

Vaccination Against COVID-19 in Those Who Are Pregnant, Plan to Conceive or Are Breastfeeding

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It is always frustrating to ask rhetorical questions to which you do not have clear answers. Such is the case when we look at COVID-19 vaccines in pregnancy and lactation.

The COVID-19 pandemic has lasted an entire year, as of this writing. For our attention-challenged, instant-result culture, this year has been exceedingly difficult.

In our country, an estimated 31 million have been diagnosed with COVID-19, and more than 560,000 have died from it, according to Worldometers. The direct effects of the virus have been compounded by the adverse effects of the mitigation measures such as social isolation, depression, drug abuse, suicide, educational stagnation, economic decline and political strife.

The United States Centers for Disease Control and Prevention (CDC) has been providing much of the expert opinion and advice used in personal, corporate and government decision making around the pandemic. CDC recently updated its recommendations regarding COVID-19 vaccination in regards to pregnancy and breastfeeding. Before we explore those recommendations, let's review the vaccines currently being administered in the US.

Three vaccines have been granted Emergency Use Authorization (EUA), the Moderna and Pfizer-BioNTech mRNA vaccines and the Janssen viral vector DNA vaccine. Keep in mind that the EUA only allows the use of these vaccines because of the extraordinary circumstance surrounding the pandemic. The EUA is not an "approval" like that given to other vaccines that have been studied more comprehensively.

None of the studies of these vaccines systematically included pregnant women or breastfeeding women. Therefore, the best answer to the question of their use in pregnant or lactating women would be, "We don't know; it has not been studied."

CDC, in its March 18 update notes, "Limited data are available about the safety of COVID-19 vaccines for people who are pregnant." Nonetheless, CDC does recommend that pregnant women receive the COVID-19 vaccine. The recommendation is based on the findings from COVID-19 pregnancy registries that pregnant women who contract COVID-19 have a higher rate of severe complications such as the need for intensive care hospitalization and mechanical ventilation. However, to put it in perspective, all women who are of childbearing age are at very low risk of severe complications of COVID-19. The multiplication of risk is a multiplication of a very small number. Also, the registries often only capture the sickest patients, the ones who get hospitalized (the "tip of the iceberg"). An interesting study conducted at UTSouthwestern Medical Center concluded that COVID-19 infection did not lead to increased hospitalizations in pregnant women.

As for safety, CDC draws on inferences and other vaccines' safety records. None of the COVID-19 vaccines are live virus vaccines, the kinds that worry researchers and doctors because they can harm developing preborn babies.

The problem is that the Moderna and Pfizer-BioNTech vaccines are the first ever mRNA vaccines used in humans. In some regards, we are participating in a grand experiment, because of the exigencies of the pandemic. The platform for the Janssen vaccine (replication-defective viral vector) has been used in one vaccine already, one for Ebola virus. However, that

vaccine is not approved in the US and has only been used extensively in Africa. Although the data show no adverse effects in pregnant and breast-feeding women, their studies may not be as trustworthy as those scrutinized by our Food and Drug Administration (FDA).

As for effects on fertility, we have no data. Such data will be hard to gather. I suspect that we will not find any effects on fertility.

How should a person decide? I think each individual should weigh the potential benefits of vaccination with the theoretical and unknown risks. If a pregnant or breastfeeding woman has risk factors for severe disease such as obesity, diabetes, heart disease or lung disease, then getting the vaccine may make sense. If the pregnant woman is very healthy, she may wish to accept the risk of more severe disease due to pregnancy rather than the possible risks of vaccination.

Another consideration is fever, from the disease or the vaccine. We know that high fever can cause poor pregnancy outcomes. Any fever should be closely monitored and treated with acetaminophen.

A breastfeeding mother may choose the vaccine in order to pass antibodies against the coronavirus to the baby through the breast milk. On the other hand, children get COVID-19 less often than adults and do not get as sick. It does seem that babies can become sicker than children over the age of 12 months, however. Additionally, we know that a very small number of children have become very seriously ill with COVID-19.