

BORN ONTARIO COVID-19 DATA COLLECTION

FREQUENTLY ASKED QUESTIONS (**UPDATED JANUARY 2022**)

GENERAL INFORMATION

1 Why is BORN Ontario asking for continued collection of COVID-19 data for pregnant individuals?

Pregnant individuals are at risk for poor outcomes associated with COVID-19. Since BORN began collecting data in March of 2020 and combining it with data from other provinces we have learned that pregnant individuals with COVID-19 have a higher risk of hospitalization and ICU admission than non-pregnant individuals in the same age categories. The babies of pregnant individuals with COVID-19 are also more likely to be born preterm. As the new variants have emerged, BORN continues to collect data to add to what is known and to try and determine the longer term effects on pregnant individuals and their newborns. We are also using the information to link outcomes to vaccination status.

In view of these uncertainties, we continue to ask hospitals and midwifery practice groups to submit Case Report Forms at the time of birth for:

- 1) Any pregnant individual with CURRENT COVID-19 (confirmed, suspected or probable) at the time of hospital birth or out-of-hospital birth
- 2) Any pregnant individuals at the time of hospital birth or out-of-hospital birth with a PAST HISTORY of COVID-19 during this pregnancy (confirmed, suspected or probable) from which they have recovered

2 Why are these COVID-19 data variables being collected through the BORN Ontario Registry?

Data are needed because of the public health emergency and to provide credible information to care providers, health system planners, and pregnant individuals and families to help guide decision making. Because about 40% of all births in Canada each year occur in Ontario, information collected here can make an important contribution to national knowledge on this issue.

BORN Ontario is bringing the COVID-19 data into the Registry in furtherance of its mandate to improve and facilitate the provision of healthcare in Ontario; for example, see specific purposes C, E, and F (see below). For the participating hospitals and midwifery practice groups, we will be amending their data sharing agreements (DSA) to permit this collection.

Purpose C: **Raise alerts** where maternal and/or newborn outcomes are clinically or statistically discrepant with accepted norms

Purpose E: ***Identify strategies to improve*** the quality and efficiency of care for mothers, infants and children

Purpose F: **Create reports** that can be used to provide the Ministry of Health and Long-Term Care, Local Health Integration Networks (LHIN) and Public Health Units with comprehensive and timely information ***to support effective planning and management of health care delivery*** for mothers, babies and children in the province

On regional, national and international calls, there was overwhelming support from the experts that the BORN Ontario registry should take on this data collection in Ontario, where data can be rapidly collected without consent from individual hospitals and midwifery practice groups, and combined at the provincial level.

BORN Ontario is asking care providers to provide data specifically related to COVID-19 illness, as pregnancy/birth outcome information will be obtained through a linkage with the BORN Ontario registry. As of January 2022, we have significantly shortened the Case Report Forms to only collect what we cannot obtain from linkage with other data sources.

3 How will this information help Ontario?

Information collected during this public health crisis will be summarized and distributed to provide the Ministry of Health and Long-Term Care, Public Health Ontario, Ontario Health, Local Health Integration Networks (LHIN), Public Health Units, Association of Ontario Midwives, hospitals and maternal and newborn care providers with comprehensive information to support effective planning and management of health care delivery for mothers, babies and children in the province.

4 Do we need institutional research ethics approval to collect this information at our hospital and/or midwifery practice group and transfer it to BORN Ontario?

No. You **DO NOT** need to get institutional Research Ethics Board approval to collect this information at your hospital or midwifery practice group and transfer it to BORN.

These data are being brought into the registry for the registry purposes described above. This is already covered by the existing data sharing agreement (DSA) the hospitals or midwifery practice groups already have with BORN Ontario (which will be amended in the coming months). Any use of the data for research will have to go through the normal data request processes, which will include an REB approval for use of the data for a particular project.

5 Will individual hospitals and midwifery practice groups be able to use their own COVID-19 data?

Yes, each hospital and midwifery practice group can review the COVID-19 data specific to their organization and share internally with their Infection Prevention and Control Services or other clinical and administrative stakeholders within their hospital for the purpose of improving patient care. Sharing data externally with other research groups would have to follow institutional policies for research ethics.

6 Is this duplicating any other data collection about COVID-19 in pregnant people?

BORN Ontario has been in communication with front line care providers in many Ontario hospitals and midwifery practice groups who want to collect this important information. There are several existing COVID-19 case registries for pregnant individual, including one in Canada, one in the United States, and at least two international registries (led by groups in the United Kingdom and Switzerland).

| Initiative | Lead |
|---|--|
| Canadian COVID-19 Registry | Dr. Deborah Money UBC |
| UK-led International Registry | Dr. Marian Knight UK Obstetrical Surveillance System Oxford, UK |
| Swiss-led International Registry | Dr. David Baud Lausanne University Hospital Lausanne, Switzerland |

In developing the Ontario data variables, we consulted with each of the other registries listed above, especially the pan-Canadian registry (hosted by UBC), to ensure that the

Ontario data is compatible with the other registries for possible future reporting and collaboration, once the pandemic has ended.

