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Universal SARS-Cov-2 Screening in Women Admitted for Delivery in a Large Managed Care Organization

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Abstract

Objective The coronavirus disease 2019 (COVID-19) pandemic has created a need for data regarding the prevalence of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection in pregnant women. After implementing universal screening for COVID-19 in women admitted for delivery, we sought to describe the characteristics of COVID-19 in this large cohort of women.

Study Design An observational study of women admitted to labor and delivery units in Kaiser Permanente Southern California (KPSC) hospitals between April 6 and May 11, 2020 who were universally offered testing for SARS-CoV-2 infection ($n = 3{,}963$). Hospital inpatient and outpatient physician encounter, and laboratory records were used to ascertain universal testing levels, test results, and medical and obstetrical histories. The prevalence of SARS-CoV-2 infection was estimated from the number of women who tested positive during labor per 100 women delivered.

Results Of women delivered during the study period, 3,923 (99.0%) underwent SARS-CoV-2 testing. A total of 17 (0.43%; 95% confidence interval: 0.23–0.63%) women tested positive, and none of them were symptomatic on admission. There was no difference in terms of characteristics between SARS-CoV-2 positive and negative tested women. One woman developed a headache attributed to COVID-19 3 days postpartum. No neonates had a positive test at 24 hours of life.

Keywords
- SARS-CoV-2
- pregnancy
- COVID-19
- screening

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Conclusion The findings suggest that in pregnant women admitted for delivery between April 6 and May 11, 2020 in this large integrated health care system in Southern California, prevalence of SARS-CoV-2 test positive was very low and all patients were asymptomatic on admission.

Key Points

- The prevalence of SARS-CoV-2 infection in a large diverse cohort of term pregnant women was 0.43%.
- 99% of women accepted SARS-CoV-2 screening on admission to labor and delivery.
- All women with positive test results were asymptomatic at the time of testing.

Since identification of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and associated coronavirus disease 2019 (COVID-19) in early 2020, infection has reached pandemic levels and has strained health care delivery systems worldwide. Although not currently seen as a group at high risk for complications from COVID-19,[1] the care of pregnant women and their newborns involves many areas of outpatient and inpatient care in the peripartum period. Early experiences from a hospital system in New York in mid-March 2020 supported the concept of universal screening of women admitted for delivery, and the results of universal screening of 215 women from this same hospital system were recently published, noting a 13.5% prevalence of asymptomatic, SARS-CoV-2 infection.[2,3] In developing plans for maternity care at Kaiser Permanente Southern California (KPSC) during the COVID-19 pandemic, the inclusion of universal testing on admission for delivery was seen as a key concept, allowing for (1) rapid determination of the woman's SARS-CoV-2 status, (2) risk-appropriate use of personal protective equipment (PPE), and (3) timely and appropriate neonatal testing, rooming practices, and care. The objective of this study was to estimate the prevalence of SARS-CoV-2 infection through universal screening of a large ethnically diverse population of pregnant women admitted for labor and delivery in the KPSC health care system.

Materials and Methods

Women admitted to obstetrical units for delivery in all 15 KPSC hospitals between April 6 and May 11, 2020 were universally offered SARS-CoV-2 testing on admission. Following KPSC standard protocol, a single swab collection from both the posterior oropharynx and nasopharynx was obtained and tested for SARS-CoV-2. If the anticipated admission-delivery interval was less than 24 hours, the sample was processed without the use of transport media at the local medical center laboratory using the Abbott IDNOW COVID-19 assay (Abbott Diagnostics Scarborough, Inc., Scarborough, ME)[4] according to manufacturer's specifications. Initial samples with an "invalid" result were repeated immediately, and if valid, the second result used for this analysis. For estimated admission-delivery interval greater than 24 hours, the sample was placed in transport media and processed at one of two KPSC regional reference laboratories using the Roche cobas 6800 real-time polymerase chain reaction SARS-CoV-2 assay (Roche Diagnostics, Indianapolis, IN).[5] All neonates born to women with confirmed COVID-19 infection were tested at 24 hours of life with a single oropharyngeal/nasopharyngeal combination swab using the Roche test platform. Electronic health records (EHR) were used to obtain information on maternal age, race/ethnicity (categorized as non-Hispanic white, non-Hispanic black, Hispanic, Asian/Pacific Islander, and other/mixed racial/ethnic groups) timing of prenatal care initiation (early or after the first trimester), parity (nullipara or multipara), gravida (0, 1, and $\geq$2), smoking during pregnancy (yes/no), maternal pre-pregnancy body mass index (kg/m^2) measured routinely at first antenatal visit, gestational age based on clinical estimates obtained from perinatal EHR records and maternal comorbidities (pregestational hypertension, diabetes, asthma, and chronic obstructive pulmonary disease), and evidence of COVID-19 through the time of hospital discharge.

