

COVID-19 Vaccination A Guide for Community Conversations

Partners In Health United States

March 2022

Context for these materials

This deck is intended to provide guidance for trusted messengers and community leaders to conduct community-based conversations around the COVID-19 vaccines. The goal of this deck is to share accurate, science-based evidence and engage in discussion that enables individuals to make informed decisions about their own health. This slide deck guides a short, 15-minute presentation and is intended to prompt a more comprehensive Q&A session.

Supplementing this deck with up-to-date local information (on vaccine availability, eligibility criteria, and registration procedures) is critical.

Please see additional information on how to facilitate this forum and answer common questions.

The ideas presented in this deck reflect the latest public health thinking and scientific evidence as of March 2022. You are advised that the COVID-19 vaccine landscape remains highly fluid, and it is your responsibility to ensure that decisions are made based on the most up-to-date information available.

Partners In Health does not provide medical advice, diagnosis or treatment in the United States. The information, including but not limited to, text, graphics, images and other material contained in this slide deck, are intended for informational purposes only.

AGENDA

Why get Vaccinated?

Available Vaccines in the U.S.

COVID-19 Vaccine Science

Vaccine Eligibility: Children

Vaccine Safety

Vaccine Frequently Asked Questions

Next Steps: Getting Vaccinated

Annex – Additional FAQs

The goal of today's session is to share key vaccine information, answer questions about vaccine safety, and engage in honest, non-judgmental conversation.

Why should I consider getting the COVID-19 vaccine?



Getting the COVID-19 vaccine helps prevent severe illness, hospitalization, and death by COVID-19.

To help you:

Even in young, healthy people, COVID-19 can cause very serious illness and death. Older people and persons with health conditions like diabetes are at an even greater risk.

To help your family, friends, and community:

The more people who get the vaccine, the better we can protect our families and communities, and ensure people can go back to their jobs.



To move forward, together:

The best way to achieve normalcy is for all of us to get vaccinated for the coronavirus so we can collectively end this pandemic and provide justice to communities that have been especially impacted.

Approved COVID-19 vaccines in the U.S.

There are 2 COVID-19 vaccines that have received the FDA's full approval, and 1 approved with emergency use authorization (EUA). Several other COVID-19 vaccines are currently in development. Primary series vaccination protocol shown here.

As of March 2022



Named: Comirnaty

Type of vaccine: mRNA

Approved population: 5+

Dosing: 2 shots, **3-8 weeks** apart

Approval status: Fully approved

for 16+; EUA for 5-15



Named: SpikeVax

Type of vaccine: mRNA

Approved population: 18+

Dosing: 2 shots, 4-8 weeks apart

Approval status: Fully approved

for 18+



Type of vaccine: Viral vector

Approved population: 18+

Dosing: 1 shot

Approval status: EUA

ALL 3 vaccines are highly effective at preventing severe illness, hospitalization, and death. The CDC has updated its recommendation with a preference for mRNA vaccines (Pfizer or Moderna), in most situations, where possible.

Refer to your healthcare provider and/or the CDC website for dose timing recommendations and considerations.

Explaining mRNA vaccines: Pfizer & Moderna



How does it work?

- mRNA is a normal part of human biology. Your body is full of mRNA right now!
- These vaccines work by using mRNA as a "messenger" that contains a blueprint for the COVID-19 spike protein. This tells your body: make this protein.
- You then develop antibodies against COVID-19 spike proteins, creating immunity.
- Once your cells make the protein, the mRNA breaks down and does not stay in your body permanently.
- mRNA does <u>not</u> enter your cell's nucleus and cannot alter your DNA.



Is mRNA new technology?

- No. Though this is the first mRNA vaccine to be approved for use, research on mRNA for other diseases, such as Zika, cancer, and the flu, has been underway for 10 years.
- Vaccines based on injecting viral proteins (flu, tetanus, pneumonia) or live virus (oral polio, Chickenpox) take longer to produce.
- Because mRNA vaccines work off a blueprint, they can be created quickly.
- The COVID-19 vaccine passed every FDA approval step. No corners were cut in the creation of these vaccines.

