

COVID-19 Vaccination and Reproduction: Pregnancy, Lactation, and Fertility

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Disclosures

Sarah L. Berga MD

January 2021

CONSULTING:

Ava AG Advisory Meeting, 2.27.19, Chicago, IL

Ferring Pharmaceuticals SW Reproductive Health Advisory Board, 10.25.19, Denver, CO

ClearBlue Medical Advisory Board, 11.20.19, Washington DC

EDITORIAL BOARDS & POSITIONS:

American Journal of Obstetrics and Gynecology, Advisory Board: 2003-present (*Gratis*)

Human Reproduction Update, Associate Editor, 2017 to 2020 (*gratis*)

International Society for Gynecological Endocrinology, Executive Committee Member: 2004-present (*Gratis*)

Journal of Obstetrics and Gynecology Canada, International Editorial Board: 2017-present (*Gratis*)

Mayo Clinic Proceedings, Editorial Board: 2019-present (*Gratis*)

Menopause, Editorial Board: 1999-present (*Gratis*)

UpToDate, Peer Review Board: 2005-present

SERVICE:

Member, Board of Trustees, Salem Academy and College, Salem, NC: 2018-present (*Gratis*)



Leading with CARE

Learning Objectives

- Identify what is known and not known about the impact of COVID-19 infection and COVID-19 vaccination on reproductive function
- Address common questions posed by patients and providers about safety of COVID-19 vaccination in patients planning to conceive and in those who are pregnant and lactating
- Share the guidance offered by professional organizations

COVID-19 Vaccination and Reproduction: Pregnancy, Lactation, and Fertility Quick Summary

- **Vaccination is safer for all aspects of reproductive function than COVID-19 infection**
- Women and men seeking to conceive or undergoing infertility care should get vaccinated
- Women who are currently pregnant should get vaccinated
- Women who are currently lactating should get vaccinated
- We need more research to determine the impact of COVID-19 and vaccination on gametogenesis, particularly for men and women undergoing fertility preservation, but vaccination is likely to be better for fertility than COVID-19 infection
- **Clinicians need clear sound bites to confidently convey the safety of COVID-19 vaccination**

Reproductive function including fertility

FAQS: COVID-19 and Reproductive Function

Q: Is it safe to try to conceive or to undergo infertility treatment now?

A: Yes, it is relatively safe, but it would be better to get vaccinated first

A: COVID-19 infection is likely to compromise fertility, so if you have had a recent COVID-19 infection, you may experience a delay in conception



AMERICAN SOCIETY FOR REPRODUCTIVE MEDICINE (ASRM)
PATIENT MANAGEMENT AND CLINICAL RECOMMENDATIONS DURING THE
CORONAVIRUS (COVID-19) PANDEMIC

Update #3 (April 24, 2020 through May 11, 2020), pp 1-11.

The Task Force¹ reaffirms that **fertility care is an essential health service.** Nonetheless, the Task Force recognizes the need to minimize the spread of COVID-19 and preserve critically needed local healthcare resources to address the pandemic, while simultaneously acknowledging the essential timeliness and importance of access to fertility treatment.

