Case definitions of the mother/infant dyads

For inborn infants (born at your reporting institution) and outborn infants (born at a referring hospital and transferred to your institution):

A pregnant woman who had virologic testing positive for SARS-CoV-2 prior to delivery who is non-infectious by clinical criteria (at least 10 days since onset of COVID-19 symptoms) or by testing criteria (two negative tests for SARS-CoV-2 at least 24 hours apart); and her infant(s).

Definitions of data elements

Age of mother
Completed years of age of mother, based on date of birth

Gravidity
The number of times the mother has been pregnant, including the current pregnancy

Race of mother

Black or African American
If the biological mother is a person having origins in any of the black racial groups of Africa

White
If the biological mother is a person having origins in any of the original peoples of Europe, the Middle East, or North Africa

Asian
If the biological mother is a person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam

American Indian or Alaska Native
If the biological mother is a person having origins in any of the original peoples of North and South America (including Central America), and who maintains tribal affiliation or community attachment

Native Hawaiian or Other Pacific Islander
If the biological mother is a person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands

Other
If none of the race categories above applies to the biological mother
Ethnicity of mother

**Hispanic**
If the biological mother is a person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race

**Non-Hispanic**
If the biological mother's ethnicity is not of Hispanic or Latino origin as defined above.

**Unknown**

Completed weeks of gestation of first positive SARS-CoV-2 test
Enter the completed weeks of gestation at which the mother had her first positive test for SARS-CoV-2

Enter 0 if unknown

Completed weeks of gestation of last positive SARS-CoV-2 test
Enter the completed weeks of gestation at which the mother had her last positive test for SARS-CoV-2

Enter -1 if the first diagnostic test was the only one done before delivery

Enter 0 if an additional last test was done before delivery but the completed weeks of gestation is unknown

Completed weeks of gestation of first negative SARS-CoV-2 test
Enter the completed weeks of gestation at which the mother had her first negative test for SARS-CoV-2

Enter -1 if there was not a negative test obtained before delivery

Enter 0 if it is unknown whether a negative test was obtained

Final maternal disposition status

**Discharged home**
Mother was discharged home from your institution

**Transferred to other facility**
Mother was transferred from your institution to another hospital, either as a step up for acute care, or as a step down for discharge planning

**Expired (provide reason below)**
The mother died before discharge home. If you select this answer, you will be prompted to complete an additional field detailing the cause of maternal death:

- Related to COVID-19
- Not related to COVID-19
- Unknown

**Unknown**
What was the severity of the previously resolved COVID-19 infection:

**Asymptomatic**
No known signs or symptoms of COVID-19 infection

**Sick at home**
Mother had one or more symptoms of COVID-19 infection, but did not require hospital admission.

**Required hospitalization for SARS-CoV-2 before delivery (anytime within 14 days prior to delivery)**

Mother was admitted to a hospital within 14 days prior to delivery for an illness known to be or later identified as COVID-19 infection (If selected, you will be prompted to identify maternal therapies: choose all that apply; and to provide the duration of hospitalization for COVID-19 infection).

- **IV fluids**
- **Supplemental O2**
- **CPAP**
- **Mechanical ventilation**
- **ECMO**
- **Unknown**
- **Other:** Provide description in the textbox

Unknown.

Total days of hospitalization for previously resolved COVID-19 infection (number):
Enter the number of days of maternal hospitalization

Enter 0 if unknown

**Labor (choose one)**

**Spontaneous**
Labor onset occurs without cervical ripening or intravenous agents.

**Augmented**
Stimulation of the uterus to increase the frequency, duration and intensity of contractions after the onset of spontaneous labor.
If you select augmented or induced, additional questions will populate regarding maternal or fetal indications

**Induced**
Stimulation of uterine contractions after spontaneous onset of labor
If you select augmented or induced, additional questions will populate regarding maternal or fetal indications

None
Delivery occurred without labor

If labor was augmented or induced OR delivery was by c-section, what was (were) the indication(s)? (choose all that apply)

Route of delivery
Vaginal

C-section
If you selected spontaneous labor and c-section, additional questions will populate regarding maternal or fetal indications that led to c-section delivery

Maternal indications (choose all that apply)

Post dates
Infant not delivered by 41 weeks’ gestation

Preeclampsia
High blood pressure, hyperreflexia, and proteinuria

Arrest of descent
Failure for the head to progress in the second stage after the cervix is completely dilated

Abruption
Partial or complete separation of the placenta from the inner wall of the uterus prior to delivery

Chorioamnionitis
A clinical diagnosis suggesting inflammation of the amnion and chorion of the placenta, due to bacterial infection

Other
Any indication not represented by the causes listed above. Please provide detail in textbox provided.

Fetal indications (choose all that apply)

Severe intrauterine growth restriction
Weight estimated to be less than the 10th percentile for the gestational age as per the population growth charts

Fetal distress
Concern that the fetus has inadequate oxygen delivery or blood flow. May be evidenced by fluctuations in fetal HR such as late decelerations, variable decelerations, or prolonged bradycardia

Hydrops fetalis
Fetal edema, ascites, and/or pleural effusions
Malpresentation
When a fetal part other than the head engages maternal pelvis (i.e. a breech presentation)

Other
Any indication not represented by the causes listed above. Please provide detail in the textbox provided.