DATA COLLECTION INFORMATION

7 What is the definition of a case?

There are two types of cases:

1. Any pregnant individual who had a positive PCR test at anytime in the pregnancy, ***regardless of gestational age***
2. Probable/suspected cases (even if no PCR test was completed) when there are:
 - highly suspicious clinical signs/symptoms and the individual has been in close contact with an infected person or
 - the individual tested positive on a rapid antigen test

NEW – Submit CRFs at the time of birth, rather than during the pregnancy

8 Is the data collection voluntary or mandatory?

Data collection is voluntary ***but strongly encouraged***. These data are extremely important to enable us to see what is happening to our own population and to help us improve and facilitate care.

9 How long should we continue this data collection?

As the pandemic continues on and new variants are identified, BORN needs to continue collecting this important data. We will keep you informed about when the data collection can stop. As of January 2022, we have significantly shortened the CRF.

10 How will data collection occur for infected individuals who are midwife clients admitted to hospital?

- If there is a transfer of care to obstetrics for a midwife client with COVID-19 (CURRENT or PAST), hospital staff would assume all routine documentation for the BORN Information System (BIS) and COVID-19 data. COVID-19 status information will be communicated to the consultant at the time of transfer, to ensure data are added to the BORN Ontario COVID-19 Case Report Form.
- If a midwife remains MRP for a client in labour and birth with COVID-19 (CURRENT or PAST) and admitted to hospital, then the routine process for BIS data entry at their site would occur. Midwives are encouraged to enter data directly into the Hospital's BORN Ontario COVID-19 Case Report Form.

11 Where do we put the case information once it is extracted?

BORN has developed a fillable PDF data collection tool for information about COVID-19. Hospitals and midwifery practice groups can contribute data by entering data on cases directly into a fillable PDF : <https://www.bornontario.ca/en/whats-happening/resources/Documents/BORN-Ontario-COVID-19-Case-Report-Form---V6.1.pdf>

12 Why can't we enter these COVID-19 variables directly into the BORN Information System with the other pregnancy information we already contribute?

Unfortunately, we are unable to change the complex BORN Information System interface or upload specifications. BORN has developed a BORN Ontario COVID-19 Case Report Form, which is a fillable PDF data collection tool for information about COVID-19. We are, therefore, hoping Ontario Hospitals and midwifery practice groups can contribute data by entering data on cases directly into the BORN Ontario COVID-19 Case Report Form and then securely transfer it to BORN.

13 How often do hospitals and midwifery practice groups transfer information to BORN Ontario?

Please collect data using one form per COVID-19 positive pregnant individual.

Hospitals and midwifery practice groups should keep their electronic copy of the forms and transmit the case forms as they occur, unless multiple case forms are expected. In that case, batch-send completed forms electronically to BORN biweekly.

Do NOT send the PDF form to BORN by email – this would be a privacy breach!

Please use the following file naming convention:

Hospital/Midwifery Practice Group name + date of file transfer + file # being sent

- E.g., Hospital name –date of file transfer – file #
- Mt. Sinai– Jan 20 2022 – 1 (first BORN Ontario COVID-19 Case Report Form transferred)
- Mt. Sinai – Jan 20 2022 – 2 (second BORN COVID-19 Case Report Form transferred)

14 How do we securely transfer information to BORN Ontario?

There are 2 methods available to electronically send your completed BORN Ontario COVID-19 Case Report Forms to BORN.

- 1) If you have a BORN Information System (BIS) Account, use the messaging functionality built into the BIS. All BIS users have access to this feature and can use it to securely send personal health information (PHI) to BORN. Select the user [BORNOntario](#), [COVID19](#) within BIS Messaging.
- 2) Use the BORN secure FTP server. If your organization does not have an account, you can request one from covid@bornontario.ca and instructions will be provided. This service allows for the secure transmission of personal health information (PHI) to BORN.

If you need support with logins, please speak to the BORN lead at your institution or your BORN Coordinator to obtain BORN credentials.

***DO NOT* email the completed case forms to a BORN Coordinator or anyone else.**

15 If the same person is submitting cases to BORN for two different hospitals (e.g., partner hospitals) should they be submitted to BORN together or separately?

It is up to you if you wish to send the cases together or separately. However, please make sure the file names clearly identify which specific place/hospital you are referring to.

ADDITIONAL INFORMATION

16 What kind of information is being collected?

The information collected in the BORN Ontario COVID-19 Case Report Form is based on the data being collected by the Canadian National COVID-19 in Pregnancy Registry and contains detailed clinical information. This was significantly shortened in January 2022.

