

COVID-19 Vaccine FAQs for Healthcare Providers

December 21, 2020

Please note that the FAQs will be updated as more information are available.

INFORMATION REGARDING mRNA VACCINES:

The Pfizer and Moderna vaccines are a new type of vaccine called mRNA vaccine. What is an mRNA vaccine? How is it different than other vaccines?

- Intensive research has been underway on mRNA for about 25 years and it becomes apparent that mRNA could provide a way to provide more specific and potentially safer vaccines than the traditional vaccines. Several mRNA vaccines are already being used to effectively treat certain cancers like melanoma, so the mRNA vaccine know-how is not new and the mRNA cancer vaccines have a good safety record.
- mRNA is the abbreviation for “messenger” RNA. The mRNA is quite fragile and requires encasement within a lipid nanoparticle so that it can safely enter the cell’s cytoplasm.
- The mRNA does NOT enter a cell’s nucleus and cannot alter one’s DNA.
- Once in the cytoplasm, the mRNA prompts the cell to make the SARS-COV2 spike protein. The spike protein is then presented to immune “fighting cells” so that appropriate antibodies can be initiated.
- mRNA vaccine methodology has provided a way to develop and produce a targeted vaccine against an emerging or new threat like the COVID-19 virus in a much shorter time. It is like setting up a basic template or platform that can be reconfigured to specific specifications as the need arises. You do not have to start from square one.
- mRNA vaccines do not contain a live virus and do not carry a risk of causing disease in the vaccinated person.

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

- Every new vaccine must be tested for safety and then for effectiveness. In the U.S., the FDA requires a specific series of steps of testing of a new vaccine and each step must be completed before the vaccine receives any FDA approval.
- The COVID vaccine has been required to follow the FDA’s required steps in testing with no shortcuts.
- After FDA approval, all vaccines used in the U.S., old and new, are monitored through a national adverse event reporting system where any adverse event that might be remotely related to a vaccine is required to be reported and investigated to determine whether there is new information about the safety of the vaccine.
- During a pandemic or other emergency, the FDA can issue an Emergency Use Authorization (EUA) for a new vaccine or medication if the all required steps are completed and that all the

available evidence is consistent that the vaccine is safe and sufficiently effective to save lives in the pandemic and protect people and the community. Monitoring and analysis of the EUA vaccine or medication is continued to watch for any previously undetected information about the vaccine's effectiveness or safety.

- Currently, clinical trials are evaluating several COVID-19 vaccines in tens of thousands of study participants to generate scientific data and other information for the Food and Drug Administration (FDA) to determine their safety and effectiveness. These clinical trials are being conducted according to the rigorous standards set forth by the FDA. If FDA determines that a vaccine meets its safety and effectiveness standards, it can make these vaccines available for use in the United States by approval or emergency use authorization. The FDA can also deny approval.
- For the Pfizer and Moderna, and all other COVID-19 vaccine candidates, the FDA convenes a special expert panel to make recommendations to the FDA.
- In addition, immunization and vaccine experts from CA, NV, OR, and WA also review the safety and efficacy data of each COVID-19 vaccine and makes their recommendations.

How do we know that the COVID-19 mRNA vaccines are effective?

- Each new COVID-19 vaccine must be tested for safety and effectiveness just like any other vaccine or medication before it can be approved for use by the FDA.
- Both the Pfizer and Moderna vaccines have reported 95% and 94% efficacy, respectively. This means that the two-dose vaccine (Pfizer or Moderna) is highly effective in preventing COVID-19 disease.

CLINICAL CONSIDERATIONS OF PFIZER VACCINE:

Have the Pfizer and Moderna vaccines been approved?

- Pfizer vaccine
 - The FDA approved the Pfizer COVID-19 vaccine for use in individuals age 16 years and older on December 11, 2020.
 - The Advisory Committee on Immunization Practices (ACIP) also recommended the use of the Pfizer vaccine in individuals age 16 years and older on December 12, 2020.
- Moderna vaccine
 - The FDA approved the Moderna COVID-19 vaccine for use in individuals age 18 years and older on December 18, 2020.
 - ACIP recommended the used of the Moderna vaccine in individuals age 18 years and older on December 19, 2020.

How is the Pfizer vaccine administered?

- 2-dose series (30 microgram, 0.3 ml each), administered intramuscularly, **three** weeks apart
- Four-day grace period between day 17 and 21. If second dose administered before day 17, does not need to be repeated. If administered after day 21, second dose should be given as soon as possible but series does not need to start over.

How is the Moderna vaccine administered?

