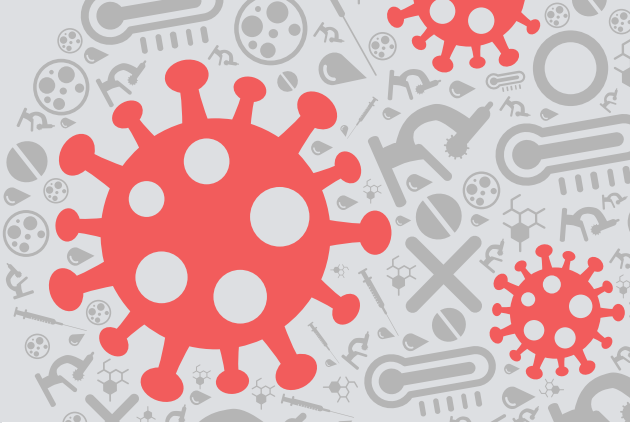
caring communities

COVID-19 Vaccine FAQs



How will we know if a vaccine is safe and effective?
The safety and efficacy of a vaccine is determined through clinical trials. Phase 1 clinical trials assess the safety and dosage of a vaccine in a small number of people, typically a dozen to several dozen healthy volunteers. Vaccine safety is also assessed in Phase 2 studies, in which adverse events not detected in Phase 1 trials may be identified because a larger and more diverse group of people receive the vaccine. However, only in the much larger Phase 3 clinical trials can it be demonstrated whether a vaccine is actually protective against disease and safety more fully assessed. Assessing safety is also a major goal of Phase 3 trials, both short-term safety (e.g., fever, tenderness, muscle aches) and long-term safety (e.g., autoimmune conditions or enhanced disease following infection). After a vaccine is approved and in more widespread use, it is critically important to continue to monitor for both safety and effectiveness. Some very rare side effects may only be detectable when large numbers of people have been vaccinated. *(Source: Johns Hopkins University Coronavirus Resource Center)*

How long will protection last following vaccination?
We do not know how long protection will last following vaccination. It will be critically important to measure long-term protection in Phase 3 trials and in other groups prioritized for early vaccination (at least two years). We are still learning about the duration of protection following infection with SARS-CoV-2, and it is too early to tell how long protection will last.

There are ways to potentially make protection after vaccination more durable than the protection that follows a natural infection, such as with an adjuvant, which is an ingredient used in some vaccines that helps create a stronger immune response, or with booster doses of vaccine. These strategies to enhance vaccines may be particularly important for vulnerable populations, such as the elderly and those with underlying diseases, who are at particular risk of severe COVID-19 but are also less likely to develop a protective immune response to a vaccine. *(Source: Johns Hopkins University Coronavirus Resource Center)*

How many shots of the COVID-19 vaccine will be needed?
All but one of the COVID-19 vaccines currently in Phase 3 clinical trials in the United States need two shots to be effective. The other COVID-19 vaccine uses one shot. *(Source: CDC.gov)*

If I already had COVID-19, do I still need to get the vaccine?
There is not enough information currently available to say if or for how long after infection someone is protected from getting COVID-19 again — this is called natural immunity. Early evidence suggests natural immunity from COVID-19 may not last very long, and more studies are needed to better understand this. Until we have a vaccine available and the Advisory Committee on Immunization Practices makes recommendations on how to best use COVID-19 vaccines, we cannot comment on whether people who had COVID-19 should get a COVID-19 vaccine. *(Source: CDC.gov)*

Do I still need to wear a mask and avoid close contact with others if I have had two doses of the vaccine?
Yes. While experts learn more about the protection that COVID-19 vaccines provide under real-life conditions, it will be important for everyone to continue using **every available tool** to help stop this pandemic: cover your mouth and nose with a mask, wash your hands often, and stay at least 6 feet away from others. Together, the COVID-19 vaccination and following the CDC's recommendations for how to protect yourself and others will offer the best protection from getting and spreading COVID-19. Experts need to understand more about the protection that COVID-19 vaccines provide before changing their recommendations on the steps everyone should take to slow the spread of the virus that causes COVID-19. Other factors, including how many people get vaccinated and how the virus is spreading in communities, will also affect this decision. *(Source: CDC.gov)*

We have already heard concerns from clients and patients about the safety of a new vaccine. How do we address this?
The CDC and FDA will address vaccine confidence throughout the COVID-19 vaccination campaign. The CDC is in the process of developing communication resources to address concerns about COVID-19 vaccines. Additional information will be shared when the resources are available.

It is vital that your staff understand the importance of vaccination as well as the benefits and risks:

- Communicate transparently about the COVID-19 vaccine risks and recommendations, immunization recommendations, public health recommendations, and prevention measures.
- Communicate early about the safety of vaccines in general and have government information to address myths, questions, and concerns easily accessible.
- Regularly visit CDC.gov and your state and local health department websites for updated information.

Communicating what is currently known about COVID-19 and its vaccine, regularly updating this information, and continuing dialogue with residents, staff, and families throughout the vaccine distribution and administration process is essential to establish and maintain trust and credibility.

Can we require employees to take the vaccine?
No*. Vaccines authorized under the FDA's emergency use authority, as the COVID-19 vaccinations will be at the start, should **not** be mandated. Any COVID-19 vaccine brought to market under an EUA instead of the normal non-emergency approval process will, by necessity, lack long-term safety data. Therefore, mandating the use of a vaccine authorized only by EUA could raise potential OSHA issues, among others.

**Please take note of state and local mandates which may occur when the vaccine is released, as there could be special exemptions created for the healthcare industry.*

What is the difference between a EUA and FDA Approval?
During a public health emergency, the FDA can use its Emergency Use Authorization (EUA) authority to allow the use of unapproved medical products, or unapproved uses of approved medical products, to diagnose, treat, or prevent serious or life-threatening diseases when certain criteria are met, including that there are no adequate, approved, and available alternatives.

The issuance of an EUA allows manufacturers to temporarily circumvent the typical approval process in one of two ways: a manufacturer may distribute an approved product for an unapproved use or temporarily distribute an unapproved product.

To issue an EUA, the FDA along with representatives from a task force of other HHS agency members must find that the following conditions are met:

- The public health emergency identifies a serious or life-threatening disease or condition.
- Based on available quality evidence, it is reasonable to believe that an unapproved product may be effective in responding to the disease or condition.
- Known potential benefits of the product outweigh known potential risks.
- No adequate FDA-approved substitute exists.

These requirements closely mirror other statutory and regulatory exceptions to the FDA approvals process. Under such conditions, the FDA generally disclaims that unapproved products have not undergone sufficient safety or efficacy testing. The type of review that FDA conducts for an EUA is considerably less rigorous than how the agency would normally review a product for approval. However, under the emergent conditions, they may offer some benefit given the absence of any alternative. *(Source: FDA.gov)*