

NATIONAL REGISTRY FOR SURVEILLANCE AND EPIDEMIOLOGY OF PERINATAL COVID-19 INFECTION

Case definitions of the mother/infant dyads

For inborn infants (born at your reporting institution):

A pregnant woman (1) who is known to have had virologic testing positive for SARS-CoV-2 within 14 days prior to delivery or (2) who is admitted as a PUI and whose peri-delivery testing obtained through 72 hours after delivery is reported to be positive for SARS-CoV-2; and her infant(s).

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

A mother who is known to have had virologic testing positive for SARS-CoV-2 obtained within 14 days prior to through 72 hours after delivery at an outside hospital; and her infant(s) who is (are) transported to your hospital for a higher level of care.

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.

COVID-19 status at delivery **(Must provide a value)**

Confirmed COVID-19

If results of virological testing for COVID-19 performed in the 14 days before delivery are known to be positive at the time of delivery

PUI (Person Under Investigation)

If the initial positive results of virological testing for COVID-19 obtained from 14 days before delivery to 3 days after delivery first become known after delivery

Interval (days) between date of admission for delivery and date of neonatal birth

Example:

A mother is admitted to your institution on June 1st and delivers on June 3rd. The interval is 2 days.

Note: If infant was outborn and these data are unavailable, please leave blank

Interval (days) between first positive maternal test for SARS-CoV-2 and date of birth

Examples:

The date of the first positive laboratory result for SARS-CoV-2 is June 1st and the infant is delivered on June 3rd. The interval is +2 days.

The date of birth was June 3rd and the date of the first positive laboratory result for SARS-CoV-2 was June 5th. The interval is -2 days.

Note: If infant was outborn and these data are unavailable, please leave blank

Duration of maternal hospitalization (days)

Example:

A mother is admitted to your institution on June 1st, and discharged on June 20th. The total days of hospitalization is 20 days.

Note: If infant was outborn and these data are unavailable, please leave blank

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

Indication for which mother was tested (choose all that apply)

URI symptoms

Cough, nasal congestion, sinus congestion, sore throat

LRI symptoms

Respiratory distress, cough, wheezing

Fever

Defined as measured temperature $\geq 37.8^{\circ}$ C

GI symptoms

Vomiting, diarrhea, nausea

Myalgia and fatigue

Muscle pains and aches, loss of energy

Anosmia/ageusia

Defined as loss of smell or taste, may be partial or complete

Contact with SARS-CoV-2 case

Direct exposure to a known laboratory positive SARS-CoV-2 individual in the 14 days prior to testing

Travel

Any travel outside of the US, travelers returning from high risk countries, cruise ship travel, travel to high risk areas domestically where COVID-19 cases are known to be high (i.e. New York City)

Unknown

Mother tested for unknown causes

Other

Testing performed for a reason not represented in selections above. Please provide detailed explanation in box provided

Note: If infant was outborn and these data are unavailable, please leave blank

Maternal condition before admission for delivery

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. (If selected, you will be prompted to identify symptoms which are the same as those listed under “Indication for which mother was tested”

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).

IV fluids

Supplemental O2

CPAP

Mechanical ventilation

Other

Provide description in the textbox.

Days of illness before delivery (number)

Example:

A mother begins to feel ill on June 1st, and the mother delivers on June 20^t. The days of illness are 20.

Note: If infant was outborn and these data are unavailable, please leave blank

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

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

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

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

Concern about worsening maternal condition due to COVID-19 infection should pregnancy continue

Acute decompensation of mother requiring interventions such as intubation, ventilation, and cardiovascular support

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

Hydrop 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.

Rupture of Membranes (ROM)

Spontaneous

Natural rupture of the amniotic sac

Artificial

Rupture accomplished by external procedure.

Duration of ROM (hours)

Length of time in hours from initial rupture of membranes until the delivery of the fetus.

Did mother have negative SARS-CoV-2 testing after the positive test?

Yes

If mother had negative SARS-CoV-2 testing after delivery. (If you select yes, then a box will appear asking you to enter the number of days from delivery that mother had the negative test).

Example:

A mother delivered June 1st and on June 3rd had a negative SARS-CoV-2 test. The days would be 2.

No

If mother did not have a negative SARS-CoV-2 test after delivery

Unknown

If it is unknown whether the mother had a negative SARS-CoV-2 test after delivery

Did mother receive betamethasone before delivery

Yes

Mother received at least 1 dose prior to delivery

No

Mother did not receive any betamethasone prior to delivery

Unknown

It is unknown whether mother received betamethasone prior to delivery

Did mother receive specific treatment for SARS-CoV-2?

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

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

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.)

