

FAQ on Covid-19 Vaccination

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This FAQ will be updated as more information about Covid-19 vaccination emerges.

TABLE OF CONTENTS

What vaccine is currently available? WITH UPDATE ON THE J&J VACCINE

What is NUHW's recommendation on vaccination?

What is the process through which vaccines are studied and approved?

When will healthcare workers have access to a vaccine?

When will the rest of the population have access to a vaccine?

Is Covid-19 vaccination effective?

Is Covid-19 vaccination safe?

What are the side effects of the vaccine?

Has Covid-19 vaccination been studied during pregnancy or while people are nursing?

Has Covid-19 vaccination been studied in immunocompromised patients?

Can children get the vaccine?

What if I have had an allergic reaction to a vaccine or injectable drug in the past?

How does the vaccine work?

Can the vaccine give me Covid-19?

How many doses of the vaccine do I need?

Do I need to take both doses of the vaccine?

How soon after I get my vaccine does it start to be effective?

How long does protection against symptomatic infection from vaccination last?

Does vaccination mean I will not spread the virus?

Does vaccination mean we can stop masking and social distancing?

Does vaccination mean I don't need to wear PPE?

Why should I get the vaccine if I am young and healthy?

Will the Covid-19 vaccine cause me to test positive on Covid-19 viral tests?

What about vaccination in people who have already been infected with Covid-19?

What about getting the Covid-19 vaccine at the same time as other vaccines?

Can my employer require me to be vaccinated?

Will I have to pay for the vaccine?

Who was studied in the Pfizer and Moderna trials?

What if I want more information about Covid-19 vaccination?

Other resources to learn more about the vaccine

What vaccine is currently available?

On December 11, 2020 the FDA issued an Emergency Use Authorization (EUA) for Pfizer-BioNTech's Covid-19 vaccine. The vaccine can be used in people age 12 and older. (See below questions on specific populations like pregnant, nursing, or immunocompromised individuals as well as those with a history of severe allergic reaction to a vaccine or injectable drug.)

On December 18, 2020 the FDA issued an Emergency Use Authorization (EUA) for Moderna's Covid-19 vaccine. The vaccine can be used in people age 18 and older. (See below questions on specific populations like pregnant, nursing, or immunocompromised individuals as well as those with a history of severe allergic reaction to a vaccine or injectable drug.)

Johnson & Johnson Vaccine:

*****April 30, 2021 Update:

After placing a pause on the administration of the Janssen (Johnson & Johnson) vaccine to investigate reports of a very rare adverse event, the CDC and FDA have recommended to resume its administration stating they, "have confidence that this vaccine is safe and effective in preventing COVID-19." Please see the CDC for more information on the resumption of the vaccine. Please also see the CDC for updated "considerations for use of the Janssen COVID-19 vaccine in certain populations" including women under age 50.

On February 27, 2021 the FDA issued an EUA for the Johnson & Johnson vaccine. The vaccine is authorized in individuals ages 18 years and older. It is an adenovirus vaccine which uses an adenovirus vector to deliver genes that produce the SARS-CoV-2 spike protein. In response, our body mounts an immune response. The modified adenovirus in the J&J vaccine can enter cells but it can not replicate inside cells or cause illness. For more on how the J&J vaccine works see here.

In J&J's clinical trial (see <u>FDA press release</u> here), "overall the vaccine was approximately 67% effective in preventing moderate to severe/critical COVID-19 occurring at least 14 days after vaccination and 66% effective in preventing moderate to severe/critical COVID-19 occurring at least 28 days after vaccination. Additionally, the vaccine was approximately 77% effective in preventing severe/critical COVID-19 occurring at least 14 days after vaccination and 85% effective in preventing severe/critical COVID-19 occurring at least 28 days after vaccination." In the US specifically, the vaccine's efficacy against laboratory-confirmed moderate-to-severe/critical Covid-19 was 72% after at least 14 days post-vaccination. The vaccine showed 100% efficacy against death.

Unlike the Pfizer and Moderna vaccines, the J&J vaccine only requires a single dose. It can be stored at normal refrigerator temperatures.

There were no significant safety issues during the J&J trial, in which a racially diverse group of nearly 22,000 people received the vaccine. Some people vaccinated experienced mild side effects like pain at the injection site, fatigue, muscle aches, headache, and nausea which lasted one to two days.

What is NUHW's recommendation on vaccination?

NUHW recommends vaccination to prevent healthcare workers from getting sick with Covid-19, which can cause severe illness and has killed hundreds of thousands of people in the US including over <u>2,900 healthcare workers</u> (as of 12/23/2020). NUHW stands with medical professionals and public health experts across the country who are encouraging vaccination as a safe and effective way to protect people from Covid-19 and save countless lives.

What is the process through which vaccines are studied and approved?

