



The following information resources have been selected by the National Health Library and Knowledge Service Evidence Virtual Team in response to a question from the National Immunisation Advisory Committee (NIAC). The resources are listed in our estimated order of relevance to practicing healthcare professionals confronted with this scenario in an Irish context. In respect of the evolving global situation and rapidly changing evidence base, it is advised to use hyperlinked sources in this document to ensure that the information you are disseminating to the public or applying in clinical practice is the most current, valid and accurate. For further information on the methodology used in the compilation of this document — including a complete list of sources consulted — please see our [National Health Library and Knowledge Service Summary of Evidence Protocol](#).

## QUESTION 197

What is the safety of COVID-19 vaccines in pregnancy? Are there any associated adverse events or benefits for pregnant or lactating mothers, or for the foetus?

Question 207 was prepared by the National Health Library and Knowledge Service in collaboration with the Research Subgroup of the National Immunisation Advisory Committee (NIAC).



National Health Library and  
Knowledge Service | Evidence  
Team



NIAC

*What is the safety of COVID-19 vaccines in pregnancy?  
Are there any associated adverse events or benefits for  
pregnant or lactating mothers, or for the foetus?*

## Main Points

1. No unexpected pregnancy or infant outcomes have been observed related to the 96,000+ Pfizer-BioNTech or Moderna mRNA COVID-19 vaccinations administered during pregnancy in the United States, or to a similar number of Pfizer-BioNTech vaccinations administered in Israel.
2. Pregnant women and their obstetric caregivers should engage in shared decision-making in advance of vaccination to best balance the risks of vaccination with the risks of remaining unvaccinated.
3. Where the risk-benefit assessment is favourable, two doses of the mRNA vaccines Pfizer-BioNTech or Moderna should be given 28 days apart between 14 and 36 completed weeks of gestation.
4. There is no known reason for vaccine recipients to avoid breastfeeding.
5. If an individual becomes pregnant after receiving the first dose of a two-dose COVID-19 vaccine series, the second dose should be administered when indicated. 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.



Please refer to the [National Health Library Levels of Evidence Table](#) used to grade the levels of evidence included below.

<input checked="" type="checkbox"/>	Inclusion All levels. criteria:
<input checked="" type="checkbox"/>	Exclusion None. criteria:

Please note that individual studies may not have been critically appraised and that designation at a certain level is not a final determination of the quality of a given study.

## Summary of Evidence

The National Immunisation Advisory Committee (NIAC) advises in respect of the mRNA vaccines Pfizer-BioNTech and Moderna that animal reproductive toxicology studies of the mRNA vaccines did not identify any safety concerns. There is no evidence that any COVID-19 vaccine affects fertility or the foetus. Over 96,000 mRNA vaccinations in pregnancy have been reported to CDC in the United States up to 13 April 2021. A similar number have received the Pfizer-BioNTech vaccine in Israel. No unexpected pregnancy or infant outcomes have been observed related to COVID-19 vaccination during pregnancy. Long-term follow up of vaccine recipients is ongoing<sup>1</sup>.

In one cohort study<sup>10</sup>, mRNA vaccine-induced immune responses were equivalent in pregnant (n = 84), lactating (n = 31) and non-pregnant females (n = 16); antibody titers were higher than those induced by SARS-CoV-2 infection during pregnancy; and vaccine-generated antibodies were present in umbilical cord blood and breastmilk samples<sup>7, 10</sup>.

Pregnant women and their obstetric caregivers should engage in shared decision-making in advance of vaccination to best balance the risks of vaccination with the risks of remaining unvaccinated [1, 3, 4, 11, 12, 13](#). Counselling 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<sup>1</sup>. Issues to consider when counselling pregnant persons include: data from animal studies and inadvertently exposed pregnancies during vaccine clinical trials, when available; potential risks to pregnancy of vaccine reactogenicity; timing of vaccination during pregnancy; evidence for safety of other vaccines during pregnancy; risk of COVID-19 complications due to pregnancy; the pregnant person's underlying conditions; and risk of exposure to SARS-CoV-2, and potential for risk mitigation<sup>13</sup>.

NIAC advises that where the risk-benefit assessment is favourable, the two doses of the mRNA vaccines Pfizer-BioNTech or Moderna should be given 28 days apart. The two-dose schedule should be given between 14 and 36 completed weeks of gestation<sup>1</sup>.

There is no known reason for vaccine recipients to avoid breastfeeding<sup>1, 4, 15</sup>.

NIAC advises that the AstraZeneca vaccine is not recommended for those aged under 50 years, including those with medical conditions with very high or high risk of severe COVID-19 disease; and in respect of Janssen that the vaccine is not recommended for pregnant women including those with medical conditions with very high or high risk of severe COVID-19 disease<sup>1</sup>.

