



Perinatal COVID-19: guideline development, implementation, and challenges

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Purpose of review

The aim of this review was to describe the process of and challenges in developing national guidance for management of infants born to mothers with COVID-19.

Recent findings

Beginning in January 2020, infection with the novel coronavirus SARS-CoV-2 spread across the USA, causing the illness COVID-19. As pregnant women began to present for delivery while sick with COVID-19, the American Academy of Pediatrics (AAP) convened a writing group in March 2020 to develop guidance for the management of their newborns. The initial guidance was developed emergently and was forced to rely on extremely limited data from China. The initial guidance advocated for a conservative approach that included temporary physical separation of infected mother and newborn. To address the knowledge deficit, the AAP sponsored a volunteer registry to collect data on perinatal infection and management. As data have emerged informing the natural history of COVID-19, the performance of PCR-based diagnostics, the value of infection control measures and the risk of infant disease, AAP has issued serial updates to newborn guidance.

Summary

Evolving knowledge on the epidemiology of perinatal COVID-19 has informed newborn guidance. The most recent guidance focuses on the use of infection control measures to support maternal-newborn contact and breastfeeding.

Keywords

COVID-19, neonatal, pandemic, SARS-CoV-2

INTRODUCTION

The WHO first recognized an outbreak of a pneumonia of unknown cause in Wuhan, China, in December 2019 [1]. This illness was termed coronavirus disease 2019 (COVID-19) and identified as being caused by a novel coronavirus, designated severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The morbidity and mortality associated with this pandemic triggered immediate responses from governmental agencies and medical organizations worldwide, who sought to provide guidance to the public as well as to healthcare workers and facilities, despite a limited initial understanding of the pathogenesis of the new infection. Here, we describe the approach taken by members of the American Academy of Pediatrics (AAP) to meet the need for newborn guidance [2].

THE IMPACT OF AN EVOLVING PANDEMIC ON PREGNANCY AND NEWBORN CARE

The rapidity with which SARS-CoV-2 initially spread among vulnerable populations and the severity of

the resulting illness overwhelmed healthcare settings across the world. As international reports described overflowing emergency departments, inpatient floors at capacity and ICUs running out of ventilators, the initial U.S. sites of the pandemic responded by limiting access to discretionary healthcare. Hospitals cancelled elective surgeries, suspended screening procedures and preventive care (such as mammography and screening colonoscopy) and where possible, transitioned outpatient care to telehealth platforms [3]. Perinatal care faced unique challenges with COVID-19 management

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KEY POINTS

- The COVID-19 pandemic created acute clinical needs in newborn care that have been addressed with guidance provided by the American Academy of Pediatrics.
- The guidance has been serially updated with rapidly emerging evidence that has informed the epidemiology, immunology and clinical implications of maternal SARS-CoV-2 infection near the time of delivery.
- Current guidance emphasizes that neonatal clinicians should use appropriate infection control precautions when providing care in the delivery room, neonatal ICU and in the course of well newborn care.
- In the absence of severe illness, infected mothers may room-in with their newborns and should be instructed on the use of infection control precautions to prevent neonatal infection.
- Mothers should be supported and encouraged to breastfeed their infants, as there is no evidence that breast milk is a source of newborn infection.

and could not be so readily transformed. Although some prenatal care visits were transitioned to virtual, procedures such as phlebotomy, urinalysis, blood pressure measurement, Group B *Streptococcus* screening and ultrasound monitoring of foetal well being all required interaction with medical facilities and personnel. The current U.S. healthcare system also relies on inpatient hospitals for labour, delivery and newborn care. Clinicians sought urgent guidance for practical questions related to perinatal COVID-19 management, addressing delivery room, well newborn and neonatal intensive care, as well as the optimal approach to protecting healthcare workers from infection while providing such care. Initial questions arose from a limited understanding of the pathogenesis of SARS-CoV-2 infection during pregnancy and the peripartum period:

- (1) Can SARS-CoV-2 be vertically transmitted before birth, or during the birth process?
- (2) What is the risk of horizontal transmission from infected mother to newborn after birth?
- (3) Is SARS-CoV-2 present in breast milk and can milk transmit the virus?
- (4) Do newborns get sick from SARS-CoV-2?
- (5) If they do get sick, what are the characteristics that illness?

The lack of knowledge made it difficult to address issues of newborn management, such as:

- (1) Should we test newborns for the virus, and if so, when?
- (2) What is the best way to minimize the risk of horizontal transmission of SARS-CoV-2 infection from mother to newborn?
- (3) Should mothers with COVID-19 breastfeed?
- (4) How shall we counsel parents and community paediatricians when the newborn goes home?

