

### Frequently Asked Questions (FAQs) COVID-19 Vaccines and Immunization

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These FAQs were created to help provide science-based information and resources on the development and safety of COVID-19 vaccines.

### • Are COVID-19 vaccines safe?

Yes. Approved vaccines have gone through <u>U.S Food and Drug Administration's</u> (FDA) regulatory clearance that is dependent on strong evidence of vaccine effectiveness and safety and is the result of a thorough review of the data by its advisory committee. <u>The U.S. Centers for Disease Control and Prevention (CDC)</u> also provides additional information on the safety of COVID-19 vaccines in the United States.

#### How were the vaccines developed so rapidly?

The federal government collaborated closely with vaccine manufacturers since the start of the pandemic to make a vaccine available to the public. Importantly manufacturers have taken advantage of novel advances in science and technology including the ability to rapidly sequence the viral genome and utilize innovative mRNA-based tools. Consequently, the complicated and timeconsuming traditional vaccine development process could be replaced with new technologies that were able to propel COVID-19 vaccine development efforts at an unprecedented pace. In addition, FDA expedited its vaccine authorization timeline minimizing regulatory red tape in its process to evaluate vaccine effectiveness while ensuring vaccine safety as the top priority.

#### • Should I get the COVID-19 vaccine?

Yes. Vaccines provide protection (immunity) to the coronavirus and are recommended for individuals aged 16+. <u>The CDC outlines benefits of getting a</u> <u>COVID-19 vaccine</u>.<sup>1</sup>

• What is the vaccination prioritization and administration schedule?

CDC's Advisory Committee on Immunization Practices (ACIP) <u>developed an</u> <u>administration schedule</u> and prioritized vaccines for high-risk population groups.<sup>2</sup> Generally, the job function, age, and health status of an individual will determine the prioritization of an individual's vaccination schedule. Briefly CDC's prioritization includes the below scheme:

<sup>&</sup>lt;sup>1</sup> https://www.cdc.gov/coronavirus/2019-ncov/vaccines/vaccine-benefits.html

<sup>&</sup>lt;sup>2</sup> https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations.html

- Phase 1a: Healthcare personnel and long-term care facility residents.
- Phase 1b: Frontline essential workers (food and agriculture sector) and persons aged 75+.
- Phase 1c: Persons aged 65-74 and persons aged 16-64 with high-risk conditions and any essential workers not included in phase 1b.
- Phase 2: All persons aged 16+ not in phase 1, who are recommended for vaccination.

It is important to note that state and local public health authorities may modify these federal recommendations and prioritize immunization schedules to meet their communities' specific needs.

### • How do COVID-19 vaccines work?

There are multiple COVID-19 vaccine technologies that are approved or still being evaluated by FDA.

The first two vaccines that were approved in December 2020 were developed by Pfizer and Moderna.<sup>3,4</sup> These are mRNA-based vaccines, which do not utilize the traditional mechanism of a weakened or inactive version of a virus, or a laboratory-generated protein. Instead, the technology makes use of the viral genetic code (mRNA) to instruct the body's cells to assemble the coronavirus spike protein (present on the surface of SARS-CoV-2), thus allowing the human immune system to recognize these molecules as if the individual acquired the SARS-CoV-2 infection. In short, mRNA vaccines do not contain a live virus and do not carry a risk of causing disease in the vaccinated person. After the mRNA is used to make the spike protein, the body's cell breaks down the mRNA strand and disposes of them using other enzymes in the cell. It is important to note that the mRNA strand also never enters the cell's nucleus or affects human genetic material.<sup>5</sup>

The third vaccine approved in February 2021 was developed by Johnson & Johnson (J&J) and is a recombinant vector vaccine, which uses Adenovirus (a harmless cold-causing virus) to deliver the genetic code of the coronavirus spike protein to the body's cells. When administered these cells assemble the coronavirus spike protein allowing the immune system to recognize this virus as if it were coronavirus itself (this strategy has previously been used for developing a vaccine for Ebola virus).

<sup>&</sup>lt;sup>3</sup> https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html

<sup>&</sup>lt;sup>4</sup> https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/index.html

<sup>&</sup>lt;sup>5</sup> https://www.cdc.gov/vaccines/covid-19/hcp/mrna-vaccine-basics.html

Additional vaccines that are still in large-scale (Phase 3) clinical trials include those being developed by Novavax, Astra Zeneca, which utilize innovative nanoparticle and viral vector-based vaccine development technologies.

