

## COVID-19 Pandemic: Frequently Asked Questions

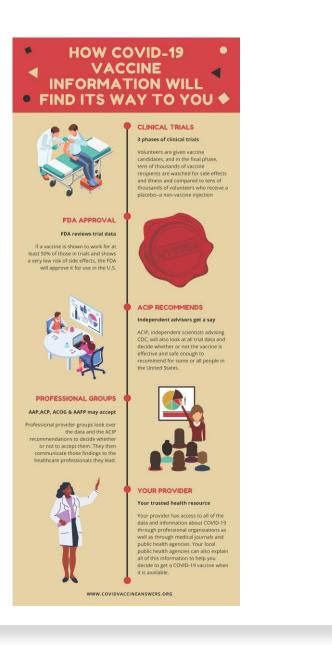


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## Can you explain the approval process that the vaccines have undergone?

Please see the following link below about the vaccine approval process:

https://www.state.nj.us/health/cd/documen ts/topics/NCOV/vaccine\_approval\_process\_a stho.pdf



What are the side effects of the vaccine? (short term and long term)

#### **Side Effects from Vaccination**

- Most individuals will have to wait 15 minutes after vaccination for observation. Those with a history of severe allergic reaction will have to wait a minimum of 30 minutes.
- Most individuals experience little to no side effects after the initial dose. More individuals report side effects after the second dose. Most side effects last only 24-48 hours post vaccination.
- Typical side effects include:
  - Sore Arm
  - Headache
  - Muscle Aches
  - Fever
  - Nausea/Upset Stomach

Long term effects are still unknown and being studied.

# What are the ingredients (active and inactive) of the vaccine?

The ingredients in currently available mRNA COVID-19 vaccines include: mRNA, lipids, salts, sugars, buffers (which help maintain the stability of the pH solution)

The ingredients in the currently available viral vector COVID-19 vaccine include: genetically modified virus (adenovirus type 26), lipids, salts, sugars, buffers (which help maintain the stability of the pH solution)

Vaccine ingredients can vary by manufacturer. The available COVID-19 vaccines **DO NOT** contain human cells, fetal cells, animal by-products, eggs, preservatives, aluminum or latex.

• To learn more about the ingredients in authorized COVID-19 vaccines, see:

Pfizer Emergency Use Authorization Sheet

Moderna Emergency Use Authorization Sheet

Janssen Emergency Use Authorization Sheet

# After the second dose, how many times will the public have to take the vaccine?

#### **Vaccination Protection**

- Most of the vaccines are **2 doses**, 3-4 weeks apart
- Protection occurs 1-2 weeks after the second dose
- We will most likely not know how long the vaccine will be protective once we receive it. We will know more as more time passes in the current research
- May need to have vaccine shots for COVID-19 on a regular basis (like the flu shot)

#### **Second Dose Information**

- YOU MUST GET THE SECOND DOSE because the vaccine will not protect you if only get one dose
- It is important to get the SAME VACCINE as the first dose

Can you explain the implications of "herd immunity" for people who will receive the vaccine and for those who will not?

Herd immunity means that enough people in a community are protected from getting a disease because they've already had the disease or because they've vaccinated.

Herd immunity makes it hard for the disease to spread from person to person, and even protects those who cannot be vaccinated, like newborns or people who are allergic to the vaccine.

At this time, we do not know how long someone can be protected after having COVID-19. Some research suggests potential immunity for up to 90 days; however, more research is needed to determine how long natural immunity lasts. We do know that immunity from the vaccine lasts longer than that of natural immunity.

Herd Immunity? a workshop by the CDC

Herd immunity and COVID-19: what you need to know

What is the difference between the 2 round vaccinations and the 1 round? The currently authorized vaccines to prevent COVID-19 in the United States require two shots to get the most protection. Janssen (Johnson & Johnson) only requires one shot.

Pfizer doses should be given three weeks (21 days) apart

https://www.cdc.gov/coronavirus/2019ncov/vaccines/different-vaccines/Pfizer-BioNTech.html

• Moderna doses should be given one month (28 days) apart-

https://www.cdc.gov/coronavirus/2019ncov/vaccines/different-vaccines/Moderna.html

• Janssen vaccine is a single dose shot

https://www.cdc.gov/vaccines/covid-19/info-byproduct/janssen/index.html Why do people in the high-risk category have to wait so long to receive the vaccine?

