

COVID-19: VACCINATION FOR WOMEN WHO ARE PREGNANT OR LACTATING



A Rapid Guidance Summary from the Penn Medicine Center for Evidence-based Practice
 Last updated December 24, 2020. All links rechecked December 24 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

- Should women who are pregnant, breastfeeding, or attempting to conceive be vaccinated against COVID-19?

Summary of major recommendations

- Guidelines note the lack of clinical evidence on the safety or effectiveness of COVID-19 vaccines in women who are pregnant, breastfeeding, or attempting to conceive.
- Two major US specialty societies recommend shared decision-making to best balance the risks of vaccination with the risks of remaining unvaccinated. They do not consider pregnancy or breastfeeding to be an absolute contraindication to COVID-19 vaccination.
- Most US medical centers that have taken a position on COVID-19 vaccination endorse the US societies' recommendations for shared decision-making and will offer vaccination to women who are pregnant or breastfeeding.
- Organizations in the United Kingdom consider pregnancy and breastfeeding to be contraindications to COVID-19 vaccination.

Public health agency and professional society guidelines on COVID-19 vaccination of women who are pregnant

Source	Recommendations
NACI Dec. 23	NACI recommends that COVID-19 vaccine should not be offered to individuals who are pregnant until after completion of pregnancy, until further evidence is available (Strong Recommendation). However, a complete series of COVID-19 vaccine may be offered to pregnant individuals in the authorized age group if a risk assessment deems that the benefits outweigh the potential risks for the individual and the fetus, and if informed consent includes discussion about the absence of evidence on COVID-19 vaccine in this population. (Discretionary Recommendation)
ECDC Dec. 22	No recommendations for or against vaccination of women who are pregnant or lactating.
ACOG Dec. 21	ACOG recommends that COVID-19 vaccines should not be withheld from pregnant individuals who meet criteria for vaccination based on ACIP-recommended priority groups. 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: <ul style="list-style-type: none"> • the level of activity of the virus in the community • the potential efficacy of the vaccine • the risk and potential severity of maternal disease, including the effects of disease on the fetus and newborn • the safety of the vaccine for the pregnant patient and the fetus.

