

Collecting Data for COVID-19 Surveillance in Pregnant Women

APRIL 6, 2020



Early health. Lifelong health.
Début en santé. Longue vie en santé.



COVID-19 Data Collection - A Partnership

- BORN Ontario
- Guidance from Ontario medical advisors to the national COVID-19 surveillance group

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- Regional Maternal-Child Networks
- Maternal child hospitals

Outline

- What we know...so far
- Data collection process
- Variables
- Data transfer process
- Agreements
- Knowledge Translation
- Next Steps
- Key contacts



What we Know...So Far

- Limited information to guide pregnant individuals and care providers about optimal care and effects of COVID-19 infection during pregnancy
 - Pregnant individuals are not more likely to become infected with COVID-19 than the general population
 - Pregnant individuals seem to have similar signs and symptoms of the disease as non-pregnant adults of similar age
 - Transmission of the virus (SARS-CoV-2) from mother to fetus/infant via placenta, breastmilk, or the birth process cannot be ruled out at this moment

What we Know...So Far

- Still too early to know the impact COVID-19 in early pregnancy; however,
 - Evidence that prolonged high fever, especially in 1st 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

What we Need to Know!

- Very limited data on COVID-19 in pregnancy including any adverse impacts on the fetus
- Evidence of poor maternal and perinatal outcomes from other recent outbreaks of viral respiratory illness (e.g., 2009 A/H1N1 influenza pandemic, SARS)
- There is an urgent need for enhanced monitoring of pregnant individuals during this pandemic to determine whether COVID-19 poses any threat to maternal, fetal or infant health

BORN's Response to COVID-19 Data Collection

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

BORN's Response to COVID-19 Data Collection

- As a prescribed registry under PHIPA, BORN can collect personal health information from health information custodians (e.g. hospitals, midwives) without consent for the express purpose of *facilitating or improving* care
- Bringing the COVID-19 data into the registry corresponds to the following specific purposes:
 - **Raise alerts** where maternal and/or newborn outcomes are clinically or statistically discrepant with accepted norms
 - **Identify strategies to improve** the quality and efficiency of care for mothers, infants and children
 - Create reports that can be used to provide the MOHLTC, Ontario Health, LHINs, and PHUs with comprehensive and timely information **to support effective planning and management** of health care delivery for mothers, babies and children in the province

Data Collection Process



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Data Collection Tool

- Why not use the BORN Information System (BIS) for data collection?
 - Unfortunately, BORN is unable to change the complex BIS interface or upload specifications quickly enough to respond to this public health emergency
- BORN has developed a fillable PDF case report form for variables about COVID-19
 - Hospitals and midwifery practice groups can contribute by entering data on cases directly into a fillable PDF and then securely transfer it to BORN

Time Period for Data Collection

- Extract information on *any* COVID-19 cases (meeting case definition):
 - March 1, 2020 and March 1, 2021 (or 40 weeks past pandemic is declared over)
 - Any recent cases (prior to the data collection tool being released) should be entered and submitted as soon as possible

Other COVID-19 Data Collection

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

- BORN Ontario and the Medical Advisors on the Ontario data collection have been in contact with these other groups to align data collection variables and to facilitate potential future collaboration

Case Definition – 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

Case Definition – Two Types of Cases

2. Any pregnant individual with a *PAST HISTORY* of COVID-19 during pregnancy, *which is resolved*
- Confirmed, suspected or probable
 - 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 receive more than one record for an individual – these will be integrated by BORN Ontario**

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) **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** (fever and at least one sign/symptom of respiratory disease) **AND** 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) **AND** hospitalization **AND** in the absence of an alternative diagnosis that fully explains the clinical presentation

WHO definitions for confirmed, suspected or probable COVID-19:

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

Case Identification

- You will need to check with your organization to see how pregnant individuals with current COVID-19 can be identified

Variables

- BORN is asking hospitals and midwifery practice groups to provide COVID-19-related information, as pregnancy/birth outcomes will be obtained through a linkage with the BIS
- The fillable PDF is based on the Canadian COVID-19 in Pregnancy Registry and contains detailed clinical information
 - Includes a **subset of 'core' variables** that are identified as priority variables both for Ontario and for national and international comparisons

Variables

- There are two data collection options (both within one data collection 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*

COVID-19 Case Report Form

	'Preferred' variables	'Required' core variables (subset)
Type of case	1	1
Identifiers for record linkage	8	8
Maternal SARS-CoV-2 exposure history	5	0
Maternal SARS-CoV-2 testing (e.g., NP swabs; blood; breastmilk; amniotic fluid)	Up to 34 if applicable	3
Other samples tested for SARS-CoV-2 at birth (e.g., placenta; cord blood; high vaginal swab)	6	0
Maternal COVID-19 clinical symptoms (e.g., fever, cough, shortness of breath, myalgia)	Up to 39 if applicable	3
Maternal chest imaging performed	8	2