Pregnant women were not included in COVID-19 vaccine clinical trials<sup>2</sup>. This is not because of any specific safety concerns but as a matter of caution, similar to that applied to trials of most other medicines<sup>6</sup>. Based on limited self-reported information, no specific safety signals have been observed in pregnant people; however, longitudinal follow-up is needed<sup>2</sup>. Early data from CDC's *v-safe* pregnancy registry demonstrate that the side-effects and adverse events observed among pregnant individuals in *v-safe* did not indicate any safety concerns<sup>2</sup>.

Injection site and systemic events are common: pain at the site of injection, fever, muscle pain, joint pain,



headaches, fatigue and other symptoms may be present after vaccination. These side-effects are a normal part of the body's reaction to the vaccine and developing antibodies to protect against COVID-19 illness<sup>2</sup>.

Ongoing safety monitoring is planned through many government and non-government programs.

If an individual becomes pregnant after receiving the first dose of a two-dose COVID-19 vaccine series, the second dose should be administered when indicated<sup>7</sup>.

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<sup>2, 4</sup>.



# Irish and/or International Guidance

Level 1

[Health Service Executive, National Immunisation Advisory Committee \(2021\) Immunisation Guidelines: Chapter 5A - COVID-19<sup>1</sup>](#)

See Section: mRNA VACCINES

## **Pfizer-BioNTech and Moderna**

### **Pregnancy**

Animal reproductive toxicology studies of the mRNA vaccines did not identify any safety concerns. There is no evidence that any COVID-19 vaccine affects fertility or the foetus. Over 96,000 mRNA vaccinations in pregnancy have been reported to CDC in the United States up to 13 April 2021. A similar number have received the Pfizer-BioNTech vaccine in Israel. No unexpected pregnancy or infant outcomes have been observed related to COVID-19 vaccination during pregnancy. Long-term follow up of vaccine recipients is ongoing. Pregnant women and their obstetric caregivers should engage in shared decision-making in advance of vaccination. Counselling 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. Where the risk-benefit assessment is favourable, the two doses should be given 28 days apart. The two-dose schedule should be given between 14 and 36 completed weeks of gestation.

### Breastfeeding

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1 Health Service Executive (2021). Immunisation Guidelines (Chapter 5A - COVID-19). <https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/covid19.pdf>. [Accessed 25 May 2021].



There is no known reason for vaccine recipients to avoid breastfeeding. Breastfeeding mothers should be vaccinated according to their risk grouping.

## AstraZeneca

### Pregnancy

This vaccine is not recommended for those aged under 50 years, including those with medical conditions with very high or high risk of severe COVID-19 disease.

See Section: PRECAUTIONS for those who have received a first dose.

### Breastfeeding

There is no known reason for vaccine recipients to avoid breastfeeding. Breastfeeding mothers should be vaccinated according to their risk grouping.

## Janssen

### Pregnancy

This vaccine is not recommended for pregnant women including those with medical conditions with very high or high risk of severe COVID-19 disease.

### Breastfeeding

There is no known reason for vaccine recipients to avoid breastfeeding. Breastfeeding mothers should be vaccinated according to their risk grouping.

 Level 1

[American College of Obstetricians and Gynecologists \(2021\) COVID-19 Vaccines and Pregnancy: Conversation Guide for Clinicians<sup>2</sup>](#)

Safety of COVID-19 Vaccines

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<sup>2</sup> American College of Obstetricians and Gynecologists (2021). COVID-19 Vaccines and Pregnancy: Conversation Guide for Clinicians. <https://www.acog.org/covid-19/covid-19-vaccines-and-pregnancy-conversation-guide-for-clinicians>. [Accessed 14 April 2021].



Pregnant women were not included in COVID-19 vaccine clinical trials. However, observational data from vaccinated pregnant individuals is being collected by CDC and manufacturers. Based on limited self-reported information, no specific safety signals have been observed in pregnant people; however, longitudinal follow-up is needed. Early data from CDC's *v-safe* pregnancy registry demonstrate that the side-effects and adverse events observed among pregnant individuals in *v-safe* did not indicate any safety concerns.

Data from developmental and reproductive toxicity (DART) animal-model studies for the Pfizer-BioNTech, Moderna and Janssen COVID-19 vaccines have not demonstrated any safety concerns in pregnancy.

Based on the mechanism of action of these vaccines and the demonstrated safety and efficacy in phase II and phase III clinical trials, it is expected that the safety and efficacy profile of the vaccine for pregnant individuals would be similar to that observed in non-pregnant individuals. None of the COVID-19 vaccines available for use under emergency use authorization cause infertility.

