

# Outcomes of Neonates Born to Mothers With Severe Acute Respiratory Syndrome Coronavirus 2 Infection at a Large Medical Center in New York City

Dani Dumitriu, MD, PhD; Ukachi N. Emeruwa, MD, MPH; Erin Hanft, MD; Grace V. Liao, MD; Elizabeth Ludwig, MD; Lauren Walzer, DO; Brittany Arditi, MD, MSCR; Minna Saslaw, MD; Maria Andrikopoulou, MD, PhD; Tessa Scripps, MD; Caitlin Baptiste, MD; Adrita Khan, MD; Noelle Breslin, MD; David Rubenstein, MD; Lynn L. Simpson, MD; Margaret H. Kyle, BA; Alexander M. Friedman, MD, MPH; Daniel S. Hirsch, MD; Russell S. Miller, MD; Cristina R. Fernández, MD, MPH; Karin M. Fuchs, MD, MHA; M. Kathleen Keown, MD; Melissa E. Glassman, MD, MPH, IBCLC; Ashley Stephens, MD; Archana Gupta, MD; Sally Sultan, MD; Caroline Sibbles, MD; Susan Whittier, PhD; Wanda Abreu, MD, IBCLC; Francis Akita, MD; Anna Penn, MD, PhD; Mary E. D'Alton, MD; Jordan S. Orange, MD, PhD; Dena Goffman, MD; Lisa Saiman, MD, MPH; Melissa S. Stockwell, MD, MPH; Cynthia Gyamfi-Bannerman, MD, MSc

**IMPORTANCE** Limited data on vertical and perinatal transmission of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and health outcomes of neonates born to mothers with symptomatic or asymptomatic coronavirus disease 2019 (COVID-19) are available. Studies are needed to inform evidence-based infection prevention and control (IP&C) policies.

**OBJECTIVE** To describe the outcomes of neonates born to mothers with perinatal SARS-CoV-2 infection and the IP&C practices associated with these outcomes.

**DESIGN, SETTING, AND PARTICIPANTS** This retrospective cohort analysis reviewed the medical records for maternal and newborn data for all 101 neonates born to 100 mothers positive for or with suspected SARS-CoV-2 infection from March 13 to April 24, 2020. Testing for SARS-CoV-2 was performed using Cobas (Roche Diagnostics) or Xpert Xpress (Cepheid) assays. Newborns were admitted to well-baby nurseries (WBNs) (82 infants) and neonatal intensive care units (NICUs) (19 infants) in 2 affiliate hospitals at a large academic medical center in New York, New York. Newborns from the WBNs roomed-in with their mothers, who were required to wear masks. Direct breastfeeding after appropriate hygiene was encouraged.

**EXPOSURES** Perinatal exposure to maternal asymptomatic/mild vs severe/critical COVID-19.

**MAIN OUTCOMES AND MEASURES** The primary outcome was newborn SARS-CoV-2 testing results. Maternal COVID-19 status was classified as asymptomatic/mildly symptomatic vs severe/critical. Newborn characteristics and clinical courses were compared across maternal COVID-19 severity.

**RESULTS** In total, 141 tests were obtained from 101 newborns (54 girls [53.5%]) on 0 to 25 days of life (DOL-0 to DOL-25) (median, DOL-1; interquartile range [IQR], DOL-1 to DOL-3). Two newborns had indeterminate test results, indicative of low viral load (2.0%; 95% CI, 0.2%-7.0%); 1 newborn never underwent retesting but remained well on follow-up, and the other had negative results on retesting. Maternal severe/critical COVID-19 was associated with newborns born approximately 1 week earlier (median gestational age, 37.9 [IQR, 37.1-38.4] vs 39.1 [IQR, 38.3-40.2] weeks;  $P = .02$ ) and at increased risk of requiring phototherapy (3 of 10 [30.0%] vs 6 of 91 [7.0%];  $P = .04$ ) compared with newborns of mothers with asymptomatic/mild COVID-19. Fifty-five newborns were followed up in a new COVID-19 Newborn Follow-up Clinic at DOL-3 to DOL-10 and remained well. Twenty of these newborns plus 3 newborns followed up elsewhere had 32 nonroutine encounters documented at DOL-3 to DOL-25, and none had evidence of SARS-CoV-2 infection, including 6 with negative retesting results.

**CONCLUSIONS AND RELEVANCE** No clinical evidence of vertical transmission was identified in 101 newborns of mothers positive for or with suspected SARS-CoV-2 infection, despite most newborns rooming-in and direct breastfeeding practices.

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**Author Affiliations:** Author affiliations are listed at the end of this article.

**Corresponding Authors:** Cynthia Gyamfi-Bannerman, MD, MSc, Division of Maternal-Fetal Medicine, Department of Obstetrics and Gynecology, Columbia University Irving Medical Center, 622 W 168th St, PH 16-66, New York, NY 10032 (cg2231@cumc.columbia.edu); Melissa S. Stockwell, MD, MPH, Division of Child and Adolescent Health, Department of Pediatrics, Columbia University Irving Medical Center, 622 W 168th St, VC 417, New York, NY 10032 (mss2112@cumc.columbia.edu).

New York, New York, has been an epicenter of the coronavirus disease 2019 (COVID-19) pandemic, with 9401 deaths as of April 27, 2020.<sup>1</sup> Although much has been written about the course of COVID-19 in adults, fewer data are available for pregnant women and their newborns. For other viral infections, pregnancy confers increased risk of morbidity, with a well-described risk of vertical transmission and adverse outcomes in newborns.<sup>2-5</sup> However, studies evaluating the potential for vertical and/or postnatal transmission of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) are few in number, have small sample sizes, and come primarily from China, from which results might not generalize to all populations. Although some studies<sup>6-10</sup> have shown no evidence of vertical transmission, a few others occasionally describe newborns with SARS-CoV-2 detected by polymerase chain reaction assay from upper respiratory tract swabs and mild respiratory disease<sup>11-13</sup> or self-resolving pneumonia.<sup>14,15</sup> In the first series outside of China, Breslin et al<sup>16</sup> evaluated an initial 2 weeks of confirmed SARS-CoV-2 infection in pregnant women with similarly reassuring findings, suggesting no evidence for vertical transmission immediately post partum. Given continued worldwide spread of SARS-CoV-2, rapid dissemination of the experiences of large medical centers with pregnant women positive for SARS-CoV-2 and their newborns is imperative.

Multiple organizations have released interim guidance for the management of pregnant women with SARS-CoV-2 infection and their newborns.<sup>17-21</sup> Recommended practices have included mother-newborn separation, no direct breastfeeding, and early bathing of newborns. These conservative recommendations were undertaken in the context of the absence of data on rates of vertical and perinatal transmission. Furthermore, recommendations sometimes conflict with each other. Studies to date have not described implementation of infection prevention and control (IP&C) measures and their effects on transmission.

