

COVID-19: EFFECTS OF VACCINES ON FERTILITY AND PREGNANCY OUTCOMES



A Rapid Guidance Summary from the Penn Medicine Center for Evidence-based Practice
Last updated May 28, 2021. All links rechecked May 28 unless otherwise noted.

This Rapid Guidance Summary is a description of existing guidance and evidence reviews from a variety of sources that was in effect at the time of publication. It should not be used or interpreted as a clinical practice guideline, but instead can be used in development of local recommendations and policies.

Key questions answered in this summary

- Does COVID-19 vaccination affect fertility?
- Does COVID-19 vaccination affect the menstrual cycle?
- Does COVID-19 vaccination affect pregnancy loss and related outcomes?

CEP has published a separate Rapid Guidance Summary on vaccination recommendations for women who are pregnant or breastfeeding.

Summary of major recommendations

- There is no evidence that COVID-19 vaccines impair fertility in men or women, impact the menstrual cycle, or cause adverse pregnancy outcomes.
- Rates of adverse pregnancy outcomes in patients participating in the v-safe vaccine registry are similar to rates of these outcomes before the pandemic.
- COVID-19 disease is associated with a significant increase in risk of pregnancy loss, preterm birth, and other adverse pregnancy outcomes.
- Guidelines issued by public health agencies and professional societies unanimously support vaccination of women who are trying to become pregnant.

Public health agency guidance on COVID-19 vaccination of women who are pregnant or intend to get pregnant

Source	Recommendations
CDC May 28	<p>Pregnant people are more likely to get severely ill with COVID-19 compared with non-pregnant people. If you are pregnant, you can receive a COVID-19 vaccine. Getting a COVID-19 vaccine during pregnancy can protect you from severe illness from COVID-19. If you have questions about getting vaccinated, a conversation with your healthcare provider might help, but is not required for vaccination.</p> <p>If you are trying to become pregnant now or want to get pregnant in the future, you can receive a COVID-19 vaccine. There is currently no evidence that COVID-19 vaccination causes any problems with pregnancy, including the development of the placenta. In addition, there is no evidence that fertility problems are a side effect of any vaccine, including COVID-19 vaccines.</p> <p>Your menstrual cycle cannot be affected by being near someone who received a COVID-19 vaccine. Many things can affect menstrual cycles, including stress, changes in your schedule, problems with sleep, and changes in diet or exercise. Infections may also affect menstrual cycles</p>

NACI May 28	<p>NACI preferentially recommends that a complete vaccine series with an mRNA COVID19 vaccine should be offered to individuals in the authorized age group who are pregnant. If an mRNA vaccine is contraindicated, another authorized COVID-19 vaccine should be offered. Informed consent should include discussion about emerging evidence on the safety of mRNA COVID-19 vaccines in this population. (Strong NACI Recommendation)</p> <p>NACI recommends that a complete series with a viral vector COVID-19 vaccine may be offered to individuals 30 years of age and older who are pregnant if the conditions outlined in Recommendation #2 [risk/benefit assessment for use of an adenovirus vaccine] are met AND a risk assessment deems the benefits outweigh the potential risks for the individual and the fetus (considering concerns about possible complexities of treatment of VITT in pregnancy, should it occur). Informed consent should include discussion about limited evidence on the use of viral vector vaccines in this population. (Discretionary NACI Recommendation)</p>
PHE May 19	<p>There is no need to avoid pregnancy after COVID-19 vaccination. There is no evidence that COVID-19 vaccines have any effect on fertility or your chances of becoming pregnant. Pfizer and Moderna vaccines are the preferred vaccines for pregnant women of any age who are coming for their first dose.</p>
JCVI May 19	<p>JCVI has advised that pregnant women should be offered COVID-19 vaccines at the same time as people of the same age or risk group. In the USA, around 90,000 pregnant women have been vaccinated mainly with mRNA vaccines and no safety concerns have been identified.</p> <p>mRNA vaccines are the preferred vaccines for pregnant women of any age who are coming for their first dose. There is no evidence that COVID-19 vaccines have any effect on fertility or your chances of becoming pregnant.</p>
EMA various	<p>Animal studies do not show any harmful effects of COVID-19 vaccines in pregnancy. However, data on the use of COVID-19 vaccines during pregnancy are very limited.</p> <p>The decision on whether to use the vaccine in pregnant women should be made in close consultation with a healthcare professional after considering the benefits and risks.</p>
MHRA April 7	<p>Pregnancy predisposes to thrombosis, therefore women should discuss with their healthcare professional whether the benefits of having the AstraZeneca vaccine outweigh the risks for them.</p>
NIAID Not dated	<p>Based on current knowledge, experts believe that COVID-19 vaccines are unlikely to pose a risk to a person trying to become pregnant in the short or long term. Scientists study every vaccine carefully for side effects immediately and for years afterward, and people who get vaccinated track their symptoms. COVID-19 vaccines are being studied carefully now, and the side effects data will continue to be studied for many years, similar to other vaccines.</p> <p>There is currently no evidence that antibodies formed from COVID-19 vaccination cause any problems with pregnancy. In addition, there is no evidence suggesting that fertility problems are a side effect of ANY vaccine. People who are trying to become pregnant now or who plan to try in the future may receive the COVID-19 vaccine when it becomes available to them.</p>