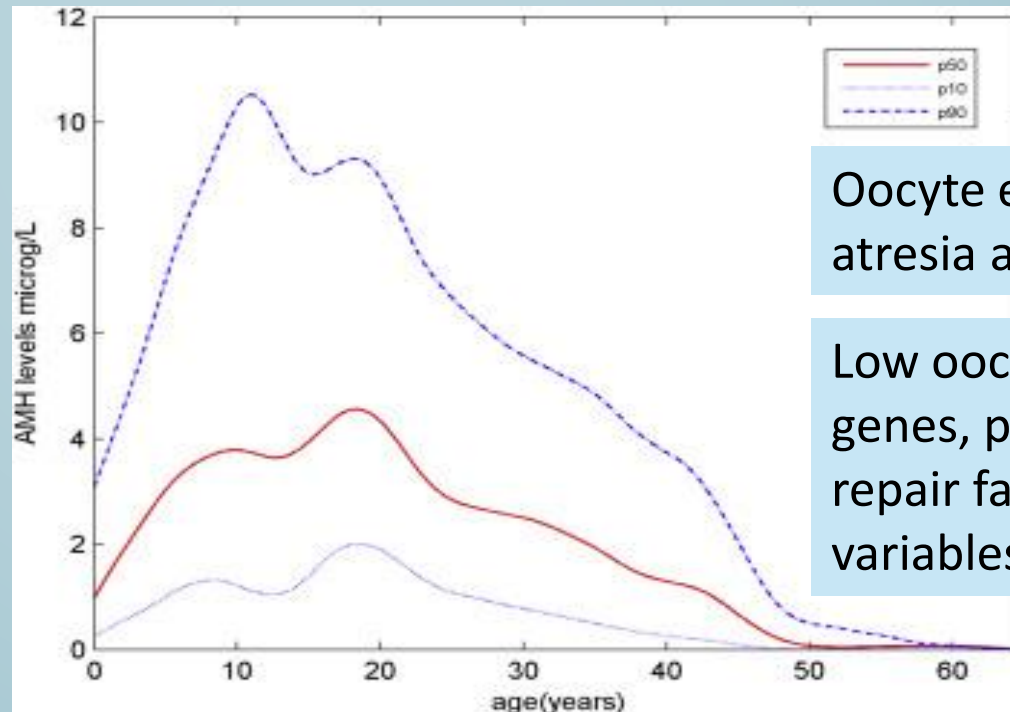
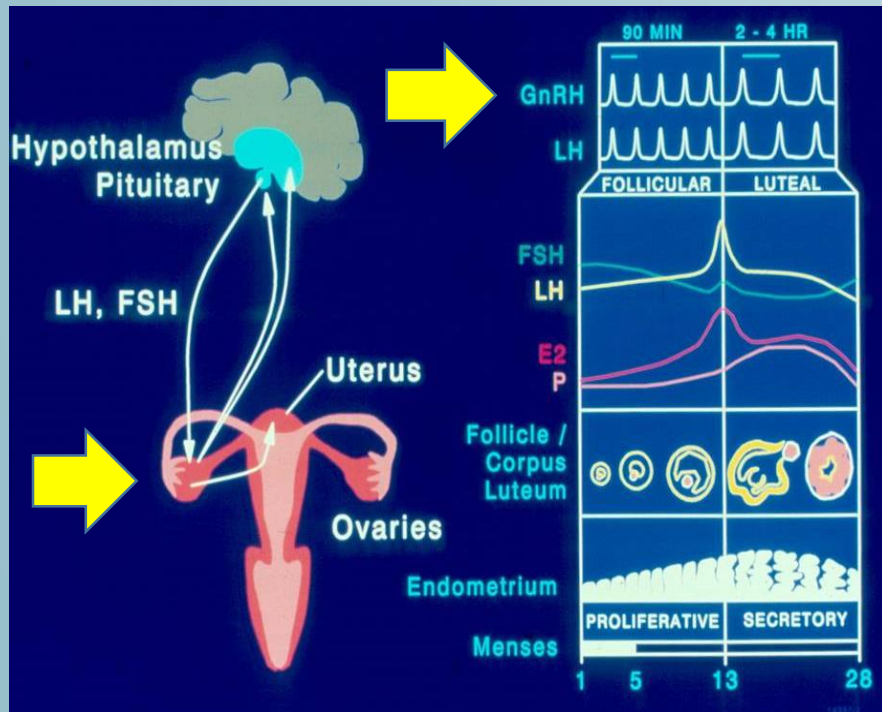
In considering when and how to provide reproductive care, the risk of viral transmission to patients, physicians, and staff, and the utilization of critically needed healthcare resources must be weighed against the **time sensitive nature of infertility.** This calculation includes understanding the worsening prognosis of treatments with the passage of time, and the threat of decreased access to care that occurs with further delays.

In 2017, last validated data, ~300,000 cycles of assisted reproduction (IVF, ART) in USA
Top 3 indications: diminished ovarian reserve 32%, fertility preservation 31%, and male infertility 28%

FAQS: COVID-19 and Reproductive Function

Q: Does having COVID-19 compromise fertility and if so by what mechanisms?

A: Likely - by multiple mechanisms - including suppression of hypothalamic GnRH drive to gonads (ovaries and testes), oophoritis and orchitis, and causing other endocrinopathies



Oocyte endowment and rates of atresia are highly variable

Low oocyte count attributable to genes, particularly SNPs in DNA repair factors, stress, and other variables

Impact of SARS-Cov-2 Virus Infection on the Endocrine System

Somasundaram NP et al. J Endocr Soc. 2020 Jul 2;4(8):bvaa082.

Pathology	Possible Mechanisms	Hormonal Patterns	Clinical Features	Management
Central hypocortisolism or hypercortisolism, hypothyroidism, hypogonadism	Destruction of ACE2 in hypothalamus, Hypophysitis, illness	Impaired ACTH, low TSH, low T3 and T4	Postviral syndrome	Evaluate adrenal function Measure TSH, T4 Measure LH, FSH, estradiol (women), testosterone (men) Replace as needed
Hyperprolactinemia	Dopamine stress response	Transient	Asymptomatic if not prolonged	Measure prolactin
Hypoadrenalism	Adrenal necrosis and vasculitis	Hypocortisolism	Postural hypotension Persistently low BP Hyperkalemia and hyponatremia	Monitor electrolytes
Hypothyroidism	Thyroiditis, hypophysitis, hypothalamic dysfunction	Sick euthyroid syndrome		
Hypogonadism	Entry of virus into spermatogonia and somatic cells using ACE2 receptors, immune mediated orchitis	Impaired spermatogenesis and androgen synthesis	Infertility and hypogonadism	Semenanalysis, LH, FSH, TSH, T4, prolactin,

FAQS: COVID-19 and Reproductive Function

Q: Many infections persist in semen. Is there COVID-19 in semen? If so, is it infectious? If so, does it compromise fertility or outcomes associated with ART?

