



COVID-19 Vaccine Discussion

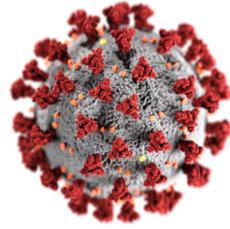
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Agenda – answering these questions ...



- How do they work?
- Who is eligible to get them?
 - Children?
 - People who have or have had COVID-19?
- Messages to families about the vaccine; addressing vaccine hesitancy
- Vaccine recommendations for immunocompromised patients
- Why do people need to keep wearing masks and distancing even after receiving the vaccine?
- Where can I find good information and materials about the vaccines?

Coronaviruses



- Enveloped, non-segmented, single-stranded, positive-sense RNA viruses
- Corona = “crown-like” surface proteins
- Infect humans, variety of animals
- Diverse clinical syndromes

• Severe Acute Respiratory Syndrome Coronavirus (SARS)

- Global outbreak 2002-2003
- More severe symptoms, though also a spectrum
- Disproportionately affected adults
- 20% required intubation and ventilation
- 10% overall mortality (~ 50% case fatality rate >60 yrs)
- No infant or child deaths documented

- Human coronaviruses 229E, OC43, NL63 and HKU1
 - Spectrum of Illness
 - Common: URI +/- mild fever, AOM, asthma exacerbations
 - Less Common: bronchiolitis, croup, PNA (infants, immunocompromised)
 - Self-limited, peak day 3-4

• Middle Eastern Respiratory Syndrome (MERS) 2012 (Saudi Arabia)

- Spectrum of illness (asymptomatic infection, mild to severe disease)
- Primarily male adults with comorbidities
- Children present with milder symptoms



COVID-19

- Caused by the virus **SARS-CoV-2**
 - Identified in Wuhan, China in December 2019
 - Early in the outbreak, many patients were reported to have a link to a large seafood and live animal market
 - Later, no link to the market indicating person-to-person spread of the disease
 - Source from an animal, likely a bat
 - Travel-related exportation of cases reported
- Wide range of symptoms reported
 - Fever or chills
 - Cough
 - Shortness of breath or difficulty breathing
 - Headache
 - Nasal congestion or runny nose
 - Muscle or body aches
 - Sore throat
 - New loss of smell or taste
 - Gastrointestinal symptoms/diarrhea



Multisystem Inflammatory Syndrome in Children (MIS-C)



UK
April 2020

- Previously healthy children severe inflammatory syndrome, Kawasaki disease-like features
- Current/recent SARS-CoV-2 or epidemiologic link to COVID-19 case
- Persistent fever, constellation of symptoms, multiorgan involvement, elevated inflammatory markers

NY
April - May 2020

- NYC sees 15 patients (2-15 yrs) hospitalized with multisystem inflammatory syndrome
- 102 cases in NY state, most w/SARS-CoV-2 by PCR or serology

CDC
May 2020

- Recommends healthcare providers report suspected cases to public health to better characterize newly recognized condition



MIS-C: Case Definition



- An individual aged <21 years presenting with fever*, laboratory evidence of inflammation**, and evidence of clinically severe illness requiring hospitalization, with multisystem (≥ 2) organ involvement (cardiac, renal, respiratory, hematologic, gastrointestinal, dermatologic or neurological); AND
- No alternative plausible diagnoses; AND
- Positive for current or recent SARS-CoV-2 infection by RT-PCR, serology, or antigen test; or exposure to a suspected or confirmed COVID-19 case within the 4 weeks prior to the onset of symptoms.

*Fever $\geq 38.0^{\circ}\text{C}$ for ≥ 24 hours, or report of subjective fever lasting ≥ 24 hours

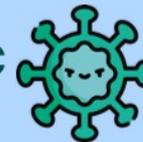
**Including, but not limited to, one or more of the following: an elevated C-reactive protein (CRP), erythrocyte sedimentation rate (ESR), fibrinogen, procalcitonin, d-dimer, ferritin, lactic acid dehydrogenase (LDH), or interleukin 6 (IL-6), elevated neutrophils, reduced lymphocytes and low albumin

Acute COVID-19 vs MIS-C



Distinguishing Acute COVID-19 from MIS-C

Acute COVID-19 and MIS-C have **overlapping features**.
These findings may help to differentiate between them.



