 Vaccine Registry for Pregnant & Lactating Individuals (COVERED): An Evaluation of Safety, Effectiveness & Acceptability

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SUMMARY

Title	Canadian COVID-19 Vaccine Registry for Pregnant & Lactating Individuals (COVERED): An Evaluation of Safety, Effectiveness & Acceptability
Goal	Provide a national registry of unvaccinated and vaccinated pregnant and lactating individuals who will be followed to determine data on safety for any of the vaccine types and how well they protect against COVID-19.
Objectives	Primary objectives: 1. To assess the safety of COVID-19 vaccines in pregnant and lactating individuals 2. To describe the effectiveness of COVID-19 vaccines in pregnant and lactating individuals 3. To examine attitudes towards COVID-19 vaccination, and other vaccines, including RSV, among pregnant and lactating individuals 4. To examine the immunogenicity of COVID-19 vaccines within a subset of pregnant individuals and for their infants 5. To assess attitudes and the impact of co-administration of the COVID-19 vaccine with other regular vaccinations, such as the influenza vaccine, among pregnant and lactating individuals
Timeline	May 2021--March 2024
Project design	Prospective Cohort
Inclusion criteria	(1) At least 19 years of age (2) Became pregnant in 2023
Data collection and time points	• Baseline survey administered at start of enrollment • 2 time-based follow up surveys administered: December 1st 2023 and February 1st 2024 • Reminders to follow up surveys will be sent out periodically throughout study duration
Data collection and timepoints for immune sub-study	• Access to previously collected antenatal samples • Maternal/gestational parent blood samples will be collected four weeks to up to one day before vaccination, four weeks after vaccination, 12 weeks after vaccination, delivery +/- 2 days, and 4-6 weeks after delivery. • Umbilical Cord blood samples at delivery and infant blood samples and breast milk at 4-6 weeks post delivery

1.0 BACKGROUND

1.1 Epidemiology of SARS-CoV-2

In December 2019, a novel coronavirus, eventually termed Severe Acute Respiratory Syndrome associated Coronavirus-2 (SARS-CoV-2), was identified in Wuhan, China. On March 11, 2020, the WHO declared Coronavirus Disease 19 (COVID-19), the respiratory illness caused by SARS-CoV-2 infection, an official global pandemic. As of April 19, 2021, globally, SARS-CoV-2 has infected >141,000,000 people and caused over 3,000,000 deaths (1). As of April 19, 2021, Canada has 1,131,773 confirmed cases and 23,667 deaths, with cases occurring in individuals returning from international travel or their close contacts and via extensive community spread (2).

Pregnant women and individuals are a key population for COVID-19 prevention due to increased risk of hospitalization and ICU admission (3-5). Rapid evaluation of COVID-19 vaccination in this population is therefore imperative. Building upon the established national expert network CANCOVID-Preg, our team is well positioned to conduct vaccine evaluation in this important population.

1.2 Study Rationale

There have been no formal trials of approved or candidate vaccines in pregnancy to date and as such, there will not be adequate data in pregnancy, and particularly among pregnant individuals with comorbidities, for the foreseeable future. Priority groups to receive the vaccine initially included health care workers, a large proportion of whom are reproductive age females. In recent weeks, many provinces have moved to offering vaccines to all pregnant people based on the data from our other project, CANCOVID-Preg (https://ridprogram.med.ubc.ca/cancovid-preg/) that has shown that hospitalization and ICU admission rates for pregnant individuals are equivalent to the age grouping of 55-59 in the general population. The National Advisory Committee on Immunizations (NACI), Society of Obstetricians and Gynaecologists of Canada (SOGC), American College of Obstetrics & Gynecology (ACOG), and other national and international organizations have endorsed vaccinations being made available to pregnant women and for them to make an informed decision on whether to take that opportunity (6-8). Data on the use of COVID-19 vaccines in this population is limited to an initial v-safe report (9) resulting in a major knowledge gap in the roll out of vaccine in Canada and globally, which may contribute to decreased vaccine confidence in this population which historically experiences lower vaccine confidence (10). This project will use a prospective cohort design in conjunction with both traditional and social media campaigns to capture data on the safety, effectiveness, and immunogenicity of COVID-19 vaccines in pregnant or lactating individuals.