### • Will there be a choice on which vaccine to receive?

Given vaccines will be in limited supply in the near-term and vaccine administration will follow a specific prioritization based on CDC's recommendations, it is unlikely the public will be offered different options in the coming months. This situation is further exacerbated with stringent and varying storage conditions making it unlikely that two different vaccines are available in the same location. However, as the J&J vaccine does not require ultra-cold storage this might increase vaccine distribution and supply. We anticipate further changes as vaccine production ramps up.

• How many doses are needed for effectiveness? Are both doses required to achieve full immunity?

The approved vaccines require two doses, although the strength of dose and spacing period between the two does may vary for each type. Where two shots are required, both doses are needed to provide the best protection against COVID-19. The first dose primes the immune system, helping it recognize the virus and the second shot strengthens the immune response. Here is what we know:

- The Pfizer (mRNA-based) vaccine requires a second shot of the same strength after 21 days.
- The Moderna (mRNA-based) vaccine requires a second shot of the same strength after 28 days.
- $_{\odot}$  The advantage of the J&J vaccine is that only a single dose is administered.
- We know from the immunization scheduled for the Astra Zeneca vaccine used in other parts of the world that it will also require a second shot after one month.

# • Do both doses need to be the same vaccine type to achieve full immunity?

Yes, both doses of the same vaccine are required to achieve immunity. Vaccines may not be mixed across the administration regimen for an individual, meaning if you receive the Pfizer vaccine as your first dose, your second dose must also be the Pfizer vaccine. CDC and state and local health authorities are working to ensure people receive the same vaccine type across both doses. As pointed out above, other vaccines that are likely to be approved by FDA will require only one shot to achieve full immunity.

### • What is the duration of protection after vaccination?

It is too early to determine this information as data is still being collected on the extent to which protection will last after a vaccination.

## • Do individuals still need to mask and physically distance after vaccination?

As vaccination distribution ramps up, it is expected that it will take several months to immunize a reasonable proportion of the population to stop the spread of the virus. Therefore, even those individuals who have been vaccinated will need to wear masks and practice physical distancing, handwashing, and other hygiene measures. In addition, FDA's threshold used for approving the Moderna, Pfizer, and J&J vaccines was whether their products protect people from COVID-19 symptoms. FDA did not consider the question of whether the vaccines would prevent vaccinated individuals from spreading the virus to others. The concern therefore may be that even after an individual is vaccinated, there is the possibility that they may develop an asymptomatic infection (showing no symptoms) and thus despite immunization, may be able to shed the virus and infect others. Therefore, the scientific community needs to understand more about the protection that COVID-19 vaccines provide, before deciding on any modifications to existing public health recommendations pertaining to COVID-19 prevention and control.

# • Should someone who has previously had a COVID-19 infection be vaccinated?

Yes, COVID-19 vaccination should be offered to individuals regardless of whether they have already had COVID-19 infection. One should not be required to have an antibody test before you are vaccinated.

## • Should someone who is currently infected with COVID-19 be vaccinated?

Yes, anyone currently infected with COVID-19 should wait to get vaccinated until after their illness has resolved and after they have met the criteria to discontinue isolation.<sup>6</sup>

# • Should someone who previously tested positive for COVID-19 but was asymptomatic be vaccinated?

Yes, COVID-19 vaccination should be offered to individuals regardless of whether they have previously tested positive for COVID-19. One should not be required to have an antibody test before you are vaccinated.

<sup>&</sup>lt;sup>6</sup> https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-in-home-patients.html

## • What are the allergic reactions, side effects and long-term issues associated with COVID-19 vaccine?

### Allergic reactions

- Although rare, some allergic (anaphylactic) reactions have been reported following vaccination with mRNA-basedCOVID-19 vaccines. The most recent CDC monitoring data detected approximately 11.1 cases of anaphylaxis after administration per million vaccine doses and these reactions occurred within 15 min. of vaccination (hence it is recommended individuals wait for 15 min. after vaccination at the same location).<sup>7</sup>
- It is likely allergic reactions may result from any of the components of the mRNA COVID-19 vaccine. Persons with an immediate allergic reaction to the first dose of an mRNA COVID-19 vaccine should not receive additional doses of either of the mRNA COVID-19 vaccines.
- Individuals who are allergic to polyethylene glycol (PEG) or polysorbate should not get an mRNA COVID-19 vaccine.
- However, allergic reactions (including severe allergic reactions) not related to vaccines, injectable medications such as food, animals, venom, environmental or latex allergies may get vaccinated.
- In addition, as the mRNA COVID-19 vaccines do not contain eggs or gelatin, persons with allergies to these substances do not have a contraindication or precaution to vaccination. Additionally, vial stoppers used to store mRNA vaccines are not made with natural rubber latex.