Injection site and systemic events are common: eg pain at the site of injection, fever, muscle pain, joint pain, headaches, fatigue and other symptoms may be present after vaccination. Acetaminophen is recommended for pregnant women who experience fever or if desired for other side-effects. These side-effects are a normal part of the body's reaction to the vaccine and developing antibodies to protect against COVID-19 illness.

Ongoing safety monitoring is planned through many government and non-government programs.



Level 1

[American College of Obstetricians and Gynecologists \(December 2020\) \[Evidence Synopsis\] COVID-19: Vaccination for women who are pregnant or breastfeeding<sup>3</sup>](#)

- ❑ 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 a 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.

Level 1

[Royal College of Obstetricians and Gynaecologists \(Great Britain\) \(2021\) COVID-19 vaccines, pregnancy and breastfeeding<sup>4</sup>](#)

- ❑ The latest advice from the Joint Committee on Vaccination and Immunisation (JCVI) is that COVID-19 vaccines should be considered for pregnant women when their risk of exposure to the virus is high and cannot be avoided, or if the woman has underlying

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3 American College of Obstetricians and Gynecologists (2021) COVID-19: Vaccination for women who are pregnant or breastfeeding. <http://www.uphs.upenn.edu/cep/COVID/Vaccine%20in%20pregnancy%20final.pdf>. Accessed 16 April 2021.

4 Royal College of Obstetricians & Gynaecologists (2021). COVID-19 vaccines, pregnancy and breastfeeding. <https://www.rcog.org.uk/en/guidelines-research-services/coronavirus-covid-19-pregnancy-and-womens-health/covid-19-vaccines-and-pregnancy/covid-19-vaccines-pregnancy-and-breastfeeding/>. Accessed 16 April 2021.



conditions that place her at high risk of complications from COVID-19.

- ❑ COVID-19 vaccines should only be considered for use in pregnancy when the potential benefits outweigh any potential risks for the woman and her baby.
- ❑ Pregnant individuals should discuss the benefits and risks of having the vaccine with their healthcare professional and reach a joint decision based on individual circumstances.
- ❑ Breastfeeding mothers should not stop breastfeeding in order to be vaccinated against COVID-19.
- ❑ 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.
- ❑ Having a COVID-19 vaccine will not remove the requirement for employers to carry out a risk assessment for pregnant employees.

See also our [statement](#) in response to change in guidance around the Oxford AstraZeneca vaccine.

 Level 1

[Centers for Disease Control and Prevention \(United States\) \(2021\) Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States<sup>5</sup>](#)

The potential risks of COVID-19 vaccines to the pregnant person and the foetus are unknown because these vaccines have not been studied in pregnant people. Clinical trials to evaluate the safety and efficacy of COVID-19 vaccines in pregnant people are underway or planned. Vaccine manufacturers are also following outcomes in people in the clinical trials who became pregnant.

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<sup>5</sup> Centers for Disease Control and Prevention (2021). Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States. <https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>. Accessed 16 April 2021.



National Health Library and Knowledge Service | Evidence Team  
CURRENT AS AT 15 APRIL 2020  
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Level 1

[Public Health England \(2021\) The safety of COVID-19 vaccines when given in pregnancy<sup>6</sup>](#)

The COVID-19 vaccines available in Britain have been shown to be effective and to have a good safety profile. These vaccines do not contain live coronavirus and cannot infect a pregnant woman or her unborn baby in the womb. There is no known risk with giving inactivated virus or bacterial vaccines or toxoids during pregnancy or while breast-feeding. The Joint Committee on Vaccination and Immunisation (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.

Evidence so far reviewed by the Medicines and Healthcare Products Regulatory Agency (MHRA) in Britain has raised no specific concerns for safety in pregnancy. Evidence on COVID-19 vaccines is being continuously reviewed by the World Health Organization and regulatory bodies internationally. In the USA, over 100,000 pregnant women have been vaccinated, mainly with Pfizer and Moderna vaccines, and no safety concerns have been identified. Pfizer and Moderna vaccines are therefore the preferred vaccines for pregnant women of any age who are coming for their first dose. If a different COVID-19 vaccine is given to a pregnant woman, she should be reassured that the vaccine does not contain live coronavirus and therefore cannot cause COVID-19 infection in her or in her baby. Some COVID-19 vaccines contain a different harmless virus to help deliver the vaccine. This virus cannot multiply and so will not cause infection in a pregnant woman or her baby.

The data for each licensed COVID-19 vaccine in pregnancy is limited because pregnant women are not included in vaccine trials. This is not because of any specific

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<sup>6</sup> Public Health England (2021) The safety of COVID-19 vaccines when given in pregnancy. <https://www.gov.uk/government/publications/safety-of-covid-19-vaccines-when-given-in-pregnancy/the-safety-of-covid-19-vaccines-when-given-in-pregnancy>. Accessed 16 April 2021.



safety concerns but as a matter of caution, similar to that applied to trials of most other medicines.

