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COVID-19 Vaccine FAQ

Why has it taken so long to develop a COVID-19 vaccine? It only took a few months for the H1N1 influenza (flu) vaccine to be developed.

When a new flu strain is identified, like H1N1 in 2009, vaccine manufacturers can use the same processes that are used to make the annual seasonal flu vaccine, saving valuable time. Unlike flue, coronaviruses do not yet have licensed vaccines or processes to build on. In addition, the coronavirus that causes COVID-19 is a new virus, so entirely new vaccines must be developed and tested to ensure they work and are safe. There are many steps in the vaccine testing and approval process. Multiple agencies and groups in the United States are working together to make sure that a safe and effective COVID-19 vaccine is available as quickly as possible.

Testing and approval process: https://www.cdc.gov/vaccines/basics/test-approve.html

Who is making recommendations and determinations on the priority for COVID-19 vaccinations?

The Centers for Disease Control (CDC) is making coronavirus disease 2019 (COVID-19) vaccination recommendations based on input from an Advisory Committee on Immunization Practices (ACIP). ACIP is a federal advisory committee made up of medical and public health experts who develop recommendations on the use of vaccines in the U.S. public. ACIP holds regular meetings, which are open to the public and provide opportunity for public comment.

After ACIP publishes its guidance and recommendations, it is then up to the states and their governors to determine the priority of vaccinations in their respective states.

States are working in real time to develop vaccination priorities anticipating a first round of vaccines doses in the coming weeks. Many have interim plans in place for vaccine allocation, and an initial analysis of these by LeadingAge finds that states are prioritizing long-term care residents and workers in their plans. The ACIP recommendations may help inform state plan refinements and/or continued prioritization of long-term care.

When will a COVID-19 vaccine be available in the United States?

The Food and Drug Administration granted an emergency use authorization (EUA) for the Pfizer-BioNTech COVID-19 vaccine late Friday, December 10. The federal government and its private sector partners immediately began shipping the vaccine to designated sites across the country, according to Department of Health and Human Services officials.

Updated: 12/23/2020

The FDA granted an EUAs to Moderna for another COVID-19 vaccine December 18. Other vaccines are likely to follow.

When a vaccine is authorized or approved in the United States, there may not be enough doses available for all adults. Supplies will increase over time, and all adults should be able to get vaccinated later in 2021. However, a COVID-19 vaccine may not be available for young children until more studies are completed.

At this time, the Pfizer BioNTech vaccine is authorized for use on people age 16 and older. The Moderna vaccine is authorized for use on people age 18 and older.

What is the FDA's Emergency Use Authorization (EUA) and how does the process work?

In order to help make a vaccine available as soon as possible, the FDA would need to authorize its distribution under an Emergency Use Authorization (EUA). The agency has issued guidance for the criteria that will be used to evaluate any EUA application. The FDA evaluates:

- Safety: Whether the chemical, biological, radiological or nuclear (CBRN) agent can cause a serious or life-threatening disease or condition. The known and potential benefits of the product, when used to diagnose, prevent or treat the identified serious or life-threatening disease or condition, outweigh the known and potential risks of the product.
- Efficacy: If the product is determined to be effective in preventing COVID-19.
- There is no adequate, approved and available alternative to the product for diagnosing, preventing or treating the disease or condition.

Under the EUA, any investigational vaccines developed to prevent COVID-19 will be assessed on a case-by-case basis considering the target population, the characteristics of the product, the preclinical and human clinical study data on the product and the totality of available scientific evidence relevant to the product. The final guidance specific to EUA for vaccines to prevent COVID-19 can be found here: https://www.fda.gov/media/142749/download.

While the vaccine has received emergency use authorization, that is not the same as FDA approval.

Are the vaccines safe?

Safety is the most important priority in vaccine approval. Most side effects occur within six weeks of vaccination. To be more cautious, the FDA requires 8 weeks of safety monitoring for COVID-19 vaccines. To assess safety, the FDA typically advises developers to include a minimum of 3,000 participants in a vaccine trial. The current COVID vaccine trials include 30,000 to 50,000 participants, well above the FDA requirement.

The FDA used the same strict standards that it has for decades in evaluating the COVID-19 vaccines. No steps are skipped.

The COVID-19 vaccines were developed so quickly due to a global effort with the world's leading scientists focused on a single task – developing the COVID-19 vaccine. They had nearly unlimited resources at their disposal – money, knowledge, manpower and technology. And there was a large pool of diverse adult volunteer trial participants in the vaccine studies.

The COVID-19 vaccine is mRNA vaccine. What does that mean?

The mRNA technology is new in vaccine production, but it is already being used in cancer treatment and has been studied for more than 10 years. COVID-19 mRNA vaccines give instructions for our cells to make a harmless piece that looks like the "spike protein" found on the surface of the COVID-19 virus. The virus is often pictured as a white ball with red spikes protruding from it.