During a public health emergency, the FDA can provide Emergency Use Authorization (EUA) for vaccines. To obtain EUA, a vaccine must go through three stages of rigorous clinical trials using tens of thousands of study participants. In Phase 1, the vaccine is given to a small number of generally healthy people to assess its safety. In absence of safety concerns, Phase 2 studies include more people and studies various doses and varying health statuses and different demographic groups in randomized controlled studies. In Phase 3, the vaccine is administered to thousands of people in randomized controlled studies in order to evaluate effectiveness and safety. (See the FDA's explainer on EUAs) Vaccine safety and efficacy data is reviewed by the FDA's Vaccines and Related Biological Products Advisory Committee which approves EUA requests. The CDC's Advisory Committee on Immunization Practices (ACIP) then makes

recommendations about a vaccine's use for different populations. California then provides another layer of safety review through the <u>Western States Scientific Safety Review Workgroup</u> which is made up of immunization, public health, academic and other subject matter experts.

What is an Emergency Use Authorization (EUA)?

An EUA is a mechanism for the FDA to facilitate the availability of medical products including drugs, vaccines or medical devices which respond to public health emergencies including pandemics. The <u>FDA assesses an EUA request</u> using a risk-benefit analysis, where the known and potential benefits of the product must outweigh the known and potential risks of the product. EUA is not the same as FDA licensure.

When will healthcare workers have access to a vaccine?

Healthcare workers are in the top priority group to receive the vaccine and will be the first members of the US population to be vaccinated. Many healthcare workers got access to the vaccinate in the last two weeks of December. Initially, while vaccine supplies are limited, healthcare workers in the highest risk settings (acute care hospitals, skilled nursing facilities, correctional facility hospitals) may get access before other health care workers (for example in outpatient settings). Local health departments will allocate limited supplies to providers based on CDPH guidance. Given initial limited supply, not all healthcare workers will be vaccinated before the end of the year and vaccination will continue in 2021.

If you are a healthcare worker, your employer will be offering on-the-job vaccination.

When will the rest of the population have access to a vaccine?

Due to limited supply of vaccine doses over the next few months, the federal government and states will be prioritizing vaccination to certain groups.

Each state is charged with developing its vaccine rollout plan. In California and Hawaii, the residents of long-term care facility residents (skilled nursing facilities, assisted living facilities, and similar settings for older or medically vulnerable individuals) are also in the first priority group, along with healthcare workers.

After healthcare workers and long-term care residents, the vaccine is likely to be given to other essential workers (teachers, police and firefighters, agricultural and food service workers etc.) and individuals over age 65 and with underlying medical conditions that put them at risk for serious illness from Covid-19. Vaccine supply to cover the rest of the adult population is unlikely to be available until spring or summer of 2021.

Is Covid-19 vaccination effective?

Both the Pfizer and Moderna vaccine trials have demonstrated that vaccination is very effective at preventing people from getting sick with Covid-19.

<u>Pfizer</u> enrolled close to 44,000 participants in its Phase 3 Trial. It has reported that its vaccine is 95% effective at preventing symptomatic Covid-19 infection (170 confirmed cases of Covid-19 were evaluated, with 162 observed in the placebo group versus 8 in the vaccine group). Pfizer reported that of the 10 severe cases of Covid-19 observed in the trial, nine occurred in the placebo group and only one in the vaccine group.

Moderna enrolled over 30,000 participants in its Phase 3 Trial. It has reported that its vaccine is 94.5% effective at preventing symptomatic Covid-19 infection (out of 95 cases of symptomatic Covid-19 infection, 90 cases of Covid-19 were observed in the placebo group versus 5 cases in the vaccine group). Moderna also noted that of the 11 severe cases in study participants, all occurred in the placebo group.

Neither vaccine trial indicates whether vaccination protects against asymptomatic infection or prevents transmission. Vaccinated individuals may still be susceptible to asymptomatic infection and spreading the virus. (Also see question on transmission below.)

Is Covid-19 vaccination safe?

Experts in the public health community are recommending vaccination as a safe way to protect people from Covid-19, which can cause severe illness and death.

Both Pfizer and Moderna vaccines went through all the normal safety and efficacy trials (Phase 1-3 clinical trials) as other vaccines and drugs are required to go through. Both companies were required to submit safety and efficacy data for two months following the second dose of the vaccine. Neither company reported any serious safety concerns. Pfizer and Moderna as well as the FDA will continue to follow safety and efficacy over the next two years.

What are the side effects of the vaccine?

<u>Pfizer</u> reported side effects were mostly mild to moderate including pain, redness, and swelling at the injection site as well as fever, headache, and muscle aches. <u>Moderna</u> reported similar side effects. These side effects are an expected part of the body's building of immunity in response to vaccination.