Acute COVID-19

COVID exposure within ~2 weeks
Less likely +COVID antibodies
More likely +COVID PCR
Prominent upper and/or lower
respiratory symptoms
Acute loss of taste and/or smell

MIS-C

Onset of symptoms 2-6 weeks after infection
or exposure
More likely +COVID antibodies
Less likely +COVID PCR
Oral mucosal changes
Swollen hands / feet
Erythema of palms or soles
Extremely elevated ferritin (>10K)
Coronary artery aneurysms
Elevated BNP OR
Evidence of cardiac dysfunction

COVID-19



- What are the latest data on the pandemic?

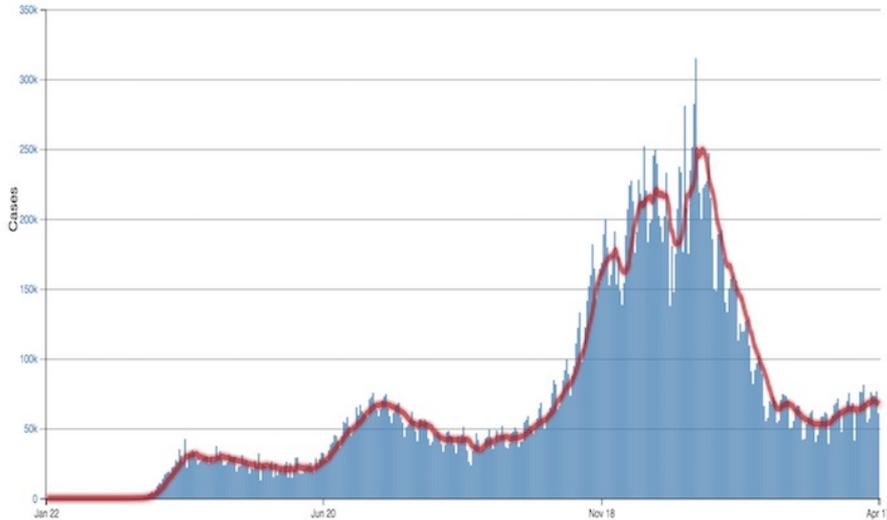


COVID-19 Epidemiology

CDC Data as of April 14, 2021



Daily Trends in Number of COVID-19 Cases in the United States Reported to CDC



73,622
New Cases Reported

69,577
Current 7-Day
Average*

31,231,869
Total Cases Reported

64,340
Prior 7-Day Average

249,861
Peak of 7-Day
Average**

+8.1%
Change in 7-Day
Average since Prior
Week

Source: CDC.gov

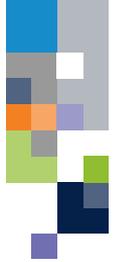
COVID-19 Epidemiology

TOTAL CASES
31,444,706
+60,947 New Cases

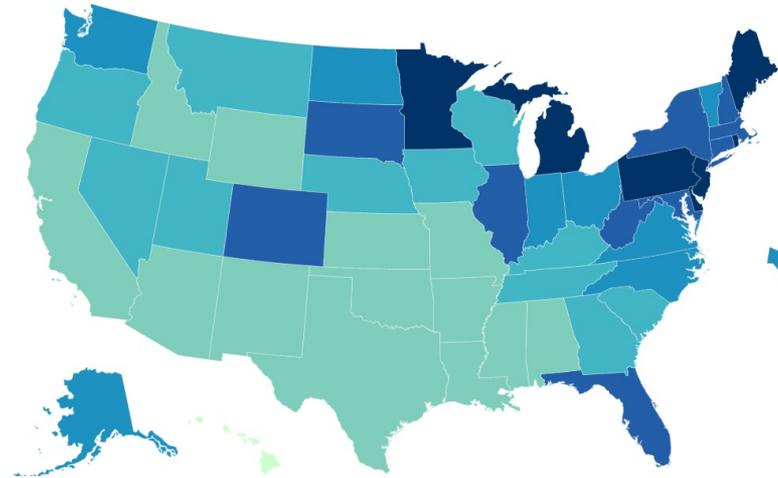
7-DAY CASE RATE PER 100,000
142.2

TOTAL DEATHS
563,980
+694 New Deaths

CDC | Data as of: Sunday, April 18, 2021 12:30 PM ET. Posted: Monday, April 19, 2021 10:24 AM ET



