Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

Impact of the COVID-19 pandemic on labor and delivery research operations

OBJECTIVE: Many research studies in the United States came to an abrupt halt when the World Health Organization declared the COVID-19 pandemic in March 2020, including ongoing perinatal studies addressing the national maternal and fetal morbidity rates. Research on labor and delivery (L&D) units was particularly vulnerable to setbacks because of the universal COVID-19 testing policies and asymptomatic infection rates that were approximately 16 times higher than that of other surgical units.[1] We evaluated the impact of the COVID-19 pandemic on L&D research operations and recruitment at a single center.

STUDY DESIGN: This cross-sectional study, performed at a tertiary care academic center, evaluated temporal trends in research recruitment among women admitted for labor or induction of labor at ≥37 weeks' gestation. This study was institutional review board exempt. On-site research recruitment was paused on March 16, 2020, with phased resumption starting July 6, 2020. By August 6, 2020, all L&D studies resumed recruitment. Universal COVID-19 testing on L&D started in May 2020. On resuming recruitment, only patients with negative COVID-19 tests were approached by research staff. Patients with pending COVID-19 results at the time of active labor or those who declined testing for COVID-19, were not approached. We calculated the approach rates as the number of women "approached" for enrollment among all women admitted for delivery and consent rates as the number of women who "consented" for participation in at least 1 study among those admitted for delivery. Univariate analyses were used to compare the approach and consent rates before the research pause (November 2019−March 2020) with the rates after the research pause (August 2020−December 2020). A single approach process was used for all studies both before the research pause and after the research pause.

RESULTS: Four studies (3 randomized trials and 1 prospective cohort study) recruited patients before the research pause. After the research pause, the same 4 studies resumed recruitment, and 2 additional studies (1 randomized trial and 1 prospective cohort study) initiated recruitment. The inclusion criteria for all 6 studies were women with singleton pregnancies admitted for spontaneous labor or induction of labor at ≥37 weeks' gestation. More than 75% of the principal investigators for all the studies were trainees or pretenure faculty. The number of research staff was the same before and after the research pause. There were 1213 and 1219 deliveries in the preresearch and postresearch pause periods, respectively, with no difference in patient demographics between the periods. Most patients who delivered in both the periods were of Black race (53.3% before the research pause vs 52.5% after the research pause; P=.50). The COVID-19 positivity rate was 5% during and after the research pause. There was a lower proportion of women approached for enrollment in the postresearch pause period (46.1% vs 33.8%; P<.001). The proportion of women admitted for delivery who consented to research decreased from 35.1% to 24.0% (P<.001), although the number of women who agreed to participate among all those approached for enrollment remained stable (74.8% vs 71.2%; P=.08) (Figure). To investigate whether the changes in approach and consent rates were related to the pandemic and not a consequence of normal seasonal or temporal trends in research recruitment, we assessed the approach and consent rates in the 2 years preceding the pandemic (2017−2019), and found consistent approach and consent rates throughout the year, suggesting minimal seasonal changes in research recruitment.

CONCLUSION: The pandemic posed a threat to L&D research recruitment. Despite stable delivery volume and research staff capacity, fewer patients were approached and consented to research participation during the pandemic. These results were likely explained by COVID-19 status and testing protocols as patients with pending, unknown, or positive COVID-19 tests were not approached. An alternate consideration for lower approach rates during the pandemic was research staff apprehension. Decreased research participation during the pandemic was less likely to be attributed to patient apprehension, as the proportion of women who consented among those approached remained stable. In addition to the impact on scientific advancement, these results have implications for research conducted by trainees and junior faculty and speak to broader initiatives to address disruptions to tenure clocks and graduation requirements. Potential techniques for maintaining research integrity and productivity include virtual consent platforms and post hoc analyses accounting for recruitment disruption.[2−4] If innovative approaches to research processes are not adequately addressed, we may observe a protracted shift in research recruitment rates, a delay in evidence-based recommendations, and altered career trajectories for junior investigators. All scenarios pose barriers for critical national initiatives to reduce maternal morbidity and mortality rates.

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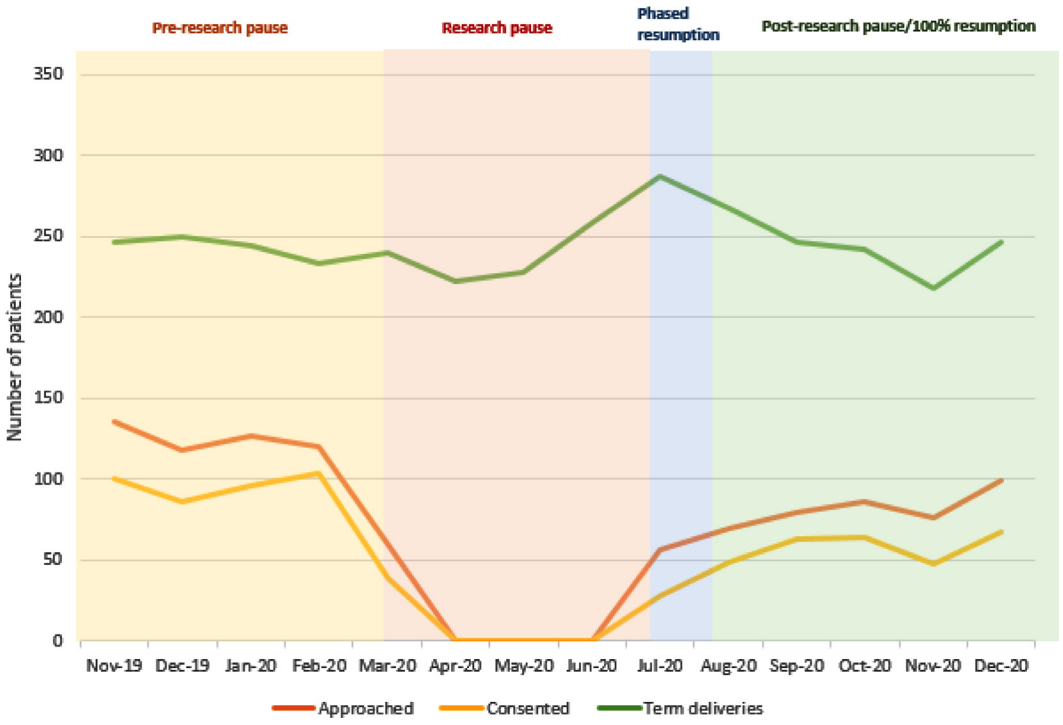
FIGURE
Temporal trends in labor and delivery research recruitment



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