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University of Arkansas for Medical Sciences

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Dear Colleagues,

Many of our colleagues and patients have asked about the safety of the COVID-19 vaccine for pregnant or breastfeeding women. We do not hesitate to recommend the vaccine in these circumstances.

Unfortunately, the vaccine trials for the two current COVID-19 vaccines were designed to not include pregnant or lactating women. A small number of women became pregnant in the trials, but there is limited data available at this point. While we do not have clinical trial data upon which to base our decisions, we do understand the biology of the vaccine and how it works and can draw some meaningful conclusions.

The vaccine is made of lipid nanoparticles that contain mRNA for the SARS-COV-2 spike protein (the identifying part of the virus). Once injected intramuscularly, the mRNA largely remains isolated to the area of injection and is taken up by the local muscle and antigen presenting cells in regional lymph nodes for transcription. The transcribed product is the spike protein, which stimulates a response from your own immune system (but NOT an infection with the actual virus). The symptoms some people experience after receiving the vaccine (fever, aches, nausea and headache) are due to their immune response to the vaccine. (However, lack of any side effects does NOT mean the vaccine didn't work for you.) Through this mechanism of action it is unlikely that this vaccine will cross the placenta. However, should there be crossing of the placental barrier via studies of this vaccine, it appears fragmented and will not change the DNA material. It will not get into the nucleus of the DNA cell and therefore cannot change fetal DNA cells.

During lactation, there is an incredibly low likelihood that the lipid nanoparticles or mRNA will enter a woman's blood stream and reach the breast tissue intact. There is even less of a chance that the particles will cross from the blood stream into the mother's milk. But even if it these particles were able to enter breast milk, enzymes in the baby's digestive system would make them inactive.

There are potential benefits to getting the vaccine during pregnancy or while breastfeeding. Antibodies or T-cells stimulated by the vaccine may cross the placenta, or transfer into the breastmilk, and these may provide passive immunity to the infant.

The science is reassuring. Given the potential risks of COVID-19 infection, including death, and the safety of the vaccine that has been demonstrated in other patients, we believe the vaccine is safe and beneficial to both mother and baby.

We encourage any woman of childbearing age to discuss her individual risk and concerns with her healthcare provider and to consider getting the vaccine when it becomes available to her, even if she is pregnant or breastfeeding.

Additional information can be found in the statements below from the Academy of Breastfeeding Medicine and the American College of Obstetricians and Gynecologists:

https://www.bfmed.org/abm-statement-considerations-for-covid-19-vaccination-in-lactation

https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2020/12/vaccinating-pregnant-and-lactating-patients-against-covid-19

Sincerely,

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