

September 17, 2021



Out of abundance of caution, the Medical Center is screening all guests before providing entrance into the facility. To ensure our team is able to address your needs; we kindly ask to be as forthcoming as possible regarding your visit and provide all symptoms you may be experiencing.

Safety of COVID-19 Vaccines

Millions of People Have Safely Received a COVID-19 Vaccine

Over 380 million doses of COVID-19 vaccine have been given in the United States from December 14, 2020, through September 13, 2021.

COVID-19 vaccines are **safe and effective**. COVID-19 vaccines were evaluated in tens of thousands of participants in clinical trials. The vaccines met the Food and Drug Administration's (FDA) rigorous



scientific standards for safety, effectiveness, and manufacturing quality needed to support approval or authorization of a vaccine.

Millions of people in the United States have received COVID-19 vaccines since they were authorized for emergency use by FDA. These vaccines have undergone and will continue to undergo the most intensive safety monitoring in U.S. history. This monitoring includes using both <u>established and new safety</u> <u>monitoring systems pdf icon [PDF – 83 KB]</u> to make sure that COVID-19 vaccines are safe.

COVID-19 Vaccine Booster Shot

Updated Sept. 1, 2021

It's not clear if or when boosters doses of Covid-19 vaccines will be OK'd for fully vaccinated people in the United States, but state and local health departments across the United States are moving ahead with plans for a potential rollout next week.

Last month, US health officials announced plans for booster doses of Covid-19 vaccine to be offered starting the week of September 20, subject to sign-off from the US Food and Drug Administration and the US Centers for Disease Control and Prevention.

Those conversations are getting underway this week, including a key meeting of FDA vaccine advisers on Friday, but the decision isn't a slam dunk, experts have said. The Medical Center is actively monitoring the situation and will adjust our vaccination strategy accordingly. In the meantime MCOR continues to administer 1^{st} , 2^{nd} , and Booster doses to those individuals who qualify under current CDC/FDA guidelines. If you are interested in a vaccine, please call the Medical Center to schedule an appointment.

HHS <u>announced a plan</u> to begin offering COVID-19 vaccine booster shots this fall. CDC's independent advisory committee, the Advisory Committee on Immunization Practices, will continue to meet and discuss data on the evolution of the pandemic and the use of COVID-19 vaccines. ACIP will make further recommendations on the use of boosters for the public after a thorough review of the evidence.

When can I get a COVID-19 vaccine booster?

Not immediately. The goal is for people to start receiving a COVID-19 booster shot beginning in the fall, with individuals being eligible starting 8 months after they received their <u>second dose</u> of an mRNA vaccine (either <u>Pfizer-BioNTech</u> or <u>Moderna</u>). This is subject to authorization by the U.S. Food and Drug Administration and recommendation by CDC's Advisory Committee on Immunization Practices (ACIP). FDA is conducting an independent evaluation to determine the safety and effectiveness of a booster dose of the mRNA vaccines. ACIP will decide whether to issue a booster dose recommendation based on a thorough review of the evidence.

Who will be the first people to get a booster dose?

If the FDA authorizes and ACIP recommends a booster dose, people who were first to receive a COVID-19 vaccination when they became available in early 2021 (e.g., those who are most at risk) are likely to be



the first people eligible for a booster. This includes healthcare providers, residents of long-term care facilities, and other older adults.

Why is the United States waiting to start offering COVID-19 vaccine boosters?

The <u>COVID-19 vaccines authorized in the United States</u> continue to be <u>highly effective</u> in reducing risk of severe disease, hospitalization, and death, even against the widely circulating <u>Delta variant</u>. However, COVID-19 constantly evolves. Experts are looking at all available data to understand how well the vaccines are working, including how new variants, like Delta, affect vaccine effectiveness. If FDA authorizes and ACIP recommends it, the goal is for people to start receiving a COVID-19 booster shot this fall.

Can people who received Johnson & Johnson's Janssen (J&J/Janssen) COVID-19 Vaccine get a booster dose of an mRNA vaccine?

No, there aren't enough data currently to support getting an mRNA vaccine dose (either <u>Pfizer-BioNTech</u> or <u>Moderna</u>) if someone has previously gotten a <u>J&J/Janssen vaccine</u>. People who got the J&J/Janssen vaccine will likely need a booster dose of the J&J/Janssen vaccine, and more data are expected in the coming weeks. With those data in hand, CDC will keep the public informed with a timely plan for J&J/Janssen booster shots.

Will people who received Johnson & Johnson's Janssen (J&J/Janssen) COVID-19 Vaccine need a booster shot?

It is likely that people who received a J&J COVID-19 vaccine will need a booster dose. Because the J&J/Janssen vaccine wasn't given in the United States until 70 days after the first mRNA vaccine doses (<u>Pfizer-BioNTech</u> and <u>Moderna</u>), the data needed to make this decision aren't available yet. These data are expected in the coming weeks. With those data in hand, CDC will keep the public informed with a timely plan for J&J/Janssen booster shots.

If we need a booster dose, does that mean that the vaccines aren't working?