Explaining viral vector vaccines: Johnson & Johnson



How does it work?

- Viral vector vaccines use a common virus
 ["adenovirus"] to alert your body's immune system.

 The virus is weakened and cannot cause disease.
- Like mRNA, the harmless virus delivers a blueprint, telling your body to make COVID-19 spike proteins.
- Antibodies develop to the spike protein, creating immunity.
- The harmless virus does not stay in your body.



Are viral vectors new technology?

- No, Johnson & Johnson has already used this method to develop an approved Ebola vaccine, and the technology has been used for a long time for gene therapy.
- The AstraZeneca vaccine, currently approved for use in other countries, and in final vaccine trials in the U.S., uses the same technology.
- The Johnson & Johnson vaccine was the first COVID-19 viral vector vaccine authorized under EUA and passed every FDA evaluation step required.

This vaccine cannot give you COVID-19 because it uses a different, harmless virus to create immunity.

Who can get the COVID-19 vaccines?

Everyone age 5+ regardless of allergies, medications, pregnancy, or underlying medical conditions is eligible to receive a COVID-19 vaccine.

The only groups NOT eligible to receive COVID-19 vaccination are:

- Children under 5 years old for Pfizer (Comirnaty), and under 18 years old for Moderna (Spikevax) and Johnson & Johnson. No vaccine has yet been authorized for children under 5, but approvals may be coming soon.
- Those who experience a severe allergic reaction to the first dose of a two dose COVID-19 vaccine.



All vaccines provided through the U.S. government will be free of charge to all, including those without insurance. For those who have insurance, information will be collected, but there will be no out of pocket cost to the individual.

COVID-19 vaccines for children 5 years and older

Children 5 years and older are eligible to receive the two-dose Pfizer vaccine

Facts about vaccines for children 5+

- Pfizer's two-dose vaccine received Emergency Use Authorization
 (EUA) for kids ages 5-11 in November 2021; older children have
 been eligible since July 2021
- The vaccine is administered in **two doses three weeks apart**
- Kids 5-11 receive 1/3 the dose of adults
- The vaccine can be safely and effectively administered at the same time as other vaccines

Children can get their vaccine at a variety of

locations:

- Pediatrician's office
- School-based clinics
- Pharmacies
- Children's hospitals
- Other sites, such as county health clinics





COVID-19 vaccines for children 5 years and older

Why should my child get vaccinated?

- The vaccine is safe and effective at preventing children from becoming severely ill from COVID-19.
- Most children with COVID-19 have mild symptoms, but some can become extremely ill, resulting in hospitalization and death.
- Vaccination safeguards your child's health, and protects others
 who may be elderly, immunocompromised, or too young to
 become vaccinated.
- Vaccination will allow children to return safely to activities that foster mental, physical, and intellectual growth.

Are there short-term or long-term side effects?

- Side effects are usually mild and last 1-3 days and are similar to those experienced by adults: pain at the injection site, fatigue, headache, chills, muscle pain, fever, and joint pain.
- Regulatory agencies are monitoring limited reports of heart issues after COVID-19 vaccination.
- These cardiac issues are extremely rare, and the risk of these conditions is higher for those who become infected with COVID-19.

The CDC, FDA, public health and medical experts are constantly monitoring the safety of the vaccines. Speak with your pediatrician to address any concerns over vaccine safety.

Are the COVID-19 vaccines safe for pregnant people and their babies?

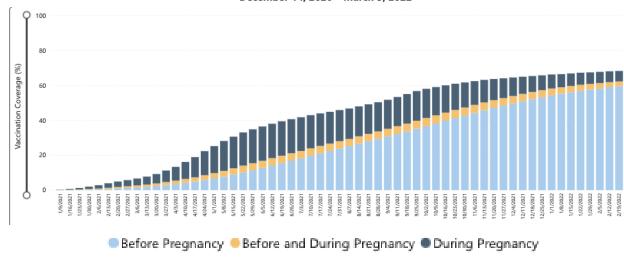
Yes, the benefits of getting a COVID-19 vaccine far outweigh the risks for *both mothers and their babies*.

