

## History of vaccines offers lessons on COVID-19 for pregnant women

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Pregnant women, who are at increased risk of preterm birth or pregnancy loss if they develop a severe case of COVID-19, need the best possible guidance on whether they should receive a COVID-19 vaccine,



according to an article by two UT Southwestern obstetricians published today in *JAMA*. That guidance can take lessons from what is already known about other vaccines given during pregnancy.

In the Viewpoint article, Emily H. Adhikari, M.D., and Catherine Y. Spong, M.D., describe how the available safety and effectiveness data, basic science of mRNA vaccines, and long history of successful administering of other vaccines in <u>pregnant women</u> worldwide sets the backdrop for obstetricians to outline the potential benefits of COVID-19 prevention with their patients.

Vaccines against diseases such as influenza and whooping cough have shown to be lifesaving for <u>women</u> and newborns when administered to pregnant women. The <u>pertussis vaccine</u> reduced whooping cough, a potentially fatal respiratory illness in infants, by 85 percent compared with waiting until after pregnancy. Influenza vaccination during pregnancy reduced both mother and infant influenza illness by 20 and 30 percent, respectively. Although it is not known what level of infant protection might be provided against COVID-19 by maternal vaccination, Adhikari says the potential for protection exists.

In the article, Adhikari and Spong describe how pregnant and lactating women were excluded from <u>clinical trials</u> during the development of COVID-19 vaccines due to concerns over liability. As a result, guidance issued by professional organizations on the topic has been limited, leaving physicians responsible for discussing the pros and cons with patients based on benefits of other vaccines used during pregnancy, evidence from COVID-19 vaccine trials in nonpregnant patients, and basic vaccine science suggesting safety for the fetus.

"We still need granular data on safety in pregnancy and data that shows no adverse pregnancy outcomes," says Adhikari, an assistant professor of obstetrics and gynecology at UT Southwestern.



"But without that data, we still have to care for our patients. It's not something where we can just wait," says Spong, a UTSW professor of obstetrics and gynecology, who will speak about the issue in a virtual *JAMA* panel discussion today.

Both the American College of Obstetricians and Gynecologists and the Society for Maternal-Fetal Medicine have advocated for making COVID-19 vaccines available to pregnant and lactating women. The World Health Organization on Jan. 26 recommended against vaccinating pregnant women using the Moderna vaccine except in select circumstances, but three days later revised its statement to more permissive language, supporting offering the vaccine to pregnant women at high risk of exposure or with comorbidities in consultation with their health care provider. However, the change in language caused significant anxiety despite no concerning data that was made available.

"I am very supportive of any woman who decides to get the vaccine," Adhikari says. "I fully support that woman's choice. I understand if a woman decides she's not ready for the vaccine, but I also think it's an opportunity for education about vaccines in general."

Adhikari <u>previously published</u> a study of 3,374 pregnant women, including 252 who had contracted COVID-19 during pregnancy and 3,122 who tested negative. They found no increase in adverse pregnancy outcomes overall. But among the 5 percent of pregnant women who were hospitalized for COVID-19 respiratory illness, preterm births increased.

The Viewpoint article reviews how the major risks to a pregnancy are from maternal respiratory illness from COVID-19, and states that prevention is key.

"Women who are pregnant, who have severe respiratory distress, who need significant oxygen support—some intubated for months—have



most risk to the pregnancy," says Spong, who holds the Gillette Professorship of Obstetrics and Gynecology.

For a wider context, the piece reviews how the messenger RNA vaccines proved safe and effective in preventing COVID-19, and that the same technology has been tested in trials for prevention or treatment of other diseases.

"We are doing ongoing data collection to demonstrate what we anticipate but have not shown—that this vaccine is safe in pregnant women, does not result in harm, and results in no difference in <u>pregnancy</u> outcomes," Adhikari says. "It's important for us to study that. That's going to help establish an evidence basis that will allow the public and clinicians to feel more comfortable with the vaccine."

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