US COVID-19 7-Day Case Rate per 100,000, by State/Territory



Territories



7-Day Case Rate per 100,000



Source: CDC.gov

COVID-19 Epidemiology

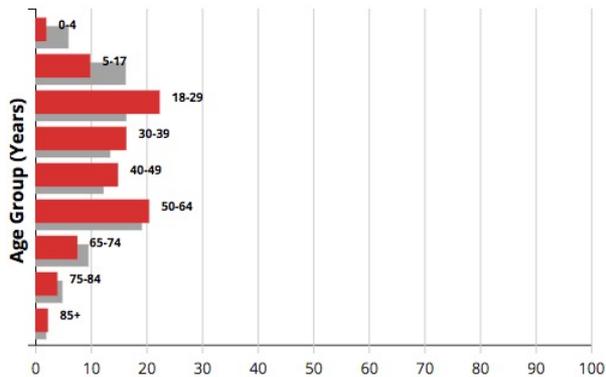
Demographic Trends in the US as of April 19, 2021



Cases by Age Group:

 Download 

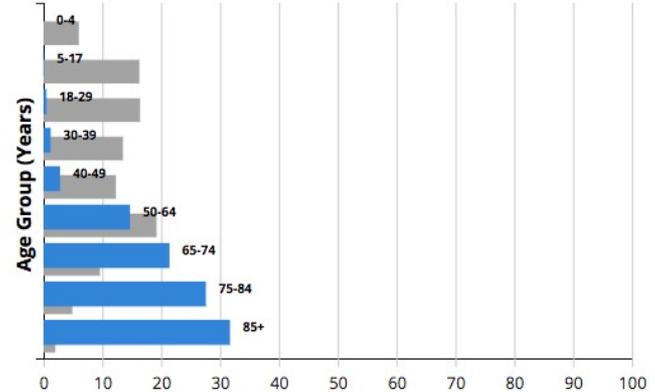
Data from 24,726,290 cases. Age group was available for 24,551,320 (99%) cases.



Deaths by Age Group:

 Download 

Data from 437,186 deaths. Age group was available for 437,147 (99%) deaths.



Source: CDC.gov

COVID-19 Epidemiology California

As of April 19, California has 3,618,695 confirmed cases of COVID-19, resulting in 59,772 deaths.

Cases

3,618,695 Total

1,916 Today

↘ 5.0 New cases per 100K

Deaths

59,772 Total

4 Today

↘ 0.1 New deaths per 100K

Tests

57,934,087 Total

200,627 Today

↘ 1.4% Test positivity

Vaccines Administered

25,790,401 Total

[State and County Data](#)

Updated April 19, 2021 at 10:00 AM with data from April 18, 2021

San Francisco Data as of April 14, 2021

- 35,634 Cases
- 517 Deaths
- 21,000 doses of vaccines are administered per day
- Over 61% of San Franciscans over age 16 have at least received 1 dose
- 39% of San Franciscans have completed the vaccine series

COVID-19



How can we improve these numbers and thus decrease the chance of contracting the virus or spreading it to others?

Masks and social distancing help, but they are not enough . . .



COVID-19 Vaccines

Vaccines are the key!!!