- 2- dose series (100 microgram, 0.5 ml each), administered intramuscularly, **four** weeks apart
- Second doses administered within a grace period of ≤ 4 days from the recommended date for the second dose are considered valid; however, doses administered earlier do not need to be repeated. The second dose should be administered as close to the recommended interval as possible. However, there is no maximum interval between the first and second dose for either vaccine.

Can the Pfizer vaccine be interchanged with Moderna or another COVID-19 vaccine?

- No, COVID-19 vaccines are not interchangeable.
- If a person got the Pfizer vaccine as first dose, then the second dose should also be Pfizer.
- In the event of inadvertent mixing of the vaccines, no additional vaccine doses are recommended by CDC at this time.
 - *Please note that this is still evolving and recommendations regarding this may change as more information is known.*

Can the Pfizer or Moderna vaccine be given simultaneously with other vaccines (for example, flu vaccine)?

- No. There is a lack of data on safety and efficacy of Pfizer and Moderna vaccine administered within a 14-day time frame with other vaccines. Therefore, the Pfizer and Moderna vaccines should be administered alone, with a minimum interval of 14 days before or after administration with any other vaccines.
- If inadvertently administered within 14-days of other vaccines, doses do not need to be repeated for any of the vaccines.

Can a prior positive COVID-19 case get vaccinated?

- Yes. Previously positive COVID-19 cases can safely get the Pfizer or Moderna vaccine.
- Positive COVID-19 patients should wait until they are no longer infectious based on the CDC's criteria for when to discontinue from transmission-based precautions – usually defined as 10 days from symptoms onset date or if asymptomatic, 10 days from positive test date for non-hospitalized, mild-moderate cases.

- Given the temporary immunity within 90 days of COVID-19 infection and the limited vaccine supply currently, positive COVID-19 cases may opt to wait until after their 90 days to allow others to get the vaccine first.
- If a patient has gotten monoclonal antibody treatment for COVID-19, vaccination should be deferred for 90 days to avoid vaccine-induced immune responses.

Can a close contact currently under quarantine for COVID-19 get vaccinated?

- Close contacts of positive COVID-19 cases should wait until they finish their quarantine period, and are not having any signs or symptoms concerning for COVID-19 before they receive COVID-19 vaccination.

Can people with underlying medical conditions get the Pfizer or Moderna vaccine?

- Yes. Both the Pfizer and Moderna vaccines may be administered to persons with underlying medical conditions who have no contraindications to vaccination.

Can immunocompromised persons get the Pfizer or Moderna vaccine?

- Yes. Immunocompromised individuals may still receive COVID-19 vaccination if they have no contraindications to vaccination. However, they should be counseled about the unknown vaccine safety profile and effectiveness in immunocompromised populations, as well as the potential for reduced immune responses.

What about pregnant and lactating women?

- The American College of Obstetricians and Gynecologists (ACOG) strongly recommended to FDA to include pregnant and lactating women in the approval categories for the Pfizer and Moderna vaccine.
- Though the data is limited, pregnant and lactating women should be offered the Pfizer and Moderna vaccine if there are no other contraindications. Studies in pregnant women are planned.
- There is no need to check pregnancy status prior to vaccination.
- Those trying to become pregnant do not need to avoid pregnancy after the Pfizer or Moderna vaccine.
- mRNA vaccines are not thought to pose a risk to breastfeeding infants.

What side effects have been reported for the COVID-19 mRNA vaccine?

- The most common adverse effects reported so far have been short term fatigue, headache, chills, myalgia (muscle pain) or pain at the injection site. Systemic adverse events such as fever were more common following the second vaccination, but resolve within 2-3 days.

- Some tens of thousands of persons have been part of vaccine trials so far and there is ongoing close scrutiny looking for any potential severe adverse events associated with getting the vaccine.

What about reports of anaphylaxis?

- CDC has recommended that all individuals vaccinated for COVID-19 with the Pfizer vaccine be monitored for 15 minutes. Those with reported history of allergies to food, insects, and oral medications, are also be monitored for 15 minutes post-vaccination.
- For those with a history of anaphylaxis to an injectable medication or another vaccine, not Pfizer, monitoring of 30 minutes is recommended.
- Here's the CDC recommendation for medical equipment and supplies to have on hand during a Pfizer vaccination clinic: <https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html>

Is there any contraindication to the Pfizer vaccine?

- Patients with a history of anaphylaxis to any components of the Pfizer vaccine should not be vaccinated with it.
- Here's the list of ingredients in the Pfizer vaccine: <https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>.

Is there any contraindication to the Moderna vaccine?