A: Maybe.

Q: Should men who have had COVID-19 wait to try to conceive or to donate sperm? If so, for how long?

A: No clear answers. At least 90-180 days after recovery from acute COVID-19.

- Reports indicate ↓ sperm concentration and ↓ motility for 72–90 days following COVID-19 infection
- Gonadotropin-dependent expression of ACE2 was found in human ovaries, but it is unclear whether COVID-19 adversely affects female gametogenesis.
- COVID-19 infections in pregnancy are associated with preterm delivery.
- Postpartum neonatal transmission from mother to child has been reported.

Fertil Steril 2020 113:1140-1149.



AMERICAN SOCIETY FOR REPRODUCTIVE MEDICINE (ASRM)
PATIENT MANAGEMENT AND CLINICAL RECOMMENDATIONS DURING THE
CORONAVIRUS (COVID-19) PANDEMIC

UPDATE No. 11 – COVID-19 Vaccination
December 16, 2020

- All mitigation measures as outlined in the Task Force's [Update #3](#) should remain firmly in place while vaccination efforts get underway, as: 1) it is not yet known whether a vaccinated individual can spread the virus if they become infected with SARS-COV-2; 2) protective immunity against COVID-19 takes time to develop; and 3) although a two-dose regimen of the Pfizer-BioNTech vaccine is 95% effective against the development of COVID-19, it does not confer 100% immunity.
- **The Task Force does not recommend withholding the vaccine from patients who are planning to conceive, who are currently pregnant, or who are lactating (1,2,3).** These recommendations are in line with those of the Advisory Committee for Immunization Practices (ACIP) of the U.S. Centers for Disease Prevention and Control (CDC), the American College of Obstetricians and Gynecologists (ACOG), and the Society for Maternal-Fetal Medicine (SMFM).
- 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.



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- **A shared decision-making model between patients and providers should be used when considering vaccination and should take into consideration the ethical principles of autonomy, beneficence, and non-maleficence.** Consideration of local COVID-19 transmission and risk of acquisition, personal risk of contracting COVID-19, risks of COVID-19 to the patient and potential risks to a fetus, efficacy of the vaccine and known side effects, and the lack of data about the vaccine during pregnancy should all be taken into consideration as patients make decisions regarding vaccination. Some individuals may elect to defer conception attempts until both doses of vaccine have been administered.
- **Recent studies have suggested that pregnancy is a risk factor for severe COVID-19 disease (4-8).** Furthermore, many women who are pregnant or contemplating pregnancy have additional risk factors such as obesity, hypertension or diabetes which may further increase the chance of severe disease from COVID-19 infection. These considerations should be included in decisions regarding vaccination.
- **Because COVID-19 mRNA vaccines are not composed of live virus, they are not thought to cause an increased risk of infertility, first or second trimester loss, stillbirth, or congenital anomalies.** It should be noted that pregnant and lactating women were excluded from the initial phase III trials of these two vaccines, so specific safety data in these populations are not yet available and further studies are planned. However, the mechanism of action of mRNA vaccines and existing safety data provide reassurance regarding the safety of COVID-19 mRNA vaccines during pregnancy. The FDA EUA letter permits the vaccination of pregnant and breastfeeding individuals with a requirement that the company engage in post-authorization observational studies in pregnancy (9).

Pregnancy

Disclosures

Heather M. Link MD/MPH

January 2021

CONSULTING:

World Health Organization, Geneva Switzerland March 2020, *paid*

COVID-19 Vaccination and Reproduction: Pregnancy, Lactation, and Fertility

Before, during and after childbirth, all women have the right to high quality care. This includes:



Antenatal and
intrapartum



Newborn



Postnatal



Mental health

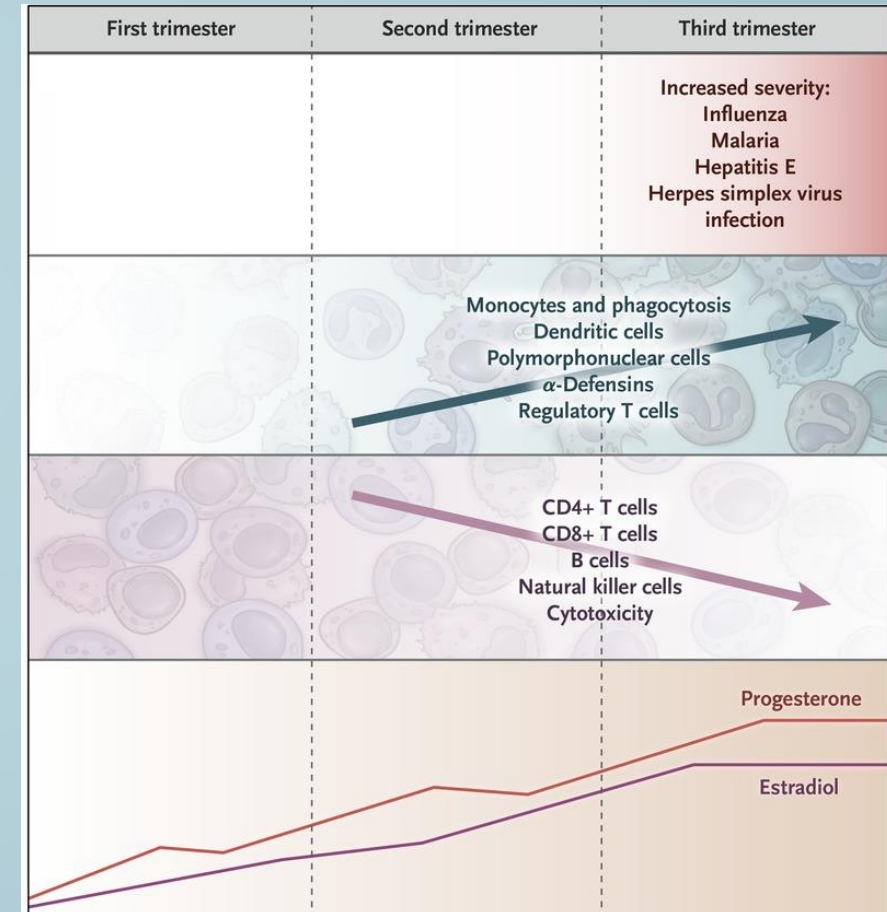


World Health
Organization

#COVID19 #CORONAVIRUS

Immunologic Changes of Pregnancy

- Adaption of the maternal inflammatory response
 - Changing TH1:TH2 cytokine profiles
 - Hormonal shifts mediate inflammatory pathways



Update: Characteristics of Symptomatic Women of Reproductive Age with Laboratory-Confirmed SARS-CoV-2 Infection by Pregnancy Status — United States, January 22–October 3, 2020

Laura D. Zambrano, PhD^{1,*}; Sascha Ellington, PhD^{1,*}; Penelope Strid, MPH¹; Romeo R. Galang, MD¹; Titilope Oduyebo, MD¹; Van T. Tong, MPH¹; Kate R. Woodworth, MD¹; John F. Nahabedian III, MS¹; Eduardo Azziz-Baumgartner, MD¹; Suzanne M. Gilboa, PhD¹; Dana Meaney-Delman, MD¹; CDC COVID-19 Response Pregnancy and Infant Linked Outcomes Team

- 1,300,938 infections in women 15-44yo
- 461,825 with known pregnancy status
 - 23,434 (6.6%) pregnant
 - 431,410 (93.4%) not pregnant

TABLE 2. Intensive care unit (ICU) admissions, receipt of invasive ventilation, receipt of extracorporeal membrane oxygenation (ECMO), and deaths among symptomatic women of reproductive age with laboratory-confirmed SARS-CoV-2 (N = 409,462), by pregnancy status, age, race/ethnicity, and underlying health conditions — United States, January 22–October 3, 2020







Outcome ^a /Characteristic	No. (per 1,000 cases) of symptomatic women		Risk ratio (95% CI)	
	Pregnant (n = 23,434)	Nonpregnant (n = 386,028)	Crude [†]	Adjusted ^{†,§}
Invasive ventilation^{††}				
All	67 (2.9)	412 (1.1)	2.7 (2.1–3.5)	2.9 (2.2–3.8)

Outcome ^a /Characteristic	No. (per 1,000 cases) of symptomatic women		Risk ratio (95% CI)	
	Pregnant (n = 23,434)	Nonpregnant (n = 386,028)	Crude [†]	Adjusted ^{†,§}
ICU admission[§]				
All	245 (10.5)	1,492 (3.9)	2.7 (2.4–3.1)	3.0 (2.6–3.4)




ECMO^{***}				
All	17 (0.7)	120 (0.3)	2.3 (1.4–3.9)	2.4 (1.5–4.0)

Death^{§§§}				
All	34 (1.5)	447 (1.2)	1.3 (0.9–1.8)	1.7 (1.2–2.4)


Physiologic Changes of Pregnancy

- **Respiratory:**  reserve volumes,  increase in the tidal volume, minute ventilation, inspiratory capacity and oxygen requirements.
- **ABG:** mild  in PH with a normal range in pregnancy of 7.4-7.44, Normal PCO₂: 28-32 and PO₂ 100-104 mmhg.
- **SVR:**  nadir in the mid second trimester approximately 35-40% below baseline. This increases slowly from the nadir for the remainder of pregnancy resulting in normal pre-pregnancy levels postpartum.
- **GFR:** Vasodilation results in  renal plasma flow and GFR with subsequent  in serum creatinine, urea and uric acid.