We herein present our experience with mothers who tested positive for SARS-CoV-2 and their newborns in a medical center located in New York City during the first 6 weeks of the COVID-19 pandemic. The objectives of this study are to (1) describe the rate of vertical transmission among newborns born to mothers with perinatal SARS-CoV-2 infection, (2) detail institutional IP&C practices associated with these outcomes, and (3) report the clinical characteristics and clinical courses of neonates in the immediate postpartum period.

## Methods

### Study Design, Study Sites, and Study Population

We conducted a retrospective cohort analysis of all newborns born to mothers positive for or with suspected SARS-CoV-2 infection at the NewYork-Presbyterian Morgan Stanley Children's Hospital or NewYork-Presbyterian Allen Hospital from March 13 (first diagnosed maternal COVID-19 case at Morgan Stanley Children's Hospital) to April 24, 2020. These hospitals are both located in northern Manhattan and affiliated with Columbia University Irving Medical Center. This study was ap-

## Key Points

**Question** What is the risk of mother-to-newborn transmission of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)?

**Findings** In this cohort analysis of the first 101 neonates born to mothers with perinatal SARS-CoV-2 infections at a single institution, 2 (2.0%) had positive test results for SARS-CoV-2, but none had clinical evidence of coronavirus disease 2019 (COVID-19), despite most infants rooming-in with mothers and direct breastfeeding. Fifty-five infants were followed up in the first 2 weeks of life in a new COVID-19 Newborn Follow-up Clinic, all of whom remained healthy.

**Meaning** These findings suggest that during the COVID-19 pandemic, separation of affected mothers and newborns may not be warranted, and direct breastfeeding appears to be safe.

proved by the institutional review board of Columbia University Irving Medical Center with a waiver of informed consent because the study was retrospective. This study followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) reporting guideline.

From March 13 to March 21, only women who were symptomatic on presentation and those with unexplained peripartum respiratory findings were tested for SARS-CoV-2. Universal SARS-CoV-2 testing of women admitted to labor and delivery was implemented on March 22. A publication of the pooled New York City experience reported outcomes of 67 women and their 68 infants from our center.<sup>22</sup> Of those 67 mothers, data were previously published on 43 with only 18 infants described because most of the women in that series did not deliver.<sup>16</sup>

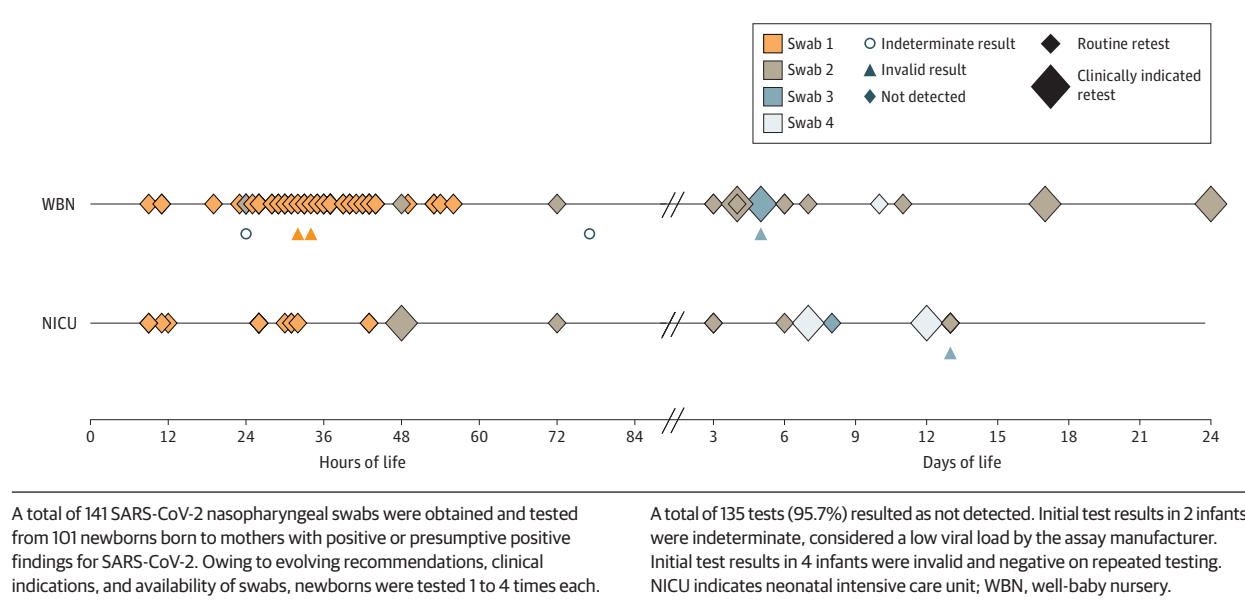
### Maternal Testing for SARS-CoV-2

Nasopharyngeal swab specimens were tested for SARS-CoV-2 at the Clinical Microbiology Laboratory at Columbia University Irving Medical Center. The Cobas SARS-CoV-2 polymerase chain reaction assay (Roche Diagnostics) was initially used exclusively and continues to be used in preadmission testing. On April 10, the Xpert Xpress SARS-CoV-2 polymerase chain reaction assay (Cepheid) replaced testing in the labor and delivery unit, owing to its more rapid turnaround time. Both assays received emergency use authorization from the US Food and Drug Administration. Testing occurred either on admission to the labor and delivery unit, at a preadmission testing clinic the day before scheduled deliveries, or on presentation for evaluation of COVID-19 symptoms.

### Newborn COVID-19 Testing

A minimum of 1 nasopharyngeal swab specimen was obtained from each newborn and tested for SARS-CoV-2 using the Cobas or Xpert Xpress tests described above (Figure). Newborn swabbing was standardized to ensure adequate sampling.<sup>23-26</sup> Number of times and exact age at which newborns were tested changed during the study period owing to evolving insights about transmission and availability of test collection kits. Additional testing of newborns was performed for changes in clinical status. Newborns with invalid test results

Figure. Newborn Testing for Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)



underwent retesting.<sup>16</sup> Newborns with indeterminate results, reflecting low viral load per the assay manufacturer, were presumed to have positive findings and variably underwent retesting.

### Obstetric and Newborn Care

The IP&C practices to minimize patient-to-staff and mother-to-child transmission are described in Table 1. With the exception of implementation of appropriate transmission precautions and use of personal protective equipment, obstetric care remained per usual standard. Unless otherwise contraindicated, practices continued to include delayed cord clamping, vaginal delivery (including in severe COVID-19 illness), mother-infant skin-to-skin contact, and direct breastfeeding after appropriate hand and breast hygiene (consisting of washing hands and breast with soap and water). However, all mothers, including those with COVID-19, were discharged a mean of 1 day earlier if determined to be medically and socially appropriate (ie, postpartum day 1 after vaginal deliveries and postoperative day 2 after cesarean deliveries). All mothers received a follow-up telephone call within 48 to 72 hours of discharge.