1.3 Immune Sub-Study

Participants in BC, who have access to a study site or the ability to provide study samples, and who intend to receive a COVID-19 vaccine during pregnancy, will be offered the option of participating in an immune sub-study. Consent will be obtained to access previously collected antenatal serology and the prospective collecting of parent and infant blood for serological assessment. Initial engagement has been established at two BC sites; BC Women's Hospital and Surrey Memorial Hospital with the potential of additional sites throughout BC.

2.0 OBJECTIVES

Primary objectives:
1. To assess the safety of COVID-19 vaccines in pregnant and lactating individuals
2. To describe the effectiveness of COVID-19 vaccines in pregnant and lactating individuals
3. To examine attitudes towards COVID-19 vaccination, and other vaccinations, including RSV, among pregnant and lactating individuals
4. To examine the immunogenicity of COVID-19 vaccines within a subset of pregnant individuals and for their infants
5. To assess attitudes and the impact of co-administration of the COVID-19 vaccine with other regular vaccinations, such as the influenza vaccine, among pregnant and lactating individuals

3.0 STUDY DESIGN

3.1 Study Design

Objectives will be addressed using a prospective cohort design. A public campaign will be launched to invite pregnant and lactating women and individuals to participate in online surveys with self-reported outcomes. This methodology has been modeled after U.S. efforts led by the University of Washington (11). The project will provide the Public Health Agency of Canada (PHAC), NACI, and provincial vaccine advisory committees with Canadian data to guide recommendations as the study rolls out. This project will be leveraging the national CANCOVID-Preg network and existing collaborations with public health partners.

3.2 Inclusion Criteria

(1) At least 19 years of age
(2) Became pregnant in 2023

4.0 PROTOCOL

4.1 Recruitment

Vaccinated and unvaccinated women and individuals will be invited to participate in a voluntary web-based surveillance. They will be followed prospectively as a cohort to collect data on attitudes and outcomes associated with vaccination. Recruitment will be targeted based on the inclusion criteria, regardless of vaccination status or intention. Recruitment will occur through a social media and traditional media campaign and through dissemination of recruitment materials by health care providers. The study will have a UBC supported website that will contain information as well as a link that for individuals to be directed to the study e-consent. Once the research data base is built, the link will route potentially interested participants to the study information and consent. For those individuals that expressed an interest in the study, the study team will send the website information once ethics approval has been obtained. We plan to engage with physicians, midwives, The Society of Obstetricians & Gynaecologists of Canada, Black Physicians of Canada, Indigenous Physicians Association of Canada, and La Leche League to reach a diverse study population. We plan to recruit from local maternity, family medicine, and midwifery clinics, like Pomegranate and the Vancouver Family Practice Centre, as well as on the REACH BC website. We will also engage with the Oak Tree Clinic and the Maternal Fetal Medicine Clinic at BC Women's Hospital. We plan to implement a poster campaign with QR codes as well as utilize social media posts to share the study website using Instagram, Facebook and Twitter. Study postcards will be distributed that contain the

inclusion criteria, study objectives and a QR code that will take a potential participant to the registry e-consent. As demographic data are collected from participants in the baseline survey, our team will be able to rapidly adjust the media campaign to target areas of the country or populations with lower enrollment.

