1 Why is BORN Ontario asking for new data element collection on COVID-19 in pregnant individuals?
There are limited data on the clinical characteristics of COVID-19 infection in pregnant individuals, including any adverse impacts on the fetus. Evidence of poor maternal and perinatal outcomes from other outbreaks of viral respiratory illness over the past 20 years (i.e., 2009 A/H1N1 influenza pandemic, severe acute respiratory syndrome [SARS] and Middle East respiratory syndrome [MERS]) indicate a need for enhanced monitoring of pregnant individuals during this current pandemic to determine whether COVID-19 poses any threat to maternal, fetal or infant health.

In view of these uncertainties, BORN Ontario is urgently initiating data collection through the BORN registry for any cases of COVID-19 infected pregnant individuals admitted to Ontario hospitals or midwifery practice groups between March 1, 2020 and March 1, 2021 (or until the pandemic is declared over and 40 weeks pass to allow collection from newly pregnant individuals at the time it is declared over).

2 What is the risk to pregnant individuals, fetuses and infants from COVID-19 illness?
What we know to-date:

- There is currently limited information to guide pregnant individuals and their care providers about optimal care and effects of infection during pregnancy on the fetus and newborn. Based on the limited evidence available as of April 6, 2020, transmission of the virus (SARS-CoV-2) from mother to fetus/infant via the placenta, breastmilk, or the birth process cannot be ruled out at this moment.

- Evidence to-date suggests that pregnant individuals are not more likely to become infected with COVID-19 than the general population.

- Pregnant individuals seem to have similar clinical signs and symptoms of the disease as those experienced by non-pregnant individuals and include fever, cough, shortness of breath, body aches, fatigue and sore throat. Should you experience any of these symptoms, please contact your health care provider.
- It is still too early to know the potential impact of COVID-19 in early pregnancy. However, there is some evidence that prolonged high fever, particularly in the first trimester, carries a small increased risk for some birth defects.

- Small studies from China suggest newborns of pregnant individuals with COVID-19 pneumonia may be born too early or too small and have longer hospital stays.

It is clear that certain infections can cause problems for pregnant individuals, likely because of the body’s adaptations to pregnancy. This happened with the 2009 H1N1 flu pandemic and other viral outbreaks such as severe acute respiratory syndrome (SARS) and Middle East respiratory syndrome (MERS). Fever and other illness symptoms may lead to infants being born too early or too small.

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

Data are urgently 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. We will not ask for any duplication, other than the identifiers needed for linking to the BORN Information System data that are already routinely collected, as well as a small number of about six core outcome variables, to enable rapid reporting to key stakeholders during this public health emergency.

4 **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.

5 **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.

6 **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.

7 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 COVID-19 case registries for pregnant women being set up, including one in Canada, one in the United States, and at least two international registries (led by groups in the United Kingdom and Switzerland).

<table>
<thead>
<tr>
<th>Initiative</th>
<th>Lead</th>
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</thead>
<tbody>
<tr>
<td>Canadian COVID-19 Registry</td>
<td>Dr. Deborah Money</td>
</tr>
<tr>
<td></td>
<td>UBC</td>
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<tr>
<td>UK-led International Registry</td>
<td>Dr. Marian Knight</td>
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<tr>
<td></td>
<td>UK Obstetrical Surveillance System</td>
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<td></td>
<td>Oxford, UK</td>
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<tr>
<td>Swiss-led International Registry</td>
<td>Dr. David Baud</td>
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<td></td>
<td>Lausanne University Hospital</td>
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<td></td>
<td>Lausanne, Switzerland</td>
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</table>

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 will be compatible with the other registries for possible future reporting and collaboration, once the pandemic has ended.

In Ontario, we are fortunate that we only need to collect the COVID-19 specific data because the BORN Ontario birth registry already contains the pregnancy and birth outcomes. Although data collection and entry can be challenging in this time of pressure on the health care system, we are encouraging hospitals and midwifery practice groups to continue their usual data entry into the BORN Information System as quickly as possible because of the urgent need to link the COVID-19 data with pregnancy outcome data.
What is the definition of a case?