The newborns of mothers who were positive for SARS-CoV-2 were admitted to the well-baby nursery (WBN) (n = 82) unless they required neonatal intensive care unit (NICU) admission (n = 19) for standard indications. Aside from 6 mothers requiring ICU-level care, 76 mothers roomed-in with their newborns on the postpartum unit/WBN in private rooms placed on contact and droplet precautions. Newborns were in isolettes approximately 180 cm away from mothers' beds. Delayed bathing remained optional. In the NICU, mothers positive for SARS-CoV-2 were not permitted to visit during the 14-day isolation period. A COVID-19 Newborn Follow-up Clinic was established at Morgan Stanley Children's Hospital on March 23 for newborns of mothers positive for SARS-CoV-2 born at

either hospital to accommodate newborn visits if their pediatrician could not accommodate them during the 14-day observation period.

### Outcomes and Statistical Analyses

All maternal data were collected from the electronic medical records. Extracted demographics include age, gravidity, parity, body mass index, and maternal comorbidities (diabetes, chronic hypertension, hypertensive disorders of pregnancy, asthma). Self-reported race and ethnicity data were collected from electronic medical records and are reported given known COVID-19 racial/ethnic disparities. Extracted clinical courses include gestational age at presentation and delivery, SARS-CoV-2 testing and symptoms, antenatal complications (intrauterine growth restriction, oligohydramnios, or fetal anomalies identified on ultrasonography), and obstetric complications (preterm premature rupture of membranes, preterm labor, preterm delivery, chorioamnionitis). COVID-19 illness was classified in accordance with the summary by Wu and McGoogan<sup>27</sup> (eMethods in the Supplement). Women were grouped as having asymptomatic/mildly symptomatic or severe/critical illness.

The primary study outcome investigated was the newborn SARS-CoV-2 test results. Vertical transmission was defined as positive SARS-CoV-2 test results on initial newborn swab, and postnatal transmission was defined as subsequent positive SARS-CoV-2 test results, either during hospitalization or after discharge as available within our records. We also looked for associations between maternal COVID-19 severity and newborn characteristics (mode of delivery, sex, birth weight, small for gestational age, large for gestational age) and clinical courses (NICU admissions, Apgar scores, breastfeeding frequency, hour of life at newborn bath, need for resuscitation, phototherapy if performed, weight loss, laboratory and radiology data as applicable for NICU courses, and age at dis-

Table 1. Infection Prevention and Control Strategies for SARS-CoV-2-Positive Mothers and Their Infants

| IP&C strategies                 | Description                                                                                                                                          |
|---------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Staff</b>                    |                                                                                                                                                      |
| Self-monitor for symptoms       | Every 12 h, self-monitor for temperature 37.8 °C, fever, cough, sore throat, shortness of breath, myalgia, fatigue, diarrhea, loss of smell or taste |
| PPE                             | Fit check N95 respirator before each use                                                                                                             |
|                                 | Extended use and reuse of N95 respirators                                                                                                            |
|                                 | Surgical face mask or face shield worn over N95 respirator to extend N95 use                                                                         |
| PPE education                   | Videos, graphics, memos, huddles                                                                                                                     |
| <b>Patients</b>                 |                                                                                                                                                      |
| <b>Room placement</b>           |                                                                                                                                                      |
| L&D                             | Single-patient room                                                                                                                                  |
| WBN                             | Single-patient room, infants in isolettes >180 cm from mother                                                                                        |
| NICU                            | Single-patient room in isolettes                                                                                                                     |
|                                 | When single room unavailable, cohort in isolettes >180 cm apart                                                                                      |
| <b>Transmission precautions</b> |                                                                                                                                                      |
| L&D                             | Contact/droplet precautions plus airborne precautions for aerosol-generating procedures (negative pressure room preferred)                           |
|                                 | Mothers wear mask at all times                                                                                                                       |
| WBN                             | Contact/droplet precautions for mothers and their infants                                                                                            |
|                                 | Mothers continue to wear mask when interacting with staff or infant                                                                                  |
| NICU                            | Contact/droplet precautions plus airborne precautions for aerosol-generating procedures until DOL-14 (negative pressure room preferred)              |
| <b>Visitors</b>                 |                                                                                                                                                      |
| <b>Restrictions</b>             |                                                                                                                                                      |
| L&D                             | Only 1 asymptomatic support person permitted                                                                                                         |
| WBN                             | No visitors permitted                                                                                                                                |
| NICU                            | Only 1 asymptomatic parent/guardian permitted (mother not permitted until DOL-14)                                                                    |
| Screening                       | Every 12 h, monitor for temperature 38.7 °C, fever, cough, sore throat, shortness of breath, myalgia, fatigue, diarrhea, loss of smell or taste      |
| <b>PPE</b>                      |                                                                                                                                                      |
| L&D                             | Surgical face mask, gown, gloves in patient room                                                                                                     |
| WBN                             | NA                                                                                                                                                   |
| NICU                            | Surgical face mask, gown, gloves in patient room                                                                                                     |

Abbreviations: DOL, day of life; IP&C, infection prevention and control; L&D, labor and delivery; NA, not applicable; NICU, neonatal intensive care unit; PPE, personal protective equipment; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2; WBN, well-baby nursery.

charge). We also examined encounters that occurred in the COVID-19 Newborn Follow-up Clinic and nonroutine encounters (telehealth, emergency department, hospitalizations, or clinic) identified through April 27 at our medical center.

### Statistical Analysis

Maternal and newborn demographic and clinical characteristics were compared for women classified with asymptomatic/mild illness vs severe/critical disease. Owing to the small sample size, continuous variables were compared using the Wilcoxon rank sum test. We used the Fisher exact test to compare dichotomous variables. A binomial test was used to estimate the probability of a positive test result in infants. All analyses were conducted using R, version 3.6.1 (R Foundation). Two-sided  $P < .05$  indicated significance.

## Results

### Maternal Demographic and Clinical Characteristics

One hundred women who delivered 101 live newborns (99 singletons and 1 twin pair) from March 13 to April 24, 2020, were included in the study. Ninety-nine women had positive

test results for SARS-CoV-2, and 1 woman who presented with symptoms and chest radiographic findings consistent with COVID-19 tested negative for SARS-CoV-2 but was treated as presumptive positive. Seventy-three women (73.0%) underwent testing on admission to labor and delivery; 5 (5.0%), in preadmission clinic; and 22 (22.0%), for symptoms (Table 2).