**Approximate number of variables*

COVID-19 Case Report Form

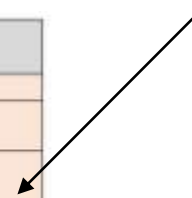
	'Preferred' variables	'Required' core variables (subset)
Maternal SARS-CoV-2 complications (e.g., pneumonia, ICU admission, maternal death)	Up to 24 if applicable	6
Maternal treatment (e.g., ECMO, mechanical ventilation, high-flow nasal cannula O ₂)	Up to 17 if applicable	1
COVID-19 medications (e.g., acetaminophen, ibuprofen, corticosteroids, chloroquine)	Up to 23 if applicable	0
Delivery [majority to come from linkage to BIS]	6	6
Newborn(s) from birth to discharge (e.g., infant isolated from mother, NICU admission)	2	2
Newborn(s) feeding	1	1
Newborn(s) SARS-CoV-2 testing	Up to 18 if applicable	2

**Approximate number of variables*

COVID-19 Case Report Form

- E.g.,

Maternal SARS-CoV-2 complications (in pregnancy or at birth)		
CORE VARIABLES		
Hospitalized for COVID-19 illness?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	
- IF YES, date of hospital admission	M/D/YYYY	
- IF YES, date of hospital discharge	M/D/YYYY	
- IF YES, was person admitted to ICU during this admission?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	
Was there a maternal death related to COVID-19 illness?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	
- IF YES, date of death	M/D/YYYY	- Leave blank if not applicable
ADDITIONAL CLINICAL VARIABLES		
Pneumonia?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	
- IF YES, date	M/D/YYYY	- Leave blank if not applicable
Sepsis?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	
- IF YES, date	M/D/YYYY	- Leave blank if not applicable
Respiratory failure?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	
- IF YES, date	M/D/YYYY	- Leave blank if not applicable
Acute respiratory distress syndrome?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	
- IF YES, date	M/D/YYYY	- Leave blank if not applicable



'Required' variables for core dataset are shaded

Where to Find the Tools

- BORN ONTARIO COVID-19 CASE REPORT FORM
- BORN ONTARIO COVID-19 CASE STATUS UPDATE FORM
 - for a previously-submitted probable case who subsequently tests negative

BORN website:

<https://www.bornontario.ca/en/news/born-data-collection-on-covid-19.aspx>

From a BORN Coordinator

Data Entry

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

Data Transfer Process

- Please electronically complete *one form per pregnant individual meeting the case definition*
- Organizations should keep their copy of the form and electronically batch-send completed forms to BORN biweekly
- Standardized file naming is contained in the Q&A document (e.g.):
 - Hospital/MPG name –date - # of file (if more than 1 being sent)
 - Mt. Sinai – April 6 2020 – 1
 - Mt. Sinai – April 6 2020 – 2
- ***Do NOT send the completed PDF form to BORN by email – this would be a privacy breach!***

Secure Data Transfer – 2 Options

FTP Server

- 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.

BIS messaging

- 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 safely send PHI data to BORN.
- Select the user BORNOntario, COVID19 within BIS Messaging.

If you need support with log-ins, please speak to the BORN lead at your institution or your BORN Coordinator to obtain BORN credentials



COVID-19 and eHBHC Encounter

- We are adding a COVID-19 variable into the HBHC encounter in the BIS.
 - HBHC form is completed at mother's discharge and baby's discharge if in NICU/SCN
 - This will act as a double check for BORN to ensure we have captured all possible cases
 - This will also support Public Health to have an awareness of COVID-19 infected mom/babies to provide appropriate supports when discharged from hospital
 - Further communications to stakeholders will follow

Baby Discharged With Yes No

Discharge Infant Weight: Discharge Weight Unknown

Feeding (check all that apply): Breast Milk Breast Milk Substitute

Discharge Date Mother:  Discharge Date Infant: 

COVID-19 question

Consent and REB

- You **DO NOT** need to get institutional Research Ethics Board approval or patient consent to collect this information at your hospital or midwifery practice group and transfer to BORN.
- BORN is a prescribed registry and the data is being brought into the registry for registry purposes
- COVID-19 data from contributing organizations can be directly linked to the routine data collection in the BIS. This means that hospitals and midwifery practice groups don't have to extract information on pregnancy outcomes, and can focus their effort instead on COVID-19 variables.

Agreements

- BORN already has data sharing agreements with all maternal child hospitals and midwifery practice groups in ON which covers 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 will be delayed until administrative work is again possible
- When the time comes to use this data for research, normal processes of applying for REB approval will be required

Knowledge Translation

- Information collected during the COVID-19 public health crisis will be summarized and shared to help facilitate and improve care
- Each hospital and midwifery practice group can review the COVID-19 data specific to their organization and share internally with stakeholders for improving patient care
- BORN will be able to return the collated COVID-19 and pregnancy/birth outcomes back to each contributing organization

Next Steps

- If you are able to participate 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**
 - 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 coming months when administrative work is again possible

Resources

- The slides and a recording of today's webinar will be posted on BORN Ontario's website www.bornontario.ca
- A Q&A document about the rationale and process for data collection will be posted on BORN Ontario's website
- The completed BORN COVID-19 Case Report Form will be circulated to participating hospitals and posted on the website

Need help? Key Contacts

General questions: covid@bornontario.ca

Hospital-specific questions re your own BIS use/accounts

- 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:
 - [Email: mpoole@BORNOntario.ca](mailto:mpoole@BORNOntario.ca)
 - [Telephone: 226-268-2819](tel:226-268-2819)

HUGE THANKS!

BORN is ***proud and honoured*** to team up with all of the front line care providers in Ontario working to protect mothers and babies

THANKS for all you are doing!



Question Time