No. <u>COVID-19 vaccines are working very well</u> to prevent severe illness, hospitalization, and death, even against the widely circulating <u>Delta variant</u>. However, with the Delta variant, public health experts are starting to see reduced protection against mild and moderate disease. For that reason, the U.S. Department of Health and Human Services (HHS) is planning for a booster shot so vaccinated people maintain protection over the coming months.

What's the difference between a booster dose and an additional dose?

Sometimes people who are <u>moderately to severely immunocompromised</u> do not build enough (or any) protection when they first get a vaccination. When this happens, getting another dose of the vaccine can sometimes help them build more protection against the disease. This appears to be the case for some immunocompromised people and COVID-19 vaccines. CDC recommends moderately to severely immunocompromised people consider receiving an additional (third) dose of an mRNA COVID-19 vaccine (<u>Pfizer-BioNTech</u> or <u>Moderna</u>) at least 28 days after the completion of the initial 2-dose mRNA COVID-19 vaccine series.



In contrast, a "booster dose" refers to another dose of a vaccine that is given to someone who built enough protection after vaccination, but then that protection decreased over time (this is called waning immunity). HHS has <u>developed a plan</u> to begin offering COVID-19 booster shots to people this fall. Implementation of the plan is subject to FDA's authorization and ACIP's recommendation.



How many COVID-19 vaccines has Florida administered?

- In Florida, 14,065,421 people or 65% of the state has received at least one dose.
- Overall, 11,845,110 people or 55% of Florida's population has been fully vaccinated.

The links below provides an abundance of tracking information you may find of interest:

- <u>https://usafacts.org/visualizations/covid-vaccine-tracker-states/state/florida</u>
- https://www.mayoclinic.org/coronavirus-covid-19/vaccine-tracker
- <u>https://www.axios.com/pfizer-covid-vaccine-boosters-fda-approval-69ff9870-5e9a-4099-98ff-24085091cc7f.html</u>
- <u>https://www.cnn.com/interactive/2020/health/coronavirus-questions-answers/</u>



Infections and Spread

The Delta variant causes more infections and spreads faster than early forms of SARS-CoV-2, the virus that causes COVID-19



- The Delta variant is more contagious: The Delta variant is highly contagious, more than 2x as contagious as previous variants.
- Some data suggest the Delta variant might cause more severe illness than previous variants in unvaccinated people. In two different studies from Canada and Scotland, patients infected with the Delta variant were more likely to be hospitalized than patients infected with Alpha or the original virus that causes COVID-19. Even so, the vast majority of hospitalization and death caused by COVID-19 are in unvaccinated people.

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Unvaccinated people remain the greatest concern: The greatest risk of transmission is among unvaccinated people who are much more likely to get infected, and therefore transmit the virus. Fully vaccinated people get COVID-19 (known as <u>breakthrough infections</u>) less often than unvaccinated people. People infected with the Delta variant, including fully vaccinated people with symptomatic breakthrough infections, can transmit the virus to others. CDC is continuing to assess data on whether fully vaccinated people with asymptomatic breakthrough infections can transmit the virus.

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• Fully vaccinated people with Delta variant breakthrough infections can spread the virus to others. However, vaccinated people appear to spread the virus for a shorter time: For prior variants, lower amounts of viral genetic material were found in samples taken from fully vaccinated people who had breakthrough infections than from unvaccinated people with COVID-19. For people infected with the Delta variant, similar amounts of viral genetic material have been found among both unvaccinated and fully vaccinated people. However, like prior variants, the amount of viral genetic material may go down faster in fully vaccinated people when compared to unvaccinated people. This means fully vaccinated people will likely spread the virus for less time than unvaccinated people.

Vaccines

Vaccines in the US are highly effective, including against the Delta variant

- The COVID-19 vaccines approved or authorized in the United States are highly effective at preventing severe disease and death, including against the Delta variant. But they are not 100% effective, and some fully vaccinated people will become infected (called a breakthrough infection) and experience illness. For all people, the vaccine provides the best protection against serious illness and death.
- Vaccines are playing a crucial role in limiting spread of the virus and minimizing severe disease. Although vaccines are highly effective, they are not perfect, and there will be vaccine breakthrough infections. Millions of Americans are vaccinated, and that number is growing. This means that even though the risk of breakthrough infections is low, there will be thousands of fully vaccinated people who become infected and able to infect others, especially with the surging spread of the Delta variant. <u>Low vaccination coverage</u> in many communities is driving the current rapid surge in cases involving the Delta variant, which also increases the chances that even more concerning variants could emerge.
- Vaccination is the best way to protect yourself, your family, and your community. High vaccination coverage will reduce spread of the virus and help prevent new variants from emerging. CDC recommends that everyone aged 12 years and older get vaccinated as soon as possible.

Masks

Given what we know about the Delta variant, vaccine effectiveness, and current vaccine coverage, layered prevention strategies, including wearing masks, are needed to reduce the transmission of this variant



• At this time, as we build the level of vaccination nationwide, we must also use all the prevention strategies available, including masking indoors in public places, to stop transmission and stop the pandemic. Everyone who is able, including fully vaccinated people, should wear masks in public indoor places in areas of <u>substantial or high transmission</u>.

COVID-19 Travel Recommendations by Destination





RESOURCE

Additional information, links to community and local resources, MCOR's updated COVID-19 tracking grid and more is available at:

WWW.MCOR.ORG