	<p>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.</p> <p>Vaccines currently available under EUA have not been tested in pregnant women. Therefore, there are no safety data specific to use in pregnancy.</p> <p>Pregnancy testing should not be a requirement prior to receiving any EUA-approved vaccine.</p> <p>Pregnant patients who decline vaccination should be supported in their decision. Regardless of their decision to receive or not receive the vaccine, these conversations provide an opportunity to remind patients about the importance of other prevention measures such as hand washing, physical distancing, and wearing a mask.</p> <p>Expected side effects should be explained as part of counseling patients, including that they are a normal part of the body's reaction to the vaccine and developing antibodies to protect against COVID-19 illness.</p> <p>The mRNA vaccines are not live virus vaccines, nor do they use an adjuvant to enhance vaccine efficacy. These vaccines do not enter the nucleus and do not alter human DNA in vaccine recipients. As a result, mRNA vaccines cannot cause any genetic changes.</p>
<p>SOGI Dec. 18</p>	<p>For individuals who are at high risk of infection and/or morbidity from COVID-19, it is the SOGC's position that the documented risk of not getting the COVID-19 vaccine outweighs the theorized and undescribed risk of being vaccinated during pregnancy or while breastfeeding and vaccination should be offered.</p> <p>Decades of experience with other vaccines administered during pregnancy would suggest that we could expect a similar efficacy for the COVID-19 vaccines in pregnant women compared to non-pregnant women. Vaccines in general are immunogenic, safe, and efficacious when delivered to pregnant women. While there have been no red flags or hypothesized mechanisms for potential harm associated with administration of an mRNA vaccine during pregnancy, until more data is available, the potential risks of vaccination to a pregnant individual and fetus remain unknown. What is known, however, is that an unvaccinated pregnant individual remains at risk of COVID-19 infection and remains at heightened risk of severe morbidity if infected compared to non-pregnant counterparts.</p> <p>Universal exclusion of pregnant women from receipt of the COVID-19 vaccine based on an undocumented and hypothetical risk to the fetus would leave pregnant women vulnerable to severe morbidity, which could also compromise fetal health. Conversely, lack of safety and efficacy data for this population precludes making a recommendation for routine COVID-19 vaccination for all pregnant and breastfeeding individuals.</p>
<p>PHE Dec. 11</p>	<p>Although the currently available data do not indicate any safety concerns or harm to pregnancy, there is currently insufficient evidence to recommend the use of COVID-19 vaccines during pregnancy. Given the lack of evidence, it is recommended that COVID-19 vaccine is not given in pregnancy and women should be advised not to attend for vaccination if they are, or may be pregnant, or are planning a pregnancy within three months of the first dose.</p> <p>Vaccinated women who are not pregnant should be advised to avoid becoming pregnant for two months after the second dose of vaccine.</p> <p>If a woman finds out she is pregnant after she has started a course of vaccine, she should complete her pregnancy before finishing the recommended schedule. Termination of pregnancy following inadvertent immunization should not be recommended.</p>
<p>FDA Dec. 11</p>	<p>Even though there are insufficient data to inform vaccine-associated risks in pregnancy, there are also no data warranting a contraindication.</p> <p><i>CEP NOTE: This is the guidance from the Emergency Use Authorization for the Pfizer-BioNTech vaccine.</i></p>
<p>SHEA Dec. 11</p>	<p>ACOG and others have stated that pregnancy should be a precaution rather than a contraindication for COVID-19 vaccine, given the increased risk of severe COVID-19 in this population; however, "off-label" use is not allowed under an EUA. This may change as more data become available.</p>
<p>AAP Dec. 22</p>	<p>No pregnancy related data have yet been released. Typically, in large trials, there are some inadvertent pregnancies. They will be followed for birth outcomes. Pregnancy and breastfeeding will probably not be contraindications to receiving COVID-19 vaccine; however, there is no safety data in the pregnant woman, her fetus or infants at this time. <i>CEP NOTE: AAP also references the ACOG guidance in their recommendations.</i></p>

RCM Dec. 9	<p>Pregnant women and women planning a pregnancy within the next 3 months should not be offered COVID-19 vaccination.</p> <p>Pregnant women at high risk, including health care workers, should be offered vaccine as soon as possible after birth.</p> <p>Women eligible to receive a vaccine, including health workers and those clinically vulnerable, planning to become pregnant are should be offered a full course of vaccination and be advised to wait three months after the first dose/two months after the second dose before getting pregnant.</p> <p>Vaccinated women who are not pregnant should be advised to avoid becoming pregnant for two months after the second dose of vaccine.</p>
CDC Dec. 3	<p>Evidence suggests that pregnant women are potentially at increased risk for severe COVID-19-associated illness and death compared to non-pregnant women, underscoring the importance of disease prevention in this population. Given the predominance of women of child-bearing potential among the healthcare workforce, a substantial number of health care providers (HCP) are estimated to be pregnant or breastfeeding at any given time. Currently, there are no data on the safety and efficacy of COVID-19 vaccines in these populations to inform vaccine recommendations. Further considerations around use of COVID-19 vaccines in pregnant or breastfeeding HCP will be provided once data from phase III clinical trials and conditions of FDA Emergency Use Authorization are reviewed.</p>
JCVI Dec. 2	<p>There are no data as yet on the safety of COVID-19 vaccines in pregnancy, either from human or animal studies. Given the lack of evidence, JCVI favours a precautionary approach, and does not currently advise COVID-19 vaccination in pregnancy. Women should be advised not to come forward for vaccination if they may be pregnant or are planning a pregnancy within three months of the first dose.</p>
SMFM Dec. 1	<p>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.</p>