Resuscitation at birth (check all that apply)

Drying and stimulation only

Infant requires on drying and stimulation for resuscitation

Oxygen

Infant requires oxygen as part of resuscitation (blow-by only, or with other modalities)

Positive pressure (CPAP or mask ventilation)

Infant requires positive pressure to be applied via CPAP or face mask ventilation (may be with or without oxygen).

Intubation

Infant requires intubation as part of resuscitation

Chest compressions

Infant requires any chest compressions as part of resuscitation

Epinephrine

Infant requires the use of epinephrine as part of resuscitation (via endotracheal tube or IV)

Volume expansion

Infants requires volume expansion as part of resuscitation (i.e normal saline bolus)

Were mother and infant separated at your hospital at birth (if inborn) or was mother not given visitation rights until she was virologically cleared (if outborn)?

Yes

No

Unknown

Was the infant isolated at your hospital (choose all that apply)?

Yes – enhanced respiratory droplet

Yes – airborne precautions

Yes – negative pressure room

Yes – other (Provide below)

If yes, enter other isolation method in textbox.

No

Unknown

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

Nursery setting separate from mother

The infant was cared for separate from mother in the newborn nursery

Room-in with mother

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

Negative pressure isolation room

The infant was cared for in a negative pressure isolation room, (a negatively pressured room with respect to adjacent areas to prevent airborne contaminants / pathogens from drifting to other areas) where Airborne Precautions were in place

Regular isolation room

The infant was cared for in a standard isolation room where Respiratory Droplet Precautions were in place

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

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

Clinical illness presumed related to COVID-19 infection

Other clinical illness not presumed to be related to COVID-19 infection

No clinical illness; transport due to maternal COVID-19 diagnosis

N/A (infant was inborn at your hospital)

Neonatal signs during hospitalization (choose all that apply)

None

The infant had no signs or symptoms of concern

Fever (>37.8° C)

The infant had at least one measured temperature >37.8° C

Cough

Vomiting/diarrhea

Respiratory distress diagnosis (provide below)

The infant had a diagnosis of respiratory distress (If checked, enter details in textbox)

Hypotonia

The infant had decreased muscle tone

Maximal level of respiratory support during hospitalization (select one):

None

Supplemental oxygen

CPAP

Mechanical ventilation

ECMO

Other diagnoses (choose all that apply)

None

Delayed transition

The infant had signs of respiratory distress that resolved within the first few hours of life (i.e transient tachypnea)

Surfactant deficiency

The infant had a clinical diagnosis of RDS

Pulmonary hypertension

The infant had documented pulmonary hypertension on cardiac echo

Hypotension

The infant had blood pressures that were treated with volume, pressors, or steroids

Hypoglycemia

The infant had documental blood glucose less than 30 mg/dL in the first 24 hours of life and/or less than 45 mg/dL thereafter

Hypothermia

The infant has measured core temperature less than 35 C

Culture-confirmed bacterial sepsis (organism) (Provide below)

The infant had a positive blood culture that is positive. (If you check this diagnosis, enter the organism(s) in the textbox)

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 day of life due to brain injury (i.e. birth asphyxia, cerebral hypoxia, HIE)

Congenital anomalies (provide below)

If you select this option, enter anomaly(ies) in the textbox

Other

If you select this option, enter information in the textbox

Other administered intensive care (choose all that apply)

None

Antibiotics

Antivirals

If you select this option, enter information in the textbox.

Intravenous fluids

Inhaled nitric oxide or prostacyclin

Pressors

If you select this option, choose all that apply

**Dopamine
Dobutamine
Epinephrine**

Surfactant

Hydrocortisone

Dexamethasone

Therapeutic hypothermia

The infant received full body or selective head cooling

ECMO

Other

If you select this option, choose all that apply

[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 the first 14 days of life?

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

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

Did the mother provide breast milk (choose all that apply) –

Yes – direct nursing by mother

The infant latched on and fed at the breast

Yes – expressed maternal milk fed by mother

The infant fed milk provided by the mother via breast pump that was bottle fed to the infant

Yes – expressed maternal milk fed by another caregiver

The infant fed milk provided by the mother via breast pump that was fed to the infant by another caregiver (bottle or feeding tube)

Yes – donor milk

The infant was fed donor breast milk

No

The infant did not receive breast milk

Unknown

If the infant received mother's own milk, either by direct breast feeding or by expression, what was the viral testing status of the mother at that time?

Positive

The mother's viral testing for SARS-CoV-2 was documented as positive

Pending

The mother's viral testing is pending and has not been resulted prior to feeding

Negative

The mother's viral testing is documented as negative

Not tested

The mother never received viral testing

Unknown

The mother's viral testing status is unknown.

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 in order with cardinal numbers beginning with 1. Only your team will be able to link your site and patient tracking number to the patient MRN, which allows your submission to be de-identified. Please enter mother/infant dyad data according to the chronological order of birth.

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