## Point-of-Care Tools

 Level 2

[UpToDate \(2021\) Coronavirus disease 2019 \(COVID-19\): Pregnancy issues and antenatal care<sup>7</sup>](#)

### Vaccines

Numerous vaccines are being evaluated for prevention of COVID-19, but pregnant or lactating people have been excluded from these trials. In the United States, two mRNA vaccines (Pfizer-BioNTech, Moderna) and one vaccine based on a replication-incompetent adenovirus recombinant vector (Janssen) have received emergency use authorization; other vaccines are available worldwide. None of these vaccines contain virus that replicates; thus, they do not cause disease, but nonspecific side effects from activation of the immune system may occur. Based on how mRNA and viral vector vaccines work, experts believe they are unlikely to pose a risk for pregnant persons, the foetus, or breastfeeding newborns. Data from animal studies, vaccinated pregnant people and small prospective cohort studies have not shown harmful effects, and have demonstrated a maternal immune response and transfer of maternal antibodies to confer passive immunity against SARS-CoV-2 in newborns after maternal vaccination. In one cohort study, mRNA vaccine-induced immune responses were equivalent in pregnant (n = 84), lactating (n = 31) and nonpregnant females (n = 16); antibody titers were higher than those induced by SARS-CoV-2 infection during pregnancy; and vaccine-generated antibodies were present in umbilical cord blood and breastmilk samples. Over 30,000 pregnancies have been

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7 UpToDate (2021). Coronavirus disease 2019 (COVID-19): Pregnancy issues and antenatal care. <https://www.uptodate.com/contents/coronavirus-disease-2019-covid-19-pregnancy-issues-and-antenatal-care> [Accessed 02 March 2021].



self-reported to the CDC's *V-safe After Vaccination Health Checker*. This registry has data on 275 completed pregnancies. The CDC's *Vaccine Adverse Event Reporting System (VAERS)* has data on 154 pregnancies. No excess in side effects or adverse events has been observed in these early data compared with the CDC national birth data. The CDC's *Vaccine Safety Datalink (VSD)* and the *Clinical Immunization Safety Assessment (CISA)* are also collecting data.

The American College of Obstetricians and Gynecologists, CDC and others have recommended not withholding these vaccines on the basis of pregnancy/lactation alone for those who desire vaccination. Some groups have taken the approach of offering vaccination in pregnancy/lactation, advising clinicians and patients to consider the risk of exposure to SARS-CoV-2 infection, underlying conditions that increase risk of serious complications of COVID-19, and the patient's values/preferences and understanding of available limited information.

If COVID-19 vaccination is elected, ideally it should be timed so that patients do not receive the vaccine within 14 days of receipt of a routine vaccination, such as the Tdap or influenza. However, a shorter interval between administration of COVID-19 vaccines and other vaccines is reasonable when timely administration of the other vaccine is important or if it would avoid unnecessary delay in COVID-19 vaccination.

Anti-D immunoglobulin does not interfere with the immune response to vaccines, so timing of administration for prevention of alloimmunization is based on standard clinical protocols.

If an individual becomes pregnant after receiving the first dose of a two-dose COVID-19 vaccine series, the second dose should be administered when indicated.

Pregnant persons should be included in future COVID-19 vaccine studies. As preclinical and clinical vaccination data for this population become available, more specific vaccine recommendations will be made (eg whether gestational age should be considered).



# Irish and/or International Literature

Level 1

## [European Medicines Agency \(2021\) Assessment Report: COVID-19 Vaccine Moderna<sup>8</sup>](#)

There are no conclusive data available on the use of the mRNA-1273 vaccine during pregnancy. 12 pregnancies have been reported in study p301: 6 subjects received the study vaccine, and 6 received the placebo. As of 11 November 2020, all 6 pregnancies in the vaccine group were ongoing with no reported complications. In the placebo group, one participant was lost to follow-up and the pregnancy outcome is unknown. For the two pregnancies with known outcome in the placebo group: one participant experienced a spontaneous abortion at approx.. 7 gestation weeks; and one participant had an elective abortion at approx.. 6 gestation weeks.

Level 1

## [European Medicines Agency \(2021\) Assessment Report: COVID-19 Vaccine AstraZeneca<sup>9</sup>](#)

There were 10 pregnancies within the clinical trials submitted in subjects exposed to the AstraZeneca vaccine, and 7 in subjects exposed to the control. It is not

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8 European Medicines Agency (2021) Assessment Report: COVID-19 Vaccine Moderna. [https://www.ema.europa.eu/en/documents/assessment-report/covid-19-vaccine-moderna-epar-public-assessment-report\\_en.pdf](https://www.ema.europa.eu/en/documents/assessment-report/covid-19-vaccine-moderna-epar-public-assessment-report_en.pdf). Accessed 25 May 2021.

