National Registry for Surveillance and Epidemiology of Perinatal COVID-19 Infection

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Abstract and Background:

Pregnant women are at risk for COVID-19 infection during the current pandemic. To date, information about the different routes (transplacental, perinatal, and postnatal) and risks of transmission of this disease to newborn infants is anecdotal and not population-based. Given that SARS-CoV-2 is a respiratory virus, the risk of transplacental transmission might be presumed to be very low to absent. The risk of perinatal transmission is unknown. The risk of postnatal transmission is likely to be very high if the newborn is not immediately separated from the mother, and the severity of postnatally acquired disease in the newborn is unknown.

This National Registry represents a collaboration between the American Academy of Pediatrics SONPM, the Vermont-Oxford Network (VON), and MedNAX (an organization of private neonatologists). It has been informed by discussion with Dr. Karen Puopolo at the University of Pennsylvania, by Dr. Jeffrey Horbar at VON and Dr. Reese Clark at MedNAX, and by international colleagues who are organizing similar efforts in their countries through their neonatal networks. The SONPM National Registry will provide population data on dyads of mothers who deliver who test positive for COVID-19 infection between 14 days before through 3 days after delivery, and their infants. The case report forms will collect de-identified data on infection control practices, virological testing, maternal and infant clinical signs and symptoms, disease severity, modalities of treatment, use of breast milk, and maternal and infant outcomes. These data will help inform the neonatal care community about the risk of different types of transmission, the severity of disease in the newborn, and the efficacy of different infection control practices.

This National Registry will solicit the participation of hospitals with newborn delivery services that have the capability for neonatal intensive care under the auspices of the AAP, VON, and MedNAX. These organization will send an invitation on behalf of the PI to the neonatologists and neonatal hospitalists on their listserv that will describe the aims and potential benefits of the Registry and encourage participation. The invitation will include instructions on how to meet regulatory requirements to participate and the UF form that must be completed and returned to enable participation.

Specific Aims:

To provide real-time cumulative information on a weekly basis concerning:

(1) The number of cases of COVID-19 infection among mothers who deliver at participating hospital;
(2) The likelihood of perinatal transmission of COVID-19 from mother to baby
(3) The likelihood of post-natal transmission of COVID-19 from mother to baby and the risk factors associated with that transmission
(4) The spectrum of disease severity in newborns with COVID-19 infection and the risk factors for more severe disease
(5) The outcomes of infants with acquired COVID-19 infection
(6) The infection control procedures that hospitals are practicing (immediate maternal-newborn separation vs. rooming-in; direct nursing vs. expressed breast milk feedings; etc.)

While the early phase of this Registry will compile information about mother/infant dyads whose mother acquired COVID-19 infection within 2 weeks of birth, the Registry is positioned to accumulate data on the outcomes of mothers and their infant(s) if maternal infection was acquired earlier in pregnancy and the mother's virological testing near the time of delivery was negative. These data will inform us of the effects of early maternal infection on fetal outcomes.

Research Plan:

The National Registry is a non-interventional study that seeks to compile de-identified data from volunteering participating sites. Data will be stored on a server at the University of Florida and protected by internal procedures. Local investigators will have "write-only" access to the databank. Cumulative descriptive data summaries will be provided to participating hospitals on a weekly basis on the SONPM website.

There is no DSMB for this registry study.

Risks and Discomforts: Not applicable; this study involves no patient interventions.

Possible Benefits:

It is anticipated that weekly descriptive studies will provide information to hospitals and neonatal care providers across the country that will improve counseling of pregnant women with COVID-19 infections, assist hospitals with optimizing infection control practices, and aid the neonatal care team with prognostication of infant risks and severity of disease. It is hoped that this population-based study will provide definitive information about the relative risks of perinatal and postnatal transmission.

Conflict of Interest:

The PI has no conflicts of interest to declare.