Demographic and clinical characteristics of women with asymptomatic/mild illness (90 [90.0%]) were compared with women with severe/critical disease (10 [10.0%]) (Table 2). Overall, median maternal age was 28.5 (interquartile range [IQR], 24.0-34.0; range, 18-47) years. A total of 63 women were Hispanic or Latinx; 36 had asthma, diabetes, chronic hypertension, and/or hypertensive disorder of pregnancy; and 54 had a body mass index (calculated as weight in kilograms divided by height in meters squared) greater than 30.0. When compared with women with asymptomatic/mild infections, women with severe/critical disease were less likely to be identified by universal testing (3 of 10 [30.0%] vs 75 of 90 [83.3%];  $P < .001$ ), were older (median age, 34.0 [IQR, 30.8-35.0] vs 28.0 [IQR, 24.0-33.0] years;  $P = .04$ ), were more likely to have pregestational diabetes (2 of 10 [20.0%] vs 1 of 90 [1.1%];  $P = .03$ ), and had infants with a lower gestational age at delivery (median,

Table 2. Characteristics of Mothers With Asymptomatic/Mild vs Severe/Critical COVID-19

|                                                 | Mothers by severity of COVID-19 |                               |                             |                                       |            |
|-------------------------------------------------|---------------------------------|-------------------------------|-----------------------------|---------------------------------------|------------|
| Variable                                        | All<br>(n = 100)                | Mild/asymptomatic<br>(n = 90) | Severe/critical<br>(n = 10) | Difference (95% CI)                   | P<br>value |
| SARS-CoV-2 clinical characteristics             |                                 |                               |                             |                                       |            |
| Gestational age at diagnosis, median (IQR), wk  | 39.0 (37.4 to 40.0)             | 39.0 (37.4 to 39.9)           | 38.0 (37.1 to 38.1)         | 1.4 (−3.6 × 10 <sup>−5</sup> to 2.4)  | .053       |
| Indication for testing, No. (%)                 |                                 |                               |                             |                                       |            |
| COVID-19 symptoms                               | 22 (22.0)                       | 15 (16.7)                     | 7 (70.0)                    | 0.09 (0.01 to 0.4)                    | <.001      |
| Universal testing                               | 78 (78.0)                       | 75 (83.3)                     | 3 (30.0)                    | 0.09 (0.01 to 0.4)                    | <.001      |
| Asymptomatic <sup>a</sup>                       | 67 (85.9)                       | 66 (88.0)                     | 1 (33.3)                    | 0.07 (0.001 to 1.5)                   | .051       |
| Atypical presentation <sup>b</sup>              | 14 (14.0)                       | 13 (14.4)                     | 1 (10.0)                    | NA                                    | .35        |
| Diagnosis to delivery interval, d               |                                 |                               |                             |                                       |            |
| COVID-19 symptoms, median (IQR)                 | 7.0 (0.0 to 15.0)               | 14.0 (2.5 to 16.0)            | 0 (0 to 5.3)                | 8.0 (−1.8 × 10 <sup>−5</sup> to 19.0) | .10        |
| Universal testing, median (IQR)                 | 1.0 (0.0 to 1.0)                | 1.0 (0.0 to 1.0)              | 1.0 (1.0 to 1.0)            | NA                                    | .32        |
| Demographics, median (IQR)                      |                                 |                               |                             |                                       |            |
| Maternal age, y                                 | 28.5 (24.0 to 34.0)             | 28.0 (24.0 to 33.0)           | 34.0 (30.8 to 35.0)         | 5.0 (1.5 × 10 <sup>−6</sup> to 10.0)  | .04        |
| Gravidity                                       | 2.0 (1.0 to 3.3)                | 2.0 (1.0 to 3.0)              | 3.0 (2.0 to 4.8)            | 1.0 (−6.8 × 10 <sup>−6</sup> to 2.0)  | .07        |
| Parity                                          | 1.0 (0.0 to 2.0)                | 1.0 (0 to 2.0)                | 1.0 (0.3 to 2.0)            | NA                                    | .35        |
| Ethnicity, No. (%)                              |                                 |                               |                             |                                       |            |
| Hispanic or Latinx                              | 63 (63.0)                       | 56 (62.2)                     | 7 (70.0)                    | NA                                    | .74        |
| Not Hispanic or Latinx                          | 18 (18.0)                       | 16 (17.8)                     | 2 (20.0)                    | NA                                    | .61        |
| Unknown, not reported, or undefined             | 19 (19.0)                       | 18 (20.0)                     | 1 (10.0)                    | NA                                    | .68        |
| Race, No. (%)                                   |                                 |                               |                             |                                       |            |
| American Indian/Alaska Native                   | 0                               | 0                             | 0                           | NA                                    | NA         |
| Asian                                           | 2 (2.0)                         | 2 (2.2)                       | 0                           | NA                                    | >.99       |
| Native Hawaiian/other Pacific Islander          | 1 (1.0)                         | 1 (1.1)                       | 0                           | NA                                    | >.99       |
| Black or African American                       | 13 (13.0)                       | 13 (14.4)                     | 0                           | NA                                    | .59        |
| White                                           | 31 (31.0)                       | 28 (31.1)                     | 3 (30.0)                    | NA                                    | >.99       |
| Other combinations not described                | 9 (9.0)                         | 8 (8.9)                       | 1 (10.0)                    | NA                                    | .58        |
| Unknown, not reported, or undefined             | 47 (47.0)                       | 41 (45.6)                     | 6 (60.0)                    | NA                                    | .34        |
| BMI, median (IQR)                               | 30.4 (28.1 to 34.5)             | 30.4 (28.1 to 34.1)           | 29.8 (28.7 to 35.3)         | NA                                    | .87        |
| Comorbid conditions, No. (%)                    |                                 |                               |                             |                                       |            |
| Asthma                                          | 11 (11.0)                       | 9 (10.0)                      | 2 (20.0)                    | NA                                    | .30        |
| Pregestational diabetes                         | 3 (3.0)                         | 1 (1.1)                       | 2 (20.0)                    | 20.7 (1.0 to 1312.0)                  | .03        |
| Gestational diabetes                            | 9 (9.0)                         | 7 (7.8)                       | 2 (20.0)                    | NA                                    | .22        |
| Chronic hypertension                            | 2 (2.0)                         | 2 (2.2)                       | 0                           | NA                                    | >.99       |
| Gestational hypertension                        | 6 (6.0)                         | 6 (6.7)                       | 0                           | NA                                    | >.99       |
| Preeclampsia                                    | 5 (5.0)                         | 3 (3.3)                       | 2 (20.0)                    | 7.0 (0.5 to 71.1)                     | .08        |
| Obesity                                         | 54 (54.0)                       | 50 (55.6)                     | 4 (40.0)                    | NA                                    | .73        |
| Antenatal and obstetric clinical data           |                                 |                               |                             |                                       |            |
| Gestational age at delivery, median (IQR), wk   | 39.0 (37.9 to 40.1)             | 39.1 (38.3 to 40.2)           | 37.9 (37.1 to 38.4)         | 1.4 (0.3 to 2.3)                      | .02        |
| IUGR, No. (%)                                   | 3 (3.0)                         | 2 (2.2)                       | 1 (10.0)                    | NA                                    | .27        |
| Oligohydramnios, No. (%)                        | 5 (5.0)                         | 5 (5.6)                       | 0                           | NA                                    | >.99       |
| Prenatally diagnosed fetal anomalies, No. (%)   | 11 (11.0)                       | 9 (10.0)                      | 2 (20.0)                    | NA                                    | .30        |
| Preterm premature rupture of membranes, No. (%) | 5 (5.0)                         | 5 (5.6)                       | 0                           | NA                                    | >.99       |
| Preterm labor, No. (%)                          | 3 (3.0)                         | 3 (3.3)                       | 0                           | NA                                    | >.99       |
| Preterm delivery, No. (%)                       | 11 (11.0)                       | 10 (11.1)                     | 1 (10.0)                    | NA                                    | >.99       |
| Chorioamnionitis, No. (%)                       | 9 (9.0)                         | 7 (7.8)                       | 2 (20.0)                    | NA                                    | .22        |

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by square of height in meters); COVID-19, coronavirus disease 2019; IQR, interquartile range; IUGR, intrauterine growth restriction; NA, not applicable; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2.