There are two types of cases:

1. Any pregnant individual with **CURRENT** COVID-19 (confirmed, suspected or probable), **regardless of gestational age**

   This includes:
   a) pregnant individuals admitted to hospital for current COVID-19-related issues (e.g., pneumonia)
   b) pregnant individuals admitted to hospital for birth or any other pregnancy-related issues (e.g., preeclampsia, bleeding, etc.), who happen to currently have COVID-19
   c) pregnant individuals cared for outside the hospital (e.g., home or birth centre) by midwives

2. Any pregnant individual with a **PAST HISTORY** of COVID-19 during pregnancy (confirmed, suspected or probable), **which is resolved**

   This includes:
   a) Pregnant individuals at the time of hospital birth or out-of-hospital birth who have a history of COVID-19 during this pregnancy, from which they have recovered

* We recognize we may get more than one record for an individual. These will be integrated by BORN Ontario.

*World Health Organization (WHO) definitions for confirmed, suspected or probable COVID-19:

  **Confirmed COVID-19:**
  i. person with laboratory confirmation of COVID-19 infection, irrespective of clinical signs and symptoms

  **Suspected COVID-19:**
  i. person with **acute respiratory illness** (fever and at least one sign/symptom of respiratory disease, e.g., cough, shortness of breath) **AND** a history of travel to or residence in a location reporting community transmission of COVID-19 disease during the 14 days prior to symptom onset; OR
  ii. person with **acute respiratory illness AND** having been in contact with a
confirmed or probable COVID-19 case in the last 14 days prior to symptom onset; OR

iii. person with severe acute respiratory illness (fever and at least one sign/symptom of respiratory disease, e.g., cough, shortness of breath; AND requiring hospitalization) AND in the absence of an alternative diagnosis that fully explains the clinical presentation

Probable COVID-19:

i. suspected case for whom testing for the COVID-19 virus is inconclusive; OR

ii. suspected case for whom testing could not be performed for any reason


9 If a mother has a post-partum swab for COVID-19 but does not meet the identified criteria as ‘probable’, should data be collected on her?

This might depend on each hospital’s approach to testing. For example, was the decision to perform the swab based on the mother having symptoms? If yes, then she would be considered a suspected case and a BORN Ontario COVID-19 Case Report Form should be completed and submitted.

10 When a mother who is a probable COVID-19 case is tested in hospital but the results are unavailable, how do we collect this data?

The mother should be treated as a suspected case at that moment and data should be collected on her using the regular BORN Ontario COVID-19 Case Report Form. If the hospital later receives notification that the test result was negative, please submit a BORN Ontario COVID-19 Case Status Update Form. This update form should only be completed for a previously-submitted suspected or probable case who subsequently tests negative.

11 Should we only collect data on admitted patients or should we also collect data on patients who come to outpatient clinic appointments?

Yes, a case report form should be completed for pregnant individuals with current COVID-19 if they are seen in outpatient appointments at hospitals, or if they are seen at home by a midwife. Later, when the pregnant individual presents for birth, another case report form will be completed (i.e. as a “past history” case). These two reports will be
12 Is BORN only collecting data on pregnant individuals and not newborns? What about COVID-19 infected newborns who do not have infected mothers (e.g., was exposed from a healthcare provider or relative while in the NICU)?

The case report form does include some questions pertaining to the baby born to an infected mother (e.g., COVID-19 testing for the newborn and management of the newborn after birth). However, as of April 6, 2020, we are not collecting data on infected newborns if their mother was not a confirmed, suspected or probable case. We will be adding a data field on the Healthy Babies Healthy Children screening tool regarding COVID-19 positive mothers and/or baby. We will be able to follow-up on COVID-19 positive newborns from this.

13 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.