Physiologic Changes of Pregnancy

- **Cardiac Output:** Cardiac output  throughout pregnancy with the greatest increase occurring at the end of the first trimester and into the second.
 - **Heart Rate:** Heart rate  progressively throughout pregnancy by 10-20bpm over baseline.
 - **Total Blood Volume:**  in total blood volume, plasma volume and red blood cell mass.
 - **Echo Findings:** Typical TTE findings in normal pregnancy include mild 4-chamber dilation, with transient trivial mitral regurgitation and physiological tricuspid and pulmonary regurgitation.

Physiologic Changes of Pregnancy

- **Labs:** Pregnancy is normally associated with  alkaline phosphatase, triglyceride levels, fibrinogen and D-dimer. These changes exist in the absence of cytokine storm and should be considered when evaluating COVID patients.
- **LFTS:** Elevated liver enzyme in the absence of underlying hypertensive disease is likely to be viral.
- **Plasma Oncotic Pressure:** Maternal albumin and total plasma protein are normally decreased in pregnancy, this decreased plasma oncotic pressure has classically resulted in pulmonary fluid collections with lung ailments.

Treatment of COVID-19 in Pregnancy

- Do not withhold imaging/care due to pregnancy
- If admitted: consult Maternal Fetal Medicine / Obstetrics
 - Goal 95% O2 or greater
 - Avoid NSAIDS
 - Steroids, Azithromycin, Remdesivir are okay.
 - Proning is possible
 - Considerations for delivery will be individual to the patient, her underlying illness and gestational age.

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Appendix 2. Prone positioning in awake pregnant patient. A. Patient lies on side facing towards the oxygen source. Adjust bed to reverse Trendelenburg (~10°). Place three pillows at head, two above gravid uterus, two at level of the pelvis (line up with symphysis pubis), and two under knees. B. Help patient kneel between two lower sets of pillows (lower leg pillows may be placed once she is prone). Ensure pelvic pillows are touching her thighs. Raise head of the bed. C. Help patient lie forward onto the pillows. D. Lower head of the bed (maintain reverse Trendelenburg). Adjust padding for patient comfort. Check gravid abdomen and ensure no pressure. Replace maternal and fetal monitors.



Prone Positioning for Pregnant Women With Hypoxemia Due to Coronavirus Disease 2019 (COVID-19)

Tolcher, Mary Catherine MD, MSc; McKinney, Jennifer R. MD, MPH; Eppes, Catherine S. MD, MPH; Muigai, David MD, MMM; Shamsheer, Amir MD; Guntupalli, Kalpalatha K. MD; Nates, Joseph L. MD, MBA [Author Information](#)

Obstetrics & Gynecology: August 2020 - Volume 136 - Issue 2 - p 259-261
doi: 10.1097/AOG.0000000000004012