Finally, multiple questions arose regarding risk of transmission from infected mothers and infants to healthcare personnel:

- (1) What personal protective equipment should be used to care for the infant born to a mother with COVID-19, in the delivery room, well newborn setting or newborn ICU (NICU)?
- (2) What type of isolation is needed if the newborn requires NICU care?
- (3) What precautions should be taken with parent presence in the NICU when mother has COVID-19?

In March 2020, the AAP convened a writing group consisting of physician members of the AAP Committee on Fetus and Newborn, Committee on Infectious Diseases and Section on Neonatal-Perinatal Medicine (SONPM). In later updates, a physician from Section on Hospital Medicine joined the writing group. This group collaborated to develop guidance focused on newborn care.

OTHER RESPIRATORY INFECTIONS IN THE PERIPARTUM PERIOD

In the absence of adequate information on SARS-CoV-2, the writing group began by reviewing the approach to other serious infectious diseases transmitted by the respiratory route during pregnancy and the postpartum period. SARS-CoV-1 caused the epidemic of severe acute respiratory syndrome (SARS) that began in China in 2002. Although it caused serious and often fatal illness, the virus was not as infectious as SARS-CoV-2, and ultimately spread to nearly 8000 persons in 29 countries from 2003 to 2004 [4]. It caused more severe disease in pregnant versus nonpregnant women with high rates of pregnancy loss, premature delivery and maternal mortality [5,6[¶]]. SARS-CoV-1 did not appear to be vertically transmitted, was not found in breast milk and disease was not described in newborns; however, management approaches generally included newborn separation until maternal recovery [6[¶],7]. In contrast to the limited scope of the SARS epidemic, the H1N1 influenza pandemic in 2009–2010 affected an estimated 60 million persons

in the U.S. alone [8]. H1N1 influenza had a particularly malignant impact on pregnant women and the very young. Pregnant women, who make up nearly 1% of the population, accounted for nearly 5% of attributable mortalities [9]. Infection during pregnancy increased the risk premature delivery and poor foetal growth, and infected infants younger than 6 months had the highest rates of hospitalization and mortality among the paediatric population [10,11]. Given the risks of influenza to newborns, the Centers for Disease Control and Prevention (CDC) recommended that mothers with suspected or confirmed influenza near delivery be temporarily separated from their newborns and expressed breast milk be fed by a healthy caregiver, until the mother was afebrile without antipyretics for more than 24 h, with improving symptoms [12]. Temporary separation is also recommended for maternal active primary varicella infection near delivery, due to the risk of severe neonatal disease, until the mother's lesions are crusted and she can be assumed noninfectious [13]. The management approach to these and other infectious diseases, such as active tuberculosis, is based on the fact that these pathogens are very contagious; that neonatal disease can be severe; and in the case of influenza and varicella, that there is inadequate transplacental transfer of protective maternal antibody if the mother is infected close to delivery.

EARLY REPORTS FROM CHINA

Early case series from China in late 2019 described a highly infectious virus causing severe and often fatal respiratory disease in adults, particularly in those with underlying health conditions [14]. Pregnant women in China with COVID-19 suffered from fever, gastrointestinal symptoms, pneumonia and respiratory failure [15,16]. Foetal distress, stillbirth and premature labour were also reported [15,17]. Findings suggested that in-utero transmission to newborns could occur, albeit infrequently [18–21]. Most publications addressing Chinese newborns described them as asymptomatic or mildly symptomatic, although reports of pneumonia, haemodynamic instability, end-organ dysfunction and death were also published [15,21,22]. A case series of over 2000 paediatric patients with COVID-19 in China confirmed that children of all ages were susceptible, and although children experienced relatively milder illness than adults, young infants could develop severe illness [23].

These early reports addressing Chinese newborns were limited by small sample sizes and indeterminate delivery indications, and largely described women undergoing Caesarean deliveries

at term gestation. Most notably, Chinese guidance recommended immediate separation of newborns from infected mothers, and complete isolation from the mother and other family members for a minimum of 7–14 days [24]. Newborns were tested for SARS-CoV-2 at 24 h, 5–7 days and 14 days after birth. Mothers were encouraged to pump and discard breastmilk until they were determined to be noninfectious. In light of this approach to newborn care, it was difficult to interpret the initial Chinese communications that newborns were rarely infected with SARS-CoV-2.