Public health agency and professional society guidelines on COVID-19 vaccination of women who are attempting to conceive

Source	Recommendations
PHE Dec. 11	Vaccinated women who are not pregnant should be advised to avoid becoming pregnant for two months after the second dose of vaccine.
RCM Dec. 9	Pregnant women and women planning a pregnancy within the next 3 months should not be offered COVID-19 vaccination. Vaccinated women who are not pregnant should be advised to avoid becoming pregnant for two months after the second dose of vaccine.
JCVI Dec. 2	Women should be advised not to come forward for vaccination if they may be pregnant or are planning a pregnancy within three months of the first dose.

Public health agency and professional society guidelines on COVID-19 vaccination of women who are lactating

Source	Recommendations
NACI Dec. 23	NACI recommends that COVID-19 vaccine should not be offered to individuals who are breastfeeding, until further evidence is available (Strong NACI Recommendation). However, a complete series of COVID-19 vaccine may be offered to individuals in the authorized age group who are breastfeeding if a risk assessment deems that the benefits outweigh the potential risks for the individual and the infant, and if informed consent includes discussion about the absence of evidence on COVID-19 vaccine in this population. (Discretionary Recommendation)

AAP Dec. 22	No pregnancy related data have yet been released. Typically, in large trials, there are some inadvertent pregnancies. They will be followed for birth outcomes. Pregnancy and breastfeeding will probably not be contraindications to receiving COVID-19 vaccine; however, there is no safety data in the pregnant woman, her fetus or infants at this time. While these vaccines were not specifically tested in breastfeeding women, it is not likely (based on the mechanisms of action of the vaccines in US trials) that there would be any risk to the child.
ACOG Dec. 21	COVID-19 vaccines should be offered to lactating individuals similar to non-lactating individuals when they meet criteria for receipt of the vaccine based on prioritization groups outlined by the ACIP.
SOGI Dec. 18	For individuals who are at high risk of infection and/or morbidity from COVID-19, it is the SOGC's position that the documented risk of not getting the COVID-19 vaccine outweighs the theorized and undescribed risk of being vaccinated during pregnancy or while breastfeeding and vaccination should be offered.
PHE Dec. 11	Until more information is available, it is also recommended that women who are breastfeeding should not be vaccinated until they have finished breastfeeding.
RCM Dec. 9	Breastfeeding women should not be offered COVID-19 vaccination until they have finished breastfeeding.
CDC Dec. 3	Evidence suggests that pregnant women are potentially at increased risk for severe COVID-19-associated illness and death compared to non-pregnant women, underscoring the importance of disease prevention in this population. Given the predominance of women of child-bearing potential among the healthcare workforce, a substantial number of health care providers (HCP) are estimated to be pregnant or breastfeeding at any given time. Currently, there are no data on the safety and efficacy of COVID-19 vaccines in these populations to inform vaccine recommendations. Further considerations around use of COVID-19 vaccines in pregnant or breastfeeding HCP will be provided once data from phase III clinical trials and conditions of FDA Emergency Use Authorization are reviewed.

Evidence reviews on mRNA vaccines

Reviewer	Findings
CEP Dec. 24	There is no evidence on the safety or effectiveness of mRNA vaccines in women who are pregnant or lactating.
SOGI Dec. 18	Pregnant and breastfeeding women were excluded from the Phase II and Phase III studies for the Pfizer-BioNTech COVID-19 vaccine. However, there were 23 women (12 in the vaccine arm and 11 in the placebo arm) who reported pregnancies during the trial and are being followed for pregnancy outcomes with no reports of adverse effects to date. Currently, there are no other safety or efficacy data available for pregnant women. Similarly, breastfeeding women were also excluded from the Phase III trials available at present. Therefore, there is no data on the safety of COVID-19 vaccines in lactating women or the effects of mRNA vaccines on the breastfed infant or on milk production. Because mRNA vaccines are not considered live virus vaccines, they are not hypothesized to be a risk to the breastfeeding infant.