Statistical Analysis

Differences in the distribution of maternal and infant characteristics were assessed using the Chi-square test for categorical variables and Student's *t*-test for continuous variables. The prevalence of SARS-CoV-2 infection in women admitted for delivery was calculated from the number of women tested positive during labor after the implementation of universal testing per 100 women tested. All analyses were performed using SAS software version 9.4 (SAS Institute, Cary, NC) by two of the authors (D.G. and V.C.). This study was approved by the institutional review board of KPSC with waiver of informed consent.

Results

The cohort was comprised of 3,963 pregnant women admitted to labor and delivery units after the universal screening for SARS-CoV-2 was instituted (►Table 1). A total of 40 (1.00%) women declined testing or had no result, leaving 3,923 (99.00%) women with results for analysis. Out of those women who were tested for SARS-CoV-2, 17 women had a positive test, resulting in an 0.43% (95% confidence interval

Table 1 Study cohort and SARS-CoV-2 test status from April 6 to May 11, 2020

	Number (%)
Total deliveries	3,963 (100.00)
Number of SARS-CoV-2 tests done	3,923 (99.00)
Abbott	2,692 (68.62%, 95% CI: 66.87–70.37%)
Roche	1,229 (31.33%, 95% CI: 28.74–33.92%)
Outside laboratory	2 (0.05%, 95% CI: 0.01–0.18%)
Number declined or no result	40 (1.00)
Number tested positive	17 (0.43%, 95% CI: 0.23–0.63%)
Abbott	8 (0.30%, 95% CI: 0.09–0.51%)
Roche	8 (0.65%, 95% CI: 0.20–1.10%)
Outside laboratory	1 (0.03%, 95% CI: 0.00–0.14%)

Abbreviations: CI, confidence interval; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2.

[CI]: 0.23–0.63%) prevalence of SARS-CoV-2 infection in the population studied. All women who tested positive were asymptomatic at the time of admission. One woman developed a headache attributed to clinical COVID-19 on postpartum day 3. Of the women who tested negative, 24 had fever on admission and none of those women developed COVID-19 infection during the following 14 days. No neonates had positive SARS-CoV-2 test results at 24 hours of life.

Demographic characteristics of the study cohort are shown in ►Table 2. Over half of the women delivered during the study period were from Hispanic racial-ethnic background (51.2%) followed by non-Hispanic white (23.5%), non-Hispanic black (7.7%), Asian/Pacific Islander (15.0%), and Other/Mixed (1.8%) racial-ethnic background. There were no significant differences in demographic characteristics between women with positive test results and the remainder of the cohort.

Discussion

Principal Findings and Results

In this population-based observational study of women presenting for labor and delivery at the KPSC health care system, 99.0% of eligible patients were screened for SARS-COV-2 infection. This number represents a substantial success of our implementation of universal screening. The calculated prevalence of a positive test for SARS-CoV-2 infection was 0.43%, an estimate much lower than the 15.4% reported by Sutton et al.[3] They reported a prevalence of 13.5% asymptomatic and 1.9% symptomatic positive COVID-19 infection. Prevalence in our study is also lower than the recent report by Vintzileos et al,[6] finding SARS-CoV-2 infection in 19.9% (34% symptomatic and 66% asymptomatic) of 161 women tested on admission to labor and delivery at NYU Winthrop Hospital.

Clinical Implications

As Southern California and New York City have different population densities, travel influx, and differing timelines for public health interventions to reduce the spread of COVID-19, this lower rate of asymptomatic disease in our study population may represent the effects of these differences. Pregnant women may also be adhering more strictly to COVID-19 prevention guidelines, resulting in a lower rate of infection. Additionally, this low prevalence of SARS-CoV-2 infection can inform the development of plans for cohorting of pregnant COVID-19 patients as well as PPE optimization strategies.

The racial/ethnic composition of our study cohort is similar to that of the overall pregnant population in KPSC (►Table 3). Although our study was not designed to show racial/ethnic disparities in positive test results, there were more positive test results in women 30 or more years of age (82.36%) compared with women who tested negative (62.82%).

The absence of positive test results in this small group of neonates ($n = 17$) delivered to asymptomatic, SARS-CoV-2 positive women is reassuring (95% CI: 0.00–19.51%). Reports of 38 Chinese women with COVID-19 infection also have shown no vertical transmission.[7–10] Several case reports of potential vertical transmission, however, have also been reported,[11,12] and maternal disease severity is a potential risk factor for vertical transmission.[13] It would follow that no neonatal infections were found in our cohort of asymptomatic mothers suggesting that the likelihood of vertical or intrapartum transmission of SARS-CoV-2 is low.