INITIAL AMERICAN ACADEMY OF PEDIATRICS NEWBORN GUIDANCE

In March 2020, much remained unknown about the risk of perinatal COVID-19, but this much was clear: SARS-CoV-2 was very contagious, and it was killing people at an alarming rate. On 2 April 2020, the same day that over 1 million global cases were reported, the AAP posted its initial guidance for the management of infants born to mothers with COVID-19 on their website [25]. AAP clinical reports are normally many months in the making, undergoing reviews by multiple relevant stakeholders and numerous rounds of revision before review and approval by the AAP Board of Directors and publication in the journal *Pediatrics*. Given the emergent nature of the COVID-19 pandemic, it was decided that guidance relevant to specific parts of paediatric practice would be written by appropriate writing groups, subject to serial rapid review and approval, and would be posted on the AAP website. AAP also partnered with CDC and the American College of Obstetrics and Gynecology to ensure alignment of guidance on SARS-CoV-2 infection prevention and control in inpatient obstetric care settings [26,27]. Initial newborn guidance addressed multiple facets of perinatal care in the setting of maternal COVID-19 and was provided both in long-form PDF format, and as a series of Frequently-Asked Questions. Authors of the 2 April guidance noted 'The following interim guidance from the AAP is based on the current, quite limited evidence as of March 30, 2020 ... The clinician should anticipate that this guidance will be revised when further evidence is available to inform newborn management.

The guidelines were purposefully cautious and assumed worst case scenarios, namely that the virus was easily transmitted to newborns and would cause significant morbidity and mortality; that there was a reasonable risk to neonatal clinicians in delivery attendance and neonatal resuscitation; and that there was a risk to both clinicians and other neonatal patients if an infant born to a mother with

COVID-19 required NICU care. On the basis of limited data and experience with other respiratory viruses, the initial guidance assumed that breast milk would not be a source of neonatal infection. Key recommendations included:

- (1) Personal protective equipment: Advised clinicians to use airborne respiratory protection when attending the delivery of a mother with COVID-19, and whenever the newborn required aerosol-generating respiratory support. In all other cases, contact and droplet precautions were advised until the infant tested negative.
- (2) Newborn care: Advised temporary separation of newborn and mother with COVID-19 during the birth hospitalization, and use of contact precautions in the home until mother and other caregivers met criteria of being noninfectious. Mothers who preferred rooming-in during the birth hospitalization were advised to use a mask, hand and breast hygiene, and physical distancing between feeding and care.
- (3) Breastfeeding: Advised feeding expressed milk during periods of separation and use of a mask and hygiene during direct breastfeeding until mother met criteria for being noninfectious.
- (4) Newborn viral testing: Advised testing infants for SARS-CoV-2 at 24 h and, if still in the birth facility, at 48 h after birth, as centre resources allowed.
- (5) Postdischarge care: Frequent outpatient follow-up via telephone, telemedicine, or in-person assessments through 14 days after discharge was advised if the newborn was stable for discharge with SARS-CoV-2 infection or remained at risk for postnatal acquisition.

EVOLUTION OF AMERICAN ACADEMY OF PEDIATRICS NEONATAL COVID GUIDANCE

Since April 2020, new evidence has emerged relevant to newborn care. First, the period of time that persons with SARS-CoV-2 infection shed infectious virus and were contagious to others was clarified. This information required studies utilizing viral culture rather than PCR-based diagnostics, and provided data on how persons can be infectious before the onset of symptoms and during entirely asymptomatic infection, as well as how severely ill persons can have longer periods of infectivity [28]. Second, it was recognized that PCR-based diagnostic tests for SARS-CoV-2 could detect the virus for up to 12 weeks after a person is no longer infectious [28]. This finding was especially important given the widespread implementation of routine testing of

parturient women at hospital admission. Third, reports from Europe and from initial sites of disease activity in the U.S. demonstrated that few (<5%) newborns test positive for SARS-CoV-2 in the immediate days after birth, and most appear to be minimally if at all symptomatic [29,30[■],31[■],32,33[■],34[■]]. Maternal-newborn rooming-in with infection control precautions appeared to be effective in preventing newborn disease transmission [31[■],32]. Fourth, although several case reports documented PCR-based detection of SARS-CoV-2 in the breast milk of infected mothers, a larger study of 18 symptomatically infected women was unable to culture live virus from breast milk [35,36,37[■],38]. Studies also demonstrated that Holder pasteurization kills live virus when experimentally added to breast milk, suggesting that processes used to prepare donor milk could eliminate infectious virus, if present [37[■],38]. Finally, reports of paediatric infection found that neonates and young infants were at risk for developing community-acquired infection severe enough to require hospitalization and respiratory support [39,40[■],41,42[■],43].

Newborn guidance was serially revised, and updated versions were posted on the AAP website on 21 May, 22 July and 9 September 2020. As of this writing, another revision is under review. Guidance evolved as evidence emerged.