Our bodies recognize that the protein should not be there, so they build antibodies that will remember how to fight the virus that causes COVID-19 if we are infected in the future.

The mRNA vaccine cannot give you COVID-19 and it cannot change your DNA.

When will PMMA communities begin offering the COVID-19 vaccine to residents and staff?

All PMMA communities signed up for the Pharmacy Partnership for Long-Term Care Program. All 15 PMMA communities, which offer skilled nursing and assisted living services, were eligible to participate and signed up through either Walgreen's or CVS.

The pharmacy partners will begin contacting campuses in mid-December to schedule three vaccine clinics at each location. Clinic dates are subject to change based on the availability of the vaccine. CVS and Walgreens anticipate scheduling the first round of clinics at the end of December, with subsequent clinics scheduled in January and February.

In preparation for these clinics, PMMA communities are already working to ensure all the required consent forms and physician's orders are in place.

Kansas is expecting to receive 75,000 doses of the vaccine by the end of December. Missouri expects to receive 300,000 doses of the vaccine in the same time frame. Both states have identified frontline health care workers and skilled nursing and assisted living residents as high priority to receive the vaccine.

The COVID-19 vaccine requires a two-step process consisting of two shots to get the most protection from the virus. The first shot starts the process of building immunity protection within the body, with a second dose required a few weeks later to provide the maximum amount of protection available.

Will PMMA require staff and residents to get the vaccine?

No. **PMMA strongly encourages all eligible residents and employees to carefully consider** what these vaccinations will mean for themselves and our PMMA communities. As front-line providers of senior care services, our employees are among those at the greatest risk of COVID-19 infection, and our residents are at the greatest risk of serious illness or death if they are infected.

According to current federal and state rollout plans, those eligible to receive the vaccine at our PMMA communities include nursing and assisted living residents and PMMA clinical staff members.

Is everyone in a Continuing Care Retirement Community campus, including those in independent living, eligible for the Pharmacy Partnership program?

Independent living was not included in the list the CDC's Advisory Committee on Immunization Practices (ACIP) reviewed during is December 1 meeting and, therefore, IL is not directly included in the 1a group of individuals in long-term care group. IL is not included even when it is part of a larger continuing care retirement community (CCRC).

However, the ACIP met again December 20 and recommended that individuals age 75 and older be in the next wave of those immunized against COVID-19, along with specific front-line essential workers including emergency responders and teachers. The goal is to have 50 million people who meet these criteria vaccinated by the end of February.

Individuals age 65 to 74 and those age 16 to 64 with underlying medical conditions would make up the next wave of those to be immunized, according to the ACIP. That phase would also involve corrections officers, postal workers, public transit workers and food supply workers who were not included in the two prior waves.

Kansas and Missouri will ultimately determine how the vaccines are distributed within their borders.

What about home health aides, hospice workers, and other caregivers working outside a facility setting included in the pharmacy partnership program?

Although these workers are considered healthcare workers, they are not part of the pharmacy partnership program. These workers should be addressed by the state priority plans, so stay tuned as more information becomes available in Kansas and Missouri.

Will residents or employees be charged for the vaccine?

Section 3203 of the CARES Act generally requires issuers offering non-grandfathered group or individual health insurance coverage to cover any qualifying coronavirus preventive service, including a COVID-19 vaccine, without imposing any cost sharing requirements, such as a copay, coinsurance or deductible.

No patient will be charged for the vaccine or its administration through the Pharmacy Partnership program. Individuals who receive the vaccine through their primary care physician or other programs may be charged an administration fee, however the vaccine will be offered free of charge.

Where will the vaccine clinics take place?

CVS or Walgreens will schedule a series of vaccine clinics at each of PMMA's senior living communities.

Vaccines will be administered by appropriate trained personnel under applicable state and federal laws and guidance. CVS and Walgreens immunizers are trained and certified according to company and state specific regulations. These immunizers may include pharmacists, pharmacy interns and trained pharmacy technicians, as well as other qualified health care professionals.

How much time can there be between the first and second vaccinations?

The ACIP will issue the acceptable range of time between the first and second doses. Most vaccines require two doses with at least 21 or 28 days in between does. Clinic dates will be set with those time frames in mind.

What are the most common side effects?

For the Pfizer BioNTech vaccine, the most commonly reported side effects, which typically lasted several days, were pain at the injection site, tiredness, headache, muscle pain, chills, joint pain, and fever. Of note, more people experienced these side effects after the second dose than after the first dose, so it is important for vaccination providers and recipients to expect that there may be some side effects after either dose, but even more so after the second dose. Learn more.

