# Original Research

# Testing of Patients and Support Persons for Coronavirus Disease 2019 (COVID-19) Infection Before Scheduled Deliveries

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**OBJECTIVE:** To evaluate the rate of coronavirus disease 2019 (COVID-19) infection with the use of universal testing in our obstetric population presenting for scheduled deliveries, as well as the concordance or discordance rate among their support persons during the initial 2-week period of testing. Additionally, we assessed the utility of a screening tool in predicting severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) testing results in our cohort.

**METHODS:** This was an observational study in which all women who were scheduled for a planned delivery within the Mount Sinai Health system from April 4 to April 15, 2020, were contacted and provided with an appointment for themselves as well as their support persons to undergo COVID-19 testing 1 day before their scheduled delivery. Both the patients and the support persons were administered a standardized screen specific for COVID-19 infection by telephone interview. Those support persons who screened positive were not permitted to attend the birth. All patients and screen-negative support persons underwent SARS-CoV-2 testing.

**RESULTS:** During the study period, 155 patients and 146 support persons underwent SARS-CoV-2 testing. The prevalence of asymptomatic COVID-19 infection was 15.5% (CI 9.8–21.2%) and 9.6% (CI 4.8–14.4%) among patients and support persons, respectively. The rate of discordance among tested pairs was 7.5%. Among patients with COVID-19 infection, 58% of their support persons also had infection; in patients without infection, fewer than 3.0% of their support persons had infection.

**CONCLUSION:** We found that more than 15% of asymptomatic maternity patients tested positive for SARS-CoV-2 infection despite having screened negative with the use of a telephone screening tool. Additionally, 58% of their asymptomatic, screen-negative support persons also tested positive for SARS-CoV-2 infection. Alternatively, testing of the support persons of women who had tested negative for COVID-19 infection had a low yield for positive results. This has important implications for obstetric and newborn care practices as well as for health care professionals.

The coronavirus disease 2019 (COVID-19) caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus has been declared a pandemic by the World Health Organization as of March 11, 2020.[1] It has spread at an accelerated rate, particularly in densely populated regions such as New York City, which is considered an epicenter of COVID-19 infection. As of May 12, 2020, there have been 340,661 confirmed cases of COVID-19 infection in New York State, with 24,348 occurring in Manhattan alone.[2] In the general population, approximately 80% of infections with COVID-19 are reportedly either asymptomatic or mildly symptomatic.[3] Many of the symptoms of COVID-19 infection, if present, overlap with normal physiologic changes of pregnancy, potentially leading to a delay in diagnosis among pregnant patients.[4] Obstetric units must continue to provide the

full range of services to their patients, even during a pandemic. Therefore, identifying asymptomatic patients with infection is useful so as to guide management. It has been reported recently that approximately 14% of asymptomatic pregnant women presenting to the maternity ward at another New York City hospital tested positive for COVID-19 infection.[5] Therefore, current screening tools may not effectively detect patients with COVID-19 infection.

Within the Mount Sinai Health system, more than 15,000 deliveries are performed annually. We began to care for pregnant women with known COVID-19 infections in late March of 2020. In early April 2020, a policy was implemented to perform universal COVID-19 testing for all women planning to deliver within the Mount Sinai Health system. The intent of performing universal testing of patients is to inform obstetric and neonatal practices so that the safety of patients, newborns, staff, and support persons can be maintained. During this pandemic, the New York State Department of Health has recommended that one healthy support person be permitted to attend a pregnant patient's delivery.[6] Given the limitations of screening tools, we began performing COVID-19 testing the day before any scheduled deliveries, such as cesarean births or inductions of labor, for support persons as well as patients. COVID-19 testing of support persons was performed to reduce the risk of exposure of health care workers as well as to reduce staff anxiety regarding interactions with support persons. Numerous publications have demonstrated that health care worker performance correlates to levels of anxiety and perceptions of safety.[7,8]

In this study, we sought to evaluate the rate of COVID-19 infection with the use of universal testing in our obstetric population presenting for scheduled deliveries, as well as the concordance and discordance rates among their support persons during the initial 2-week period of testing. Additionally, we assessed the utility of a telephone screening tool in predicting SARS-CoV-2 testing results in our cohort.

## METHODS

This was an observational study in which all women who were scheduled for a planned delivery within the Mount Sinai Health system between April 4 and April 15, 2020, were contacted and provided with an appointment for themselves as well as their one designated support person to undergo COVID-19 testing the day before their scheduled delivery. Both the patient and the support person underwent a standardized screening tool specific for COVID-19 infection by telephone interview[9] (Box 1). If the support

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**Box 1. Telephone Screening Tool**

All patients must answer these questions.
1. Do you have a fever or feel hot?
2. Do you have a cough, shortness of breath, or a sore throat?
3. Are you vomiting, or do you have diarrhea?
4. Do you have a rash?