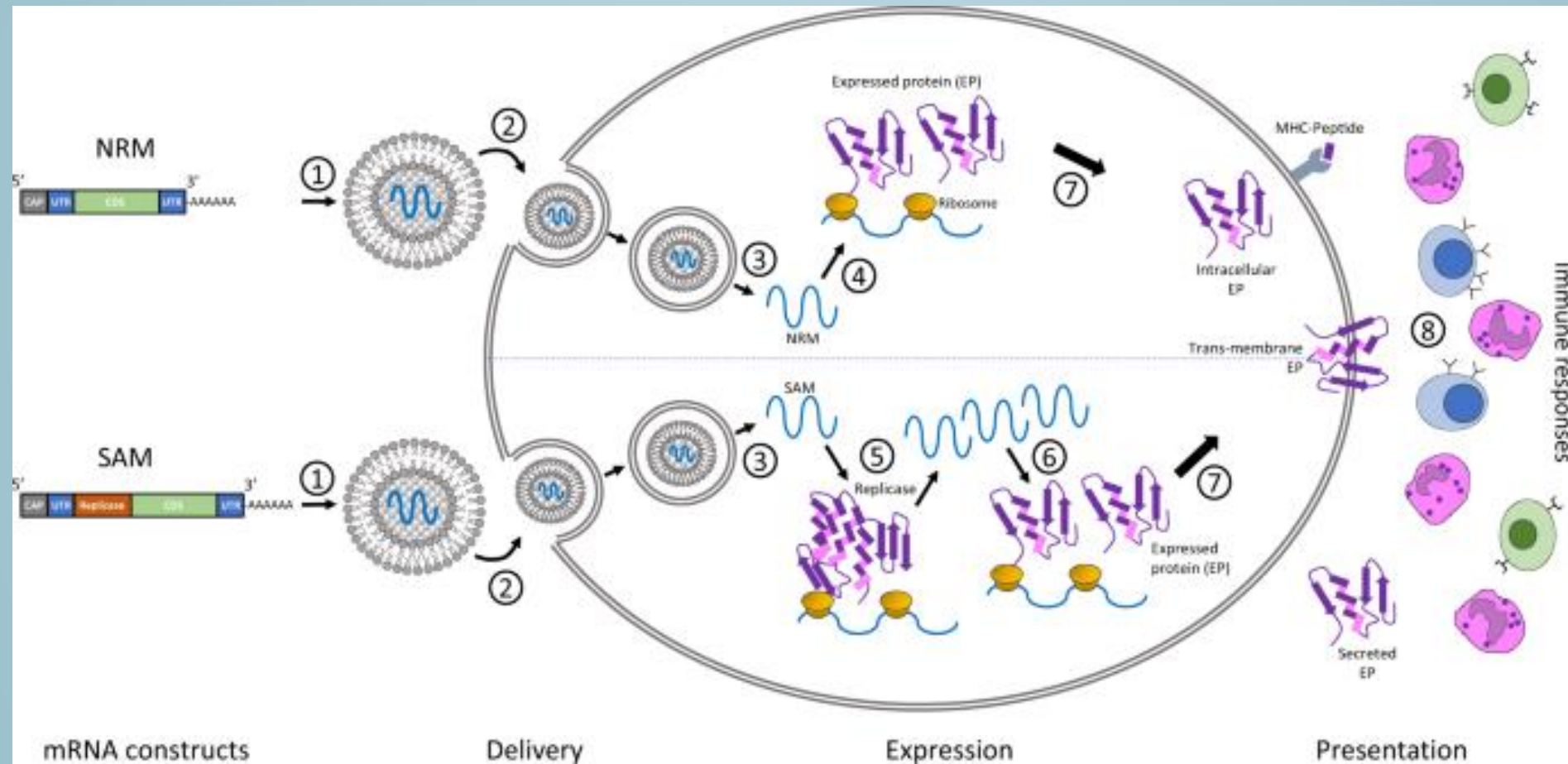
Vertical Transmission of COVID-19

- IgM has been reported in neonatal serum at birth
- SARS-COV-2 viral load has been detected in placenta
- Evidence suggests transmission may be possible but is unlikely