U.S. supply of the COVID-19 vaccine is limited right now. CDC has recommended that initial supplies of the COVID-19 vaccine be allocated to healthcare personnel and longterm care facility residents because they are at highest risk.

https://www.cdc.gov/coronavirus/2019ncov/vaccines/recommendations/hcp.html

https://www.cdc.gov/coronavirus/2019ncov/vaccines/recommendations/LTCF-residents.html

As vaccine availability increases, more people in Phases 1a, 1b, and 1c will receive the vaccine. And as vaccine availability increases, vaccination recommendations will expand to include more groups.

https://www.cdc.gov/coronavirus/2019ncov/vaccines/recommendations/specific-groups.html

#### How effective are the vaccines against the virus?

Pfizer is 95% effective

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/Pfizer-BioNTech.html

Moderna is 94.1% effective

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/Pfizer-BioNTech.html

Janssen is 72% effective

https://www.cdc.gov/vaccines/covid-19/info-by-product/janssen/index.html

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How effective are the vaccines against all the new variants that are being discovered?  Both Moderna and Pfizer have published statements that their vaccines are effective against B.1.1.7 (Known as the U.K Variant) and B.1.351 (The South African Variant). However, more research has to be done.

https://investors.modernatx.com/newsreleases/news-release-details/moderna-covid-19-vaccine-retains-neutralizing-activity-against

https://www.pfizer.com/news/pressrelease/press-release-detail/vitro-studiesdemonstrate-pfizer-and-biontech-covid-19 What is the likelihood of you contracting the virus once you receive the vaccine vs. not receiving the vaccine?

- The currently approved mRNA and viral vector COVID-19 vaccines are very effective in protecting against COVID-19. In the event that you are exposed and infected with COVID-19 the vaccines will help to prevent you from becoming severely ill, hospitalized or dying from the virus.
- The likelihood of contracting COVID-19 once you receive the vaccine is far less than not receiving the vaccine. Although wearing masks, washing hands frequently and social distancing offer protection against COVID-19, the vaccine offers much more protection.

https://www.cdc.gov/coronavirus/2019ncov/vaccines/vaccine-benefits.html

https://www.cdc.gov/coronavirus/2019-ncov/symptomstesting/symptoms.html#seek-medical-attention Have they identified what may be causing the reactions in people with no known/ documented allergies?

- Anyone who is allergic to PEG (also known as polyethylene glycol or polysorbate) has been linked to having a reaction to the vaccines.
  People who are allergic to PEG or polysorbate should not get an mRNA or viral vector COVID-19 vaccine.
- Polysorbate (PEG) is not an ingredient in either mRNA COVID-19 vaccine but is closely related to PEG, which is in the vaccines.
- PEG IS an ingredient in the viral vector COVID-19 vaccine.

https://www.cdc.gov/coronavirus/2019ncov/vaccines/safety/allergicreaction.html#:~:text=If%20you%20have%20had% 20a,not%20get%20the%20second%20dose What are some of the more severe side effects of each vaccine since there are now three companies supplying the vaccine?

 The CDC has learned of reports that some people have experienced severe allergic reactions – also known as anaphylaxis- after getting a COVID-19 vaccine. For example, an allergic reaction is considered severe when a person needs to be treated with epinephrine or EpiPen or go to the hospital.

> https://www.cdc.gov/coronavirus/2019ncov/vaccines/faq.html

• For more information about COVID-19 Vaccines and Allergic Reactions, go to

https://www.cdc.gov/coronavirus/2019ncov/vaccines/safety/allergic-reaction.html

## How safe is the COVID-19 Vaccine AstraZeneca?

Published on March 14, 2021-

https://www.astrazeneca.com/medi a-centre/pressreleases/2021/update-on-the-safetyof-covid-19-vaccineastrazeneca.html If new variants of the virus are being discovered, could that make the vaccine more like a flu shot vs. a one-time needed vaccination?

For example, would you have to receive a new vaccine yearly for the major strains from the year prior? Pharmaceutical companies are currently making upgraded versions of the vaccine to offer additional protection against variants. Vaccination providers can give a booster shots that are specific against specifics variant. A variant booster shot may need to be administered within a year or two. Researchers are not sure but have started to prepare for this possible outcome.

Based on COVID Collaborative's Fireside Chat with Dr. Fauci held on 2/9/21.

https://www.youtube.com/results?search\_query=COVID+ Collaborative%E2%80%99s+Fireside+Chat+with+Dr.+Fauci

#### What if immunocompromised individuals cannot receive the vaccine?

Currently, data is not available to establish safety and efficacy within these groups. These individuals may still receive the COVID-19 vaccine unless it is determined by a primary care doctor that it may be harmful.

However, these individuals should be counseled about:

 Unknown vaccine safety and efficacy profiles in immunocompromised persons

– Potential for reduced immune responses

 Need to continue to follow all current guidance to protect themselves against COVID-19

https://www.cdc.gov/coronavirus/2019-ncov/need-extraprecautions/people-with-medical-conditions.html

Note: People living with HIV were included in clinical trials

Although people who have autoimmune conditions were eligible for enrollment in clinical trials, there none who were participated in the clinical trials Why is it that there is speculation that my employer can terminate my job if I do not receive the vaccine?

