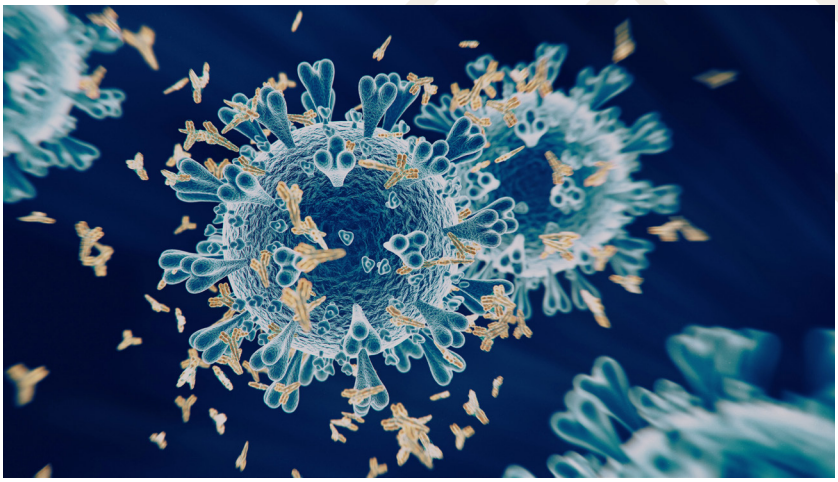
COVID-19 VACCINE QUESTIONS & ANSWERS



What COVID-19 vaccines are being used in the United States?

Three COVID-19 vaccines are available in the United States and are recommended for children and adults: Pfizer-BioNTech, Moderna, and Novavax. None of these updated 2023-2024 vaccines is preferred over another. These vaccines:

- Have been updated for 2023-2024
- Target the XBB lineage of the Omicron SARS-CoV-2 variant
- Are more effective against currently circulating SARS-CoV-2 variants
- May restore an individual's protection against severe COVID-19 that has waned over time.

FDA approved the updated 2023-2024 vaccines and CDC recommended them for use on September 12, 2023 (mRNA) and October 3, 2023 (Novavax). The J&J/Janssen vaccine, and the original and bivalent mRNA vaccines are no longer available for use in the United States.

CDC recommends being "up-to-date" with your COVID-19 vaccines. This means that you have received the doses that are currently recommended for your age, vaccination status, and health conditions. The table provides a general overview of recommended vaccine doses by age group. Other considerations may apply to certain individuals' dosages and timing.

The mission of Trivedi Consults is to provide tailored education, guidance and advice to reduce the development and spread of infections. We meet the needs of a variety of organizations including hospitals, healthcare and non-healthcare organizations and companies. As an independent contractor, our consulting uses evidence-based guidance to build practical implementation strategies based on local resources.

- COVID-19 vaccines are administered in different dosage amounts for specified ages. Individuals should receive their age-appropriate dosage(s).
- In some situations, children may receive a Moderna vaccine after a first or second Pfizer-BioNTech vaccine at the appropriate dosage, as determined by their healthcare professional.
- Individuals with immunocompromising conditions should discuss with their healthcare professional about the potential need for additional doses of the updated vaccines.
- An individual may consider delaying the updated 2023-2024 COVID-19 vaccine if they had COVID-19 in the last three months, unless they or a loved one are at higher risk of severe COVID-19 disease.
- Different considerations apply to individuals who previously received vaccine doses outside of the United States.

Age	Vaccinated		Unvaccinated
	Previously received	*Recommended 2023-2024 vaccine dose*	*Recommended 2023-2024 vaccine dose*
≥ 12 years	≥ 1 doses of Pfizer-BioNTech or Moderna ≥ 1 doses of Novavax or J&J/ Janssen, including combination withan mRNA booster	1 dose of Pfizer-BioNTech OR 1 dose of Moderna OR 1 dose of Novavax	1 dose of Pfizer-BioNTech OR 1 dose of Moderna OR 2 doses of Novavax
5-11 years	≥ 1 doses of Pfizer-BioNTech or Moderna	1 dose of Pfizer-BioNTech OR 1 dose of Moderna	1 dose of Pfizer-BioNTech OR 1 dose of Moderna
6 months -4 years	≥ 1 dose of Moderna 1 dose of Pfizer-BioNTech >1 dose of Pfizer-BioNTech	1 dose of Moderna 2 doses of Pfizer-BioNTech 1 dose of Pfizer-BioNTech	2 doses of Modern OR 3 doses of Pfizer-BioNTech

There are multiple ways to find updated COVID-19 vaccines administration sites: Vaccines.gov, texting your ZIP code to 438829, or calling 1-800-232-0233.