If a long-term care or assisted living resident has flu or influenza like symptoms after receiving the vaccine, even though the symptoms might be side effects, do they still have to be tested?

Yes. Guidance about this will be coming out along with the ACIP recommendations the week of December 14.

How will new residents/admissions and employees receive the vaccine ongoing?

This issue is developing. Ideally, there will be vaccines that can be left with the provider like flu vaccines are, however there are specific storage requirements for the Pfizer BioNTech vaccine that make leaving vaccine behind a challenge. Few have the required deep cold storage.

After staff of long-term care providers are vaccinated, must they continue to be tested?

There have not been changes to the testing requirements as set forth by CMS. CDC will release guidance on antigen testing in relation to vaccinations on or around December 12.

Should temporary staff be vaccinated?

Yes. Temporary staff are within the CDC's definition of a healthcare worker. Indeed, temp agency staff who might rotate among a number of facilities could in many ways be at highest risk.

Should someone with an active case of COVID-19 receive the vaccine?

No. Someone actively ill with COVID-19 should not get the vaccine because someone with active COVID should be in quarantine.

Should someone who previously had COVID-19 receive the vaccine?

Yes. Even if you have previously tested positive for COVID-19, you should still get the vaccine. At this time, it is believed that antibodies from a previous infection only provide protection from COVID-19 infection for a few months. Even if you previously tested positive, you should get the vaccine once you are considered recovered.

I have allergies. Should I get the vaccine?

The main allergy concern with the COVID-19 vaccine is for individuals who have had an anaphylaxis reaction to a vaccine or injection previously. Consult your primary care physician prior to seeking the vaccine. PMMA staff will consult with a resident's primary care physician before administering the vaccine to anyone who fits this criteria.

Everyone who receives the vaccine will need a 15 to 30 minute observation period following the injection for any signs or symptoms of a reaction.

Once I get the vaccine, how soon am I protected?

Most of the vaccines require 2 doses, 3 to 4 weeks apart. You must get both doses of the same vaccine because they are different. Protection occurs 1 to 2 weeks following the second dose.

How long am I protected by the vaccine?

We do not know at this time how long protection lasts as COVID-19 is a new virus and this is a new vaccine. We will know more as time passes in the current research. It is possible that individuals will need to get the COVID-19 vaccine on a regular basis, just like the seasonal flu shot.

How can people demonstrate they have been immunized?

Each vaccine dose comes with a card, which must be given to the individual or their proxy. Pharmacies may also offer additional verification on an app.

How is the CDC monitoring individuals' experiences with the COVID-19 vaccines?

The CDC is using a new system called V-Safe to monitor individuals after they receive the COVID-19 vaccines. V-Safe is a smart-phone based monitoring system that uses text messages and web surveys to check in with vaccine recipients after vaccination, and includes active telephone follow-up by CDC on reports of significant health impact.

The program is voluntary. V-Safe participants will receive health check-ins by text from CDC daily for the first week following vaccination. After the first week, check-ins go to weekly through the 6^{th} week, then at 3 months, 6 months, and 12 months post-vaccination.

Check-ins ask about clinically important health impacts such as missing work, inability to perform normal daily activities, and any resulting medical care received. Any clinically important health impacts reported will be followed up by phone by CDC.

Will I need to continue to wear a mask and avoid close contact with others if I have received 2 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 **all the tools** available to us to help stop this pandemic, like covering your mouth and nose with a mask, washing hands often, and staying at least 6 feet away from others. Together, COVID-19 vaccination and following 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 deciding to change recommendations on 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.

Vaccinations may cause staffing problems, either because staff experience side effects and have to miss work or because many residents experience side effects and need more staff time. What can providers do, can vaccines be staggered?

It is possible for the Partnership to vaccinate half the staff and for the half go to through the state program at a different time. That is not an ideal solution and the CDC is working on others.

What is the Pharmacy Partnership for Long-Term Care Program?

This program provides end-to-end management of the COVID-19 vaccination process, which includes cold chain management, on-site vaccinations, and fulfillment of reporting requirements to facilitate safe vaccination for campus residents and staff. Long-term care community staff can be vaccinated as part of the program.

The pharmacy partnership program provides critical vaccination services and is free of charge to facilities. This effort is the result of extensive coordination with jurisdictions, long-term care communities, federal partners including the Centers for Medicare and Medicaid Services (CMS), and professional organizations including LeadingAge and American Health Care Association (AHCA).

The CDC began surveying long-term care and assisted living communities in October and turned lists of partners over to Walgreens and CVS in November.

What facilities are eligible to participate in the Pharmacy Partnership for Long-Term Care Program?

Skilled nursing facilities, nursing homes, assisted living facilities, and similar congregate living settings where most individuals receiving care/supervision are older than 65 years of age.