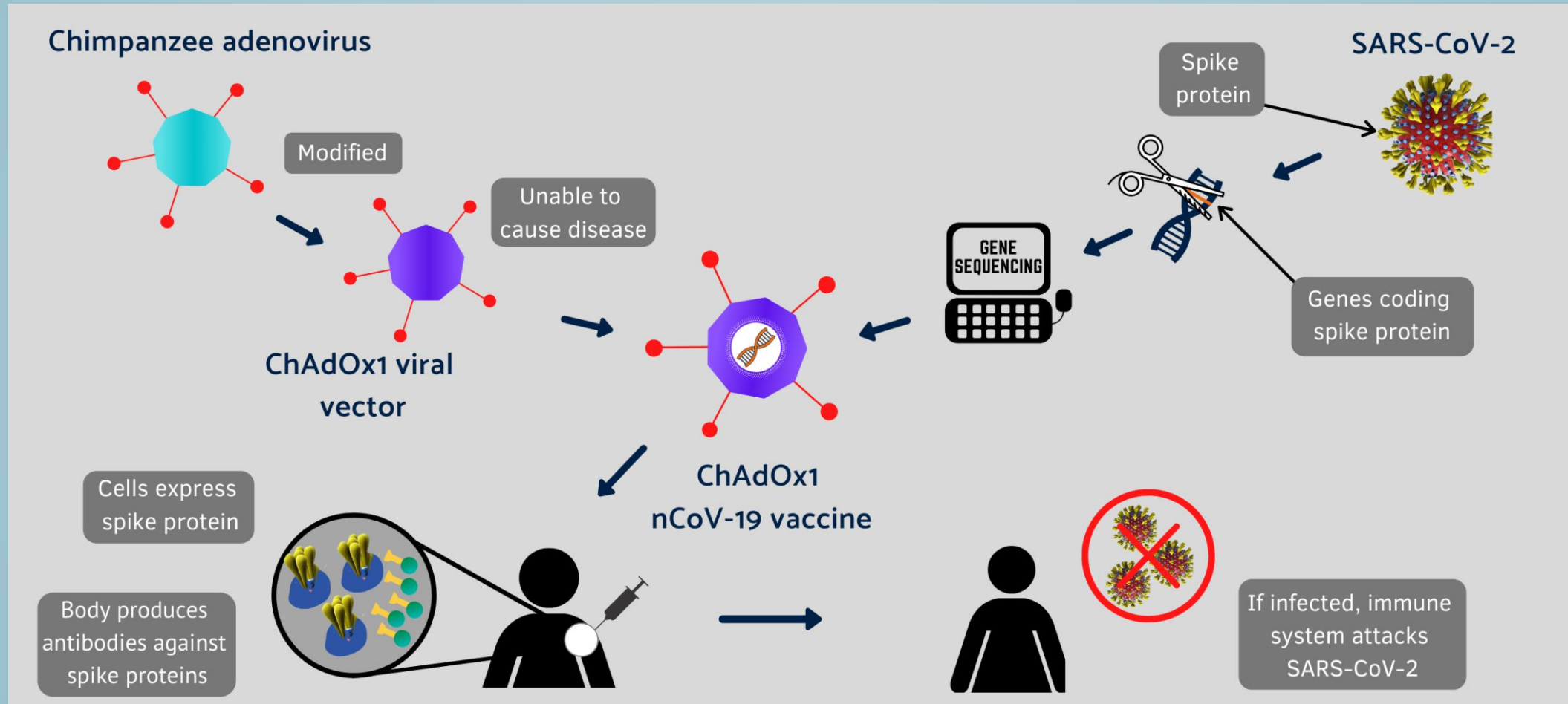
Vaccination in Pregnancy

- Vaccines currently available under the Emergency Use Authorization have not been tested in pregnant and lactating women
- Moderna + Pfizer Vaccines currently available in the US are mRNA vaccines
- Newly approved Oxford-AstraZeneca vaccine is made utilizing deactivated adenovirus

How do mRNA Vaccines work



Oxford-AstraZeneca Vaccine



ACOG Recommendations

Pregnant Individuals

ACOG recommends that COVID-19 vaccines should not be withheld from pregnant individuals who meet criteria for vaccination based on ACIP-recommended priority groups. While safety data on the use of COVID-19 vaccines in pregnancy are not currently available, there are also no data to indicate that the vaccines should be contraindicated, and no safety signals were generated from DART studies for the Pfizer-BioNtech and Moderna COVID-19 vaccines. Therefore, in the interest of allowing pregnant individuals who would otherwise be considered a priority population for vaccines approved for use under EUA to make their own decisions regarding their health, ACOG recommends that pregnant individuals should be free to make their own decision in conjunction with their clinical care team.



For media interviews, contact:
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Experts in High-Risk Pregnancy Respond to the FDA's Decision to Offer the Newly Approved COVID-19 Vaccine to Pregnant and Lactating People
Healthcare Workers Among the First Expected to Be Impacted

Vaccination Considerations for People who are Pregnant or Breastfeeding

Updated Dec. 28, 2020

Languages ▾

Print



COVID-19 Vaccination Considerations for People Who Are Pregnant

CDC and the independent Advisory Committee on Immunization Practices (ACIP) have provided information to assist pregnant people with their decision to receive the COVID-19 vaccine. At this time, ACIP recommends that [certain groups](#) (e.g., healthcare personnel, followed by other frontline essential workers) are offered vaccination during the first months of the COVID-19 vaccination program. People who are pregnant and part of a [group recommended](#) to receive the COVID-19 vaccine may choose to be vaccinated. If they have questions about getting vaccinated, a discussion with a healthcare provider might help them make an informed decision.

In general, [SMFM strongly recommends that pregnant and lactating people have access to COVID-19 vaccines](#) and that they engage in a discussion about potential benefits and unknown risks together with healthcare providers regarding receipt of the vaccine. As stated previously, counseling should balance the lack of data on vaccine safety for the fetus, risks to pregnant people from COVID-19 infection, and a person's individual risk for infection and severe disease.

Lactation

Vaccination in Lactating Women

- No vaccines have been tested in this population
- Physiology does not suggest increased risk



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Updated December 28, 2020



I'm pregnant. Should I get a COVID* vaccine?

*The information here is about the *Pfizer* and *Moderna* COVID-19 vaccines. These are also called "mRNA" vaccines.

For most people, getting the COVID vaccine as soon as possible is the safest choice.

However, these vaccines have not been tested in pregnant and breastfeeding people yet.

The information below will help you make an informed choice about whether to get an mRNA COVID vaccine while you are pregnant or trying to get pregnant.

Your options:



Get a COVID vaccine as soon as it is available



Wait for more information about the vaccines in pregnancy

What are the benefits of getting an mRNA COVID Vaccine?

1. COVID is dangerous. It is *more dangerous* for pregnant people.

- COVID patients who are pregnant are 5 times more likely to end up in the intensive care unit (ICU) or on a ventilator than COVID patients who are not pregnant.¹
- Preterm birth may be more common for pregnant people with severe COVID.²
- Pregnant people are more likely to die of COVID than non-pregnant people with COVID who are the same age.^{3,4}



2. The mRNA COVID vaccines prevent about 95% of COVID infections.

- As COVID infections go up in our communities, your risk of getting COVID goes up too.
- Getting a vaccine will prevent you from getting COVID and may help keep you from giving COVID to people around you, like your family.

3. The mRNA COVID vaccines cannot give you COVID.

- These vaccines have no live virus.⁵
- These vaccines do NOT contain ingredients that are known to be harmful to pregnant people or to the fetus.
- Many vaccines are routinely given in pregnancy and are safe (for example: tetanus, diphtheria, and flu).

