COVID-19 Vaccines

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Averaging about 10 new hospitalizations daily

What is a vaccine and how does it work?

- Vaccines prevent diseases that can be dangerous, or even deadly. They work with your body's natural defenses to safely develop protection from a disease.
- A vaccine helps your immune system to produce antibodies, just like it would if you were exposed to the disease. After getting vaccinated, you have protection from that disease, without having to get the disease first.
- This is what makes vaccines such powerful medicine. Unlike most medicines, which treat or cure diseases, vaccines *prevent* them.

What is a vaccine and how does it work?



When a new pathogen or disease enters our body, it introduces a new antigen. For every new antigen, our body needs to build a specific antibody that can grab onto the antigen and defeat the pathogen. VACCINE NEW ANTIBODY

A VACCINE is a tiny weakened non-dangerous fragment of the organism and includes parts of the antigen. It's enough that our body can learn to build the specific antibody. Then if the body encounters the real antigen later, as part of the real organism, it already knows how to defeat it.

https://www.who.int/news-room/feature-stories/detail/how-do-vaccines-work

How COVID-19 Vaccines Work

How mRNA vaccines work



The genetic sequence of the virus spike is used to make a synthetic mRNA sequence - the instructions to make the spike protein The mRNA is packaged into a naoparticle - the vaccine which can deliver the mRNA to immune cells

The immune cells follow the mRNA code to produce spike protein, which is displayed on the cell surface. This stimulates an immune response

https://www.benaroyaresearch.org/blog/post/11-things-know-about-mrna-vaccines-covid-19

Types of COVID-19 Vaccines

- COVID-19 Vaccines teach your body to make a piece of the COVID-19 virus
 - Your body then creates antibodies against this piece
 - **Cannot** cause you to get infected with COVID-19
 - Cannot alter your DNA
 - The cell breaks down and gets rid of the mRNA soon after it is finished using the instructions.
- mRNA Vaccines (Pfizer and Moderna)
 - Although COVID-19 mRNA vaccines are new, this type of vaccine has been studied in people before. mRNA vaccines against HIV, rabies, Zika and flu have been tested in phase 1 and phase 2 trials in people.
- Viral vector vaccine (Johnson and Johnson)
 - Also teaches the body to make a piece of the COVID-19 virus, like mRNA vaccines, but uses a harmless virus to deliver the genetic material
 - Has been used to make vaccines for Zika, Ebola, HIV, Flu

Type of COVID-19 Vaccines

- Three vaccines have received Emergency Use Authorization from the Food and Drug Administration from companies named Pfizer, Moderna, and Janssen (Johnson & Johnson).
- All three authorized COVID-19 vaccines are safe and highly effective against serious illness, hospitalization, and death.
- The Pfizer and Moderna vaccines require 2 doses given at least 3-4 weeks apart. People should get both doses to be fully vaccinated in order to be effective.
- Johnson & Johnson is only 1 dose.



What are the benefits of getting a COVID-19 vaccine?

- COVID-19 vaccination will help keep you from getting sick from COVID-19.
- All COVID-19 vaccines available in the U.S. have been shown to be very effective.
- The more people who get vaccinated, the faster we can get back to our normal lives.
- After being fully vaccinated (2 weeks after last dose) it is safe to spend time with other fully vaccinated and unvaccinated persons without masks.
- Fully vaccinated people do not need to quarantine if exposed to someone with COVID-19 in most situations.



How do we know if the vaccine is safe?

Vaccines go through more testing than any other pharmaceuticals:

Small groups of people receive the trial vaccine

2.

The vaccine is given to specific groups of people (i.e by age, race, and physical health).



The vaccine is given tens of thousands of people and tested for effectiveness and safety.

How do we know if the vaccine is safe?



The FDA looks at the data and decides whether to approve the vaccine.



The CDC's <u>Advisory Committee on Immunization Practices</u> looks at the data to see if the vaccine is safe and works. They also provide a recommendation.

The vaccine is only approved after **all of these steps** are done and various teams of reviewers are sure that it works and is safe.

How is it safe if it happened so fast?

The timeline was sped up but never cut corners on safety. Here is how:



We already had helpful information about coronaviruses, so we weren't starting from scratch.



The U.S. and other governments **invested a lot of money** to support vaccine companies with their work.



A lot of people participated in clinical trials and **we didn't need to spend time finding volunteers.**



Manufacturing happened **at the same time as safety studies,** so vaccines were ready to be distributed once they were approved.