<sup>a</sup> Includes the 78 women who underwent universal testing.

<sup>b</sup> Includes patients whose initial and sole symptom was an intrapartum or postpartum fever. These women were asymptomatic before and on admission to labor and delivery.

37.9 [IQR, 37.1-38.4] vs 39.1 [IQR, 38.3-40.2] weeks;  $P = .02$ ) (Table 2).

### Newborn SARS-CoV-2 Testing

The 101 neonates born to these mothers (54 girls [53.5%] and 47 boys [46.5%]) had 141 tests for SARS-CoV-2 during the study period within our hospital system (median, 1 [IQR, 1-2] test/newborn) (Figure). An initial test was performed on all newborns and obtained on 0 days of life (DOL-0) (24 hours of life [HOL-0 to HOL-24]) for 15 newborns, DOL-1 (HOL-25 to HOL-48) for 79 newborns, and DOL-2 or later (after HOL-48) for 7 newborns (median, HOL-32 [IQR, HOL-26 to HOL-38]). Seventy infants underwent testing only once. Among the newborns who underwent multiple tests, 10 tests (1 test each for 6 newborns; 2 tests each for 2 newborns) were obtained for clinical indications, including fever and new respiratory symptoms. The remainder were obtained as part of routine additional surveillance in the NICU or COVID-19 Newborn Follow-up Clinic. Of the newborns who underwent retesting, 4 had been previously described, including 1 with indeterminate results, 1 with invalid findings, 1 per a NICU protocol, and 1 in the emergency department, seen for fever on DOL-25.<sup>16</sup>

No detection of SARS-CoV-2 viral RNA was found in 135 of 141 specimens (95.7% of tests) from 100 newborns. The initial test results of 4 newborns (2.8% of tests) were ruled invalid, new specimens were sent, and all findings were negative; 1 of these 4 tests was previously reported.<sup>16</sup> Two tests in 2 newborns (1.4% of tests) had indeterminate results, and only 1 infant underwent retesting and had negative results, as previously reported.<sup>16</sup> Overall incidence of transmission was 2.0% (95% CI, 0.2%-7.0%) in 2 newborns. Details of calculated vertical and perinatal transmission rates based on testing and clinical courses can be found in Table 3.

The clinical courses of the 2 newborns with indeterminate results were not previously described in detail. Newborn 1 was born via vaginal delivery before universal SARS-CoV-2 testing and underwent testing on DOL-3 after the development of maternal symptoms.<sup>16</sup> No IP&C practices had been put in place until DOL-3. The newborn received a bath at HOL-3 for reasons unrelated to SARS-CoV-2, had a normal WBN course, and was discharged on DOL-4. Newborn 1 did not undergo retesting but was seen in the COVID-19 Newborn Follow-up Clinic on DOL-6, and no issues were identified. This newborn was only breastfed once.

Newborn 2 was born via nonemergent cesarean delivery for nonreassuring fetal heart tracing to a mother who was asymptomatic at admission but subsequently developed intrapartum fevers.<sup>16</sup> This newborn had indeterminate test results at DOL-0. On DOL-2 retesting, SARS-CoV-2 was not detected. Newborn 2 had received a bath at HOL-40 and had a similarly uncomplicated WBN course. No issues were identified at the COVID-19 Newborn Follow-up Clinic on DOL-6. The mother breastfed directly in the WBN and at home but reported mainly formula feeds. This newborn presented to the pediatric emergency department on DOL-13 with excessive crying, but had normal examination results, and no further testing was performed. A follow-up telehealth visit on DOL-23 did not identify any issues.

### Newborn Characteristics and Postpartum Newborn Care

Eighty-two newborns (81.2%), including 14 previously reported,<sup>16</sup> were admitted to the WBN. Nineteen neonates (18.8%), including 4 previously reported,<sup>16</sup> were admitted to the NICU for reasons unrelated to maternal SARS-CoV-2 infection. This relatively high rate is consistent with our usual NICU admission rate and common for tertiary referral centers. Ninety-one infants (90.1%; 75 in the WBN and 16 in the NICU) were born to asymptomatic/mildly symptomatic mothers, and 10 (9.9%; 7 in the WBN and 3 in the NICU) were born to mothers with severe/critical COVID-19 disease. The demographic and clinical characteristics of these 2 groups of newborns were compared (Table 3 and eTable in the Supplement). Characteristics were generally similar, except maternal COVID-19 severity was associated with increased risk of newborn hyperbilirubinemia requiring phototherapy (3 of 10 [30.0%] vs 6 of 91 [7.0%];  $P = .04$ ). This was only significant among newborns admitted to the WBN (4 of 82 [4.9%];  $P = .03$ ) (eTable in the Supplement).

A minority of newborns (27 [26.7%]) were bathed earlier than HOL-24. Most mothers (91 [90.1%]) breastfed at least partially, with 41 (40.6%) breastfeeding exclusively or mostly. Newborns were discharged from the WBN on a mean of HOL-50 (IQR, HOL-40 to HOL-64), with those born vaginally discharged at HOL-43 (IQR, HOL-33 to HOL-43) and those born via cesarean at HOL-60 (IQR, HOL-50 to HOL-81). As of April 27, 11 infants in the NICU (57.9%) were discharged on a mean (SD) of DOL-6.8 (DOL-4.3), and 34 newborns (33.7%) included in this study were older than 14 days.

### NICU Courses

Nineteen neonates required NICU admission for primary diagnoses of prematurity (8 [42.1%]), congenital malformations (8 [42.1%]), respiratory distress (2 [10.5%]), or sepsis concerns (1 [5.3%]). A total of 12 neonates in the NICU (63.2%) required respiratory support at variable times for transient tachypnea of the newborn ( $n = 2$ ), culture-negative sepsis ( $n = 1$ ), congenital malformations ( $n = 6$ ), and respiratory distress syndrome ( $n = 3$ ). All 12 had chest radiography findings that were either normal or consistent with their diagnosis. Rule-out sepsis evaluation was performed on admission in 10 neonates. The mothers of 5 of these neonates had been diagnosed with chorioamnionitis and/or group B *Streptococcus* infection. One neonate with transposition of the great arteries developed fever while receiving prostaglandin and underwent full sepsis workup. Results of multiple repeated tests for SARS-CoV2 were negative on DOL-2 through DOL-8.

