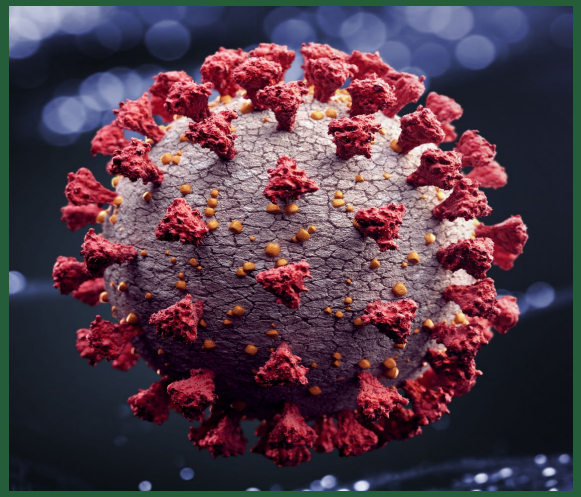
COVID- 19 Vaccination:
Answers for your Questions

Available Vaccines for COVID-19

Pfizer-BioNTech	*Moderna*
mRNA vaccine	mRNA vaccine
95% effective	94.1% effective
43,448 trial participants	30,420 trial participants
30 mcg given in 2 doses 21 days apart	100 mcg given in 2 doses 28 days apart
5 dose vials	10 dose vials
Must be diluted with 0.9% sodium chloride	No dilution required
Stored at -112 to -76 degrees Fahrenheit	Stored at -13 to -5 degrees Fahrenheit
Approved for use in ages > 16 years old	Approved for use in ages >18 years old

Polack FP, Thomas SJ, Kitchin N, et al. Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine. N Engl J Med. 2020 Dec 31;383(27):2603-2615.
Baden LR, El Sahly HM, Essink B, et al. Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine. N Engl J Med. 2020 Dec 30:NEJMoa2035389.

How do mRNA vaccines work?



Spike proteins (red) on the outside of SARS COV-2 virus

- Both the Pfizer-BioNTech and Moderna vaccines contain **mRNA coding for the spike protein of the virus**
  - The spike protein is on the outside of the virus and is used to enter the cells of our respiratory tract
- After injection mRNA is taken up by our cells and read by ribosomes in the plasma of the cell
- Ribosomes use the mRNA and build the spike protein by reading the sequence presented
- The spike protein appears on the surface of our cells and is quickly recognized by our body as foreign
  - **This promotes a strong immune response producing antibodies against the spike protein**

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/mrna.html

How were the vaccines developed and approved so quickly?

- Normally it takes years to study and bring a medication or vaccine to market, but **the Covid-19 vaccines were developed under special circumstances**
  - Global effort with the world's leading scientists focused on a single task
  - Nearly unlimited resources (money, knowledge, manpower, technology)
  - A large pool of diverse adult volunteer trial participants
- The vaccines were approved via **Emergency Use Authorization (EUA)** based on the need of a vaccine to quickly save lives during a public health emergency
- EUA is a shorter process **but no steps are skipped in the safety evaluation process**
- FDA plus separate advisory boards (VRBPAC and ACIP) carefully reviewed trial data for efficacy and safety before approval

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html

Are the vaccines safe?

- The vaccines are generally well-tolerated- **the most common side effects of both vaccines are:**
  - Mild to moderate pain, swelling, or redness at the injection site
  - Fatigue
  - Headache
  - Myalgia/arthralgia
  - Fever or chills
  - Swelling of the lymph nodes (usually in armpit of injection arm)
- These side effects are more common in younger patients (< 65 years old) and with the second dose
- There is a small chance of developing an allergic reaction which would occur a few minutes to an hour after injection
  - You may be monitored for 15 minutes after getting your dose

Polack FP, Thomas SJ, Kitchin N, et al. Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine. N Engl J Med. 2020 Dec 31;383(27):2603-2615.
Baden LR, El Sahly HM, Essink B, et al. Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine. N Engl J Med. 2020 Dec 30:NEJMoa2035389.
https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html

What is actually in the vaccines?