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person screened positive, they were not permitted to attend the birth. The patient was given the opportunity to contact a different support person, who was then screened for COVID-19 infection and tested if the interview screen was negative. Of note, patients admitted for spontaneous labor and their support persons were tested at the time of admission. Analysis of spontaneously laboring patients and their support persons will be reported separately.

Patients and their support persons underwent SARS-CoV-2 testing using nasopharyngeal swabs that were placed in a viral transport media tube and sent for a quantitative polymerase chain reaction (PCR) test to detect SARS-CoV-2. Test results are typically available in 3–4 hours, and patients and their support persons were instructed to present 24 hours before admission for testing. The test was performed at Mount Sinai Hospital using the Roche Cobas 6800 System. This test is a real-time PCR test intended for the qualitative detection of RNA from SARS-CoV-2 in nasopharyngeal and oropharyngeal samples. The assay targets ORF1, a region that is unique to SARS-CoV-2. Additionally, a conserved region in the E-gene was chosen for pan-Sarbecovirus detection, including SARS-CoV-2. Detection of target 2 without detection of target 1 is interpreted as a presumptive positive result.[10] The test is sensitive, with consistent detection limits between 1 and 10 SARS-CoV RNA copies per reaction. The reported sensitivity and specificity are 85% and 100%, respectively.[11] The sensitivity of PCR testing for SARS-CoV-2 may depend on the specimen-collection technique and the time of testing during the course of the illness.[12,13]

All patients and their support persons were informed of their SARS-CoV-2 test results before admission. Those who tested positive were counseled regarding symptomatology that should prompt medical attention. Owing to scheduling issues as well as test result turnaround time, results for support persons were, on occasion, not available before admission. Such individuals were considered Persons Under Investigation until results were obtained; however, they were permitted to accompany the patient.

At the time of admission, both the patients and their support persons underwent a repeat, in-person screening process using the same screening tool previously referenced but also including temperature assessment every 12 hours. On admission, patients known to have tested positive for SARS-CoV-2 infection were met at the hospital entrance by a triage nurse and given a mask to wear. During their admission, they were managed with appropriate contact precautions using personal protective equipment. Demographic data for women with SARS-CoV-2 infection are illustrated in Table 1. The obstetric outcomes of the women who tested positive for SARS-CoV-2 infection are the subject of another study.

All newborns born to patients who had tested positive for SARS-CoV-2 infection underwent SARS-CoV-2 testing in the same manner as described above at 24 hours of life. Those newborns with a negative SARS-CoV-2 test result at 24 hours of life underwent repeat testing at 48 hours of life. Newborns who had negative test results at 24 and 48 hours of life were considered to be SARS-CoV-2–negative. Newborns who tested positive for SARS-CoV-2 infection were managed with appropriate contact precautions and serially tested at 2-week intervals until negative. Mothers who tested positive for COVID-19 infection were informed of the current Centers for Disease Control and Prevention guidelines regarding breastfeeding and co-location with the use of social distancing.[14,15]

The prevalence of COVID-19 infection among patients and their support persons was calculated as the number who tested positive over the total number tested. The absolute and relative risk of support persons for COVID-19 compared with patients who tested positive or negative was calculated, along with their corresponding 95% CIs. The Kappa statistic was used to measure concordance between patients' and their support persons' COVID-19 test results. All analyses were conducted using SAS 9.4. This cohort study was approved by the Institutional Review Board at the Mount Sinai School of Medicine in New York.

## RESULTS

During the time period from April 4 through April 15, 2020, 158 patients who had a planned delivery were screened and 155 agreed to undergo COVID-19 testing. None of the 158 patients screened positive using the telephone screening tool. Of the 155 women tested, 24 tested positive for SARS CoV-2 infection. Therefore, the prevalence of asymptomatic positive disease in this group of women was 15.5% (CI 9.8–21.2%) Of the 155 women tested, nine did not have a support person present during labor; five of these women had tested positive for SARS CoV-2 infection.

During the same time period, 146 support persons whose interview screen was negative underwent SARS-CoV-2 testing. Of these, 14 tested positive for SARS-CoV-2 infection, for an asymptomatic carrier rate of 9.6% (CI 4.8–14.4%). The rate of discordancy among tested pairs was 7.5% (11/146), and the concordance rate was 92.5% (135/146). Four patients had a secondary support person present, rather than their originally designated support person.

Among patients who tested positive for COVID-19 infection and had a support person present, 11 of 19 (58%) support persons also tested positive for COVID-19 infection. Among patients who tested negative for COVID-19 infection and had a support person present, only 3 of 127 (2.4%) support persons tested positive for COVID-19 infection. Comparing patients who tested positive with those who tested negative, this corresponds to an absolute difference in the risk of the support person's being positive of 55.5% (95% CI 33.2–77.9%) and a relative risk of 24.5 (95% CI 7.5–79.9). The estimated Kappa for this sample was 0.63 (95% CI 0.42–0.83), indicating substantial concordance.