9 European Medicines Agency (2021) Assessment Report: COVID-19 Vaccine AstraZeneca. [https://www.ema.europa.eu/en/documents/assessment-report/covid-19-vaccine-astrazeneca-epar-public-assessment-report\\_en.pdf](https://www.ema.europa.eu/en/documents/assessment-report/covid-19-vaccine-astrazeneca-epar-public-assessment-report_en.pdf). Accessed 25 May 2021.



entirely clear that in all cases women were already pregnant at the time of exposure to the vaccine. The outcome for 8 out of 10 women in the vaccine group is not yet known. For 4 out of 7 women exposed to the control, the outcome is known and considered normal. Based on the above information, no safety signals are identified. However, data are limited.

 Level 4

[Gray et al \(2021\) \[Preprint\] \[Cohort Study\] COVID-19 vaccine response in pregnant and lactating women: a cohort study<sup>10</sup>](#)

The authors sought to evaluate the immunogenicity and reactogenicity of COVID-19 mRNA vaccination in pregnant and lactating women.

**METHODS:** 131 reproductive-age vaccine recipients (84 pregnant, 31 lactating, 16 non-pregnant) were enrolled in a prospective cohort study at two academic medical centers. Titers of SARS-CoV-2 Spike and RBD IgG, IgA and IgM were quantified in participant sera (n=131), umbilical cord sera (n=10) and breastmilk (n=31) at baseline, second vaccine dose, 2-6 weeks post second vaccine. Titers were compared to pregnant women 4-12 weeks from native infection (n=37). Post-vaccination symptoms were assessed. Kruskal-Wallis tests and a mixed-effects model, with correction for multiple comparisons, were used to assess differences between groups.

**RESULTS:** Vaccine-induced immune responses were equivalent in pregnant and lactating versus non-pregnant women. All titers were higher than those induced by SARS-CoV-2 infection during pregnancy. Vaccine-generated antibodies were present in umbilical cord blood and breastmilk samples. SARS-CoV-2 specific IgG — but not IgA — increased in maternal blood and breastmilk with vaccine

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10 Gray et al (2021) COVID-19 vaccine response in pregnant and lactating women: a cohort study. <https://pubmed.ncbi.nlm.gov/33758889/>. Accessed 26 May 2021.



boost. No differences were noted in reactogenicity between the groups.

CONCLUSION: COVID-19 mRNA vaccines generated robust humoral immunity in pregnant and lactating women, with immunogenicity and reactogenicity similar to that observed in non-pregnant women. Vaccine-induced immune responses were significantly greater than the response to natural infection. Immune transfer to neonates occurred via placenta and breastmilk.

 Level 6

[Stafford et al \(2021\) \[Narrative Review\] The coronavirus disease 2019 vaccine in pregnancy: risks, benefits, and recommendations<sup>11</sup>](#)

The coronavirus disease 2019 has caused more than 2 million deaths globally, with >412,000 deaths reported in Unites States. To date, at least 57,786 pregnant women in the United States have been infected, and 71 have died. Although pregnant persons are at higher risk of SARS-CoV-2-related illness, clinical trials for the available vaccines excluded pregnant and lactating women. The safety and efficacy of the vaccines for pregnant women, the foetus and the newborn remain unknown. A review of maternal and neonatal COVID-19 morbidity and mortality data along with perinatal vaccine safety considerations are presented to assist providers with shared decision-making regarding vaccine administration, including the health worker who is pregnant, lactating or considering pregnancy. The COVID-19 vaccine should be offered to pregnant women after discussing the lack of safety data, with preferential administration for those at highest risk of severe infection, until safety and efficacy of these novel vaccines are validated.

The Centers for Disease Control and Prevention (CDC), American College of Obstetricians and Gynecologists

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11 Stafford IA, Parchem JG, Sibai BM. The coronavirus disease 2019 vaccine in pregnancy: risks, benefits, and recommendations. Am J Obstet Gynecol. 2021 May;224(5):484-495. doi: 10.1016/j.ajog.2021.01.022. Epub 2021 Jan 30. PMID: 33529575; PMCID: PMC7847190.



(ACOG), Society for Maternal-Fetal Medicine (SMFM) and other agencies support offering vaccination to pregnant and lactating women in prioritized groups. Mild side-effects post vaccination have been reported, ranging from a >80% frequency of pain at injection site to a 40% rate of systemic complaints, including febrile morbidity, which on review has been disproven to be teratogenic to the fetus during the first trimester of pregnancy. If validated, a reduction in severe disease from COVID-19 vaccination would benefit the fetus, given the negative effects maternal illness has on fetal status, which has driven medically indicated and spontaneous preterm birth and associated neonatal sequelae. Limited unpublished data are currently available from animal developmental and reproductive toxicity (DART) studies, which have revealed no safety concerns with regard to female reproduction, or fetal, embryonal or postnatal development.