Did mother receive specific treatment for SARS-CoV-2 earlier in pregnancy?
Yes
Mother received SARS-CoV-2 treatment. (An additional question will populate regarding what drug was given for treatment)
If yes, what medication(s) did mother receive (choose all that apply)

Chloroquine

Hydroxychloroquine

Remdesivir

Ritonavir

Favipiravir

Lopinavir

Other
If you select other, enter any other treatments or medications the mother received in the text box.

No
Mother did not receive SARS-CoV-2 treatment

Unknown
It is unknown whether mother received SARS-CoV-2 treatment

NEWBORN

Gestational age at birth (to nearest completed weeks)
Please complete to nearest completed gestational week i.e. 36w3d = 36 weeks

Birth weight (g)
Enter the birth weight in grams

Birth length (cm)
Enter the length in cm

Birth head circumference (cm)
Enter the head circumference in cm
Sex

Male
Female

Apgar at 5 minutes: 5 min Apgar score at 5 minutes; if unknown, enter -1

Status at birth

Liveborn
Stillborn
Death in delivery room

Birth multiplicity

Single
Twin A
Twin B
Higher order (triplet, etc.)

What were the locations at which the infant was cared for at your hospital (choose all that apply)

Neonatal Intensive care setting
The infant was cared for in the Neonatal ICU at your institution

Room-in with mother
The infant and mother were cared for together in the same room

Other
The infant was cared for in a setting not previously mentioned above. Please enter other location(s) in textbox.

Duration of neonatal hospitalization at your hospital (days)
Example:
An infant is admitted to your institution on June 1st, and discharged on June 20th. The total days of hospitalization would be 20

Final disposition status

Discharged home
The infant is discharged directly home from your institution

Transferred to another facility
The infant is transferred from your institution as a step up for acute care, or as a step down for discharge planning
Provide reason for transfer of infant in the drop down text box

Expired (provide reason below)
The infant expired. (If you select expired, you will be prompted to complete an additional field detailing cause of newborn death)
Cause of newborn death –

- Related to COVID-19
- Not Related to COVID-19
- Unknown

Primary reason for neonatal transfer to your hospital
Enter primary diagnosis resulting in transport to your hospital
Enter N/A is infant was inborn at your hospital

Other diagnoses (choose all that apply)
- None

**Microcephaly**
The infant had a head circumference within the first 24 hours of life which is smaller than expected when compared to babies of the same sex and age (2 standard deviations smaller)

**Encephalopathy**
The infant had documented signs of abnormal neurologic function in the first few days of life due to brain injury (i.e. birth asphyxia, cerebral hypoxia, HIE)

**Congenital anomalies (provide below)**
If you select this option, check the category(ies) of congenital anomaly from the list below. Additional lists of anomalies will pop up for each category checked; select the anomaly(ies) from each list.

- Central nervous system
- Congenital heart anomalies
- Gastro-intestinal anomalies
- Genito-urinary anomalies
- Chromosomal anomalies
- Pulmonary anomalies
- Other congenital anomalies
- Other – not listed (enter in a pop-up text box)

**Other diagnosis**
If you select this option, enter information in the textbox

[For Laboratory findings from birth to day 7 (choose all recorded), a table will appear for you to record the value obtained and day of age for your results. For example, if an infant is born on June 1st, the day of birth would be day 0. If that same infant has a lab result on June 3rd, the day of age would be 2.]

Laboratory findings from birth (day 0) to day 7 (choose all recorded)
- **Lowest white count**
- **Lowest neutrophil count**
- **Lowest lymphocyte count**
Lowest hemoglobin

Highest AST

Highest ALT

Highest CRP

Did the newborn have SARS-CoV-2 testing during hospitalization?
Example:
If an infant is born on June 1st the day of birth would be day 0. If that same infant has a SARS-CoV-2 test on or prior to June 14th, then the answer would be yes
Yes

No

If yes, what tests and results can you report?

Amniotic fluid PCR or culture

Placenta PCR or culture

Gastric aspirate PCR or culture

NP swab PCR

Rectal swab PCR

Antibody test (if tested, please identify:
Antibody testing method

IgG level

IgM level

Manufacturer of antibody test

Was the newborn admitted to a higher level of care (e.g. NICU) than a newborn nursery or general hospital ward (for boarding care)?
Yes

No

Discharge medications

None

Yes

If you select yes, enter details in the textbox
Email address of the member of the study team submitting these data
  Self-populated during authentication

Assigned sequenced tracking number (e.g., 1, 2, 3, 4 etc. in order of submission)
  Please number each of your CRFs for mother/infant dyads in which the mother resolved her
  COVID-9 infection by the time of delivery in order with cardinal numbers beginning with 1.
  You may order these either by date of infant birth or by order of your entry. Only your team
  will be able to link your site and patient tracking number to the patient MRN, which allows
  your submitted data to be de-identified.

When all of your data entry is complete, hit the SUBMIT button.