Although the vaccine did not result in any serious safety concerns, fever, headache, muscle aches or other flu-like symptoms could be disruptive for one to three days, more commonly after the second dose. This may require some people to take off a day from work. It is NUHW's position that employees who have vaccine side effects that require them to take time off from work should receive additional PTO from their employer to do so.

As in the case of any vaccine, federal law requires that you be provided with an informational flyer about the vaccine, including potential side effects, at the time of vaccination.

If you have more questions about potential vaccine side effects, we encourage you to reach out to your primary care provider.

Has Covid-19 vaccination been studied during pregnancy or while people are nursing?

No. Pregnant and nursing people were excluded from the vaccine trials. Pregnant or nursing people should consult their medical provider about vaccination. Please also see the CDC's guidance on mRNA vaccines.

Has Covid-19 vaccination been studied in immunocompromised patients?

No. Immunocompromised patients were excluded from the vaccine trials. Immunocompromised people should consult their medical provider about vaccination. Please also see the CDC's guidance on mRNA vaccines.

Can children get the vaccine?

On May 10, 2021 the <u>FDA</u> expanded the emergency use authorization for the Pfizer vaccine to include anyone age 12 years and up. More studies (including by Moderna) on vaccination in the child and adolescent population are also underway.

What if I have had an allergic reaction to a vaccine or injectable drug in the past?

If you have had an allergic reaction to a vaccine or injectable drug in the past, please see the CDC's guidance entitled "COVID-19 Vaccines and Allergic Reactions" and consult with your medical provider.

How does the vaccine work?

Both the Pfizer and Moderna vaccines are messenger RNA (mRNA) based. With this vaccine technology, vaccination causes our cells to produce a protein that triggers the body to generate an immune response that will later help fight against Covid-19 infection. The vaccination does not involve the injection of actual weakened or inactivated virus. Instead, nothing about the injection is potentially or even theoretically infectious. Moreover, the mRNA from a Covid-19 vaccine never enters the nucleus of the cell, which is where your own DNA resides. So the mRNA does not affect or interact with your DNA in any way. The CDC has a helpful explanation of mRNA vaccination here.

Can the vaccine give me Covid-19?

No. It is not possible for the vaccine to infect you with Covid-19 (see above question on how the vaccine works). Some people may experience mild to moderate side effects from the vaccine but this does not mean vaccination has made you sick with Covid-19. Vaccination cannot make you sick with Covid-19.

How many doses of the vaccine do I need?

Both the Pfizer and Moderna vaccines are two-dose vaccines. They are both administered by an intramuscular injection (like the flu shot). The two doses of the Pfizer vaccine are given 21 days apart and the two doses of the Moderna vaccine are given 28 days apart. Individuals cannot mix and match the vaccines. (i.e. dose one and dose two must be with the same vaccine maker).

Do I need to take both doses of the vaccine?

Yes. If a vaccine is a two-dose vaccine, you need to receive both doses for the vaccine to be maximally effective. It is important that you complete your second vaccine dose on the date you are instructed to by your employee health department or the healthcare provider who administers your vaccine.

How soon after I get my vaccine does it start to be effective?

Pfizer reported that 95% efficacy at preventing symptomatic infection was observed seven or more days after administration of the second dose. Far less efficacy was seen after only the first dose which is why it's so important to complete both doses. Additionally, even when people are vaccinated they must continue to socially distance, wear PPE, mask in public, and engage in all other infection control practices.

How long does protection against symptomatic infection from vaccination last?

The scientific community does not yet know how long protection against symptomatic infection resulting from vaccination may last. Currently, we only have two months worth of clinical efficacy data on the Pfizer and Monderna vaccines. In other words, we know nothing about longer-term vaccine performance. More of that information will likely be forthcoming as drug companies are required to continue to monitor safety and efficacy over the next two years. If immunity is not life-long, like for other common vaccines (flu and tetanus for example), it may be that people will need booster vaccinations after their initial round of vaccine doses.

Does vaccination mean I will not spread the virus?

Neither Pfizer nor Moderna studied whether the vaccines prevent transmission of the virus after individuals are vaccinated. The studies only looked at prevention of symptomatic infection. In other words, it is still unknown whether vaccination prevents asymptomatic infection or means you will not spread Covid-19. This is a really key point because it means that efforts to decrease spread like public masking and social distancing must continue. Moreover, due to initial limited supply of vaccine doses, it will likely take several months for most of the population to have access to the vaccine making continuation of infection control practices essential.

Does vaccination mean we can stop masking and social distancing?

No. Vaccination is not a replacement for wearing a mask in public, social distancing, avoiding indoor social gatherings and all the other recommendations coming from the public health community to reduce the spread of Covid-19.

Does vaccination mean I don't need to wear PPE?

No. Wearing the appropriate PPE at work will continue to be essential as well as other infection control protocols like social distancing in the workplace, universal masking, and cohorting of patients.

