

Covid-19 Vaccination in Pregnancy and Breastfeeding

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What do we know about Covid-19 in pregnancy:

- Pregnant women are more prone to the respiratory complications of Covid-19.
- 3 times more likely to need to be hospitalized.
- 3 times more likely to need ICU care.
- 2-3 times more likely to need life support or a breathing tube.
- Increased risk of preterm delivery (for maternal or fetal indications).
- Increased risk of growth restriction in pregnancy.
- Not at increased risk of birth defects.

Delta Variant in Pregnancy

- Much more contagious
- More severe effects for everyone, including pregnant women
- A study in the UK: pregnant women admitted to the hospital with Delta Variant:
 - 45% had severe disease
 - 33% required respiratory support
 - 15% required ICU care
- 98% of pregnant women admitted with severe illness due to Covid-19 are unvaccinated.
- Pregnant women are experiencing a quicker decline- particularly in respiratory illness.
- Locally, we have had many more women in the ICU and more deaths this year than in 2020.

Impact of SARS-CoV-2 variant on the severity of maternal infection and perinatal outcomes: Data from the UK Obstetric Surveillance System national cohort. Nicola Vousden PhD, et al. July 25, 2021.

Covid-19 vaccines

- Pfizer mRNA vaccine - 2 doses, 3 weeks apart (age 12 and up)
- Moderna mRNA vaccine – 2 doses, 4 weeks apart (age 18 and up)
- Johnson and Johnson single dose vaccine (age 18 and up)
 - Reports of increase in blood clots, therefore not preferred in pregnancy
- Free and available at Publix, CVS, Walgreens, local vaccination sites
- Who should NOT be vaccinated:
 - History of severe allergic reaction to vaccines.
 - Adverse reactions to injectable or infused medications (should check with their doctor first).
 - Received treatment for Covid-19 with immunoglobulin therapy within the past 90 days.

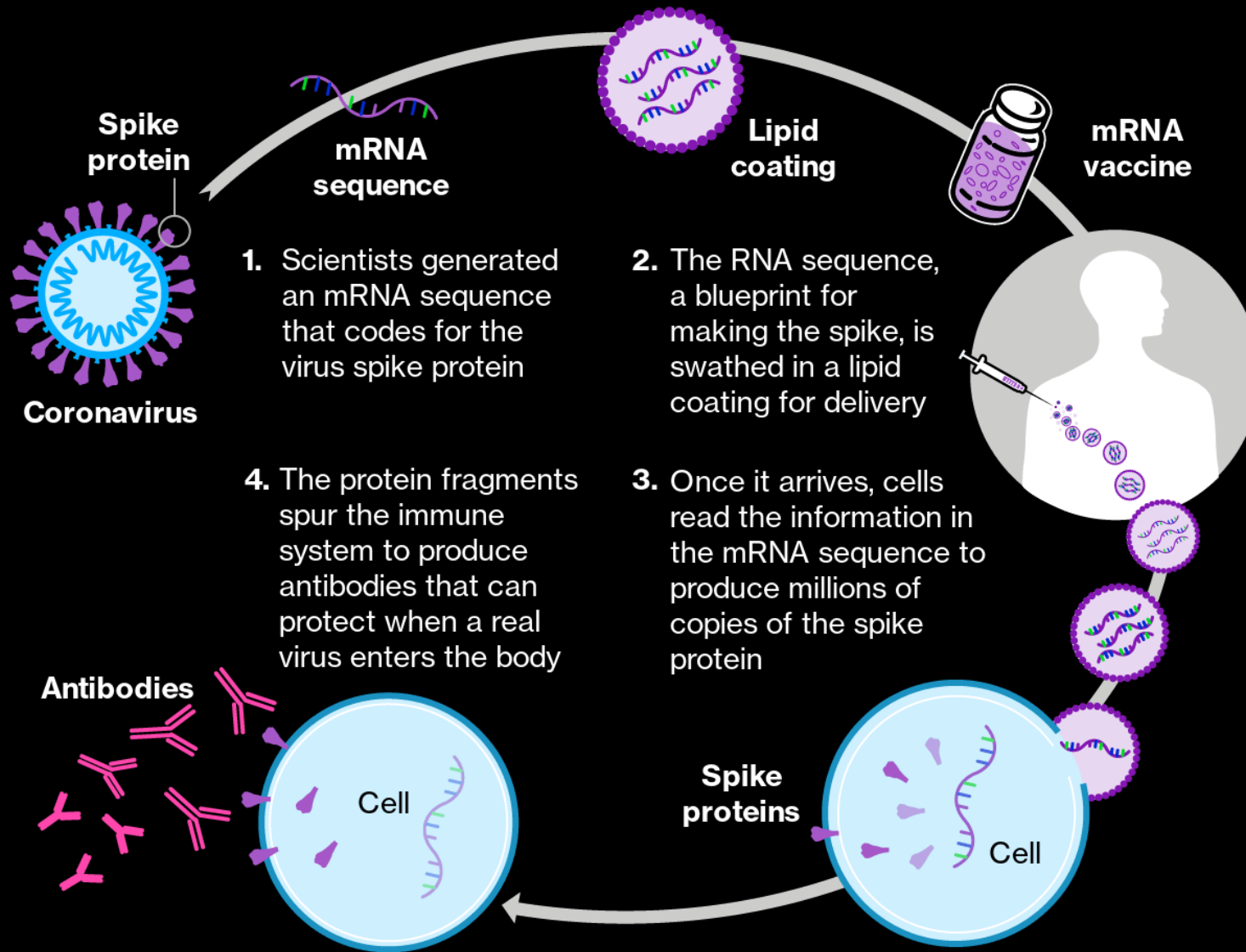
mRNA Covid-19 Vaccine (Pfizer and Moderna)