**Table 1.** Demographics of Patients Who Tested Positive or Negative for Coronavirus Disease 2019 (COVID-19) Infection

|  | COVID-19–Positive (n=24) | COVID-19–Negative (n=131) |
|---|---|---|
| Age (y) | 32.7±6.4 | 33.7±6.0 |
| Race |  |  |
| African American | 1 (4.2) | 16 (12.2) |
| Asian | 0 | 14 (10.7) |
| Caucasian | 17 (70.8) | 78 (59.5) |
| Hispanic | 4 (16.7) | 17 (13) |
| Other | 2 (8.3) | 6 (4.6) |
| Nulliparous | 8 (33.3) | 30 (22.9) |

Data are mean±SD or n (%).

In this group of patients, none were identified as likely COVID-19–positive by the telephone screening tool, but 24 tested COVID-19–positive, yielding a negative predictive value for the telephone screening tool among patients of 84.5% (131/155). Additionally, no support persons were identified as likely COVID-19–positive by the telephone screening tool, but 14 tested positive, yielding a negative predictive value among support persons of 90.4% (132/146). Combining patients and their support persons, 0 of 301 were identified by the telephone screening tool, but 38 of these were actually COVID-19–positive, yielding an overall negative predictive value of 87.4% (263/301).

Among the 24 patients who tested positive for SARS-CoV-2 infection, all of their newborns underwent testing and none were found to be positive. Also, no newborns born to patients who tested positive for SARS-CoV-2 infection were found to be symptomatic at birth.

## DISCUSSION

We found that 15.5% of our asymptomatic pregnant patients presenting for planned delivery during early April 2020 tested positive for COVID-19 infection. This rate is similar to the rate reported recently at another New York City institution.[5] The implication of this finding is that, if universal testing of pregnant patients in a high prevalence area is not performed, health care workers will be inadvertently exposed to COVID-19, unless universal precautions with personal protective equipment are taken. Given the potential need for long-term use of personal protective equipment and possibly limited access to personal protective equipment supplies, any reduction in the use of personal protective equipment has important implications. Also, the approximately 10% COVID-19–positive rate in asymptomatic support persons also has relevant consequences for protection of health care workers. In addition, without the knowledge provided by universal testing, COVID-19–positive patients and support persons will not use contact precautions with their newborn that would otherwise be recommended.[16]

We are unable to document COVID-19 infection in some of the initially designated support persons who screened positive on the telephone interview, because they were not permitted to attend the birth. This likely explains the lower rate of positive test results in the support persons who did accompany the patients. Nonetheless, more than 50% of support persons who did accompany SARS-CoV-2–positive patients (and, therefore, had screened negative),

were in fact found to be SARS-CoV-2–positive as well. This again demonstrates that the screening tools commonly used are not highly successful. This is consistent with information from passengers on repatriation flights or quarantined on cruise ships, where numerous cases of SARS-CoV-2 infection were undetectable through symptom screening but returned positive results on testing.[17–21] Viral shedding before the onset of symptoms or in patients who remain asymptomatic make infectious disease outbreaks difficult to control.[22] Our results emphasize that the true number of subclinical cases remains unknown and strongly affects screening effectiveness.

The results of SARS-CoV-2 testing also inform how patients are assigned to postpartum units. At our institution, we have grouped postpartum women on different floors based on their COVID-19 infection status. Universal testing also provides a mechanism for more accurate counseling of patients regarding issues such as newborn skin-to-skin contact and breastfeeding. The Centers for Disease Control and Prevention[14,15] recommends that newborns either be isolated from their mothers with COVID-19 infection or co-locate using social distancing (ie, maintain 6 feet from the newborn or have others care for the newborn) and appropriate precautions. We have implemented co-location and instruct parents with COVID-19 infection to wear a mask and use appropriate hand hygiene when caring for their newborns. Finally, given the finding that more than 50% of patients who tested positive for COVID-19 infection had support persons who also tested positive, perhaps COVID-19 positivity in a patient is a more significant risk factor for any of her contacts than the presence of symptoms. Despite this, we recognize that this is a small sample size from which to draw conclusions and that larger studies are needed to make a stronger estimate of this effect.

Limitations of this study include that these data may not be generalizable to other patient populations given that New York City is an epicenter of COVID-19 infection. Furthermore, there may have been an underrepresentation of the concordance between patients and their support persons given the exclusion of support persons who initially screened positive with the telephone screening tool.

Based on epidemiologic trajectories for SARS-CoV-2 infection, it is likely that obstetric units, particularly in densely populated regions, will continue to care for patients who are asymptomatic but potentially infectious.[23] We propose that universal testing of patients and support persons in high-prevalence areas will inform obstetric and newborn

care practices as well as help ensure the safety of the health care professionals caring for them.

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