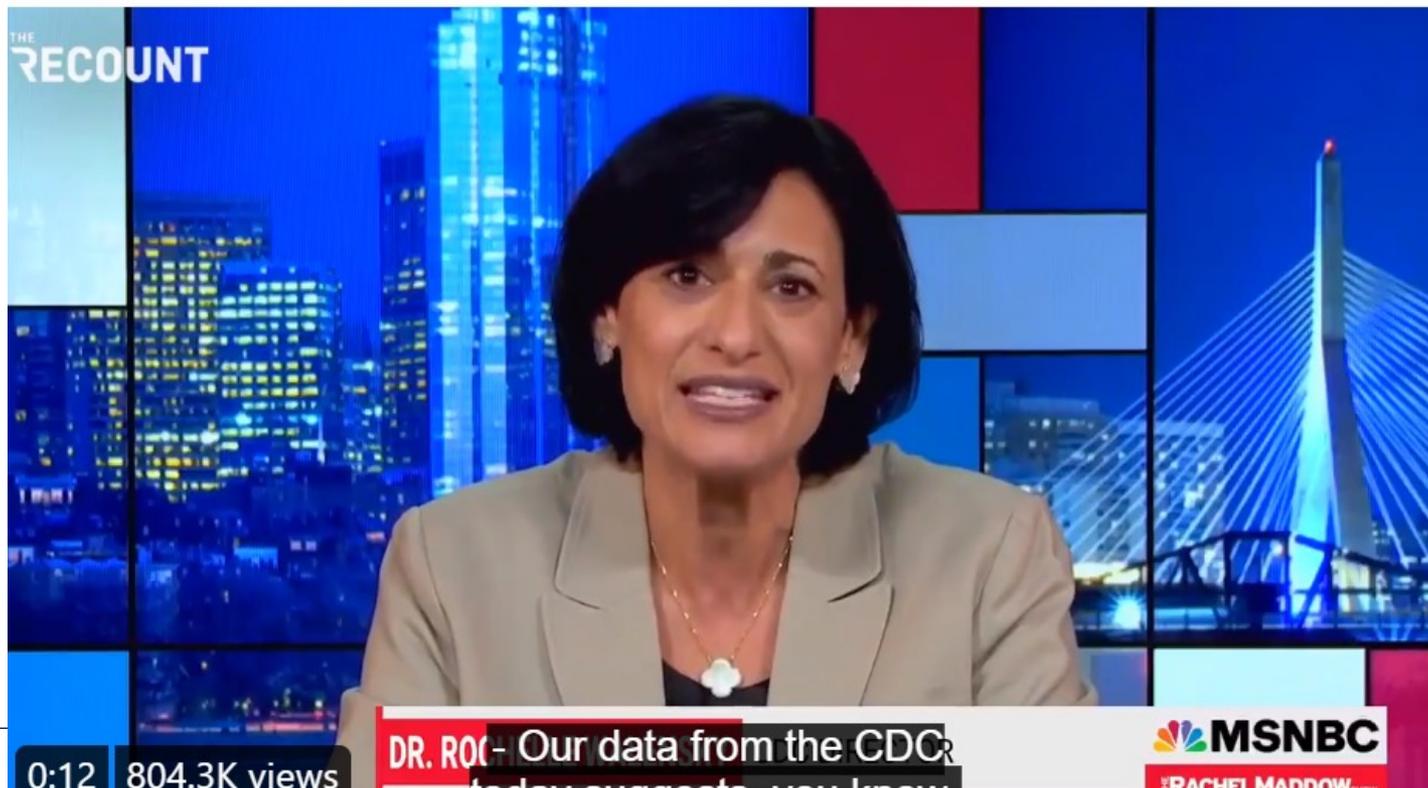


Do vaccines reduce
transmission?
Short answer: yes



March 30, 2021

CDC Director Dr. Rochelle Walensky: "Our data from the CDC today suggest that vaccinated people do not carry the virus."



Vaccines



- Prevent diseases that can be dangerous, or even deadly
- Work with your body's natural defenses to safely develop protection from a disease
- 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

COVID-19 Vaccines



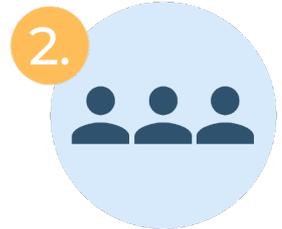
- Will help keep you from getting sick from COVID-19
- All COVID-19 vaccines available in the U.S. have been shown to be very effective
- Combination of getting vaccinated and following CDC's recommendations to protect yourself and others will offer the best protection from COVID-19
- The more people who get vaccinated, the faster we can get back to our normal lives

How do we know if the vaccine is safe?

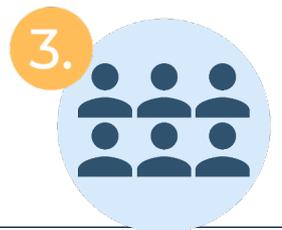
Vaccines go through more testing than any other pharmaceuticals:



Small groups of people receive the trial vaccine



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?

4.



The CDC's Advisory Committee on Immunization Practices looks at the data to see if the vaccine is safe and works. They give advice to the U.S. Food and Drug Administration (FDA)

5.