COVID-19 mRNA vaccines give instructions for our cells to make a **harmless piece** of what is called the “spike protein.” The **spike protein** is found on the surface of the virus that causes COVID-19.

1. First, COVID-19 mRNA vaccines are given in the upper arm muscle. Once the instructions (mRNA) are inside the muscle cells, the cells use them to make the protein piece. After the protein piece is made, the cell breaks down the instructions and gets rid of them.
2. Next, the cell displays the protein piece on its surface. Our immune systems recognize that the protein doesn't belong there and begin building an immune response and making antibodies, like what happens in natural infection against COVID-19.
3. At the end of the process, our bodies have learned how to protect against future infection. The benefit of mRNA vaccines, like all vaccines, is those vaccinated gain this protection without ever having to risk the serious consequences of getting sick with COVID-19.

How mRNA Vaccines Work

The vaccine spurs healthy cells to produce viral proteins that stimulate a potent immune response



Safety Data for Vaccination in Pregnancy

- 155,000 + pregnant women have been vaccinated thus far
- No increase in adverse outcomes for baby or mother have been reported
- No increased risk of birth defects, pregnancy loss, preterm delivery, or fetal growth problems
- A study of over 800 women who were vaccinated in the first trimester did not show an increased risk of miscarriage
- Of 2500 women who received the vaccine before 20 weeks, no increased risks in pregnancy
- Side effect profile of the vaccine was slightly better in pregnant women compared to the general population

V-safe pregnancy registry outcomes of interest in COVID-19 vaccinated pregnant individuals

Pregnancy Complications [†]	Background Rate	V-safe Pregnancy Registry Overall
Gestational diabetes	7-14%	10%
Preeclampsia or gestational hypertension	10-15%	15%
Eclampsia	0.27%	0%
Intrauterine growth restriction	3-7%	1%
Neonatal Outcomes*	Background Rate	V-safe Pregnancy Registry Overall
Preterm birth	8-15%	9.4%
Congenital anomalies	3%	2.2%
Small for gestational age	3.5%	3.2%
Neonatal death	0.38%	0%

*Shimabukuro TT, Kim SY, Myers TR, Moro PL, Oduyobo T, Panagiotakopoulos L, et al. Preliminary findings of mRNA Covid-19 vaccine safety in pregnant persons. CDC v-safe COVID-19 Pregnancy Registry Team (published online April 21, 2021). *N Engl J Med*. DOI: 10.1056/NEJMoa2104983. Available at: <https://www.nejm.org/doi/10.1056/NEJMoa2104983>.