- Getting vaccinated against COVID-19 while pregnant, planning to become pregnant, or breastfeeding is safe, effective, and recommended.
- Evidence suggests that COVID-19 infection increases many pregnancy-related risks for both mother and baby, not COVID-19 vaccines.
- There is **no** evidence that vaccines cause miscarriage or infertility.
- There is evidence that people vaccinated during pregnancy pass high levels of antibodies to their babies, and that people vaccinated against COVID-19 transfer SARS-CoV-2 antibodies to their breastfed infants, giving their babies passive immunity against COVID-19.

COVID-19 vaccination among pregnant people aged 18-49 years overall, by race/ethnicity, and date reported to CDC - Vaccine Safety Datalink,* United States

Figure 1: Percent of Pregnant People Ages 18–49 Years Fully Vaccinated with COVID-19 Vaccine Before and During Pregnancy, by Timing of Vaccination and Week Ending Date — Vaccine Safety Datalink,* United States

December 14, 2020 – March 5, 2022



Accure Safety Datalink is a collaboration between CDC's immunization Safety Office and nine integrated health care organizations in seven U.S. states. Eight sites provide data, and one additional site provides subject matter expertise. For more information please visitips://www.ids.gov/hacsinesafety/ensuringsafety/monitoring/visid/index.html

"Vaccination coverage" is the percent of pregnant people fully vaccinated before or during pregnancy, with the denominator including those pregnant at least 1 day during the specified week ending date, and the numerator including those who were fully vaccinated. Full vaccinated individuals received two doses of the Pfizer-BioNTech or Moderna vaccines or a single dose of the Jansen (Johnson & Schonson) vaccine; "before pregnancy," represents the percent of pregnant people who were fully vaccinated before pregnancy; "furing pregnancy," represents the percent of pregnant people who were fully vaccinated during pregnancy," represents the percent of pregnancy percent of pregnancy and one during pregnancy," represents the percent of people fully vaccinated during pregnancy, Full vaccination for moderately/severely immunocompromised people was not captured (interim Clinical Considerations for Use of COVID-19 Vaccines (CDC).

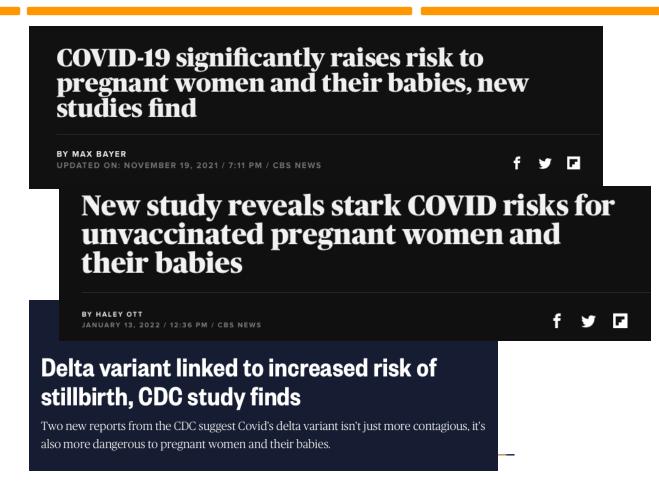
CDC strengthened its recommendation on August 11, 2021, to recommend COVID-19 vaccination for all people who are pregnant, lactating, trying to get pregnant now, or might become pregnant in the future

As of 3/15/22, about 68.6% of pregnant people have been fully vaccinated, and many pregnant people remain unprotected.

Why is vaccination critical for pregnant people?

Vaccines safely reduce the likelihood pregnant people will develop severe COVID-19.

- Pregnant people with COVID-19 are at an increased risk for preterm labor, preeclampsia, and <u>maternal mortality</u>.
- They are 2x as likely to require admission to the ICU, and 70% more likely to die than those who aren't pregnant.
- Babies whose mothers have COVID-19 are also more likely to face severe complications, such as premature birth, stillbirth, or death.