	Pfizer- BioNTech	Moderna
Active Ingredient	mRNA for the spike protein	mRNA for the spike protein
Lipids	4-hydroxybutyl azanediyl)bis(hexane-6,1 diyl)bis(2-hexyldecanoate) 2 [(PEG)-2000]-N,N-ditetradecylacetamide 1,2-Distearoyl-sn-glycero-3- phosphocholine cholesterol	SM-102 PEG-2000 dimyristoyl glycerol cholesterol 1,2-distearoyl-sn-glycero-3-phosphocholine
Electrolytes/ Buffers	potassium chloride monobasic potassium phosphate sodium chloride dibasic sodium phosphate dehydrate	tromethamine (Tris) acetic acid sodium acetate
Sugar	sucrose	sucrose

- **Excipients include lipids to protect the mRNA, electrolytes or buffers and sugar to maintain physiologic pH**

https://www.fda.gov/media/144414/download
https://www.fda.gov/media/144638/download

Special Populations

Can I receive the COVID-19 vaccines while pregnant or breastfeeding?

Covid- 19 Vaccines and Pregnancy

- **Pregnant and lactating women were excluded from both Pfizer and Moderna clinical trials**, although a few women did become pregnant between the first and second doses
  - There have been no reports of any problems with these pregnancies
- The vaccines are not considered live vaccines
- The chance the vaccine can cross the placenta is very low, therefore it is unlikely the vaccine would reach the fetus, although this is unknown

https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2020/12/vaccinating-pregnant-and-lactating-patients-against-covid-19
https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/pregnancy.html
https://www.smfm.org/covidfamily

Reproductive Data from Animal Trials

- Moderna completed a developmental and perinatal/postnatal reproductive toxicity (DART) study of its Covid-19 vaccine in rats
- FDA review of this study concluded the vaccine given prior to mating and during gestation periods did not have any adverse effects on female reproduction, fetal/embryonal development, or postnatal development
- Pfizer-BioNTech is to report results of their DART study in rats which is ongoing currently

https://www.fda.gov/media/144434/download
https://www.fda.gov/media/144246/download

COVID-19 Infection Risk During Pregnancy

- While the absolute risk is low, **pregnancy is associated with increased risk of maternal severe illness, ICU admission, mechanical ventilation and death**
  - 1-3 per 1,000 pregnant women with Covid-19 will have severe disease
  - 3 times more likely to need ICU care
  - 2-3 times more likely to be mechanically ventilated
- Pregnant patients with comorbidities such as **obesity, hypertension and gestational diabetes** may be at an **even higher risk** of severe illness
- Black and Hispanic individuals who are pregnant have disproportionately higher rates of COVID-19 infection and death

https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2020/12/vaccinating-pregnant-and-lactating-patients-against-covid-19
https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/pregnancy.html
https://www.smfm.org/covidfamily

Antibodies may be transferred from mother to baby

- **Studies suggest maternal transfer of Covid-19 antibodies to the fetus during pregnancy**
- One study looked at mothers positive for antibodies and tested infants for antibodies at delivery
  - 87% of infants had detectable IgG antibodies
  - Of the infants that did not, the maternal IgG was at lower levels
- Antibodies to the Covid vaccines take ~2 weeks from 2nd dose to optimize and optimal antibody transfer from placenta occurs after 17 weeks

Flannery DD, Gouma S, Dhudasia MB, et al. Assessment of Maternal and Neonatal Cord Blood SARS-CoV-2 Antibodies and Placental Transfer Ratios. *JAMA Pediatr.* Published online Jan 29, 2021.
Munoz FM. Can We Protect Pregnant Women and Young Infants From COVID-19 Through Maternal Immunization? *JAMA Pediatr.* Published online January 29, 2021.

Recommendations for Covid-19 vaccine while pregnant or breastfeeding

- American College of Obstetricians and Gynecologists (ACOG)
  - COVID-19 vaccines **should not be withheld** from **pregnant and lactating individuals** who meet criteria for vaccination based on ACIP-recommended priority groups
- CDC and Advisory Committee on Immunization Practices (ACIP)
  - Women who are **pregnant or breastfeeding** and part of a high risk group recommended to receive COVID-19 vaccine, such as healthcare personnel, may choose to be vaccinated.

https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2020/12/vaccinating-pregnant-and-lactating-patients-against-covid-19
https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/pregnancy.html

Recommendations for Covid-19 vaccine while pregnant or breastfeeding

- WHO original statement recommended against Covid-19 vaccination in most women unless at **high-risk of exposure** (e.g. healthcare workers)
- They have revised their statement to clarify **pregnant women at high risk of exposure** to SARS-CoV-2 (e.g. health workers) or **who have comorbidities** which add to their risk of severe disease, **may be vaccinated** in consultation with their health care provider.
- "Based on what we know about this kind of vaccine, we don't have any specific reason to believe there will be specific risks that would outweigh the benefits of vaccination for pregnant women."