• There is no mandate in the State of New Jersey that an individual must get vaccinated.

https://nj1015.com/proposed-nj-law-blocksgovernment-from-mandating-covid-vaccine/

• This is variable with each employer and industries, please check with your employer for further details. Please see the following link below from the New Jersey Department of Labor and Workforce Development page on Workers Benefits, Protections and the Coronavirus (COVID-19)

https://www.nj.gov/labor/workerprotections/earnedsick/covid.shtml

#### How is exposing protected health information to third parties under HIPPA acceptable?

• The vaccination provider may include your vaccination information in your state/local jurisdiction's Immunization Information System (IIS) or other designated systems. This will ensure that you receive the same vaccine when you return for the second dose. For more information about IIS

https://www.cdc.gov/vaccines/programs/iis/ab out.html Should I get the vaccine even if I have had COVID-19 before?

No. People with COVID-19 who have symptoms should wait to be vaccinated until they have recovered from their illness and have met the <u>criteria</u> for discontinuing isolation; those without symptoms should also wait until they <u>meet the criteria</u> before getting vaccinated. This guidance also applies to people who get COVID-19 before getting their second dose of vaccine.

https://www.cdc.gov/coronavirus/2019ncov/vaccines/faq.html What are some of the recorded side effects of the 2<sup>nd</sup> dose of these vaccines?

- injection site reactions
- fatigue
- headache
- muscle pain
- chills
- joint pain and
- fever

The VAERS (Vaccine Adverse Event Reporting System) data is available to the public and can be downloaded at <u>https://vaers.hhs.gov/data/index</u> or searched at <u>http://wonder.cdc.gov/vaers.html</u>.

	Pfizer (BNT162b2)	Moderna (mRNA- 1273)
Number of people enrolled	Over 40,000	Over 25,000
Race and ethnicity of participants	Total 30% racially diverse 10% black, 13% Hispanic	37% racially diverse 10% black, 20% Hispanic/Latino
Older adults	45% were 56-85 years	23% were >65 years

#### ARE THE COVID-19 VACCINES SAFE?

- Safety is the most important priority in vaccine approval
- Most side effects occur within 6 weeks of vaccination. To be more cautious, the FDA (Food and Drug Administration) requires 8 weeks of safety monitoring of the COVID-19 vaccines
- Monitoring for safety will continue as the vaccine is distributed to the public
- To assess safety FDA typically advises that a minimum of 3,000 participants are included in the trial. The current COVID-19 vaccine trials include 30,000 to 50,000 participants

#### **Clinical Trials**

	Janssen (JNJ-78436735)
Number of people enrolled	Over 40,000
Race and ethnicity of Participants	Very racially diverse 19.4% black, 45.3% Latino
Older adults	30% were > 60

There is a huge concern about the vaccine for people of color- can you please talk more about the safety related measures in the clinical trials?

Last updated 03/26/2021

#### Great conferences that have happened recently and the link to the recordings

#### Black Doctors.ORG YouTube Page

WHYY News - The Trust Factor: Vaccines and Communities | Facebook

New Jersey Department of Health YouTube Page

Saving Lives with the COVID-19 Vaccine in the NJ Latinx Communities

Saving Lives with the COVID-19 Vaccine in the NJ Black and Caribbean Communities

How the Johnson and Johnson Vaccine Works, New York Times

CDC's Frequently Asked Questions about COVID-19 Vaccination Page



As of February 8th, 2021

COVID 19 Briefing, Commissioner Judy Persichilli, Department of Health https://youtu.be/t\_ZJrLZKWmk?t=1505

Can the COVID vaccine give you COVID-19?

The vaccines cannot cause infection with COVID 19. In fact, the two current vaccines do not contain any live virus or attenuated virus.

> https://www.youtube.com/watch?v= KMc3vL\_MIeo

## Will the Vaccines that we have currently work against the new variants?

In most cases, yes, they have been found to be very good at stopping severe illness, hospitalization, and death. However, Oxford University said over the weekend, the early data from a small study suggested that the AstraZeneca vaccine, which is not authorized in the united states yet, only offers only minimal protection against the mild disease caused by the South African B-1.351 Variant. The lead researcher for that vaccine manufacturer said that on Sunday that they expect by fall to have a modified vaccine to deal with the South African variant.

https://www.bbc.com/news/uk-55967767

#### Should Pregnant women get vaccinated?

The CDC and the advisory committee on immunization practices recommend that women talk to their health care provider about whether they should get vaccinated. When making a decision, pregnant people, pregnant women, and their health care providers should consider the level of covid 19 community transmission. They should also consider the patient's personal risk of contracting covid 19 and the risks of covid 19 not only to the woman but the potential risk to the fetus. And any additional considerations are the efficacy of the vaccine and the side effects of the vaccine. Based on current knowledge, experts believe that the mRNA vaccines (Moderna and Pfizer) are unlikely to pose a risk to pregnant women or their fetuses. However, the potential risks of the mRNA vaccines to the pregnant woman and the fetus are unknown because these vaccines really have not been studied in pregnant women.