Strengths and Limitations

The strengths of our study are the ability to implement a universal SARS-CoV-2 screening program with nearly universal acceptance of testing by a large and ethnically diverse population. Concerns regarding the accuracy of SARS-CoV-2, however, remain. All available COVID-19 tests have been approved only under Emergency Use Authorization by the United States Food and Drug Administration (FDA). Consequently, traditional information regarding clinical test performance (sensitivity, specificity, positive, and negative predictive values) is not currently available. Both the Abbott and Roche assays reportedly have good analytical sensitivity with limits of detection of 125 genome equivalents/mL and 0.004 (target 2) to 0.007 (Target 1) TCID50/mL, respectively.[4,5] The KPSC Laboratory Care Delivery System has performed limited interplatform reproducibility testing with <1% discordance when performed on samples collected within 48 hours of one another.

Table 2 Characteristics based on SARS-COV-2 test results

Characteristics	Total deliveries $n = 3{,}923$	SARS-CoV-2 test result		*p*-Values
		Negative $n = 3{,}906$	Positive $n = 17$	
Maternal age, year mean (SD)	31.2 (5.29)	31.2 (5.29)	33.2 (5.46)	0.145
Maternal age, *n* (%)				0.390
15–24 years	463 (11.80)	462 (11.83)	1 (5.88)	
25–29 years	992 (25.29)	990 (25.35)	2 (11.76)	
30–34 years	1,375 (35.05)	1,368 (35.02)	7 (41.18)	
≥ 35 years	1,093 (27.86)	1,086 (27.80)	7 (41.18)	
Race/ethnicity, *n* (%)				0.807
Hispanic	2,009 (51.21)	1,999 (51.18)	10 (58.82)	
Non-Hispanic White	921 (23.48)	918 (23.50)	3 (17.65)	
Non-Hispanic Black	301 (7.67)	300 (7.68)	1 (5.88)	
Non-Hispanic Asian/Pacific Islander	587 (14.96)	585 (14.98)	2 (11.76)	
Other/mixed	72 (1.84)	71 (1.82)	1 (5.88)	
Unknown	33 (0.84)	33 (0.84)	0 (0.00)	
Pre-pregnancy BMI, *n* (%)				0.981
< 18.5 kg/m^2	30 (0.76)	30 (0.77)	0 (0.00)	
18.5–24.9 kg/m^2	857 (21.85)	854 (21.86)	3 (17.65)	
25.0–29.9 kg/m^2	596 (15.19)	593 (15.18)	3 (17.65)	
30.0–34.9 kg/m^2	363 (9.25)	362 (9.27)	1 (5.88)	
35.0+ kg/m^2	269 (6.86)	268 (6.86)	1 (5.88)	
Missing	1,808 (46.09)	1,799 (46.06)	9 (52.94)	
Smoking during pregnancy, *n* (%)	118 (3.01)	118 (3.02)	0 (0.00)	0.467
Early prenatal care initiation, *n* (%)	3,281 (83.63)	3,270 (83.72)	11 (64.71)	0.100
Gravidity, *n* (%)				0.530
0–1	1,162 (29.62)	1,159 (29.67)	3 (17.65)	
2	1,129 (28.78)	1,124 (28.78)	5 (29.41)	
≥ 3	1,519 (38.72)	1,510 (38.66)	9 (52.94)	
Parity, *n* (%)				0.315
Nullipara	1,663 (42.39)	1,656 (42.40)	7 (41.18)	
Multipara	2,012 (51.28)	2,002 (51.26)	10 (58.82)	
Gestational age at admission (wk), mean (SD)	38.6 (2.21)	38.6 (2.20)	37.9 (4.41)	0.701
Comorbidities[a], *n* (%)	556 (14.17)	554 (14.18)	2 (11.76)	0.775

Abbreviations: BMI, body mass index; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2; SD, standard deviation.
[a]Comorbidities are pregestational hypertension and diabetes as well as asthma and chronic obstructive pulmonary disease.

Table 3 Race/ethnicity distribution of study population and KPSC births in 2019 (age 15–45 years)

Race/ethnicity	Study population $n = 3{,}963$ (%)	KPSC births in 2019[a] $n = 41{,}430$ (%)
Hispanic	2,030 (51.22)	21,368 (51.58)
Non-Hispanic White	926 (23.37)	10,066 (24.30)
Non-Hispanic Black	308 (7.77)	2,994 (7.23)
Asian/Pacific Islander	592 (14.94)	6,056 (14.62)
Other/multiple	74 (1.87)	754 (1.82)
Unknown	33 (0.83)	192 (0.46)

Abbreviation: KPSC, Kaiser Permanente Southern California.
[a]Kaiser Permanente Southern California pregnant population delivered in 2019.

Conclusion

Universal SARS-CoV-2 screening in a large diverse cohort of pregnant women at the time of delivery in Southern California demonstrated very low prevalence of infection, allowing for risk-appropriate maternal and neonatal care as well as informing PPE use. As the COVID-19 pandemic continues to evolve, further studies are needed to provide community-specific data to guide obstetrical care and general public health measures.

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Conflict of Interest

None declared.

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