What process does the US use to approve COVID-19 vaccines?

FDA used (EUA) to approve diagnostic testing platforms, treatments, and vaccines during the COVID-19 pandemic, and prior to that for treatments for other emerging infectious diseases and threats. CDC's (ACIP) then recommends the groups who should receive vaccines in the US. Full FDA approval, requires a minimum of 6 months of safety and effectiveness data, allows the vaccine manufacturer to market the vaccine, and for clinicians to prescribe it "off-label" at their discretion.

It is important to note that authorization under EUA does not mean FDA and CDC used a simpler review and approval process than full approval. EUA approves the vaccines for treatment, meaning they are no longer experimental. CDC and FDA have collected extensive safety data. The EUA designation provides a specific structure to further quantify safety benefits.

How do we know the COVID-19 vaccines are safe?

FDA and CDC applied the same rigorous safety and efficacy evaluation as other vaccines approved for use in the US. For any vaccine being considered for the US population, independent data-safety monitoring boards and expert committees with both academic and governmental scientists review Phase 3 trial results for safety and efficacy though a transparent and publicly-accessible multiphase process. Phase 3 is the last phase of the clinical trial process for each vaccine. By the time FDA authorizes a vaccine and CDC recommends it for use, a vaccine's safety and efficacy has been studied and assessed by many experts. This process has been applied even more strictly to COVID-19 vaccines.

How do they work?

The Pfizer/BioNTech and Moderna vaccines use messenger RNA (mRNA) — small parts of genetic code that prompt the body to produce antibodies against the SARS-CoV-2. The Novavax vaccine uses components of proteins from the virus to carry genes for the COVID-19 virus that prompts an immune response.

How effective are they?

A vaccine's ability to prevent infection is described in two ways. "Efficacy" describes how well the vaccine worked for clinical trial participants, and "effectiveness" refers to how well a vaccine does in the real world. The COVID-19 vaccines have been shown to be both highly efficacious and effective at preventing severe COVID-19.

Ninety-five percent efficacy does not mean that 5% of participants developed infection, and 95% did not, but that those who received the vaccine in the clinical trial were 95% less likely to develop infection than trial participants who received the placebo.

The goals of the COVID-19 vaccine program are to prevent severe disease and death. The COVID-19 vaccines are also evaluated for their ability to prevent COVID-19 infections, both symptomatic and asymptomatic. CDC uses multiple study designs and statistical methods to evaluate vaccine effectiveness, at-home testing, and other factors that complicate findings about effectiveness have become more common.

CDC monitors vaccine effectiveness against SARS-CoV-2 using 4 platforms: ICATT, HEROES/RECOVER, PROTECT, and PREVENT.

Can people get COVID-19 after being vaccinated?

COVID-19 vaccines do not prevent all infections. SARS-CoV-2 and variants have emerged since the vaccines were initially developed that have varying degrees of immunity evasion for vaccine, natural, and hybrid-induced immunity. Vaccination has global and individual safety benefits. It reduces transmission (thus reducing the likelihood for further variants to emerge and spread in the world). Fully vaccinated persons who experience breakthrough COVID-19 infections:

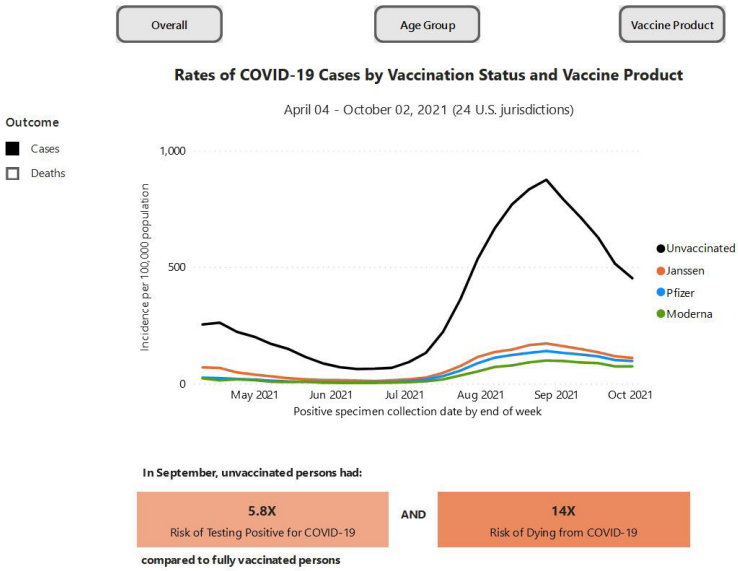
- Less likely to develop serious illness
- Have less severe symptoms, if symptomatic
- Are less likely to be hospitalized or die
- Have shorter duration of illness
- Have lower viral loads

Should fully vaccinated people wear face coverings in indoor public places?

Face coverings are an effective part of a layered strategy of prevention against COVID-19, and are recommended in addition to being fully vaccinated.

CDC recommends that fully vaccinated persons who are exposed to someone with suspected or confirmed COVID-19:

- Be tested 5 days after exposure



- Wear a mask in public indoor settings for 10 days or until they receive a negative test result regardless of the local level of transmission.

Are people who are vaccinated less likely to transmit the COVID-19 virus?

Yes. Even though vaccinated persons with variant breakthrough infections are shown to spread the virus to others, it appears that they are infectious for a shorter period of time and are therefore less infectious overall. The COVID-19 vaccines remain highly effective against hospitalization and death.

Multiple studies show that COVID-19 vaccines reduce the likelihood of transmission of the virus. A study in Lancet found that after receiving a single dose, people were 67% less likely to test positive for viral RNA two weeks later, suggesting that vaccination does not just protect against infection, but leads to fewer infections overall. Another study showed a 90% reduction in asymptomatic infection among those who

were vaccinated with the Pfizer/BioNTech vaccine, with low and likely non-infectious nasal viral loads of vaccinated persons exposed to COVID-19.

Do people experience side effects to these vaccines?

Fever, headache, fatigue, and pain at the injection site are the most common side effects reported among people who receive the vaccine. Most side effects are mild to moderate.

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Infants and Young Children Do Die from COVID-19

Deaths due to COVID-19 Higher than Other Vaccine Preventable Diseases

Disease	Deaths (Per Year)	Date Range	Age (Years)
COVID-19	74-221	2020-2022	0-4
Influenza	68-87	2018-2020	0-4
Varicella	50	1970-1994 (prevaccine)	< 15
Rubella	17	1966-1968 (prevaccine)	All
Hepatitis A	3	1990-1995 (prevaccine)	< 20
Rotavirus	20-60	1999-2007 (prevaccine)	< 5

Anderson EJ, et al. *Clin Infect Dis* 2021; 73:336 340. doi: 10.1093/cid/ciaa1425.
https://gis.cdc.gov/grasp/fluview/pedfludeath.html
https://www.cdc.gov/nchs/nvss/vsrr/covid_weekly/index.htm and https://www.cdc.gov/flu/spotlights/index.htm

Serious side effects after the vaccine are very rare. Anaphylactic reactions have been rare, with early monitoring finding 11.1 cases per million doses for the Pfizer/BioNTech vaccine and 2.5 cases per million doses for Moderna vaccine, primarily in the first 15 minutes after administration in persons with a history of allergy.

Is the vaccine safe and effective for-young adolescents?

Dosage size is specific to each age group. The trial for vaccination in 5 to 11 year olds included 2,268 participants and demonstrated very high efficacy (91%) with a strong immune response and absence of any serious side effects. (Walter E NEJM, 11/9/2021). A CDC study (January 14, 2022) found the Pfizer vaccine led to a 91% reduction in multisystem inflammatory syndrome in children (MIS-C).

Do we need to get kids vaccinated?

Although it is true that kids are less likely to be infected and have lower rates of severe disease, it has affected children as well.

Have any safety concerns emerged?