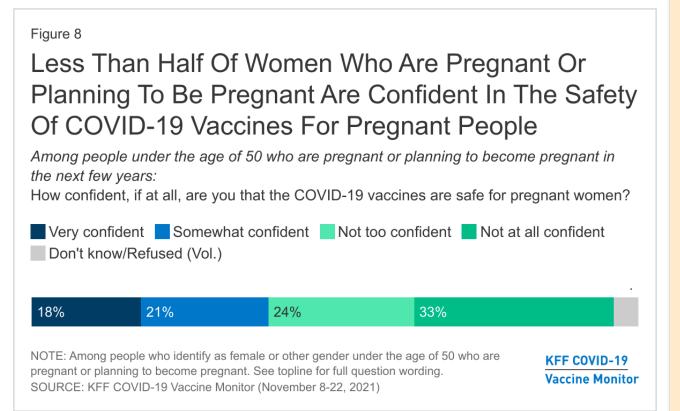
Alarm sounded about COVID-19 in pregnant women in Colorado

Seth Klamann seth.klamann@gazette.com Dec 13, 2021 Updated 17 hrs ago

The role of a trusted messenger

Vaccination rates among pregnant people remain alarmingly low, especially in Black and Latinx communities.

Nearly 57% of pregnant people say they are not confident vaccines are safe for them (KFF).



What can I do to help?

- Stay up-to-date on COVID-19 vaccine information, emphasizing the safety and effectiveness at preventing harm to both the mother and the baby. Protecting the baby is the most stated reason a pregnant person is likely to get vaccinated.
- Include the family in vaccine conversations, reiterating the safety of a fully vaccinated household for the baby, who cannot yet be vaccinated. Family has a drastic impact on a mother's decision to get vaccinated.
- Connect expectant mothers to other peer and support groups. Listening and sharing testimonials and stories about COVID-19 experiences while pregnant can provide confidence to make the right decision.

For most people, side effects from the vaccine are mild

Side effects are caused by your own body's immune response to the vaccine.

Minor side effects are common after vaccination.

These are short-lived and can include:

- Redness or swelling on the arm where you get the shot
- Weakness, fatigue
- Fever
- Muscle aches
- Headache

Talk to your doctor or vaccine provider about the use of over-the-counter medicine for side effects.

Note: Experiencing side effects <u>does not</u> mean that you have COVID-19. It is your body developing an immune responsewhich is a good thing. Not everyone has side effects. Both are normal.

Severe reactions are very rare

Your risk of severe illness from COVID-19 infection is much higher than the risk of a severe reaction to the vaccine.

- You will wait for 15 minutes after vaccination to make sure you have no serious reaction. If you have known allergies to an injectable medication, you'll wait 30 minutes.
- All vaccine sites have epinephrine on site (the medicine stored in an EpiPen) to address the rare possibility of a severe allergic reaction.

Go to your primary care provider, clinic, or alert your vaccination site if:

- Side effects do not go away within 3-4 days
- You received the J&J vaccine and are experiencing symptoms of Thrombosis with Thrombocytopenia Syndrome (TTS)

How were these vaccines created so quickly while ensuring that they are safe?

Vaccines are reviewed and approved for use by the FDA through a rigorous process:

Scientists already knew a lot about vaccine technology and were able to use this knowledge to design vaccines for trial

The companies were able to start manufacturing planning in parallel with trials, with the help of huge \$ investments from the government

After strong evidence from 3 phases of trials, the vaccines received Emergency Use Authorization (EUA)

Continued monitoring & collection of trial data

Full
approval. Pfizer
(Comirnaty)
received August
2021; Moderna
(Spikevax)
received Jan
2022

In Summary...

- FDA safety evaluations were not changed or compromised during COVID-19 vaccine development.
- The vaccine process was faster because research and development, clinical trials, manufacturing, and plans for distribution are occurring at the same time, with unprecedented levels of government spending.
- Even after EUA, there is ongoing and rigorous monitoring for adverse events.
- On Aug 23, 2021, the FDA granted full approval of the Pfizer (Comirnaty) vaccine for 16+.
- On Jan 31, 2022, the FDA granted full approval of the Moderna (Spikevax) vaccine for 18+.