Level 6

[Craig et al \(2021\) \[Narrative Review\] Coronavirus disease 2019 vaccines in pregnancy<sup>12</sup>](#)

The American College of Obstetricians and Gynecologists (ACOG), Society for Maternal-Fetal Medicine (SMFM), National Institute for Health (NIH) and National Academy of Medicine in the United States have consistently advocated the inclusion of pregnant and lactating women in vaccine trials. The authors note that COVID-19 is an active outbreak; that pregnancy is associated with increased susceptibility to disease severity; and that the best approach to protect the infant is through passive placental antibody transfer. Considering the data available regarding increased maternal morbidity and mortality associated with SARSCoV-2 infection in pregnancy, withholding FDA-approved vaccines from pregnant or lactating individuals based on theoretical

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12 Craig AM, Hughes BL, Swamy GK. Coronavirus disease 2019 vaccines in pregnancy. Am J Obstet Gynecol MF. 2021 Mar;3(2):100295. doi: 10.1016/j.ajogmf.2020.100295. Epub 2020 Dec 10. PMID: 33516986; PMCID: PMC7832570.



risks would be unethical. Pregnant individuals should be given the opportunity, along with their obstetrical provider, to weigh the potential risk of severe maternal disease against the unknown risk of fetal exposure and make an autonomous decision about whether or not to accept the vaccine until pregnancy safety data are available.



Level 7

[Rasmussen et al \(2021\) \[Expert Opinion\] Coronavirus Disease 2019 \(COVID-19\) Vaccines and Pregnancy: What Obstetricians Need to Know<sup>13</sup>](#)

Due to the fact that pregnant persons were excluded from the initial phase 3 clinical trials of COVID-19 vaccines, limited data are available on their efficacy and safety during pregnancy. After developmental and reproductive toxicology (DART) studies are completed, some companies are expected to conduct clinical trials in pregnant persons. Until then, pregnant persons and their obstetricians will need to use available data to weigh the benefits and risks of COVID-19 vaccines. Issues to consider when counselling pregnant persons include: data from animal studies and inadvertently exposed pregnancies during vaccine clinical trials, when available; potential risks to pregnancy of vaccine reactogenicity; timing of vaccination during pregnancy; evidence for safety of other vaccines during pregnancy; risk of COVID-19 complications due to pregnancy; the pregnant person's underlying conditions; and risk of exposure to SARS-CoV-2, and potential for risk mitigation.

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13 Rasmussen SA, Kelley CF, Horton JP, Jamieson DJ. Coronavirus Disease 2019 (COVID-19) Vaccines and Pregnancy: What Obstetricians Need to Know. *Obstet Gynecol*. 2021 Mar 1;137(3):408-414. doi: 10.1097/AOG.0000000000004290. Erratum in: *Obstet Gynecol*. 2021 May 1;137(5):962. PMID: 33370015; PMCID: PMC7884084.



Level 7

### [Chervenak et al \(2021\) \[Expert Opinion\] Professionally responsible coronavirus disease 2019 vaccination counseling of obstetrical and gynecologic patients<sup>14</sup>](#)

The authors focus on how physicians should counsel patients who are pregnant or planning to become pregnant and breastfeeding or planning to breastfeed about COVID-19 vaccines with government authorization for clinical use in the United States. Determining the most effective approach to counsel patients about COVID-19 vaccination is challenging. The professionally responsible counselling of 3 groups of patients is considered: those who are pregnant; those planning to become pregnant; and those breastfeeding or planning to breastfeed. 5 major challenges are identified: 1. the limited evidence base; 2. the documented increased risk for severe disease among pregnant SARS-CoV-2-infected patients; 3. conflicting guidance from government agencies and professional associations; 4. false information about COVID-19 vaccines; and 5. maternal mistrust and vaccine hesitancy. The authors give an account of how to respond proactively when patients refuse the recommended vaccination, including the legal obligation of informed refusal and the ethical obligation to ask patients to reconsider. The physician should be alert to vaccine hesitancy, ask patients to express their hesitation and reasons for it, and respectfully address their concerns. In contrast to conflicting guidance from some government agencies and professional associations, the authors assert that evidence-based professional ethics in obstetrics and gynecology provides unequivocal guidance: physicians should recommend COVID-19 vaccination to patients who are pregnant or planning to become pregnant, and breastfeeding or planning to breastfeed.