### Newborn Follow-up

Fifty-five newborns (54.5%) had newborn follow-up in the COVID-19 Newborn Follow-up Clinic at DOL-3 to DOL-10 (median, DOL-6.0 [IQR, DOL-4.3 to DOL-6.8]). Twenty-six of these newborns (47.3%) had regained or surpassed their birth weight, 29 (52.7%) remained below birth weight by a mean (SD) of 4.3% (2.7%), and no newborn had excessive weight loss (>10% decrease from birth weight). No other issues were identified.

Twenty of the newborns seen in the COVID-19 Newborn Follow-up Clinic and 3 additional newborns followed up else-

Table 3. Characteristics of Neonates Born to Mothers With Asymptomatic/Mild Illness vs Severe/Critical COVID-19

|                                                         | Maternal severity of COVID-19 |                                |                              |                     |                 |
|---------------------------------------------------------|-------------------------------|--------------------------------|------------------------------|---------------------|-----------------|
| Variable                                                | All                           | Asymptomatic/mild <sup>a</sup> | Severe/critical <sup>a</sup> | Difference (95% CI) | P value         |
| SARS-CoV-2 transmission                                 |                               |                                |                              |                     |                 |
| Testing-based transmission, No./total No. (%) [95% CI]  |                               |                                |                              |                     |                 |
| Total newborns                                          | 2/101 (2.0) [0.2 to 7.0]      | 2/91 (2.2)                     | 0/10                         | NA                  | >.99            |
| Total tests given                                       | 2/141 (1.4) [0.2 to 5.0]      | 2/123 (1.6)                    | 0/18                         | NA                  | >.99            |
| Vertical transmission                                   |                               |                                |                              |                     |                 |
| Tested ≤ HOL-23                                         | 1/15 (7.0) [0.2 to 32.0]      | 1/14 (7.1)                     | 0/1                          | NA                  | >.99            |
| Tested ≥ HOL-24                                         | 1/86 (1.2) [0.03 to 6.3]      | 1/77 (1.3)                     | 0/9                          | NA                  | >.99            |
| Perinatal transmission, retesting                       | 0/31 [0.0 to 11.2]            | 0/26                           | 0/5                          | NA                  | NA <sup>b</sup> |
| Clinical-based transmission, No./total No. (%) [95% CI] |                               |                                |                              |                     |                 |
| Vertical transmission                                   | 0/101 [0.0 to 3.6]            | 0/91                           | 0/10                         | NA                  | NA <sup>b</sup> |
| Perinatal transmission                                  | 0/55 [0.0 to 6.5]             | 0/49                           | 0/6                          | NA                  | NA <sup>b</sup> |
| Characteristics                                         |                               |                                |                              |                     |                 |
| Cesarean delivery, No./total No. (%)                    | 46/101 (45.5)                 | 37/91 (40.7)                   | 5/10 (50.0)                  | NA                  | >.99            |
| Male, No./total No. (%)                                 | 47/101 (46.5)                 | 43/91 (47.3)                   | 4/10 (40.0)                  | NA                  | .75             |
| Birth weight, median (IQR), g                           | 3295 (2875 to 3605)           | 3320 (2945 to 3630)            | 2958 (2868 to 3150)          | 320 (−15 to 650)    | .06             |
| SGA, No./total No. (%)                                  | 8/101 (7.9)                   | 8/91 (8.8)                     | 0/10                         | NA                  | >.99            |
| LGA, No./total No. (%)                                  | 7/101 (6.9)                   | 6/91 (6.6)                     | 1/10 (10.0)                  | NA                  | .53             |
| Newborn clinical data                                   |                               |                                |                              |                     |                 |
| NICU admission, No./total No. (%)                       | 19/101 (18.8)                 | 16/91 (17.6)                   | 3/10 (30.0)                  | NA                  | .39             |
| Apgar score at 1 min, median (IQR)                      | 9.0 (8.0 to 9.0)              | 9.0 (8.0 to 9.0)               | 9.0 (8.0 to 9.0)             | NA                  | .92             |
| 1-min Apgar score >7, No./total No.(%)                  | 98/101 (97.0)                 | 89/91 (97.8)                   | 9/10 (90.0)                  | NA                  | .27             |
| Apgar score at 5 min, median (IQR)                      | 9.0 (9.0 to 9.0)              | 9.0 (9.0 to 9.0)               | 9.0 (9.0 to 9.0)             | NA                  | .94             |
| 5-min Apgar >7, No. (%) <sup>c</sup>                    | 101/101 (100)                 | 91/91 (100)                    | 10/10 (100)                  | NA                  | NA <sup>c</sup> |
| Any breastfeeding, No./total No. (%)                    | 91/101 (90.1)                 | 83/91 (91.2)                   | 8/10 (80.0)                  | NA                  | .26             |
| Most or all breastfeeding, No./total No. (%)            | 41/101 (40.6)                 | 39/91 (42.9)                   | 2/10 (20.0)                  | NA                  | .19             |
| Complications during initial hospitalization            |                               |                                |                              |                     |                 |
| Resuscitation, No./total No. (%)                        | 12/101 (11.9)                 | 10/91 (11.0)                   | 2/10 (20.0)                  | NA                  | .34             |
| Phototherapy received, No./total No. (%)                | 9/101 (8.9)                   | 6/91 (6.6)                     | 3/10 (30.0)                  | 5.9 (0.8 to 36.1)   | .04             |
| Maximum weight loss, median (IQR), %                    | 4.6 (3.0 to 6.2)              | 4.5 (3.0 to 6.1)               | 5.2 (3.8 to 6.3)             | NA                  | .89             |
| Excessive weight loss, No./total No. (%)                | 6/101 (5.9)                   | 5/91 (5.5)                     | 1/10 (10.0)                  | NA                  | .47             |

Abbreviations: COVID-19, coronavirus disease 2019; HOL, hours of life; IQR, interquartile range; LGA, large for gestational age; NA, not applicable; NICU, neonatal intensive care unit; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2; SGA, small for gestational age.

<sup>a</sup> Proportions are reported as number/total number (percentage) only.

<sup>b</sup> No newborns showed evidence of these characteristics, so a comparison could not be performed.

<sup>c</sup> All newborns had an Apgar score of 7 or greater at 5 minutes.

where (23 [22.7%]) had a total of 32 additional nonroutine encounters within our medical center on DOL-3 to DOL-25, including 4 newborns requiring admission, 3 for fever and 2 for hyperbilirubinemia (Table 4). Six underwent retesting for SARS-CoV-2 during these encounters, and findings were negative. Four of these newborns were previously described.<sup>16</sup>

## Discussion

We herein present, to our knowledge, the largest series of newborns born to mothers positive for or with suspected SARS-CoV-2

infection to date and show low rates of testing-based vertical or perinatal transmission and no clinical evidence for neonatal SARS-CoV-2 infection. These data are particularly reassuring given that we describe mothers with a range of clinical presentations. Contrasting a previous report,<sup>12</sup> the small number of mothers with severe/critical COVID-19 in this cohort did not transmit SARS-CoV-2 to their newborns. Neonates born to mothers with severe/critical illness were born at an earlier gestational age, a shift that did not appear to be driven by the NICU population. Maternal severe/critical disease was also associated with overall higher incidence of hyperbilirubinemia requiring phototherapy in WBN newborns for unclear reasons.