### Side effects

- FDA will both intensely review safety data associated with the proposed vaccines and continue to monitor safety findings as vaccines are administered.
- Most importantly it is important to know that the vaccine cannot result in someone getting COVID-19.
- Most people do not have serious problems after vaccinations. However, arms may be sore, red, or warm to touch around the injection site.
- Some people report getting a headache after receiving a vaccine, however systemic adverse symptoms such as fatigue, muscle ache, headache, and chills are common.
- Fever is a potential side effect that may deem additional medical care.
- Any symptoms usually go away on their own within a week and in fact these side effects are a sign that your immune system is doing exactly what it is supposed to do as the body works to build up protection against COVID-19 disease.

<sup>&</sup>lt;sup>7</sup> https://www.cdc.gov/mmwr/volumes/70/wr/mm7002e1.htm?s\_cid=mm7002e1\_x

Potential long-term issues

- It is too early in the current vaccine administration phase to determine potential long-term effects.
- FDA and CDC will continue to monitor safety to identify and understand any long-term side effects and the ACIP will take action to address any detected safety problems.
- What if someone experiences a bad reaction after receiving the COVID-19 vaccine?
  - CDC and FDA encourage the public to report possible side effects to the Vaccine Adverse Event Reporting System (VAERS).<sup>8</sup>
  - CDC is also implementing a new smartphone-based tool called v-safe to keep track individual's health after they receive the COVID-19 vaccine.<sup>9</sup>
- Can someone who has received a COVID-19 vaccine test positive for COVID-19 on a viral test

No, none of the approved vaccines or other vaccines still in clinical trial in the United States can cause you to test positive on viral tests that are used to determine if you have a current infection. However, someone who is vaccinated today but may have been exposed to the virus immediately prior to or after the vaccinations (within 3-5 days) can test positive for COVID-19. It usually takes two weeks after the second dose to be fully immunized. Although these vaccines are highly effective, some individuals may not respond to the vaccine as expected and still be at risk for infection.

• Are all the approved vaccines also effective in immunizing individuals against the new United Kingdom (UK) variant of SARS-CoV-2?

Yes, all the vaccine providers have reiterated the approved vaccines appear to be effective against the new UK variant of SARS-CoV-2. The new UK variant has demonstrated to be more transmissible than the original pandemic strain and this is attributed to the virus' spike protein ability to attach better to host cells; however, it is not more virulent than the original pandemic strain and does not result in a more severe infection. The approved vaccines also appear to be effective against the other new variants that have arisen, for example in South Africa, Brazil, and Japan.

• Is there more information on questions about vaccine development, safety, immunity, etc.?

<sup>&</sup>lt;sup>8</sup> https://vaers.hhs.gov/reportevent.html

<sup>&</sup>lt;sup>9</sup> https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html

- Natural infection versus vaccine-derived immunity:
  - COVID-19 infections can manifest itself with only mild symptoms in some people, thereby lending itself to the public's notion that natural infection may be preferable to receiving a new vaccine.
  - There is still the potential for COVID-19 infections to cause serious disease and the risk of spreading to others that vaccines can help avoid. There also can be long-term health issues after recovery from COVID-19 disease.
  - The fact remains that scientists are still learning more about SARS-CoV-2 and it is not known whether getting COVID-19 disease will protect everyone against getting it again, or if it does, how long that protection might last. A recent study in the UK found that a natural COVID-19 infection provides some immunity for at least 5 months, but infected individuals may still carry and transmit the virus.
  - Both virus, SARS-CoV-2 and the disease, COVID-19, are all new. We do not know how long protection lasts for those who get infected or those who are vaccinated. And given what we know that COVID-19 is a serious illness and may result in death for many, and that we risk infecting others who may also get very sick or become debilitated for many months, getting the COVID-19 vaccine is a safer choice!

### **External Resources**

- The American Frozen Food Institute (AFFI) formally supports the <u>COVID-19</u> <u>Vaccine Education and Equity Project</u> to assist our essential workforce in educating a variety of critical audiences about the process and science related to the development and safety of COVID-19 vaccines.
- CDC: <u>Clinical Resources for Each COVID-19 Vaccine</u>
- CDC: <u>COVID-19 Vaccination Program Playbook</u>
- FDA: <u>COVID-19 Communication Toolkits</u>
- FDA: Portal for COVID-19 Vaccine News, Updates and Guidance