4.2 Data Collection

Once consent has been obtained, the baseline survey will automatically be pushed to the participant. The baseline answers will determine if pregnancy and or vaccine outcome surveys are to be answered at the same time. A short follow-up questionnaire will be administered on December 1st 2023 and another on February 1st 2024 to capture changes in vaccination status, COVID-19 status, pregnancy outcomes or significant health events. The follow-up surveys will determine if/when outcome surveys need to be completed. If consent is withdrawn, the study will immediately cease for the participant. The survey modules are as follows:

1. Baseline survey: Pregnancy status, vaccination status, demographics, health history, COVID-19 history & pregnancy history - Administered at enrollment starting Sept 1, 2023 until Jan 31, 2024
2. Pregnancy Outcomes: Pregnancy & infant outcomes – Administered if pregnancy started in 2023 and are not currently pregnant
3. Vaccine Outcomes: Answered if a dose of a COVID-19 vaccine received during the current pregnancy
4. Vaccine Attitudes 1: Feelings, opinions & attitudes towards vaccines– Administered at end of surveys received at baseline
5. Vaccine Attitudes 2: Feelings, opinions, and attitudes towards the Respiratory syncytial virus (RSV) – Administered following the completion of Vaccine Attitudes 1
6. Follow-up survey: 2 time-based follow-up surveys administered on December 1st, 2023, and on February 1st, 2024 with reminders sent out periodically throughout study duration
7. Health Event: Significant health events resulting in a visit to the emergency department or hospitalization – Administered if triggered by Follow-up survey

In the event of an adverse reaction or major health event, the study team will contact a participant for further health information.

Data collected from individuals who do not receive COVID-19 vaccines will act as an internal comparison group. We will also capture self-identified gender through our online demographics questionnaire and examine differences by gender. The module on COVID-19 vaccination history will include type of vaccine received, number of doses and dosing interval. Vaccine safety endpoints will be coordinated with the Canadian National Vaccine Safety Network (CANVAS) endpoints: adverse events as detailed in data collection forms, severity and duration of adverse event, resultant medical visits (including to emergency department) or hospitalization, and treatments administered.

Pregnancy and infant safety outcomes measured are key outcomes identified by the Pan-Canadian, surveillance CANCOVID-Preg team. These major pregnancy complications/outcomes include but are not limited to gestational hypertension, gestational diabetes, placental abruption, infant birthweight, preterm birth, NICU admission, congenital anomalies, spontaneous abortion or termination, and stillbirth or neonatal death. Postnatally, including infants of women vaccinated during lactation, infant SARS-CoV-2 infection, hospitalization, growth parameters, and neurodevelopment (hyper vigilance) will be ascertained.

4.3 Sample and Data Collection for Immune Sub-Study

Maternal blood samples will be collected pre- and post-vaccination. We anticipate study visits occurring 4 weeks up to vaccination, four weeks after vaccination, and again twelve weeks after vaccination. Maternal blood samples will also be collected at delivery. We anticipate these study visits to occur +/- 2 days at delivery, and 4-6 weeks after delivery. If the delivery sample is within the window of another collection time point, we will collect only one sample. SARS-CoV-2 serology will be performed for all maternal samples to determine IgG seropositivity rate and semi-quantitative antibody levels to anti-spike protein. IgG class sub-typing will be performed on maternal samples. Additionally, serology for IgG and IgA antibodies will be performed on breast milk samples. Neutralization assays for relevant variants of concern will be performed on selected maternal blood samples. Cord blood samples at delivery and infant blood samples at 4-6 weeks post-delivery will be collected and analyzed on serologic assays and compared to peripartum maternal antibody levels.

4.4 Data Management / Stewardship

Participants will enter survey data directly into a secure REDCap database housed at the national coordinating centre at the University of British Columbia (UBC). The REDCap software uses a web server designed to enable secure transfer of data between a client computer and the data centre, located in a highly-secured area at the BC Children's Hospital Research Institute. Support for data management will be provided by the Faculty of Medicine Digital Solutions Research Technology Unit.

4.5 Statistical Analysis and Metrics

To adequately power for comparisons of adverse events, we used estimates of vaccine-related adverse events (i.e. pain at injection site, redness, swelling, fever, fatigue, chills, headache, muscle pain, joint pain, grade 4 serious adverse events) from the subset of younger participants in the Pfizer vaccine trial, as an example (12). The rate of overall adverse events was 25%, and with a sample size of 451 in the vaccinated cohort we could estimate this prevalence with ±4% precision and 95% confidence. Sample sizes are highly feasible and will allow for comparison of adverse obstetrical and infant outcomes between vaccinated and unvaccinated participants. Given a sample size of 500 per group (vaccinated vs. unvaccinated) we would have 80% power to detect a minimum relative risk of 1.5.