Professional society guidance on COVID-19 vaccination and fertility

Source	Recommendations
ASRM May 20	<p>COVID-19 vaccination is recommended for women who are contemplating pregnancy or who are pregnant to minimize risks to themselves and their pregnancy.</p>
RCOG May 14	<p>Women trying to become pregnant do not need to avoid pregnancy after vaccination and there is no evidence to suggest that COVID-19 vaccines will affect fertility.</p> <p>There is no biologically plausible mechanism by which current vaccines would cause any impact on women's fertility. Evidence has not been presented that women who have been vaccinated have gone on to have fertility problems. Likewise, the theory that immunity to the spike protein could lead to fertility problems is not supported by evidence. Most people who contract COVID-19 will develop antibody to the spike and there is no evidence of fertility problems in people who have already had COVID-19.</p>
ACOG Apr. 28	<p>Unfounded claims linking COVID-19 vaccines to infertility have been scientifically disproven. ACOG recommends vaccination for all eligible people who may consider future pregnancy.</p>

RCM Apr. 26	There is no evidence to suggest that COVID-19 vaccines will affect fertility. There is no biologically plausible mechanism by which current vaccines would cause any impact on women's fertility. Evidence has not been presented that women who have been vaccinated have gone on to have fertility problems. The JCVI advises that women who are planning a pregnancy should not be advised to delay having the vaccination, or delay becoming pregnant after the vaccination course. Likewise, the theory that immunity to the spike protein could lead to fertility problems is not supported by evidence. Most people who contract COVID-19 will develop antibodies to the spike and there is no evidence of fertility problems in people who have already had COVID-19.
SOGC Mar. 18	There is absolutely no evidence, and no theoretic reason to suspect that the COVID-19 vaccine could impair male or female fertility. These rumors are unfounded and harmful. The widespread social media concern stems from misinformation about the similarities between syncytin-1 (used for placental implantation) and the SARS-CoV-2 spike protein. While the two proteins have several similar amino acids, they remain vastly different. The antibodies produced against the SARS-CoV-2 spike protein would not have cross-reactivity with syncytin-1.
ASRM Feb. 22	Patients undergoing fertility treatment and pregnant patients should be encouraged to receive vaccination based on eligibility criteria. Since the vaccine is not a live virus, there is no reason to delay pregnancy attempts because of vaccination administration or to defer treatment until the second dose has been administered. CEP NOTE: See also a letter published by ASRM relating to social media claims about vaccines and infertility.
ACOG Feb. 5	We also assure patients that there is no evidence that the vaccine can lead to loss of fertility. While fertility was not specifically studied in the clinical trials of the vaccine, no loss of fertility has been reported among trial participants or among the millions who have received the vaccines since their authorization, and no signs of infertility appeared in animal studies. Loss of fertility is scientifically unlikely. CEP NOTE: statement endorsed by ASRM and SMFM.
SMRU Jan 10	As of January 9, 2021, there are no data about the impact of the COVID-19 vaccine on male or female fertility. SMRU and SSMR recommend that COVID-19 vaccine should not be withheld from men desiring fertility who meet criteria for vaccination.

CEP NOTE: a newly-published [analysis](#) of UK birth records has found significant increases in adverse maternal and neonatal outcomes, including fetal death, preterm birth, prolonged hospital admission after birth, and others, in pregnant women with SARS-CoV-2 infection.