Additional Doses: What is a booster?

A booster shot is an additional dose of a vaccine given after the initial recommended dose.

Boosters are administered as an additional layer of defense to restore protection which may have decreased over time.

How do I know if I need one?

- Anyone who received J&J vaccine at least 2 months ago is eligible to receive a booster dose of any kind.
- Any adult (18+) who received the second dose of either Pfizer or Moderna vaccines at least 5 months ago is eligible to receive a booster dose of any kind.
- Children 12+ are also eligible for a booster dose of Pfizer 5 months after their second dose, which is recommended to increase protection against the Omicron variant.
- Immunocompromised children ages 5 and up may also receive a third dose of Pfizer's vaccine 28 (Comirnaty) days after their second dose.

*Note: The CDC has updated its recommendation with a preference for mRNA vaccines (Pfizer or Moderna), in most situations, where possible.

Additional Doses: Mixing and Matching

Can I receive a different type of vaccine from my original primary series dose as a booster dose?

Yes. You may choose (depending on supply on site). If you do receive a booster vaccine that is different from the one you received for your primary dose, you should do so at the recommended interval for the booster dose of your original vaccine.

- If you initially received the J&J vaccine, you are eligible to receive a booster of any kind at least 2 months after your initial dose.
- If you initially received either the Pfizer (12+) or Moderna (18+) vaccines for your primary series, you are eligible to receive a booster dose of any kind at least 5 months after your second dose.



Bing stock image

Additional Doses for the Immunocompromised

COVID-19 vaccines are highly effective in preventing severe outcomes among the general population. However, some immunocompromised people require additional layers of protection.

Third doses:

- Those with compromised immune systems may receive a third dose of either mRNA vaccine (Pfizer/Comirnaty or Moderna) as a part of their initial series
- May be referred to as an "immune primer" as it will "prime" immune levels for those whose bodies cannot develop immunity as well as others
- Can be received no sooner than 28 days after a second dose
- Some younger children (5-11) who are moderately or severely immunocompromised may be eligible for an additional dose 28 days after their second shot of the Pfizer vaccine

Booster doses:

 Immunocompromised adults who completed an mRNA vaccine primary series and received a third mRNA dose may receive a single booster dose of any COVID-19 vaccine at least 3 months after their third Pfizer or Moderna dose, or 2 months after a J&J dose, for a total of four COVID-19 vaccine doses.

This information is constantly evolving; immunocompromised people should speak to their clinical provider to learn more about appropriate timing of vaccination.

Will the vaccines still work against the variants?

What are the key COVID-19 variants?

- Alpha (B.1.1.7): Emerged in September 2020
- Beta (B.1.351): Emerged in September 2020
- Gamma (P.1): Emerged in October 2020
- Delta (B.1.617.2): Emerged in December 2020
- Omicron (B.1.1.529): Emerged in November 2021 (Current dominant strain in U.S. as of March 2022)

Why do viral variants arise?

- All viruses change naturally as they replicate. Mutations are expected.
- Sometimes, viruses change in a way that helps them become better at infecting people or faster at replicating.
- These changes can allow the viral variants to spread more easily from person to person.
- Low rates of vaccination and inequities in access persist globally and contribute to the emergence of new variants.

Experts are confident that **current vaccines will provide protection against severe disease.** Increasing vaccination will help prevent new variants from developing. It is important that you are **fully** vaccinated and **receive your booster when eligible** to ensure protection against the current variants, as well as those that may emerge in the future.

You can help by wearing a mask and social distancing, <u>regardless of whether or not you've been vaccinated.</u>
This will help protect those who cannot yet be vaccinated, including children, and those who are considered high-risk, such as the elderly, or those who are immunocompromised.

The Delta Variant: What made it different?

Facts about Delta

- Delta was far more contagious than other variants.

 It was estimated to be 2x more infectious than previous strains.
- Delta impacted children more than previous variants.