A 10-day pause on the J&J/Janssen vaccine in April 2021, occurred when the COVID-19 vaccine safety monitoring systems flagged cases of thrombosis with thrombocytopenia syndrome (TTS) among women ages 18-49 who recently received the J&J/Janssen vaccine. ACIP voted to lift the pause and fully recommend its use in all adults over the age of 18.

Rare reports of cases of inflammation of the heart — myocarditis and pericarditis — were flagged by vaccine safety monitoring programs. The cases occurred after the second dose of an mRNA COVID-19 vaccine (i.e., Pfizer-BioNTech, Moderna), mostly in young adult and adolescent males 12-29 years of age. It's important to note the risk of myocarditis

or pericarditis after receipt of an mRNA COVID-19 vaccine is lower than the risk of myocarditis associated with COVID-19 infection in adolescents and adults. (Boehmer MMWR 2021:70:1228-1232).

Patients responded well to treatment. The risk of myocarditis and pericarditis is slightly higher than normal but is still very low (~0.0005%) and is clinically characterized as much less severe than myocarditis with COVID-19 itself.

Do the vaccines affect fertility?

Many women have become pregnant after being vaccinated. Concerns emerged because of a purported similarity between syncytin-1, a protein that is critical to the development of the placenta, and the SARS-CoV-2 spike protein, with a suggestion that antibodies to SARS-CoV-2 could cause the body to reject the placenta. Nearly 4,000 participants enrolled in the V-safe pregnancy registry between December 14, 2020 and February 28, 2021 who received a COVID-19 mRNA vaccine. No safety signal was found. Pregnancy complications or loss among mRNA-vaccinated pregnant persons were not over the expected baseline rate (NEJM).

Additionally, a June 2021 study published by the American Society for Reproductive Medicine found no differences in reproductive outcomes among women who have antibodies to SARS-CoV-2 from vaccination, women who have antibodies from natural infection, and women who do not have antibodies (ASRM). Another study compared the placentas of 84 women in the late second or third trimester who received the Moderna or Pfizer mRNA vaccines to the placentas of 116 unvaccinated women. The results showed no evidence of placental attachment malfunction in the vaccinated women.

Studies have indicated that sperm numbers may decline due to natural COVID-19 infection in men, which has contributed to vaccine hesitancy for some men. A study in JAMA found no significant declines in any sperm parameter among the 45 men studied who were vaccinated against COVID-19.

Is COVID-19 vaccination recommended for people who are pregnant?

Yes. It is very important. Pregnant and recently pregnant persons are at higher risk of developing severe COVID-19. COVID-19 infection during pregnancy also is linked to increased risk for preterm birth and pregnancy loss (CDC). The American College of Obstetricians and Gynecologists (ACOG) and the Society for Maternal-Fetal Medicine (SMFM) strongly recommend all pregnant persons be vaccinated against COVID-19. These leading obstetric organizations cite the accumulated data from tens of thousands of pregnant people vaccinated against COVID-19 that indicate the vaccines are safe before, during, and after pregnancy. The risk of stillbirth among COVID-19 patients is nearly two times higher than the risk among patients without COVID-19.

What do we know about long-term safety?

Historically, no vaccine safety signals have been found eight weeks following vaccination. We are well beyond 8 weeks and many millions of vaccine doses have been given. Safety signals have been rare. The triggers based on these signals have been shown to be highly sensitive and fast-acting.

The COVID-19 vaccines are monitored very closely. The long-term safety monitoring systems used for all US vaccines monitor the COVID-19 vaccines. CDC has

created a vaccine safety monitoring system, V-safe, so that all COVID-19 vaccine recipients can report side effects by smartphone. V-safe elevates reports of serious side-effects to the CDC Vaccine Adverse Event Reporting System (VAERS). Anyone who has received the vaccine also can report side effects directly to VAERS.

If I have a health condition that wasn't studied during the clinical trials, should I get the vaccine?

If you have an underlying condition that puts you at higher risk for COVID-19 , you should receive the vaccine if you have no contraindications (e.g. severe allergic reaction to first mRNA dose or known allergy to the vaccines' ingredients). mRNA vaccines are not live virus vaccines so they are not risky for immunosuppressed persons or breastfeeding women. Receipt of COVID-19 vaccine in a lactating person is not known to trigger fever or other symptoms in the baby who is being breastfed.