More details about how these vaccines work can be found on page 5.

What are the risks of getting an mRNA COVID vaccine?

1. These COVID vaccines have not yet been tested in pregnant people.

- These vaccines were tested in over 40,000 people, and there were no serious side effects related to the vaccine.
- We do not know if the vaccines work as well in pregnant people as they did in non-pregnant people.
- We do not know whether there are unique downsides in pregnancy, like different side effects or an increased risk of miscarriage or fetal abnormalities.
- The Moderna vaccine was tested in female rats to look at its effects on pregnancy. No significant negative effects were found on female fertility or fetal development.
- Some women became pregnant during the vaccine studies. Eighteen of these women were in the vaccine group, and two months later none had miscarried. There were seventeen women in the placebo group who became pregnant, and two months later two of them had had miscarriages. (In general, 10-20% of pregnancies end in miscarriage).
- Because these studies are still ongoing, we don't know how the rest of the pregnancy went for these women.



2. People getting the vaccine will probably have some side effects.

- Many people had symptoms caused by their immune system's normal response to the vaccine. The most common side effects were:⁶
 - injection site reactions like sore arm (~84%)
 - fatigue (~62%)
 - headache (~55%)
 - muscle pain (~38%)
 - chills (~32%)
 - joint pain (~24%)
 - fever (~14%)
- Of 100 people who get the vaccine, 1 will get a high fever (over 102°F). A persistent high fever during the first trimester might increase the risk of fetal abnormalities or miscarriage. The CDC recommends using Tylenol (acetaminophen) during pregnancy if you have a high fever. Another option is to delay your COVID vaccine until after the first trimester.



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Updated December 28, 2020

What do the experts recommend?

Because COVID is dangerous and easily spread, the CDC says that the mRNA vaccines for COVID-19 are recommended for adults.⁷

However, because there are no studies of pregnant people yet, there are no clear recommendations for pregnant people. This is standard for a new drug and is not due to any particular concern with this vaccine.

The **Society for Maternal-Fetal Medicine** strongly recommends that pregnant individuals have access to COVID vaccines. They recommend that each person talk to their doctor or midwife about their own personal choice.⁸

The **American College of Obstetricians and Gynecologists** recommends that the COVID vaccine should not be withheld from pregnant individuals.⁹

What else should I think about to help me decide?

1

Make sure you understand as much as you can about COVID and about the vaccine. Ask a trusted source, like your midwife or doctor. Page 5 has more information about the vaccine.

2

Think about your own personal risk.

Look at the columns below and think about your risk of getting COVID (left). Think about your safety - are you able to stay safe (right)?

The risks of getting sick from COVID are higher if...

- You have contact with people outside your home
- You are 35 years old or older
- You are overweight
- You have other medical problems like diabetes, high blood pressure, or heart disease
- You are a smoker
- You are a racial or ethnic minority, or your community has a high rate of COVID infections
- You are a healthcare worker¹⁰

If you are at a higher risk of getting COVID, it probably makes sense to get the vaccine.

If you are not at higher risk for COVID and...

- You are always able to wear a mask
- You and the people you live with can socially distance from others for your whole pregnancy
- Your community does NOT have high or increasing COVID cases
- You think the vaccine itself will make you very nervous (you are more worried about the unknown risks than about getting COVID)
- You have had a severe allergic reaction to a vaccine

... it might make sense for you to wait for more information.



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Updated December 28, 2020

After vaccination: Register w/ V-safe!

V-safe After Vaccination Health Checker

Updated Jan. 5, 2021

Languages ▾

Print



Get vaccinated.
Get your smartphone.
Get started with v-safe.

Use your smartphone to tell CDC about any side effects after getting the COVID-19 vaccine. You'll also get reminders if you need a second vaccine dose.

On This Page

[Register](#)

[Complete a v-safe health check-in](#)

Resources

- <https://www.who.int/teams/sexual-and-reproductive-health-and-research/areas-of-work/sexual-reproductive-health-and-rights-in-health-emergencies/covid-19>
- file:///C:/Users/hmlink/Downloads/The_maternal_immune_system_during_pregnancy_and_it.pdf
- <https://www.nejm.org/doi/full/10.1056/nejmra1213566>
- https://cdn-links.lww.com/permalink/aog/b/aog_136_2_2020_06_02_tolcher_20-1208_sdc1.pdf
- <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html>

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- Women and men seeking to conceive or undergoing infertility care should get vaccinated
- Women who are currently pregnant should get vaccinated
- Women who are currently lactating should get vaccinated
- We need more research to determine the impact of COVID-19 and vaccination on gametogenesis, particularly for men and women undergoing fertility preservation, but vaccination is likely to be better for fertility than COVID-19 infection
- **Clinicians need clear sound bites to confidently convey the safety of COVID-19 vaccination**