Example COVID-19 vaccine timeline:



Traditional timeline:



Emergency Use Authorization

- Emergency Use Authorization by the FDA of COVID-19 Vaccines
 - A pathway created to overcome regulatory burdens in an emergency and more quickly approve a safe and effective medicine/vaccine
 - Tens of thousands were enrolled in the vaccine trials, similar to trials of other approved vaccines
 - This vaccine technology has been used in research for over 2 decades
 - Pfizer now has full FDA approval as of Aug 23rd, 2021, the same approval process for all other common vaccines

Do the COVID-19 vaccines have any side effects?

- Serious side effects from vaccines, including the COVID-19 vaccine, are rare.
- It is possible that some people may have side effects, which are normal signs that your body is building protection.
- These side effects may affect your ability to do daily activities, but they should go away in a few days.
- The most common side effects are minor, last 1-3 days and include:
 - \circ Tiredness
 - \circ Headache
 - $\,\circ\,$ Pain at the injection site
 - $\,\circ\,$ Muscle and/or joint pain
 - \circ Chills
 - $\,\circ\,$ Nausea and/or vomiting
 - \circ Fever



Frequently Asked Questions

- Johnson and Johnson vaccine associated with very rare side effect of blood clots in young women
 - Demonstrates that our safety monitoring is working
 - The side effect is so rare, that it is still much safer to get vaccinated compared with the chance of severe disease/death from COVID-19 infection
- Long term effects
 - With all other vaccines, all side effects have occurred within 8 weeks after vaccination, there are no other examples of longer-term side effects from vaccines
 - We have over a year of human research on the COVID-19 vaccines
 - Over 165 million people have had at least one COVID-19 vaccine dose in the United States
 - Ongoing safety monitoring

Frequently Asked Questions

- Variants
 - All viruses mutate over time, we are concerned if a virus changes and becomes more contagious or cause more severe disease
 - All available COVID-19 vaccines have been shown to be effective against current variants, especially in preventing severe disease and death. The Delta variant is currently over 98% of cases
 - "Data so far suggests efficacy rates of approximately 67 percent for the J&J vaccine, 66 to 95 percent for the Moderna vaccine, and 42 to 96 percent for the Pfizer-BioNTech vaccine."
- Misinformation
 - Vaccines do not contain tracking devices
 - It is not possible for these vaccines to "shed" and be spread to others around them
 - There is no evidence that being around those vaccinated can cause side effects
- Cases after vaccination
 - Some people still get infected after COVID-19 vaccination
 - Even if this occurs, the severity of disease is lessened
 - No vaccine is perfect
 - Still a way to protect oneself, like wearing a seatbelt or bicycle helmet

Vaccine effectiveness in the Pre-Delta and Delta Periods



In studies comparing the '<u>Pre-Delta</u>' and '<u>Delta</u>' periods:

- Pre-Delta vaccine effectiveness estimates high (87% or higher)
- Since the introduction of the Delta variant (varies by region)
 - VE against infection ranges from 39–84%
 - VE against hospitalization ranges from 75–95%

<u>References</u>: 1. Israel Ministry of Health (committee/he/files_publications_corona_two-dose-vaccination-data.pdf) 2. Haas et al. (Israel) https://doi.org/10.1016/S0140-6736(21)00947-8 3. Pouwels et al. (UK) survey/finalfinalcombinedve20210816.pdf 4. Puranik https://www.medrxiv.org/content/10.1101/2021.08.06.21261707v2 5. Rosenberg (US) https://www.cdc.gov/mmwr/volumes/70/wr/mm7034e1.htm 6. Tenforde (US) https://www.cdc.gov/mmwr/volumes/70/wr/mm7034e2.htm

Booster doses of COVID-19 vaccines: Adults ≥65 years of age

Preliminary VE against COVID-19–associated <u>hospitalization</u> among fully vaccinated⁺ patients aged ≥18 years, by age group and month — COVID-NET



Public Health

Problem

Source: Unpublished COVID-NET data

⁺Fully vaccinated patients received both doses of Moderna or Pfizer-BioNTech vaccine, with second dose received ≥14 days before hospitalization, or a single dose of Janssen (Johnson & Johnson) 23 vaccine ≥14 days before hospitalization

Frequently Asked Questions

- Boosters/Additional Doses
 - Additional dose with Pfizer/Moderna recommended for those with severe immunocompromise now
 - No recommendation for Johnson and Johnson at this time
 - We may have booster doses recommended for certain populations later this month, likely will be done in the same order as initial vaccine roll out

- Misinformation
 - Vaccines were not responsible for the delta variant
 - No evidence that vaccines will affect fertility