Because BORN Ontario is a Prescribed Registry under provincial privacy legislation (PHIPA), hospitals and midwifery practice groups are mainly being asked to provide COVID-19-related information, since information about the pregnancy outcomes can be obtained through a linkage with the BORN Information System. This is a major advantage, since it reduces any workload by hospital or research staff to collect additional data during a stressful time period.

- There are two data collection options (both within the BORN Ontario COVID-19 Case Report Form):

OPTION A: CORE DATASET: variables required for record linkage to the BORN Information System (BIS) + core variables about COVID-19

- *These core variables are shaded in light red*
- *These core variables are the priority*
- *Please complete ALL core variables (shaded)*

OPTION B: EXPANDED DATASET: core dataset variables + additional clinical variables about COVID-19

- ****This dataset is preferred, if possible*
- *Please complete ALL core variables (shaded), as well as all other applicable variables as completely as possible*

17 How were these variables identified? Did BORN Ontario consult with other data collection initiatives?

The variables selected were developed collaboratively with input from epidemiologists, clinicians and experts in infectious disease. We also consulted the registries that have been established for COVID-19 in pregnancy in Canada and internationally, to ensure consistency in the type of information collected.

18 Why is the Ontario list of variables not identical to other data collection initiatives?

A crucial difference in Ontario is the fact that BORN Ontario is a Prescribed Registry under provincial PHIPA legislation. As such, it is within BORN Ontario’s mandate to collect information without consent for the purpose of improving or facilitating care. Another important difference of the approach in Ontario is that COVID-19 data from contributing hospitals and midwifery practice groups can be directly linked to the routine data collection in the BORN Information System. This means that healthcare providers don’t have to extract information on pregnancy outcomes, and can focus their effort instead on COVID-19 variables.

In contrast, the other registries that have been established to collect information on COVID-19 during pregnancy may be required to obtain consent, do not contain any identifying information, and have to extract detailed pregnancy information as part of the primary data collection, since the records will not be linkable with other data sources.

The key difference in data elements, therefore, being collected in Ontario is that it is a shorter list, since the pregnancy information will come from the linkage to the BORN Information System.

19 Will data sharing agreements need to be amended?

BORN already has data sharing agreements (DSA) with all maternal child hospitals and midwifery practice groups in Ontario which cover the transfer of personal health information for specific purposes.

We will need to amend the agreement for each participating organization, but due to the public health emergency, this amendment can be delayed while data collection starts. **It is not necessary to have this amendment complete before contributing data as part of this enhanced surveillance effort.**

When the time comes to use this data for research, normal processes of applying for REB approval will be required.

20 How will the knowledge be translated?

Information collected during the COVID-19 public health crisis will be summarized at a provincial level and shared with the Ministry of Health and Long-Term Care, Public Health Ontario, Ontario Health, Local Health Integration Networks (LHIN), Public Health Units, Association of Ontario Midwives, hospitals and maternal and newborn care providers to help facilitate and improve care.

Each hospital and midwifery group can review the COVID-19 data specific to their organization and share internally with their stakeholders for improving patient care.

BORN will be able to return the collated COVID-19 and pregnancy/birth outcomes back to each contributing organization for their internal use.

CASE REPORT FORM - SPECIFIC QUESTIONS

21 If a pregnant individual comes into hospital and delivers before the COVID test can be administered but she is symptomatic, should we submit this case to BORN?

Yes. If her symptoms are highly suspicious of COVID-19 and were present during pregnancy, even if the test wasn't available, she would be considered a suspected case and the information should be collected and submitted to BORN.

22 If a pregnant individual is asymptomatic but is tested post-partum and has a positive result, do we collect data on this individual? How long after the birth is it "too late" to include this individual?

Yes. Please collect and submit data on individuals who test positive for COVID-19 in the early post-partum period despite being asymptomatic. Considering the incubation period for COVID-19 can be up to 14 days, please collect and submit any probable, suspected, or confirmed cases that arise within 14 days of giving birth (e.g., individual who becomes symptomatic or tests positive up to 14 days post-partum).

My hospital or midwifery practice group is interested in participating.

What are the next steps?

If you are interested in participating in the BORN COVID-19 data collection please:

Email covid@bornontario.ca with the following information ASAP:

- The name of your organization and contact information (email and phone number) for your organization's COVID-19 key contact person
- Name and email address of your Chief of Obstetrics and/or
- Name and email address of your Head Midwife

We need to confirm your participation in this special COVID-19 data collection for our records. Once we receive your email, we can arrange amendments to the DSA.

RESOURCES

The BORN Case Report Form is found here: <https://www.bornontario.ca/en/whats-happening/resources/Documents/BORN-Ontario-COVID-19-Case-Report-Form---V6.1.pdf>

***Please make sure you download the Case Report Forms directly from BORN Ontario's website as needed to ensure you are using the latest version of the forms.**

KEY CONTACTS

General inquiries: covid@bornontario.ca

Hospital-specific questions regarding your own BIS use:

- Contact your BORN site-lead
Don't know your BORN site-lead? Contact covid@bornontario.ca