Society for Maternal-Fetal Medicine
High-risk pregnancy experts

Society for Maternal-Fetal Medicine (SMFM) Statement: SARS-CoV-2 Vaccination in Pregnancy
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Although preventive measures (universal masking, physical distancing, hand hygiene, and prompt testing with isolation and contact tracing) can significantly decrease SARS-CoV-2 transmission, the consensus among experts is that only an effective COVID-19 vaccine will end the pandemic.[1,2] Vaccination represents the most promising strategy for combatting COVID-19 through primary prevention.

Despite the categorization of pregnancy as a high-risk condition for severe COVID-19, hospitalization, and mortality,[3–6] pregnancy remains an exclusion for participation in vaccine trials. The Society for Maternal-Fetal Medicine (SMFM) and other leading organizations, including the National Academy of Medicine, have consistently advocated for the inclusion of pregnant and lactating women in vaccination trials, particularly when the following criteria are met: (1) pregnancy poses increased susceptibility to or severity of a disease; (2) the best approach to protect the infant is through passive placental antibody transfer, which provides the most efficient and direct protection to the newborn before an infant can be vaccinated, and (3) there is an active outbreak.[7–9] Ultimately, the existing practice of "protection by exclusion" is harmful and has been characterized as clinical experimentation on pregnant women, as vaccines are distributed and adminstered without the safeguards of research protocols in place.[10,11] Furthermore, there is no biological plausibility for the exclusion of lactating women from these trials.

As of November 30, 2020, the global COVID-19 vaccine research and development landscape includes 130 vaccines under investigation, 13 of which are in phase III clinical trials, and 6 are approved for early or limited use (https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html). Three vaccines demonstrating early efficacy have been highlighted in the media (AstraZeneca's AZD1222, Moderna's mRNA-1273, Pfizer's BNT162b2), although data for only mRNA-1273 has been published in a peer-reviewed journal.[12] These vaccines employ novel next-generation platforms consisting of either vaccine expression from the nucleic acid construct, as in the mRNA-based Moderna and Pfizer vaccines, or using a viral-vector, as in AstraZeneca's vaccine. AstraZeneca's use of a viral-vector is similar to the mechanism used in the Ebola vaccine, which is the only regulated vaccine using these next-generation platforms. The Ebola vaccine has been administered during pregnancy and thus far has an acceptable safety profile.[13] Other vaccines that use conventional technologies for which there are known data for use in pregnancy (eg, the COVID-19 PiCoVacc and the NVX-CoV2373, which use technology similar to the seasonal flu vaccines) remain in phase I and II trials.[14]

In general, SMFM strongly recommends that pregnant women have access to COVID-19 vaccines in all phases of future vaccine campaigns, and that she and her healthcare professional engage in shared decision-making regarding her receipt of the vaccine. Counseling should balance available data on vaccine safety, risks to pregnant women from SARS-CoV-2 infection, and a woman's individual risk for infection and severe disease. As data emerge, counseling will likely shift, as some vaccines may be more suitable for pregnant women. mRNA vaccines, which are likely to be the first vaccines available, do not contain a live virus but rather induce humoral and cellular immune response through the use of viral mRNA. Healthcare professionals should also counsel their patients that the theoretical risk of fetal harm from mRNA vaccines is very low.

SMFM recommends that healthcare workers, who are considered prioritized for vaccination, be offered the vaccine if pregnant. A report by the National Academies of Sciences, Engineering, and Medicine entitled *Framework for Equitable Allocation of COVID-19 Vaccine* recommends that high-risk workers in health facilities or first responders should be among the first to receive the vaccine.[15] Although pregnant women are not explicitly targeted in this framework, pregnant and lactating women who are otherwise eligible should be offered the vaccine.

SMFM will continue to monitor data as it becomes available on COVID-19 vaccine efficacy and safety to evaluate appropriateness in pregnancy, and we will update recommendations on the SMFM COVID-19 website (https://www.smfm.org/covidclinical). SMFM will also continue to advocate for the ethical inclusion of pregnant women and lactating women in ongoing and future trials (https://www.smfm.org/covidadvocacy).

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