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14 Chervenak FA, McCullough LB, Bornstein E, Johnson L, Katz A, McLeod-Sordjan R, Nimaroff M, Rochelson BL, Tekbali A, Warman A, Williams K, Grünebaum A. Professionally responsible coronavirus disease 2019 vaccination counseling of obstetrical and gynecologic patients. *Am J Obstet Gynecol*. 2021 May;224(5):470-478. doi: 10.1016/j.ajog.2021.01.027. Epub 2021 Feb 1. PMID: 33539825; PMCID: PMC7849424.



Level 7

[Kalinka et al \(2021\) \[Expert Opinion\] COVID-19 impact on perinatal care: risk factors, clinical manifestation and prophylaxis. Polish experts' opinion for December 2020<sup>15</sup>](#)

The authors present practical guidelines for managing pregnant persons infected with SARS-CoV-2 and care of the newborn of a positive mother, as well as for COVID-19 vaccinations. This manuscript is based on information available as of December 2020.

See Section: VACCINATION

At the end of December, vaccinations against COVID-19 were initiated in Poland. Several questions were raised with regard to the safety of the new mRNA vaccines. During perinatal care there are two major issues related to vaccination that may require further explanation:

- *Vaccinations of Pregnant Women:* since manufacturers of the vaccines did not include pregnant women in phase 3 clinical trials, there is insufficient evidence to recommend routine use of COVID-19 vaccines during pregnancy. The Joint Committee on Vaccination and Immunization (JCVI) in Britain advises that clinicians should discuss the risks and benefits of vaccination with the pregnant woman, and should inform the patient about the absence of safety data for the vaccine during pregnancy.
- *Vaccinations of Breastfeeding Women:* due to outweighed benefits of breastfeeding as well as an absence of evidence of associated risks of non-live vaccines during breastfeeding, JCVI allow for the vaccination of breastfeeding women. Nevertheless, the absence of safety data for the vaccination procedure among breastfeeding women should be explained by medical personnel.

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15 Kalinka J, Wielgos M, Leszczynska-Gorzela B, Piekarska A, Huras H, Sieroszewski P, Czajkowski K, Wysocki J, Lauterbach R, Helwich E, Mazela J. COVID-19 impact on perinatal care: risk factors, clinical manifestation and prophylaxis. Polish experts' opinion for December 2020. *Ginekol Pol.* 2021;92(1):57-63. doi: 10.5603/GP.a2021.0023. PMID: 33576491.



JCVI does not advocate routine pregnancy testing before receipt of a COVID-19 vaccine. Those who are trying to become pregnant do not need to avoid pregnancy after vaccination. These recommendations are in sync with recommendations by the Royal College of Obstetricians and Gynecologists in Britain.

Produced by the members of the National Health Library and Knowledge Service Evidence Team<sup>†</sup>. Current as at [DD MONTH YYYY]. This evidence summary collates the best available evidence at the time of writing and does not replace clinical judgement or guidance. Emerging literature or subsequent developments in respect of COVID-19 may require amendment to the information or sources listed in the document. Although all reasonable care has been taken in the compilation of content, the National Health Library and Knowledge Service Evidence Team makes no representations or warranties expressed or implied as to the accuracy or suitability of the information or sources listed in the document. This evidence summary is the property of the National Health Library and Knowledge Service and subsequent re-use or distribution in whole or in part should include acknowledgement of the service.



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The following PICO(T) was used as a basis for the evidence summary:

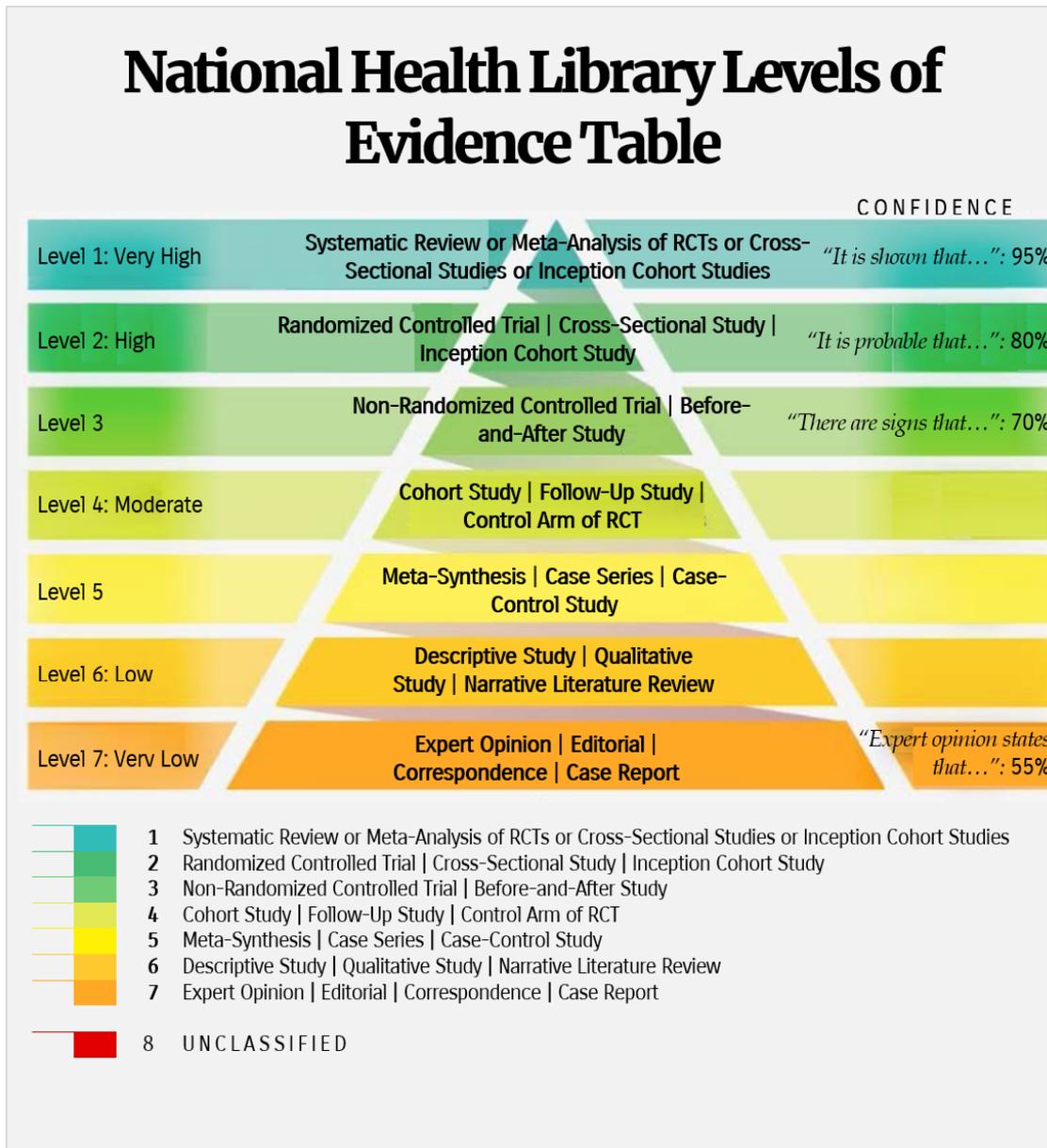
<b>P</b> Population person location condition/patient characteristic	PREGNANT OR LACTATING FEMALES
<b>I</b> Intervention length location type	COVID-19 VACCINE OR VACCINE USING SIMILAR PLATFORM: VIRAL VECTOR/ADENOVIRUS VECTOR VACCINE OR mRNA VACCINE
<b>C</b> Comparison another intervention no intervention location of the intervention	
<b>O</b> Outcome	ADVERSE EVENTS ASSOCIATED WITH VACCINE



The following search strategy was used:

```
1   exp Coronavirinae/ (33880)
2   COVID-19.ab,ti. (102428)
3   coronavirus.ab,ti. (52667)
4   "corona virus".ab,ti. (1888)
5   (Wuhan adj3 virus).ab,ti. (108)
6   ("2019-nCoV" or "2019 ncov").ab,ti. (1216)
7   "severe acute respiratory syndrome coronavirus 2".ab,ti. (10853)
8   ("2019" and (new or novel) and coronavirus).ab,ti. (8921)
9   1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 (132185)
10  exp vaccination/ (175446)
11  exp immunization/ (293507)
12  exp mass immunization/ (3673)
13  exp vaccine/ (347451)
14  "vaccin*".ab,ti. (381478)
15  10 or 11 or 12 or 13 or 14 (555122)
16  9 and 15 (11442)
17  exp pregnancy/ (691333)
18  exp lactation/ (51500)
19  exp fetus/ (200246)
20  (pregnan* or lactat* or gravid* or foetus or fetus or foetal or fetal).ab,ti.
    (1073451)
21  17 or 18 or 19 or 20 (1329759)
22  exp adverse event/ (663674)
23  exp side effect/ (595204)
24  exp complication/ (1250061)
25  ((adverse adj1 (event* or effect*)) or side-effect* or complication* or risk* or
    safe*).ab,ti. (5883370)
26  22 or 23 or 24 or 25 (6766364)
27  9 and 15 and 21 and 26 (136)
28  exp virus vector/ (76579)
29  exp messenger RNA/ (596638)
30  ((vir* or adenovir*) adj1 vector).ab,ti. (17237)
31  (messenger RNA or mRNA).ab,ti. (660277)
32  28 or 29 or 30 or 31 (854559)
33  15 and 21 and 26 and 32 (108)
34  33 and 2018:2021.(sa_year). (41)
35  27 or 34 (172)
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The following schema was used to grade the levels of evidence included:



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