Professional society guidance on COVID-19 vaccination of women who are pregnant

Source	Recommendations
RCM May 14	We would encourage all pregnant women who are offered the COVID-19 vaccine to discuss the benefits and risks, including the side effects, with a healthcare professional. Vaccination continues to offer pregnant women the best protection from COVID-19, which can be serious in some women.
SOGC May 4	Pregnant individuals should be offered vaccination at any time during pregnancy or while breastfeeding if no contraindications exist. The SOGC supports the use of all available COVID-19 vaccines approved in Canada in any trimester of pregnancy and during breastfeeding in accordance with regional eligibility. The decision to be vaccinated is based on the individual's personal values, as well as an understanding that the risk of infection and/or morbidity from COVID-19 outweighs the theorized and undescribed risk of being vaccinated during pregnancy or while breastfeeding. Individuals should not be precluded from vaccination based on pregnancy status or breastfeeding.
SMFM Apr. 29	SMFM strongly recommends that pregnant and lactating people have access to the COVID-19 vaccines and that they engage in a discussion about potential benefits and unknown risks with their healthcare providers regarding receipt of the vaccine.
ACOG Apr. 28	ACOG recommends that pregnant individuals have access to COVID-19 vaccines. Individuals considering a COVID-19 vaccine should have access to available information about the safety and efficacy of the vaccine, including information about data that are not available. A conversation between the patient and their clinical team may assist with decisions regarding the use of vaccines approved under EUA for the prevention of COVID-19 by pregnant patients. Important considerations include: the potential efficacy of the vaccine, the risk and potential severity of maternal disease, including the effects of disease on the fetus and newborn, and the safety of the vaccine for the pregnant patient and the fetus. While a conversation with a clinician may be helpful, it should not be required prior to vaccination, as this may cause unnecessary barriers to access.

RCOG Apr. 16	Clinical trials testing the vaccine in pregnant women are just starting, but robust real-world data from the US – where around 90,000 pregnant women have been vaccinated mainly with mRNA vaccines, such as Pfizer-BioNTech and Moderna – have not raised any safety concerns. Therefore, the JCVI is advising that it is preferable for the Pfizer-BioNTech or Moderna mRNA vaccines to be offered to pregnant women in the UK, where available.
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CEP NOTE: a newly-published [analysis](#) of UK birth records has found significant increases in adverse maternal and neonatal outcomes, including fetal death, preterm birth, prolonged hospital admission after birth, and others, in pregnant women with SARS-CoV-2 infection.

Clinical data on vaccination in pregnancy

Study	Findings
MHRA May 27	The current summary of “Yellow Card” reports of suspected vaccine side effects does not include any effects relating to pregnancy or fertility.
Health Canada May 21	To date, 15.3 million doses of vaccines have been administered. A total of 6 pregnancy-related adverse events of special interest (including fetal growth restriction and spontaneous abortion) have been reported. These figures include mRNA and adenovirus vaccines: the specific vaccine given to patients having these adverse events was not reported. The report does not mention fertility-related adverse events.
C-VIPER May 21	C-VIPER: COVID-19 Vaccines International Pregnancy Exposure Registry No results reported to date.
v-safe Apr. 21	Among 3,958 participants enrolled in the v-safe pregnancy registry, 827 had a completed pregnancy, of which 115 (13.9%) resulted in a pregnancy loss and 712 (86.1%) resulted in a live birth (mostly among participants with vaccination in the third trimester). Adverse neonatal outcomes included preterm birth (in 9.4%) and small size for gestational age (in 3.2%); no neonatal deaths were reported. Although not directly comparable, calculated proportions of adverse pregnancy and neonatal outcomes in persons vaccinated against COVID-19 who had a completed pregnancy were similar to incidences reported in studies involving pregnant women that were conducted before the COVID-19 pandemic. Among 221 pregnancy-related adverse events reported to the VAERS, the most frequently reported event was spontaneous abortion (46 cases).

CEP NOTE: Additional studies are in progress as part of routine post-authorization safety and effectiveness monitoring.

CEP NOTE: No relevant manuscripts were found in a May 20 search of the medRxiv preprint database.

CEP NOTE: A [systematic review](#) of adverse events reported in vaccine trials did not report outcomes relating to pregnancy because pregnant patients were usually excluded from the trials.

Guidance sources

ACOG—American College of Obstetricians and Gynecologists
 ASRM—American Society for Reproductive Medicine
 CDC—Centers for Disease Control and Prevention
 EMA—European Medicines Agency
 FDA—US Food and Drug Administration
 JCVI—Joint Committee on Vaccination and Immunisation (UK)
 MHRA—Medicines and Healthcare products Regulatory Agency (UK)
 NACI—National Advisory Committee on Immunization (Canada)
 NIAID—National Institute of Allergy and Infectious Diseases
 PHE—Public Health England
 RCM—Royal College of Midwives (UK)
 RCOG—Royal College of Obstetricians and Gynaecologists (UK)
 SMFM—Society for Maternal-Fetal Medicine
 SMRU—Society for Male Reproduction and Urology
 SOGC—Society of Obstetricians and Gynaecologists of Canada
 SSMR—Society for the Study of Male Reproduction

Update history (key additions and changes only)

May 21: Initial report.

May 28: Added key question on vaccines and the menstrual cycle. Updated guidance from CDC and NACI.

About this report

A Rapid Guidance Summary is a focused synopsis of recommendations from selected guideline issuers and health care systems, intended to provide guidance to Penn Medicine providers and administrators during times when latest guidance is urgently needed. It is not based on a complete systematic review of the evidence. Please see the CEP web site (<http://www.ups.upenn.edu/cep>) for further details on the methods for developing these reports.

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