https://www.who.int/news-room/feature-stories/detail/the-moderna-covid-19-mrna-1273-vaccine-what-you-need-to-know
https://www.acog.org/news/news-releases/2021/01/acog-and-smfm-joint-statement-on-who-recommendations-regarding-covid-19-vaccines-and-pregnant-individuals

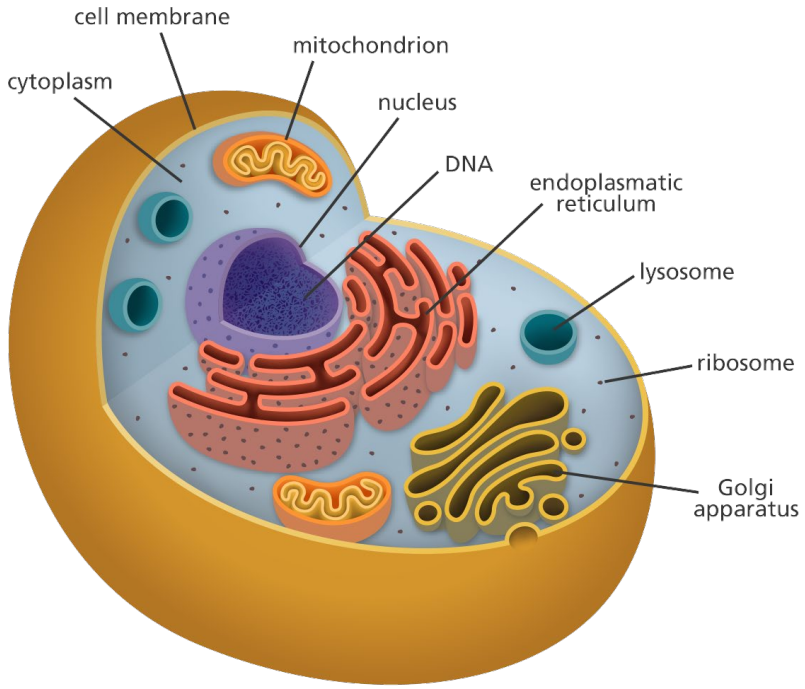
Do the Covid-19 vaccines cause infertility?

- **No- the Covid-19 vaccines will NOT cause infertility**
- This misinformation originated on social media from a former Pfizer employee who worked outside of the vaccine division
- The Covid-19 spike protein has a few amino acid sequences similar to the protein **syncytin-1** which helps the placenta form
- The amino acid sequence is too small for the immune system to misidentify it
- If this myth were true SARS COV-2 infection would also cause early miscarriages, <u>which has not been associated with infection</u>

https://www.asrm.org/globalassets/asrm/asrm-content/news-and-publications/covid-19/covidtaskforceupdate11.pdf
https://edwardnirenberg.medium.com/are-covid-19-vaccines-going-to-cause-infertility-939bbdb62b64
Cosma, S., Carosso, A. R., Cusato, J, et al. Coronavirus disease 2019 and first-trimester spontaneous abortion: a case-control study of 225 pregnant patients. Am J Obstet Gynecol. 2020 Oct 8

Do the Covid-19 vaccines change DNA?

- **No, the Covid-19 vaccines do not alter DNA.**
- mRNA vaccines do not enter the nucleus of the cell where DNA is stored, therefore they do not alter human DNA in vaccine recipients
- mRNA is read by ribosomes in the plasma of the cell



https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2020/12/vaccinating-pregnant-and-lactating-patients-against-covid-19
https://www.asrm.org/globalassets/asrm/asrm-content/news-and-publications/covid-19/covidtaskforceupdate11.pdf

Vaccination Considerations in Pregnant Women

- Side effects similar to the general population can be expected. **Pregnant women who experience fever can safely take acetaminophen.**
- There is currently no preference of one COVID-19 vaccine over another except for 16-17 year olds who are only eligible for the Pfizer-BioNtech vaccine
- Vaccines during pregnancy including Tdap and influenza should be **deferred for 14 days** after the administration of COVID-19 vaccines.
- Rhogam is not affected by the COVID-19 vaccine

https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2020/12/vaccinating-pregnant-and-lactating-patients-against-covid-19
https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/pregnancy.html