Medical center guidance on COVID-19 vaccination of women who are pregnant or lactating

Hospital	Recommendation
Penn Medicine Dec. 24 (not publicly available)	In accordance with a recent statement issued by the Society for Maternal Fetal Medicine, the University of Pennsylvania Health System supports pregnant women having access to the COVID-19 vaccine. Pregnant and breast-feeding women were not included in the vaccine clinical trials. As a result, the potential effects of the vaccine on pregnancy and/or an unborn child currently are not known. The Society for Maternal Fetal Medicine has issued a statement supporting access to the vaccines for pregnant and breast-feeding women but states that the decision on whether to receive the vaccine should be made in consultation with the woman's health care professional after careful consideration of the known risks and potential benefits. This likewise is the recommendation made in the EUA Fact Sheet for Recipients and Caregivers. You should consult your health care provider if you are pregnant or breast-feeding or plan to become pregnant before receiving the vaccine to discuss the potential benefits and risks for you and your baby of receiving the vaccine.
Mayo Dec. 24	The COVID-19 vaccine is not being offered to pregnant women. This is because researchers don't know enough about how COVID-19 vaccination can affect children, pregnant women or their babies. There is also no data on the safety of COVID-19 vaccines for breastfeeding women.
Johns Hopkins Dec. 23	Experts from the FDA and CDC believe that these vaccines are unlikely to pose a risk for women who are pregnant. There is limited data available on the safety of COVID-19 vaccines for people who are pregnant so it's always a good idea to talk to your obstetrician. Experts from the FDA and CDC believe that the authorized COVID-19 vaccines are unlikely to pose a risk to the breastfeeding infant and the mother. There is no data on the safety of COVID-19 vaccines in lactating women or on the effects of mRNA vaccines on the breastfed infant so it's always a good idea to talk to your pediatrician.
Michigan Dec. 23	Pregnant women and women trying to conceive should have a discussion with their healthcare provider about risks and benefits of the COVID-19 vaccine.
Yale Dec. 21	Given the absence of clear guidance, pregnant and breastfeeding women should discuss the risks and benefits of vaccination with their obstetrician, pediatrician, and/or midwife. If you are pregnant and/or breastfeeding and after reviewing the risks versus benefits wish to receive the vaccination, you will be able to receive the vaccine as a part of our program. This guidance may change after additional guidance from ACIP. We are offering the vaccine to individuals planning pregnancy, who should discuss this issue with their obstetrician or midwife to help weigh risks and benefits of getting vaccinated. We are aware of concerns in the public about fertility after the COVID-19 vaccine. These concerns are unfounded. We are offering the vaccine to individuals who are nursing/lactating, who should discuss this with their pediatrician to help weigh the risks and benefits of getting vaccinated. We will continue to review additional data and guidelines on the safety and effectiveness of vaccination against COVID-19 for pregnant/breastfeeding individuals as they become available.
Texas Tech Dec. 18	The use of these new vaccines in breastfeeding mothers has not been studied, largely because none of them have been approved for use. That said, it is our opinion that most of the COVID-19 vaccines are probably going to be quite safe for breastfeeding mothers and their infants. In these situations, physicians and breastfeeding mothers in consult, will have to weigh the relative risks of the vaccine to that of the infection with coronavirus in that specific mother. CEP NOTE: Guidance for women who are pregnant endorses SMFM and CDC positions.
Massachusetts Dec. 14	COVID seems to cause more harm in pregnant women than in women of the same age who are not pregnant. The risks of getting the COVID vaccine during pregnancy are thought to be small but are not totally known. You should consider your own personal risk of getting COVID. If your personal risk is high, or there are many cases of COVID in your community, it probably makes sense for you to get the vaccine while pregnant. Whether to get the vaccine during pregnancy is your choice. CEP NOTE: This text is from a decision aid developed to help with shared decision-making