†Shimabukuro T. COVID-19 vaccine safety update. Advisory Committee on Immunization Practices (ACIP). Atlanta, GA: Centers for Disease Control and Prevention; 2021. Available at: <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-02/28-03-01/05-covid-Shimabukuro.pdf>. Retrieved March 1, 2021.

Mild Side Effects Among All Study Participants*

	Injection Site Reactions	Fatigue	Chills	Muscle Pain	Joint Pain	Headaches
Moderna	91.6%	68.5%	43.4%	59.6%	44.8%	63%
Pfizer-BioNTech	84.10%	62.90%	31.90%	38.30%	23.60%	55.10%
Janssen Biotech Inc.	48.6%	38.2%	N/A	33.2%	N/A	38.9%

Table 1. *Fever was the least common side effect reported; see text above for data on frequency of fever

Fever after Vaccination

- **In the Pfizer-BioNtech study subgroup of persons age 18-55 years fever greater than 38°C occurred in 3.7% after the first dose and 15.8% after the second dose ([FDA 2020](#)). In the Moderna vaccine trials, fever greater than 38°C was reported in 0.8% of vaccine recipients after the first dose, and 15.6% of vaccine recipients after the second dose ([FDA 2020](#)). Most of these symptoms resolved by day 3 after vaccination for both vaccines**
- **Pregnant women should take Tylenol if they develop a fever after vaccination.**

Safety Data for Vaccination while Breastfeeding

- Studies of breastmilk shortly after vaccination do not demonstrate any intact vaccine in the milk.
- Ingested vaccine is digested in the stomach, and does not work (hence why we need a shot vs a pill).
- Mother will make antibodies that will be present in the milk and may provide some protection against Covid-19 infection for the infant.
- These antibodies work by coating the throat and nasal passages to stop the virus at its point of entry.
- These antibodies do not provide full protection for babies against Covid-19.

Evaluation of Messenger RNA From COVID-19 BTN162b2 and mRNA-1273 Vaccines in Human Milk *AMA Pediatr.* 2021 Jul 6 : e211929. doi: [10.1001/jamapediatrics.2021.1929](https://doi.org/10.1001/jamapediatrics.2021.1929) [Epub ahead of print]

mRNA covid-19 Vaccine Rumors

- mRNA can change your DNA – not true
 - Messenger RNA does not enter the nucleus of a cell, where DNA is kept. It is used by the cell to create proteins and then broken down and destroyed by the cell.
 - The molecules last 12-24 hours before deteriorating in your muscle cells.
- You can get Covid-19 from the vaccine – not true
 - These vaccines do not include live or inactivated virus at all.
- Infertility – there is no evidence that the vaccine causes infertility
 - Syncytin-1 protein in placental tissue is 800 amino acids.
 - Covid-19 spike protein is 1500+ amino acids.
 - They share a series of 5 amino acids. The antibodies created against the Covid-19 spike protein do NOT interact with syncytin-1.
 - Pregnancy rates are the same before and after vaccination, as well as before and after Covid-19 infection. However, there are some studies reporting reduced sperm count after Covid infection.
- Lack of Data – We actually have more data for these vaccines in pregnant patients due to the v-safe app than any vaccine given in pregnancy before.



Questions?

mRNA Vaccine

Components



mRNA (blueprint of protein)

Production



Faster because mRNA molecules are easier to produce

Process

Components are injected into the arm and serve as instructions for the body to make microbial protein

Traditional Vaccine

Components



Microbial protein or inactive microbe

Production



Slower and more difficult to produce the right type of protein

Process

Components are made in a lab and injected into the arm to stimulate immune response