> https://www.cdc.gov/coronavirus/2019ncov/vaccines/recommendations/pregnancy.html

# Are the two different vaccines interchangeable?

COVID-19 vaccines are not interchangeable with each other or with other COVID-19 vaccine products. The safety and efficacy of a mixed product series have not been evaluated. Both doses of the series should be completed with the same product.

<u>https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#:~:text=Either%20of%20the%20currently%20authorized,other%20COVID%2D19%20vaccine%20products</u>.

#### Why isn't there more vaccine?

It takes time to produce vaccines, and the production capacity of both Pfizer and Moderna vaccines is increasing slowly. It's great news that we are closer to having an additional vaccine to product the state now that J&J submitted its application to the FDA on Thursday night. The FDA is scheduled to review the candidate's clinical trial data on February 26<sup>th</sup>. Johnson and Johnson has said it hopes to provide the fed gov with 1mill doses by April. The J&J vaccine is one shot and doesn't require ultra-cold storage. What are the advantages of that vaccine? Well, there is an advantage of only having to get one shot. It will be mobile, the vaccine will travel better, and in fact, it will travel so well it will be easier to deploy the vaccine closer to where individuals live.

https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-announcesadvisory-committee-meeting-discuss-janssen-biotech-incs

## If I get vaccinated, do I still need to wear a mask or face covering?

 Yes, you will still need to wear a mask and follow all safeguarding methods until enough individuals are vaccinated to produce community protection. We know that the vaccine keeps you from getting sick, but we don't know yet if the vaccine prevents a person from contracting the virus and then spreading the virus.

https://www.cdc.gov/coronavirus/2019ncov/vaccines/faq.html#:~:text=Do%20I%20need%20to%20wear,virus %20that%20causes%20COVID%2D19.

#### When will there be more visitation at long term care facilities?

We recognize the physical separation from family and, other loved ones have taken a significant toll on our nursing home residents. We are still concerned that our long-term care facilities are still experiencing outbreaks. In fact, there are 417 active outbreaks as we sit here today. According to the Centers for Medicare and Medicaid Services, visitation is tied to the levels of spread in the community. The department has released a directive on the phased and reopening of facilities that is based on the outbreak status of the facility, its ability to meet criteria not limited to;

- testing of staff in resident,
- infection control protocols,
- adequate staffing,
- and personal protective equipment

is tied to the timing of the states reopening plans. However- end of life visits, compassionate care visits, and essential caregiver visits continue. We hope as more people get vaccinated, the spread of the virus in the community will lessen and that it will also lessen in our facilities. It is also vital that health care workers in long-term care facilities also get vaccinated. As we know, this is one way that the virus enters these long-term care facilities in time. Safe visitation will be restored.

https://www.cms.gov/files/document/covid-flexibility-reopen-essential-non-covid-services.pdf

### Resources

U.S. Department of Health & Human Services Fact Sheet Explaining Operation Warp Speed

New England Journal of Medicine Developing Safe and Effective COVID Vaccines

**MODERNA COVID-19 Vaccine** 

**Phase 3 of Pfizer and Biontech Study** 

The following videos by the JAMA Network (12 international peer-reviewed medical journals) are very helpful at understanding the science behind both of these vaccines and all the other vaccine candidates:

https://www.youtube.com/watch?v=KMc3vL MIeo

https://jamanetwork.com/journals/jama

## Resources (cont.)

Pfizerhttps://www.fda.gov/media/144245/download

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/Pfizer-BioNTech.html

Moderna-

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/Moderna.html

https://www.modernatx.com/cove-study and within that

https://www.modernatx.com/sites/default/files/content\_documents/2020-COVE-Study-Enrollment-Completion-10.22.20.pdf

and

https://www.modernatx.com/sites/default/files/content\_documents/Final%20mRNA-1273-P301%20Protocol%20Amendment%206%20-%2023Dec2020.pdf

Janssen-

https://www.fda.gov/media/146304/download

https://www.cdc.gov/vaccines/covid-19/info-by-product/janssen/index.html