- (1) May 2020: Added guidance to support delayed cord clamping and skin-to-skin practices for most infants; added language to counsel parents on the risks and benefits of temporary separation versus rooming-in to allow for informed decision making; clarified that there is no advantage to early hospital discharge for newborns.
- (2) July 2020: Changed guidance to encourage rooming-in with appropriate infection control precautions; offer temporary separation for mothers who are ill and/or unable to care for the newborn; aligned with the CDC's revised symptom and time-based approach to determine when a mother is no longer contagious.
- (3) Sept 2020: Guidance on infection prevention measures and newborn management largely unchanged. Updated statistics from the Perinatal COVID-19 Registry, and included published evidence on SARS-CoV-2 in breast milk [44].

CLINICAL NEEDS AND PAUCITY OF DATA: A CALL TO ARMS

From the beginning of the pandemic, perinatal clinicians, infection control specialists, healthcare administrators and families all sought guidance on how to manage pregnant women and their

newborns. All were cognizant that recommendations could have a significant impact on family dynamics, maternal bonding, and caretaker responsibilities. The international academic medical community quickly got to work. Within 4 months after the pandemic began, upwards of 7000 COVID-19 related reports were published in PubMed [45]. Many investigators opted for posting unreviewed manuscripts on preprint servers, renewing discussion about how to best balance timely dissemination with careful peer-review [46]. Simultaneously, investigators across the country recognized that immediate data collection and organization was needed in order to improve these recommendations over time, and to develop evidence-based guidelines to protect women and their newborns. National surveillance and clinical registry data could provide critical insights into patient demographics and characteristics, testing and treatment patterns, and clinical outcomes in patients affected by COVID-19 [47]. Although clinical trials are the gold standard for therapies, ongoing real-time data collection provides an opportunity to study the clinical effectiveness of prevention, diagnosis and treatment strategies of COVID-19 in specific patient populations [47]. Therefore, in March 2020, the AAP SONPM announced it was launching a National Registry for Surveillance and Epidemiology of Perinatal COVID-19 Infection [48]. The Registry is supported by the AAP and partially funded by the CDC with the goal to gather evidence about the relative risks of transplacental, perinatal and postnatal transmission as well as about the efficacy of infection control practices. Other similar regional and national pregnancy and birth cohorts assembled existing infrastructures or novel data collection techniques to investigate the impact of COVID-19 on pregnant women and their newborns [49].

CONCLUSION

As clinicians who have been active in the development of both neonatal guidance and evidence during this pandemic, we personally find two important lessons in this terrible time.

First, science and advocacy share common but fragile ground. The initial AAP newborn guidance was purposely and transparently conservative in recommending temporary maternal-newborn separation. It was also clearly provided as a temporary measure that awaited evidence to confirm or refute its necessity. The response from some family and breastfeeding advocates was swift condemnation and endorsement of differing guidance from the WHO [50–52]. Such advocacy failed to recognize both the history of using this approach other highly

infectious and potentially harmful for perinatal infections, not to mention the frequency with which mothers and newborns are often routinely separated for a variety of other conditions (such as for risk of early-onset sepsis or for treatment of hypoglycaemia) at many U.S. birth centres. Most importantly, it failed to recognize the terrible consequences had SARS-CoV-2 infection been a source of severe morbidity and mortality among newborns. We share (and at our birth centre, we practice daily) the commitment of the AAP to supporting and promoting skin-to-skin care after birth, maternal/newborn rooming-in and exclusive breastfeeding as optimal newborn nutrition. Only the threat of an evolving, deadly pandemic of a novel viral infection could temporarily impact that commitment. When this pandemic is behind us, we believe that the perinatal community should revisit this controversy and enter into a thoughtful discussion of how we approach the risk-benefit balance of ensuring both short-term and long-term newborn health.

Second, only science can truly inform practice. Locally, we have focused on studies of maternal serology to contribute to an evidence base that we hope will ultimately define and narrow the time period for which maternal and newborn infection control precautions are needed [53¹¹]. The international perinatal community has rapidly acquired data on the risk of COVID-19 to the pregnant woman, foetus and newborn, on the biology and immunology of maternal and neonatal infection, and on the impact of specific practices. This has been and will continue to be critically impactful. The creation of small and large just-in-time cohorts should be applauded. Yet, it is important to recognize how powerful a national population-based, longitudinal birth registry, which does not exist currently, could have been for driving evidence-based perinatal medicine during the current pandemic [54,55]. The creation and maintenance of such a database could provide invaluable data for ongoing studies and inevitable future pandemics.

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Conflicts of interest

Dr Flannery has none to report. Dr Puopolo is a member of the American Academy of Pediatrics COVID-19 newborn guidance writing group.

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