 Pediatric COVID-19 cases drastically increased with Delta, esp. before those under 12 were able to receive a vaccine.
- Delta caused more severe illness than previous strains among unvaccinated people.

The Delta variant more than doubled the risk of severe illness requiring hospitalization for unvaccinated people.

Vaccines still proved quite effective against severe disease.

Getting vaccinated and wearing a mask, regardless of vaccination status, helped to prevent COVID-19 spread in communities.



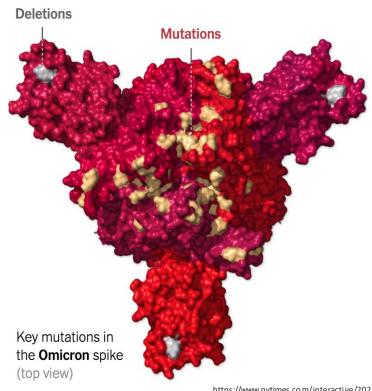
INCREASED SEVERITY

LIMITED IMMUNE ESCAPE

Now, here's Omicron. How does it measure up?

Omicron has dominated headlines since it was detected by public health authorities in late November. The Omicron variant (and its subvariants) has rapidly replaced Delta as the predominant strain.

- Omicron carries ~50 mutations not seen in this combo before including 30 in the spike protein.
- Omicron spreads very easily, even more quickly than Delta. Incubation period is shorter; symptoms similar.
- Omicron causes milder illness than Delta. Risk of hospitalization appears to be lower.
- Vaccination and previous infection provide lower protection from infection than with other variants (though vaccination offers protection against severe disease); boosters provide protection.



Breakthrough Cases: Why are fully vaccinated people still getting COVID?



Vaccines are still some of our best tools in protecting against the COVID-19 variants.

What are breakthrough cases?

- A person who is fully vaccinated and tests positive for COVID-19 is considered a *breakthrough case*.
- No vaccine can provide full protection from any disease, but
 this does not mean they are ineffective. The available
 vaccines provide a high level of protection against severe
 illness, hospitalization, and death.
- In most breakthrough cases, the symptoms are mild, and do not require hospitalization or result in death.

Why should I get the vaccine if I still can get COVID?

- No vaccine is 100% effective, and breakthrough cases are expected. The vaccines dramatically lower your chance of infection and drastically reduces your risk of severe illness, hospitalization, and death.
- In addition to protecting you, vaccines provide protection for those around you. Full vaccination reduces your chances of catching and transmitting COVID-19. Not everyone is yet eligible for vaccination, such as children under 5. For others, such as those with compromised immune systems, COVID-19 vaccines provide less protection.

Vaccine Distribution

All individuals 5 and older are eligible for vaccination. Refer to your state or local health department to learn more about how, when, and where vaccines are distributed in your area.



There are a few ways to sign up for appointments – and many sites offer walk-in options.

- 1 Through existing doctors or health care providers Individuals may be contacted by their medical provider.
- 2 Through online or phone scheduling systems
 - Visit <u>vaccines.gov</u> (English) or <u>vacunas.gov</u> (Spanish) to search and find a vaccine near you.
 - Text GETVAX (438829) for English or VACUNA (822862) for Spanish to receive three vaccine sites on your phone within seconds.
 - Call the National COVID-19 Vaccination Assistance Hotline at 1-800-232-0233 for those who prefer to get information via phone call.
- 3 Most retail pharmacies now offer walk-in vaccines

Thank You

We'd love to answer any questions!



Additional Vaccine Questions

➤ Why were the vaccines developed so fast?

The speed of COVID-19 vaccine development is <u>not</u> a result of compromised safety or quality. The vaccine process is happening faster because research and development, clinical trials, manufacturing, and plans for distribution are occurring at the same time, with unprecedented levels of government spending. No standards in the safety evaluations have been changed during this process.

> Are the COVID-19 vaccines safe?

Medical and public health experts trust the very serious and thorough FDA approval process for the vaccines, as well as the ongoing public health regulatory system that constantly monitors ongoing vaccine safety and effectiveness. Results from both clinical trials and real-world experiences reveal that the vaccines are very safe and work very well at preventing illness.