Hospital	Recommendation
Vanderbilt Dec. 14	<p>If pregnant women are part of a group (e.g., health care workers) that is otherwise recommended to get a COVID-19 vaccine, they may choose to be vaccinated. They should make an informed decision in discussion with their health care provider.</p> <p>Claims circulating on social media and anti-vaccination websites that the vaccine interferes with the formation of the placenta are FALSE. The specific claim is the spike protein formed in the immune response to the vaccine cross-reacts with another protein (syncytin-1) that is important to placenta formation. There has been no evidence that the vaccine response creates these types of cross-reacting antibodies.</p> <p>No data exist yet on the safety of COVID-19 vaccines in lactating women or the effects of mRNA vaccines on the breastfed infant or milk production and excretion. That said, RNA vaccines are not considered live virus vaccines and are not thought to be a risk to the breastfeeding infant. If a lactating woman is part of a group (e.g., health care personnel) that is recommended to receive a COVID-19 vaccine, she may choose to be vaccinated.</p>
George Washington Dec. 10	We cannot make any recommendation as far as receiving the vaccine while pregnant or breastfeeding.
Washington Dec. 8	Pregnant and breast-feeding women can get the vaccine; however, we encourage you to contact your healthcare provider before getting the vaccine.

Product labeling information

Product	Instructions
Moderna (USA) Dec. 18	<p>All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the US general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively. Available data on Moderna COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy.</p> <p>Data are not available to assess the effects of Moderna COVID-19 Vaccine on the breastfed infant or on milk production/excretion.</p>
Pfizer-BioNTech (USA) Dec. 11	<p>All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the US general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively. Available data on Pfizer-BioNTech COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy.</p> <p>Data are not available to assess the effects of Pfizer-BioNTech COVID-19 Vaccine on the breastfed infant or on milk production/excretion.</p>
Pfizer-BioNTech (UK) Dec. 10	<p>There are no or limited amount of data from the use of COVID-19 mRNA Vaccine BNT162b2. Animal reproductive toxicity studies have not been completed. COVID-19 mRNA Vaccine BNT162b2 is not recommended during pregnancy. For women of childbearing age, pregnancy should be excluded before vaccination. In addition, women of childbearing age should be advised to avoid pregnancy for at least 2 months after their second dose.</p> <p>It is unknown whether COVID-19 mRNA Vaccine BNT162b2 is excreted in human milk. A risk to the newborns/ infants cannot be excluded. COVID-19 mRNA Vaccine BNT162b2 should not be used during breast-feeding.</p> <p>It is unknown whether COVID-19 mRNA Vaccine BNT162b2 has an impact on fertility</p>

Guidance sources

ACOG—American College of Obstetricians and Gynecologists

CDC—Centers for Disease Control and Prevention

ECDC—European Centre for Disease Prevention and Control

FDA—US Food and Drug Administration

JCVI—Joint Committee on Vaccination and Immunisation (UK)

NACI– National Advisory Committee on Immunization (Canada)
PHE–Public Health England
RCM–Royal College of Midwives (UK)
RCOG–Royal College of Obstetricians and Gynaecologists (UK)
SHEA–Society for Healthcare Epidemiology of America
SMFM–Society for Maternal-Fetal Medicine
SOGC–Society of Obstetricians and Gynaecologists of Canada
WHO–World Health Organization

Sources with no relevant guidance at this time

American Academy of Family Physicians
Canadian Medical Association
Department of Health (Australia)
Infectious Diseases Society of America
Joanna Briggs Institute
National COVID-19 Clinical Evidence Taskforce (Australia)
National Institutes of Health
Beth Israel Lahey Health
Mount Sinai Health System
UC San Francisco

Update history (key additions and changes only)

December 24: Initial report.

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.uphs.upenn.edu/cep>) for further details on the methods for developing these reports.

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