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BRIEF19

A daily review of covid-19 research and policy

RESEARCH BRIEFING

Pregnancy and covid-19. More data show them to be a risky combination.

Many would-be parents have been hesitant to start family planning in the covid-19 era, and according to a new study published in [JAMA Pediatrics](#), this may be for good reason. It turns out that some anxiety around childbearing with covid-19 is well-founded: women infected with SARS-CoV-2 during pregnancy were found to be 22 times more likely to die than otherwise healthy pregnant women.

The authors of the new study compared pregnant women with and without covid-19 between March and October 2020 in 18 different countries, including the United States. Over 2,000 women were included in the study, of whom approximately one-third of whom were covid-19 positive.

It is increasingly understood that pregnancy carries a higher degree of risk in some parts of the world due to altered physiology during pregnancy, including suppressed immune systems. These changes leave women more vulnerable to a variety of infections, altered inflammatory reactions, and a host of other conditions. In addition to the increased mortality risk, the authors of this new report discovered that covid-19-positive pregnant women were more likely to suffer from other complications of pregnancy, including preeclampsia and eclampsia--a condition characterized by high blood pressures which can be a harbinger of seizures, and which can require intensive care and longer hospital stays. These conditions also impart a higher risk of preterm birth. These complications were much more likely to affect mothers who were actively symptomatic with covid-19.

It is clear that covid-19 is not benign for pregnant women. In light of these new data, when comparing the risks of getting a covid-19 vaccine while pregnant, and getting covid-19 itself, the vaccine has emerged as the safer option by a substantial margin. The vaccines are well-tolerated by pregnant persons and help fend off cases of covid-19 that would otherwise introduce profound medical suffering, disability, and even death. Furthermore, despite rumors on the internet, there is no evidence that vaccines have any effect on fertility. The more data emerges, the more we are finding that vaccination is proving to be safe for pregnant persons--and certainly far safer than SARS-CoV-2 infection.

—Joanna Parga-Belinkie, MD

Preliminary evidence points to safety of covid-19 vaccines in pregnancy.

While the clinical trials for all of the covid-19 vaccines currently available in the United States excluded certain patient populations, including children and pregnant women, most specialty societies have favored pregnant women getting vaccinated. Until now, there was not minimal clinical data for pregnant women to rely on when making a choice about whether or not to vaccinate. Fortunately, enough pregnant women have now been vaccinated and have reported their vaccination history to a database maintained by the US Centers for Disease Control and Preventino, called the [V-safe Registry](#). So far the results are highly reassuring.

Published yesterday in the [New England Journal of Medicine](#), a new paper analyzed the data from the V-safe registry to assess whether there was a difference in side effects between pregnant and non-pregnant people. Of approximately 35,000 women, this study shows that any differences in local or systemic side effects were not statistically significant. Furthermore, nearly 4,000 pregnancies had detailed records obtained from patients and obstetric providers, 827 of

which were completed. Of those completed pregnancies, over 86 percent resulted in live births, while 12.6 percent were miscarriages. This is roughly equal to the expected rate of miscarriage, meaning that coronavirus vaccination during pregnancy did not change the expected rate of miscarriage for pregnant women. The same results hold true for the expected rate of congenital anomalies, stillbirths, and infants with poor growth early in life. While data will continue to be collected, this preliminary evidence suggests that women should feel confident about getting vaccinated during pregnancy.

—Lauren Westafer, DO

POLICY BRIEFING

FDA finds unsanitary conditions at Emergent BioSolutions plant, a Johnson & Johnson vaccine production site.

This week, the US Food and Drug Administration said that a Baltimore plant run by Emergent BioSolutions, which ruined millions of Johnson & Johnson covid-19 vaccine doses, maintained conditions that were unsanitary and unsuitable for manufacturing. The FDA had asked Emergent BioSolutions to temporarily stop producing materials for covid-19 vaccines earlier this month after the agency initiated an inspection of the plant. FDA investigators found that the firm had “failed to adequately train personnel involved in manufacturing operations, quality control sampling, weigh and dispense, and engineering operations to prevent cross-contamination of bulk drug substances.” In its 13-page report, the FDA cited the plant for having “peeling paint” and black and brown residue on the walls that could affect the plant’s “ability to adequately clean and disinfect.” The report noted that the facility was “not maintained in a clean and sanitary condition [and] was not of suitable size, design and location to facilitate cleaning, maintenance and proper operations.”

The FDA, which inspected the plant over the course of eight days, said that it would work with Emergent BioSolutions to address the findings from the inspection. Production of Johnson & Johnson’s vaccine at the Emergent plant has been paused, and the FDA has said that it “will not allow the release of any product until we feel confident that it meets our expectations for quality.” Emergent said it was committed to working with the FDA and Johnson & Johnson to fix the problems identified, saying, “while we are never satisfied to see shortcomings in our manufacturing facilities or process, they are correctable and we will take swift action to remedy them.”

A Congressional investigation is now underway to determine how this Baltimore drug manufacturer won the federal contract to produce the Johnson & Johnson vaccine in the United States. On April 19, Representatives Carolyn Maloney and James Clyburn sent a letter to the top executives of Emergent BioSolutions, Inc. to launch an investigation into whether Emergent leveraged its relationship with the Trump Administration to profit from federal contracts despite a track record of raising prices and failing to meet contract requirements, and whether these actions impeded the nation’s response to the coronavirus pandemic.

—Miranda Yaver, PhD