➤ Will the vaccine change my DNA?

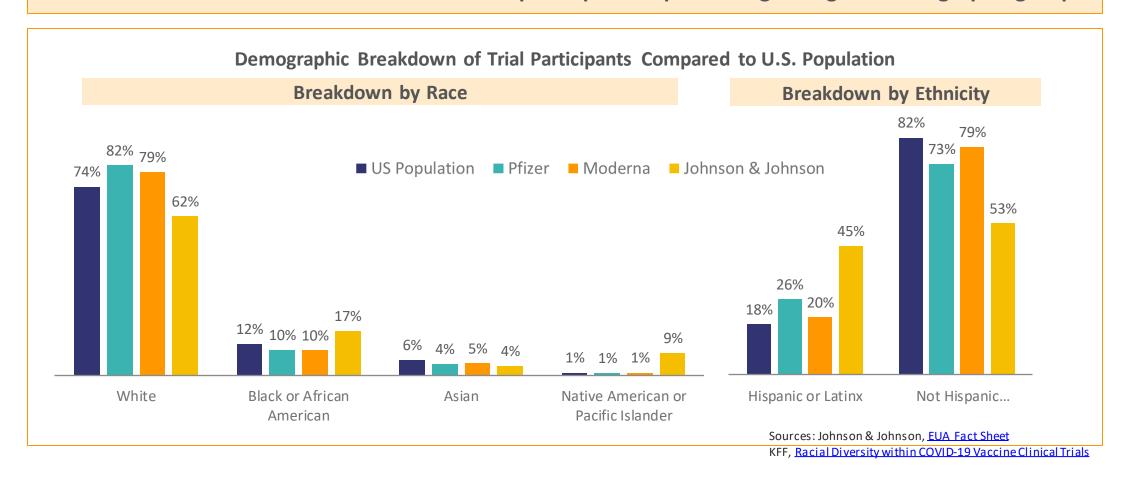
No! The Pfizer (Comirnaty) and Moderna (Spikevax) vaccines do not contain DNA, they contain mRNA, which does not enter the cell's nucleus, and cannot alter your genes. The J&J vaccine contains modified viral DNA that is only able to create spike proteins.

➤ Will I need a 3rd dose?

The 3rd shot is for patients with compromised immune systems who need an additional layer of protection. It not technically considered a "booster," but rather part of their primary vaccine series. People ages 5+ who are moderately or severely immunocompromised who received an mRNA vaccine for their 1st and 2nd doses are eligible for a 3rd dose of the shot they received, 28 days after their 2nd dose (note: only Pfizer for children ages 5-17 at this time). Immunocompromised adults who completed an mRNA vaccine primary series and received a third mRNA dose may then receive a single booster dose of any COVID-19 vaccine at least 3 months after their third Pfizer or Moderna dose, or 2 months after a J&J dose, for a total of four COVID-19 vaccine doses. This information is constantly evolving; immunocompromised people should speak to their clinical provider to learn more about appropriate timing of vaccination.

Who participated in the adult vaccine trials?

The vaccine trials included tens of thousands of participants representing a range of demographic groups



Who participated in the adult vaccine trials?

Vaccine trials were performed with many individuals with high-risk conditions.

High-risk conditions are those that place an individual at increased risk for severe COVID-19 complications.

High-Risk Condition	Pfizer (Comirnaty): % of Trial Participants	Moderna: % of Trial Participants	Johnson & Johnson: % of Trial Participants
No high-risk conditions	79.5%	77.9%	60.1%
Diabetes	8.2%	9.4%	7.2%
Chronic Lung Disease	8.6%	7.5%	1.3%
Liver Disease	0.6%	0.7%	< 1%
Significant Cardiac Disease	1.4%	4.9%	2.4%
Hypertension	24.4%	6.5%	10.3%
HIV/AIDS	0%	0.6%	2.5%

Source: FDA EUA Briefing Document (Moderna 12.17.2020; Pfizer 12.10.2020; J&J 2.26.2021)

Thank you!