R & D

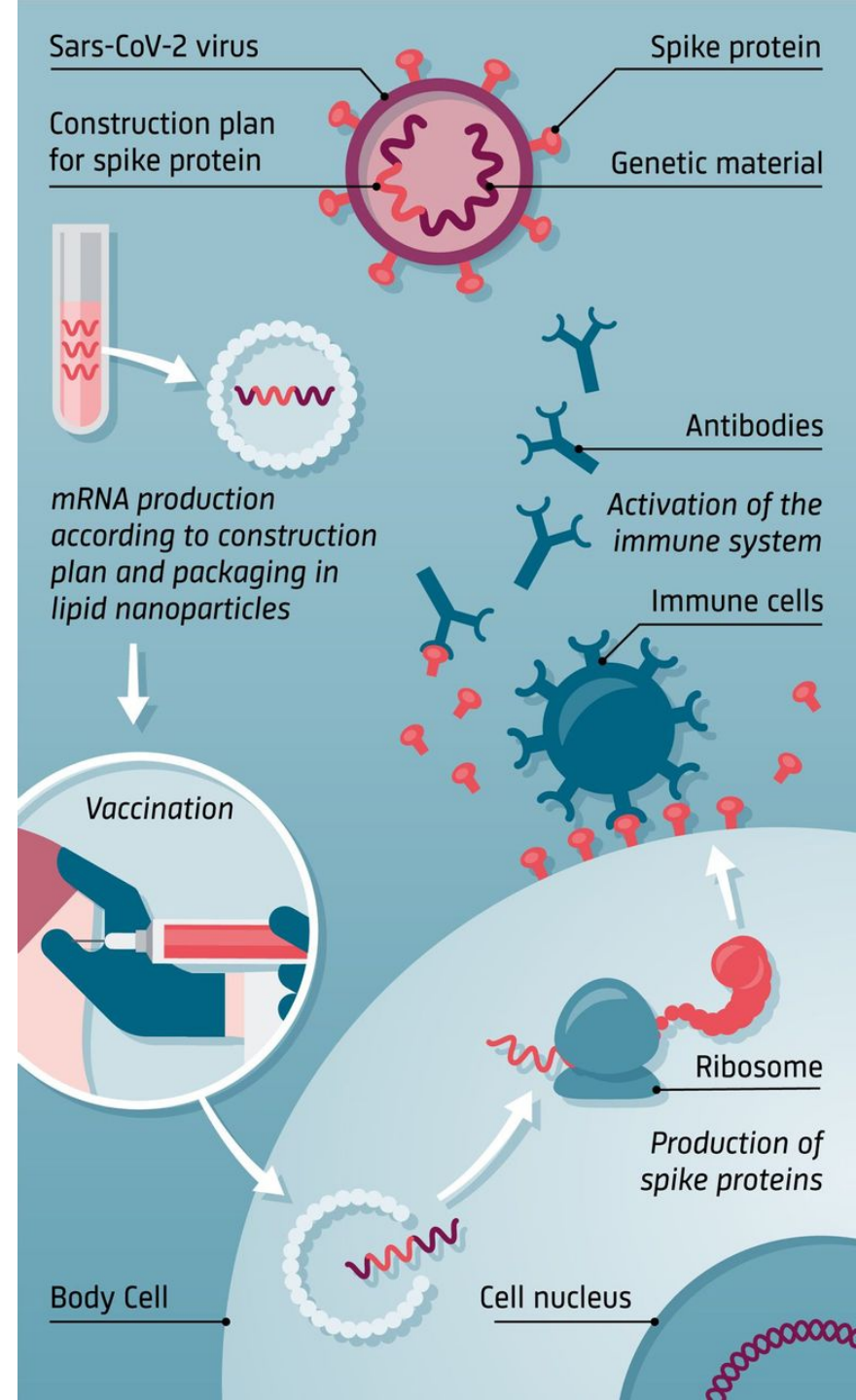
Antigen determined for immune stimulation



Result

Teaches the body to protect itself against a microbe





Understanding the virus that causes COVID-19.

Coronaviruses like the one that causes COVID-19 are named for the crown-like spikes on their surface, called **spike proteins**. These **spike proteins** are ideal targets for vaccines.

What is mRNA?