Talk to Your Provider about Vaccination

- **Discussion between you and your provider may assist with decisions regarding the risk versus benefit of getting vaccinated**
- Considerations for getting the vaccine include:
  - Level of activity of the pandemic in the community
  - Potential efficacy of the vaccine
  - Ability to limit exposure (work environment, PPE, travel, etc)
  - Potential risk and severity of maternal disease, including the effects of disease on the fetus and newborn
  - Safety of the vaccine for the pregnant patient and the fetus
- While a conversation with a clinician may be helpful, it is not required prior to vaccination
- Women should be supported in their decision to receive or decline the vaccine

https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2020/12/vaccinating-pregnant-and-lactating-patients-against-covid-19
https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/pregnancy.html

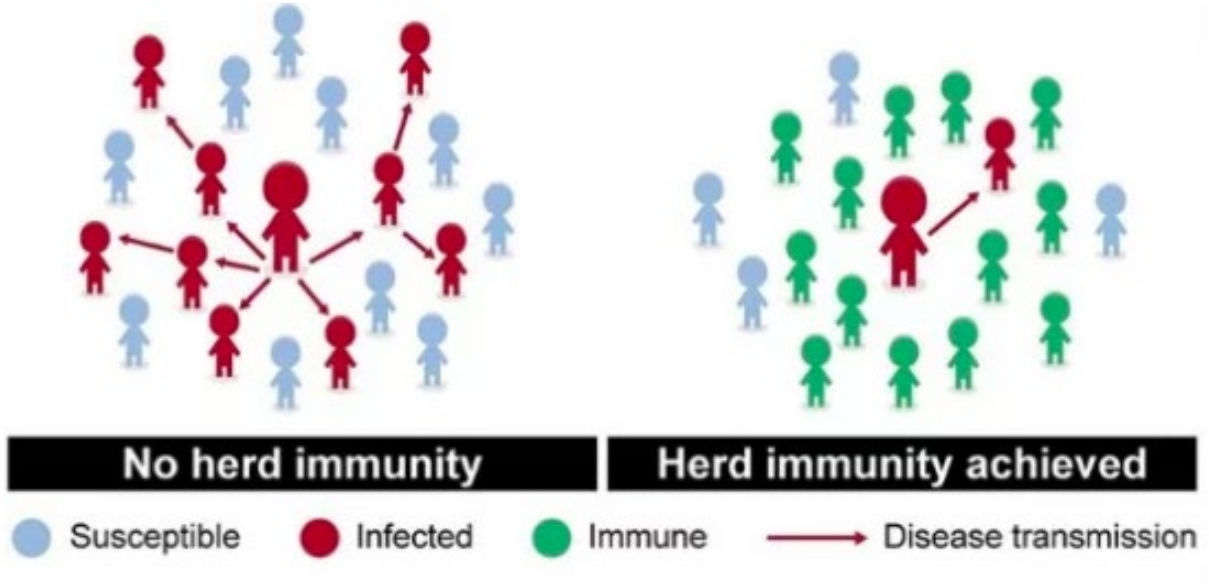
v-safe Program

- **v-safe** is a CDC endorsed smartphone-based tool that gives you personalized health check-ins after you receive a COVID-19 vaccine
- Through **v-safe**, you can quickly tell CDC if you have any side effects after getting the COVID-19 vaccine
- Depending on your answers, someone from CDC may call to check on you and get more information
- Sign up information is available in information given to you after receiving the vaccine

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html

Importance of Vaccination and Herd Immunity

- **COVID-19 vaccination is an important tool to help stop the pandemic**
- Herd immunity is the indirect protection from an infectious disease that happens when a population is immune either through vaccination or immunity developed from previous infection
- We currently do not know how many people need to be vaccinated to gain herd immunity, but most experts estimate 70-90% would need to become immune



https://www.who.int/news-room/q-a-detail/herd-immunity-lockdowns-and-covid-19
https://www.cdc.gov/coronavirus/2019-ncov/vaccines/vaccine-benefits.html

Resources for Information

Misinformation travels faster than facts!

Make sure to get your information from reliable sources.

General Vaccination Information

CDC Website

FDA approval documents

- Pfizer-BioNTech
- Moderna

Vaccination Fact Sheets

- Pfizer-BioNTech
- Moderna

Pregnancy and Vaccination

ACOG Statement

WHO Statement

CDC Website

Society for Maternal Fetal Medicine Statement

Questions?

1-888-364-3065
Vaccine@nyuhs.org