14 When should we start this data collection?

Please extract information on any cases (meeting the case definitions above) admitted to your hospital or under midwifery care between March 1st, 2020 and March 1st, 2021 (or until the pandemic is declared over and 40 weeks pass to allow collection from newly pregnant individuals at the time it is declared over).

Information from any recent cases (prior to the data collection tool being released) should be entered into a BORN Ontario COVID-19 Case Report Form and submitted as soon as possible.

15 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 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.

16 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 (BORN Ontario COVID-19 Case Report Form) and then securely transfer it to BORN.

17 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 can’t change the complex BORN Information System interface or upload specifications quickly enough to respond to this public health emergency. 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.

Please note that BORN will also be adding a box at the bottom of the Healthy Baby Healthy Child (HBHC) encounter in the BIS to indicate whether a mother and/or baby is infected with COVID-19 (confirmed, suspected or probable case). However, this is a separate data collection piece (in addition to the BORN Ontario COVID-19 Case Report Form) that will serve as a double-check for BORN, and a support for local public health units to have an awareness of COVID-19 infected individuals and babies to help appropriately support these families once discharged from hospital. Both data collection pieces (BIS COVID-19 box in the HBHC encounter and BORN Ontario COVID-19 Case Report Form) should be completed for pregnant individuals meeting the case definition.

18 Who should extract the information?

Please continue regular BORN Information system (BIS) data entry as usual (different sites contribute differently – manual entry and upload). This is really important for linkage of the COVID-19 data.
New COVID-19 data entry is in planning stages. Some hospitals have found data abstractors to enter these expected small number of cases. Other hospitals will ask their current BIS person to do it, while other hospitals still need to consider their resources.

For midwifery clients NOT admitted to hospital with PAST or CURRENT COVID-19 related issues:

- Each midwifery practice group should complete a BORN Ontario COVID-19 Case Report Form for a pregnant individual who meets the case definition, and securely send it to BORN when the case is identified and the case form completed. As small numbers are expected, please do not wait to send this to BORN. Timely documentation of each case is important. **DO NOT** email this information to a BORN Coordinator or anyone else. We will outline a secure transfer protocol below.

Please see question 19 and 20 about when and how to transfer the form.

19 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 – March 22 2020 – 1 (first BORN Ontario COVID-19 Case Report Form transferred)
- Mt. Sinai – March 22 2020 – 2 (second BORN COVID-19 Case Report Form transferred)

20 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 BORN\text{Ontario}, COVID\text{19} 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.

\textbf{DO NOT} email the completed case forms to a BORN Coordinator or anyone else.

\section*{ADDITIONAL INFORMATION}

\subsection*{21 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.

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.

\begin{itemize}
  \item There are two data collection options (both within the BORN Ontario COVID-19 Case Report Form):
  \begin{itemize}
    \item \textbf{OPTION A: CORE DATASET:} variables required for record linkage to the BORN Information System (BIS) + core variables about COVID-19
  \end{itemize}
\end{itemize}

- \textit{These core variables are shaded in light red}
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*

22 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.

23 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.

24 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 in coming months for each participating organization, but due to the public health emergency, this amendment will be delayed until administrative work is again possible. **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.

**25 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.

**26 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 name of your organization and contact information for your organization’s COVID-19 key contact person by Thursday April 9th, 2020.

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 in the coming months when administrative work is again possible.

**RESOURCES**

A recording of the webinar held on April 6, 2020 will be posted on BORN Ontario’s website.
The completed data collection tool will be circulated and posted to the BORN Ontario website on April 7th, 2020.


- BORN ONTARIO COVID-19 CASE REPORT FORM
- BORN ONTARIO COVID-19 CASE STATUS UPDATE FORM
  (For a previously-submitted suspected or probable case who subsequently tests negative)

**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 the BORN coordinator below

BORN Information System questions:

- Contact your BORN Coordinator. If you do not know your BORN Coordinator contact Monica Poole at:
  
  **Email**: mpoole@BORNOntario.ca
  
  **Telephone**: 226-268-2819