The immunogenicity sub-study would require 89 participants, assuming 10% loss to follow up to estimate a 70% seroconversion rate with±10% precision and 95% confidence. A seroconversion rate closer to 80% would require 68 participants. For comparisons of antibody levels, using estimates for the 18-55y age group (13) we would need approximately 48 participants to demonstrate a 10% difference in geometric mean titer with 95% power and assuming an attrition rate of 10% per visit.

The presence of any adverse outcomes (vaccine and pregnancy-related) will be compared between vaccinated and unvaccinated using time-varying Cox's proportional hazards models (14), stratified by vaccine type, and including important confounders. Effectiveness will be assessed descriptively through participant reporting of positive SARS-CoV-2 tests and COVID-19 diagnoses in vaccinated

and unvaccinated participants. Clinical features of breakthrough cases will be described in those vaccinated. Exploratory analyses will investigate differences between vaccinated and unvaccinated people. Clinical severity will be compared with unvaccinated people in the CANCOVID-Preg cohort. This will include tracking of infections with variants of concern where possible in both vaccinated and unvaccinated participants.

Vaccine confidence and attitudes, including intention to receive the COVID-19 vaccine, will be assessed using a validated survey grounded in the Theory of Planned Behaviour (TPB)(15) and part of the WHO Vaccine Hesitancy Scale (VHS)(16). The TPB is well established as a psychological model to predict and understand health-related behaviours. This theory defines the most significant predictors of a health behaviour as attitudes, social norms (direct, indirect), and perceived behavioural controls; measures of each of these predictors will be included in the survey. Prior evidence from Canada has shown that this model is able to accurately predict vaccine uptake (17,18). The factors included in the VHS are vaccine lack of confidence and vaccine risk. All items in the TPB and VHS are measured on a 5-point Likert scale. Vaccine attitudes will be reported overall and by vaccination status. Comparisons among subgroups (e.g. by age, region, cultural background, and gender) will be conducted using linear regressions. Importantly, comparisons among subgroups (e.g. by age, region, cultural background, and gender) will identify priority areas for vaccine education and outreach.

As gender does not exist in isolation from other socially-relevant contextual factors such as class, immigrant status, rurality, race, and indigeneity which, in turn, also affect health outcomes. We will collect data on all these factors and our analysis will adopt a SGBA+ approach to compare vaccine attitudes between gender groups and how these interact with other intersectional variables.

4.6 Statistical Analysis for the Immune Sub-Study

Seroconversion will be estimated and compared to licensure data using binomial tests. Antibody levels in pregnancy will be compared to licensure data for the relevant vaccine and dose using one-sample t-tests. We will stratify by gestational age, participant age, and other co-factors that might influence immune response. Maternal antibody levels will be compared to infant levels at birth, controlling for infant gestational age at delivery, birth weight, and infant feeding. Exploratory analysis of antibodies in breast milk will be compared to maternal serum antibody levels.

4.7 Knowledge Translation

Analysis and reporting from this project will be ongoing, as data become available. We will produce regular monthly national reports for distribution to our national and provincial public health partners and through the additional networks of the CANCOVID-Preg members. These reports will also be publicly shared, including with study participants, via our website, social media channels, and traditional media outlets. A knowledge broker will be engaged as part of the team to optimize translation of our findings to public health officials and a diverse range of the Canadian population, and to enhance translation of these findings into clinical guidance and public knowledge. In addition, we will leverage our partnerships with pan-Canadian university communications departments to expand the reach of our recruitment and knowledge translation outputs. Finally, our team includes clinician and policy knowledge users who will be active in the interpretation and dissemination of results, including amongst professional organizations that influence vaccine recommendations (e.g. SOGC).

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