- Patients with a history of anaphylaxis to any components of the Moderna vaccine should not be vaccinated with it.
- Here's the list of ingredients in the Moderna vaccine: <https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>.

PUBLIC HEALTH CONSIDERATIONS:

Some people say that getting COVID-19 is not any worse than ordinary flu. Why is it important to get COVID-19 vaccine?

- COVID-19 and flu are very different viruses even though some of the symptoms are similar. Both can cause very serious illness and death.
- There are reports of long-term health effects from COVID-19 for some people that aren't seen in flu. As the pandemic unfolds, we are learning that many organs besides the lungs are affected by COVID-19 and there are many ways the infection can affect someone's health even after recovery from the acute illness symptoms.

- The long-term significance of these effects is not yet known. CDC will continue active investigation and provide updates as new data emerge, which can inform COVID-19 clinical care as well as the public health response to COVID-19.

What do we know about the long-term effects that COVID-19 infection can have on a person's health?

- While most persons with COVID-19 recover and return to normal health, some patients can have symptoms that can last for weeks or even months after recovery from acute illness. Even people who are not hospitalized and who have mild illness can experience persistent or late symptoms.
- The most commonly reported long-term symptoms after getting COVID-19 include fatigue, shortness of breath, cough, joint pain, and chest pain.
- Other reported long-term symptoms include difficulty with thinking and concentration (sometimes referred to as "brain fog"), depression, muscle pain, headache, intermittent fever, fast-beating or pounding heart (also known as heart palpitations).
- More serious long-term complications appear to be less common but have been reported. These have been noted to affect different organ systems in the body. These include:
 - Cardiovascular: inflammation of the heart muscle
 - Respiratory: lung function abnormalities
 - Renal: acute kidney injury
 - Dermatologic: rash, hair loss
 - Neurological: smell and taste problems, sleep issues, difficulty with concentration, memory problems
 - Psychiatric: depression, anxiety, changes in mood

The CDC and other agencies are informing us that the vaccine will take time to get to everyone. Who decides who is getting the vaccine first and why?

- The priorities for the vaccine are developed through extensive consultation and discussion on how to save the most lives, prevent spread and to ensure that the vaccine is distributed fairly and equitably to all people based on risk.
- The Advisory Committee on Immunization Practices (ACIP) is an expert advisory committee established by federal law to provide advice and guidance to the Director of the CDC regarding use of vaccines and related agents for effective control of vaccine-preventable diseases in the civilian population of the United States and provide public health guidance for safe use of vaccines and related biological products.
- The ACIP has been monitoring and analyzing the COVID-19 studies and the COVID-19 epidemiology as the pandemic has evolved. The ACIP is using this data to provide recommendations and guidance in the use of COVID-19 vaccines and for prioritization of groups for the vaccine supply as it rolls out. The ACIP has specific goals and ethical principles that it is using to develop the guidance. <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations-process.html>

- The CA Allocation Workgroup and Community Advisory Committee have jointly advised the California Department of Public Health for allocation of the initial Phase 1A in California which comprise of direct healthcare workers and residents of long-term care facilities. The guidance has several tiers and the State has provided guidance to local public health departments to go sequential through the tiers: <https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/CDPH-Allocation-Guidelines-for-COVID-19-Vaccine-During-Phase-1A-Recommendations.aspx>

Could COVID-19 vaccine be made mandatory?

- No, but we hope that the strong safety and efficacy of the COVID-19 vaccines currently available will be strong encouragement for all eligible individuals to take it when offered.

After a person gets the COVID-19 vaccine, does that person need to still wear a face covering, do social distancing, and follow all the other measures to slow the spread of COVID-19?

- Yes
- The Pfizer and Moderna vaccine have been proven to be highly effective in preventing COVID-19 **disease**, but the data is still unknown in regards to prevention of **infection and therefore transmission**.
- Moreover, no vaccine is absolutely 100% effective in preventing infection and all the tools of prevention are important to slow down and prevent spread of COVID-19.
- In addition to receiving a COVID-19 vaccine, the best strategies for preventing COVID-19 infection in youth and adults are to wear a mask in public places, stay at least 6 feet away from other people, frequently wash your hands, and avoid crowds and confined or poorly ventilated spaces.

How much will COVID-19 vaccine cost to receive it?

- The COVID-19 vaccine itself is distributed at no cost to people receiving the vaccine, but there **may** be an administration fee by some vaccine providers to cover costs of staff time and supplies. Health insurance may or may not cover the vaccine administration fees or the fee may be covered by other government funding. It will be important that a fee will not stand in the way of anyone to get COVID vaccine.