Table 4. Nonroutine Encounters in the Medical Center

| Infant No. <sup>a</sup> | DOL | Setting         | Chief complaint                      | Admitted | Outcome                                               | SARS-CoV-2 retesting | SARS-CoV-2 test result |
|-------------------------|-----|-----------------|--------------------------------------|----------|-------------------------------------------------------|----------------------|------------------------|
| 1 <sup>b</sup>          | 25  | ED to hospital  | Fever                                | Yes      | ROS negative, antibiotics                             | Yes                  | Not detected           |
| 2 <sup>b</sup>          | 23  | Telehealth      | Rash                                 | No       | Prescription for nystatin                             | No                   | NA                     |
| 3 <sup>b</sup>          | 13  | ED              | Loud crying                          | No       | Anticipatory guidance given                           | No                   | NA                     |
| 3 <sup>b</sup>          | 23  | Telehealth      | ED follow-up                         | No       | Anticipatory guidance given                           | No                   | NA                     |
| 4 <sup>b</sup>          | 18  | ED              | Choking/respiratory distress         | No       | Anticipatory guidance given                           | No                   | NA                     |
| 4 <sup>b</sup>          | 20  | Telehealth      | ED follow-up                         | No       | No more choking                                       | No                   | NA                     |
| 5                       | 3   | Hospital        | Hyperbilirubinemia                   | Yes      | Phototherapy                                          | Yes                  | Not detected           |
| 6                       | 12  | Telehealth      | Constipation                         | No       | Anticipatory guidance given                           | No                   | NA                     |
| 7                       | 4   | ED              | Congestion, belly breathing          | No       | Anticipatory guidance given                           | No                   | NA                     |
| 7                       | 9   | Telehealth      | Breastfeeding concern                | No       | Breastfeeding counseling                              | No                   | NA                     |
| 8                       | 14  | Telehealth      | Fussiness                            | No       | Anticipatory guidance given                           | No                   | NA                     |
| 8                       | 19  | Clinic          | Abnormal NBS result                  | No       | Laboratory draw for repeated TFTs                     | No                   | NA                     |
| 9                       | 7   | Telehealth      | Breastfeeding concern                | No       | Breastfeeding counseling                              | No                   | NA                     |
| 10                      | 13  | Telehealth      | Breastfeeding concern                | No       | Breastfeeding counseling                              | No                   | NA                     |
| 11                      | 14  | Telehealth      | Constipation                         | No       | Anticipatory guidance given                           | No                   | NA                     |
| 11                      | 18  | ED to hospital  | Fever                                | Yes      | Antibiotics, negative ROS workup findings             | Yes                  | Not detected           |
| 12                      | 12  | Telehealth      | Umbilical drainage                   | No       | Anticipatory guidance given                           | No                   | NA                     |
| 12                      | 15  | Telehealth      | Umbilical drainage                   | No       | Anticipatory guidance given                           | No                   | NA                     |
| 13                      | 6   | Hospital        | Fever                                | Yes      | Positive ROS finding, UTI, antibiotics                | Yes                  | Not detected           |
| 13                      | 10  | COVID-19 clinic | Weight loss                          | No       | Minimal weight gain                                   | No                   | NA                     |
| 13                      | 15  | COVID-19 clinic | Weight loss                          | No       | Gaining weight                                        | No                   | NA                     |
| 14                      | 9   | Email           | Feeding concerns                     | No       | Anticipatory guidance given                           | No                   | NA                     |
| 15                      | 9   | Telehealth      | Excessive stool                      | No       | Anticipatory guidance given                           | No                   | NA                     |
| 16                      | 7   | Telehealth      | Bloody vaginal discharge             | No       | Anticipatory guidance given                           | No                   | NA                     |
| 17                      | 7   | Telehealth      | Breastfeeding concern                | No       | Breastfeeding counseling                              | No                   | NA                     |
| 18                      | 11  | COVID-19 clinic | Weight loss                          | No       | Gaining weight                                        | Yes                  | Not detected           |
| 18                      | 12  | Telehealth      | Fussiness, spit up                   | No       | Anticipatory guidance given                           | No                   | NA                     |
| 19                      | 10  | Telehealth      | Breastfeeding concern, infant sleep  | No       | Breastfeeding counseling, anticipatory guidance given | No                   | NA                     |
| 20                      | 10  | Telehealth      | Breastfeeding concern                | No       | Breastfeeding counseling                              | No                   | NA                     |
| 21                      | 5   | COVID-19 clinic | Weight loss                          | No       | Gaining weight                                        | No                   | NA                     |
| 22                      | 6   | ED              | Repeated bilirubin level measurement | No       | Bilirubin level decreased                             | No                   | NA                     |
| 23                      | 3   | ED              | Hyperbilirubinemia                   | No       | Phototherapy                                          | Yes                  | Not detected           |

Abbreviations: COVID-19, coronavirus disease 2019; DOL, days of life; ED, emergency department; NA, not applicable; NBS, newborn screening; ROS, rule-out sepsis; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2; TFTs, thyroid function tests; UTI, urinary tract infection.

<sup>a</sup> Numbering refers to the order in which these 22 infants had encounters

identified in our electronic medical record and is not reflective of newborn order in the cohort.

<sup>b</sup> Newborn was previously described.

For the 82 WBN newborns, the lack of evidence for vertical or postnatal transmission was observed while allowing mother-newborn rooming-in, encouraging delayed bathing, and promoting direct breastfeeding with appropriate hygiene. Our IP&C guidance was developed in consideration of several factors. First, we needed to accommodate a large number of mothers positive for SARS-CoV-2 hospitalized concurrently on the postpartum unit, precluding universal separation. Second, we considered the lack of available data supporting SARS-CoV-2 vertical transmission and severe disease in newborns. Third, we considered the clear benefits of breastfeeding, mother-infant contact, and delayed bathing. To mitigate the risk of postnatal

transmission, we implemented social distancing, personal protective equipment requirements, and breast and hand hygiene practices; developed educational materials for mothers; and shortened hospital stays, as appropriate. Our findings suggest that mothers positive for SARS-CoV-2, including those with clinical symptoms, and their newborns may not need to be separated in the WBN. We did, however, implement separation in the NICU in consideration of inability for rooming-in, the shared structure of the unit, and lack of data about COVID-19 in this more vulnerable population.