Why should I get the vaccine if I am young and healthy?

While severe illness from Covid-19 is less common in younger people, Covid-19 has killed or caused serious illness in many young individuals. In <u>one study</u> of over 3,000 people ages 18 to 34 who were hospitalized for Covid-19, 21 percent required intensive care and 2.7 percent died. In contrast to these severe potential outcomes from Covid-19 infection, the Pfizer and Moderna vaccine trials found no serious safety concerns.

Will the Covid-19 vaccine cause me to test positive on Covid-19 viral tests?

No. The Pfizer and Moderna vaccines do not cause individuals to test positive on a viral test for Covid-19 infection.

However, vaccination is intended to trigger an immune response, which may mean you could test positive on a serology/antibody test which is used to test for previous infection (i.e. to see if you were infected with Covid-19 in the past). Research is underway as to whether vaccination will indeed impact antibody testing results.

What about vaccination in people who have already been infected with Covid-19?

The CDC recommends vaccination for people with a history of past infection with Covid-19 although people who currently have an active Covid-19 infection should delay vaccination until they have completely recovered and completed a period of home isolation. The CDC guidance states:

"Vaccination of persons with known current SARS-CoV-2 infection should be deferred until the person has recovered from the acute illness (if the person had symptoms) and criteria have been met for them to discontinue isolation. This recommendation applies to persons who develop SARS-CoV-2 infection before receiving any vaccine doses as well as those who develop SARS-CoV-2 infection after the first dose but before receipt of the second dose. While there is otherwise no recommended minimum interval between infection and vaccination, current evidence suggests that reinfection is uncommon in the 90 days after initial infection. Thus, persons with documented acute SARS-CoV-2 infection in the preceding 90 days may delay vaccination until near the end of this period, if desired."

What about getting the Covid-19 vaccine at the same time as other vaccines?

The <u>CDC recommends</u> that mRNA Covid-19 vaccines (like the Pfizer and Moderna vaccine) be separated from other vaccines by 14 days. The CDC states: "Given the lack of data on the safety and efficacy of mRNA COVID-19 vaccines administered simultaneously with other vaccines, the vaccine series should be administered alone, with a minimum interval of 14 days before or after administration with any other vaccines. If mRNA COVID-19 vaccines are inadvertently administered within 14 days of another vaccine, doses do not need to be repeated for either vaccine."

Can my employer require me to be vaccinated?

FDA-licensed products, like the seasonal flu vaccine, can be required by employers, subject to reasonable accommodations. The Federal Food, Drug and Cosmetic Act, which allows for Emergency Use Authorization, requires that EUA vaccine recipients are informed that they have the option to accept or refuse any EUA product. (See Federal Food, Drug and Cosmetic Act, Section 564(e)(1)(A)(ii)), and in FDA EUA Guidance, pg 23: Emergency Use Authorization of Medical Products (fda.gov). The California and Federal vaccine rollout plans do not make vaccination mandatory. Many private employers are not mandating but are recommending vaccination. NUHW will continue to monitor this issue.

Will I have to pay for the vaccine?

<u>US Centers for Medicare and Medicaid Services (CMS)</u> has said that all Americans will have access to the vaccine at no cost. Providers can charge an administrative fee for delivering the shot which will be billed to your health insurance, which is required to cover a Covid-19 vaccine. (See the CDC's <u>FAQ on Vaccination</u>.)

Who was studied in the Pfizer and Moderna trials?

Pfizer: Please see <u>Pfizer's trial data</u> for more information on the trial participants. Here are some of the demographic points reported:

- Trial enrolled over 43,000 participants age 16 and over (37,706 participants had a median of at least 2 months of safety data available after the second dose)
- 42% over age 5
- Hispanic and Latinx 28%
- Black or African American 9.3%
- Asian 4.3%
- Native American or Alaska Native 0.5%
- Native Hawaiian or other Pacific Islander 0.2%
- Multiracial 2.3%

Moderna: Please see the <u>FDA's Review of Moderna's EUA</u> request for more information on the trial participants. Here are some of the demographic points reported:

- Trial enrolled over 30,000 participants age 18 and older
- 25.3% of trial participants over the age of 65
- Over 4,000 Americans who are under the age of 65 but have high-risk chronic diseases that increase the risk of severe Covid-19
- Hispanic and Latinx 20%
- Black or African American 9.7%
- Asian 4.7%
- Native American or Alaska Native 0.8%
- Native Hawaiian or other Pacific Islander 0.2%

What if I want more information about Covid-19 vaccination?

Your primary healthcare provider can answer more specific questions about vaccination you may have.

Other resources to learn more about the vaccine:

- CDC's FAQ on Vaccination
- CDC's Page on Understanding mRNA Vaccines
- California Government's Vaccine Page
- Hawaii Government's Covid-19 Page