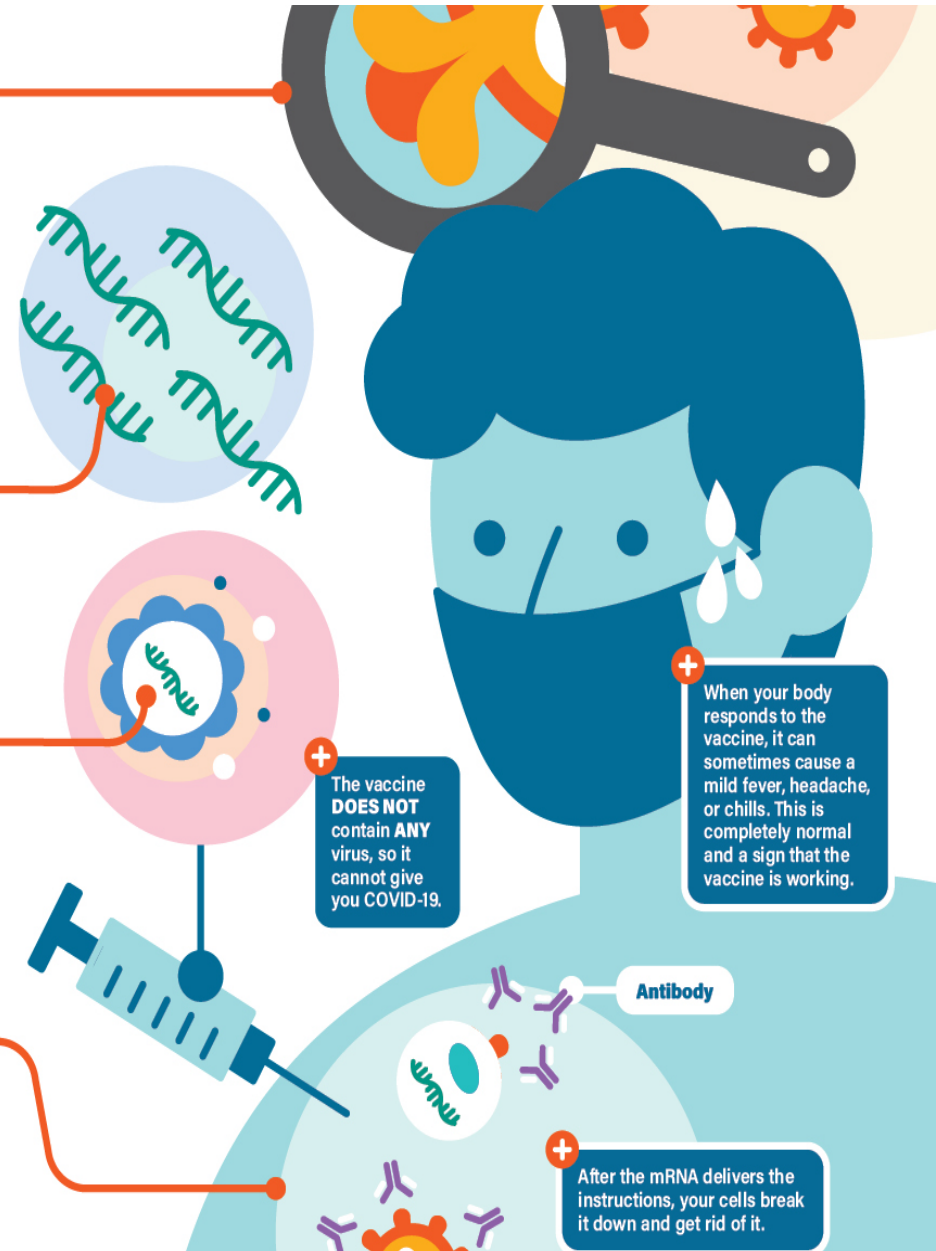
Messenger RNA, or mRNA, is genetic material that tells your body how to make proteins.

What is in the vaccine?

The vaccine is made of mRNA wrapped in a coating that makes delivery easy and keeps the body from damaging it.

How does the vaccine work?

The mRNA in the vaccine teaches your cells how to make copies of the **spike protein**. If you are exposed to the real virus later, your body will recognize it and



The vaccine **DOES NOT** contain **ANY** virus, so it cannot give you COVID-19.

When your body responds to the vaccine, it can sometimes cause a mild fever, headache, or chills. This is completely normal and a sign that the vaccine is working.

After the mRNA delivers the instructions, your cells break it down and get rid of it.

Antibody