Our findings also support retaining evidence-based newborn care practices and avoiding potentially harmful prac-

tices. Thus far, 13 infants positive for SARS-CoV-2 have been described.<sup>11-14,28-30</sup> Twelve of these were born by cesarean delivery and most were isolated from their mothers and received formula feeding.<sup>12,14,28-30</sup> Breast milk might play a protective role against newborn SARS-CoV-2 infection. Breast milk is known to be protective against numerous pathogens,<sup>31,32</sup> most studies have not found SARS-CoV-2 in breast milk,<sup>6,28,30,33</sup> and breast milk has been found to contain anti-SARS-CoV-2 IgA.<sup>34</sup> In addition, maternal vaginal secretions and skin-to-skin contact are involved in development of infant immunogenic responses.<sup>35,36</sup> Delayed bathing has significant benefits, including potential to increase rates of exclusive breastfeeding,<sup>37-41</sup> and early bathing has significant risks, including hypothermia and hypoglycemia.<sup>39,42</sup>

The 2 infants with indeterminate test results, considered presumptive positive by Roche Diagnostics, were both followed up at our medical center, and neither developed any symptoms suggestive of COVID-19. No IP&C practices were put in place for 1 of the newborns whose test result was indeterminate until DOL-3, owing to postpartum COVID-19 diagnosis in the mother. This is consistent with possible mother-to-infant transmission when the mother does not use a mask and appropriate hand and breast hygiene and mirrors a similar recent report from Italy.<sup>13</sup>

### Limitations and Strengths

There are several limitations to this study. Findings from a pandemic epicenter may not be generalizable to other areas. Another limitation is that our cohort consisted entirely of women infected in the third trimester, with most at term. Further stud-

ies are needed to evaluate the congenital neonatal risks of vertical transmission in utero. In addition, our study design does not allow comparison of outcomes in newborns of mothers positive vs negative for SARS-CoV-2. However, characteristics of our cohort are consistent with national means for gestational age,<sup>43</sup> Apgar scores,<sup>44</sup> birth weight,<sup>43</sup> percentage requiring resuscitation at delivery,<sup>45</sup> mean maximum weight loss at WBN discharge,<sup>46</sup> and proportion of newborns requiring phototherapy.<sup>47</sup> Finally, most newborns admitted to the WBN did not undergo retesting for SARS-CoV-2 at the end of their 14-day observation period. However, those who underwent retesting all had negative findings, including many who returned to our medical center for nonroutine encounters and 4 who were hospitalized. The strengths of the study include large sample size, follow-up beyond newborn discharge home, and well-characterized obstetric outcomes of SARS-CoV-2-positive mothers.

### Conclusions

In this cohort study, no evidence of vertical transmission of SARS-CoV-2 was identified in the first 101 newborns born to mothers positive for or with suspected SARS-CoV-2 infections at a large medical center in an epicenter of the COVID-19 pandemic. This study endorses the benefits of rooming-in, establishing breastfeeding, and delaying bathing on newborn outcomes and suggests that separating mothers positive for SARS-CoV-2 and their newborns and avoiding direct breastfeeding may not be warranted to prevent SARS-CoV-2 transmission.

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**Author Affiliations:** Division of Child and Adolescent Health, Department of Pediatrics, Columbia University Irving Medical Center, New York, New York (Dumitriu, Walzer, Saslaw, Scripps, Khan, Fernández, Keown, Glassman, Stephens, Sultan, Abreu, Stockwell); NewYork-Presbyterian Hospital, New York, New York (Dumitriu, Emeruwa, Ludwig, Walzer, Ardit, Saslaw, Andrikopoulou, Scripps, Baptiste, Khan, Breslin, Rubenstein, Simpson, Friedman, Hirsch, Miller, Fernández, Fuchs, Keown, Glassman, Stephens, Gupta, Sultan, Sibbles, Abreu, Akita, Penn, D'Alton, Orange, Goffman, Saiman, Stockwell, Gyamfi-Bannerman); Division of Developmental Neuroscience, Department of Psychiatry, Columbia University Irving Medical Center, New York, New York (Dumitriu, Kyle); Sackler Institute, Zuckerman Institute, and the Columbia Population Research Center, Columbia University, New York, New York (Dumitriu); Division of Maternal-Fetal Medicine, Department of Obstetrics and Gynecology, Columbia University Irving Medical Center, New York, New York (Emeruwa, Ardit, Andrikopoulou, Baptiste, Breslin, Simpson, Friedman, Miller, Fuchs, Goffman, Gyamfi-Bannerman); Division of Neonatology, Department of Pediatrics, Columbia University Irving Medical Center, New York, New York (Hanft, Liao, Rubenstein, Hirsch, Gupta,

Sibbles, Akita, Penn); Department of Obstetrics and Gynecology, Columbia University Irving Medical Center, New York, New York (Ludwig, D'Alton, Goffman); Department of Pathology and Cell Biology, Columbia University Irving Medical Center, New York, New York (Whittier); Department of Pediatrics, Columbia University Irving Medical Center, New York, New York (Orange); Division of Pediatric Infectious Diseases, Department of Pediatrics, Columbia University Irving Medical Center, New York, New York (Saiman); Department of Population and Family Health, Mailman School of Public Health, Columbia University Irving Medical Center, New York, New York (Stockwell).

**Author Contributions:** Drs Dumitriu and Emeruwa contributed equally to this study. Drs Dumitriu and Emeruwa had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

**Concept and design:** Dumitriu, Emeruwa, Liao, Walzer, Ardit, Andrikopoulou, Scripps, Simpson, Friedman, Hirsch, Miller, Glassman, Akita, Penn, D'Alton, Orange, Goffman, Saiman, Stockwell, Gyamfi-Bannerman.

**Acquisition, analysis, or interpretation of data:** Dumitriu, Emeruwa, Hanft, Liao, Ludwig, Walzer, Ardit, Saslaw, Andrikopoulou, Scripps, Baptiste, Khan, Breslin, Rubenstein, Kyle, Hirsch, Fernandez, Fuchs, Keown, Stephens, Gupta, Sultan, Sibbles, Whittier, Abreu, Penn, Goffman, Stockwell, Gyamfi-Bannerman.

**Drafting of the manuscript:** Dumitriu, Emeruwa, Hanft, Liao, Ludwig, Ardit, Saslaw, Scripps, Khan,

Rubenstein, Simpson, Kyle, Miller, Glassman, Akita, Gyamfi-Bannerman.

**Critical revision of the manuscript for important intellectual content:** Dumitriu, Emeruwa, Hanft, Liao, Walzer, Ardit, Saslaw, Andrikopoulou, Scripps, Baptiste, Khan, Breslin, Rubenstein, Friedman, Hirsch, Miller, Fernandez, Fuchs, Keown, Glassman, Stephens, Gupta, Sultan, Sibbles, Whittier, Abreu, Penn, D'Alton, Orange, Goffman, Saiman, Stockwell, Gyamfi-Bannerman.

**Statistical analysis:** Dumitriu, Emeruwa, Liao, Ludwig, Ardit, Kyle.

**Administrative, technical, or material support:** Dumitriu, Liao, Walzer, Ardit, Saslaw, Scripps, Baptiste, Breslin, Rubenstein, Kyle, Hirsch, Fernandez, Fuchs, Keown, Stephens, Sibbles, Whittier, Abreu, Akita, Penn, D'Alton, Orange, Goffman, Saiman.

**Supervision:** Dumitriu, Miller, Glassman, Sultan, Penn, D'Alton, Orange, Goffman, Saiman, Stockwell, Gyamfi-Bannerman.

**Other - research for discussion section:** Gupta.

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