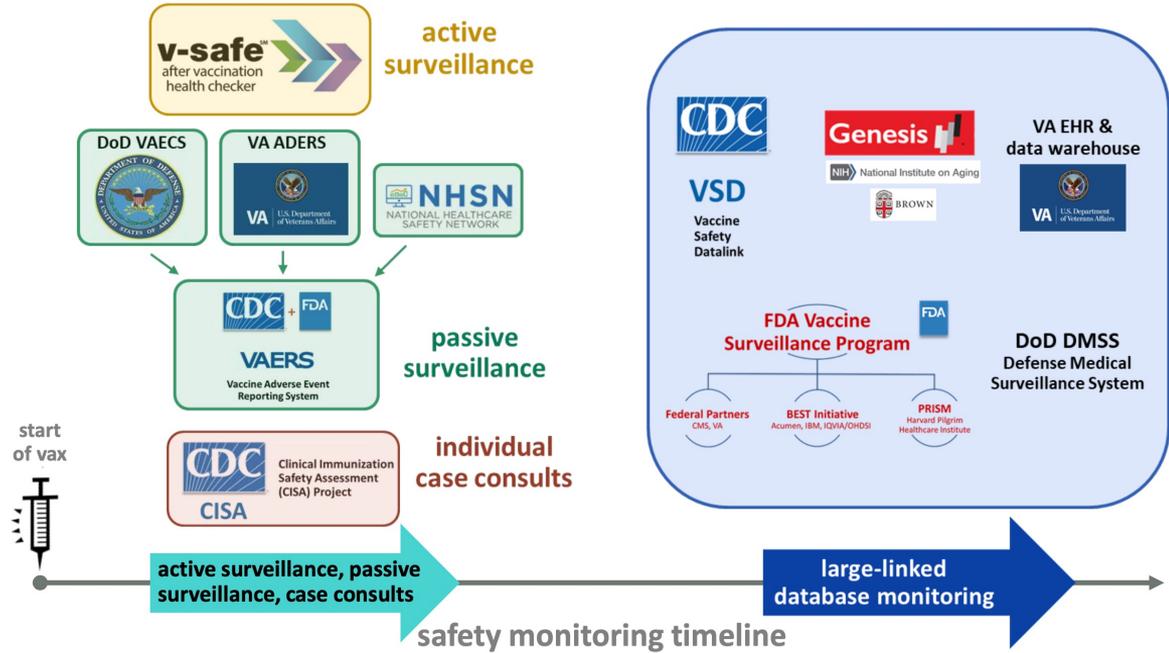


The FDA looks at the data and the advice from the Advisory Committee and decides whether to approve the vaccine

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

No Serious Safety Concerns During Trials

- Robust recruitment numbers and diversity
- Data Review: FDA, CDC ACIP
- Active and passive surveillance, case consults, large-linked database monitoring



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

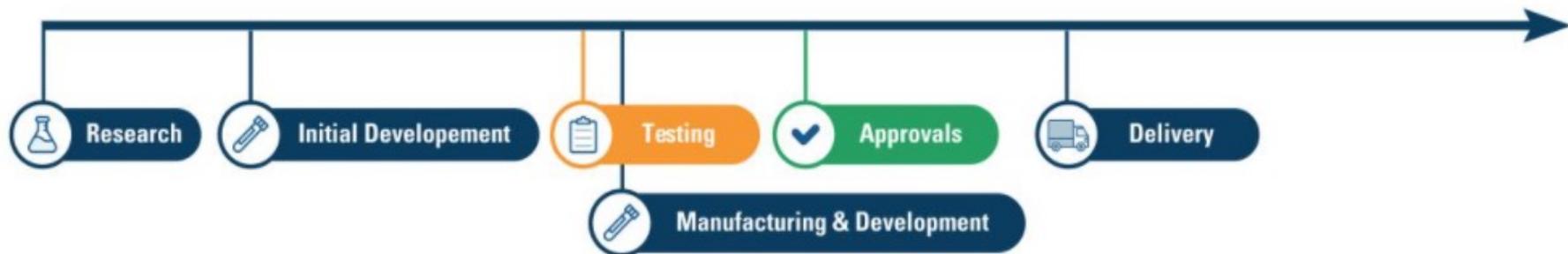


A lot of people participated in clinical trials and **we didn't need to spend time finding volunteers**



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:



In General, How Do Our Current Vaccines Work?



	Live-Attenuated	Inactivated
What Is It?	Vaccine contains living microorganisms that have been altered so that they don't cause disease.	Vaccine contains microorganisms that have been killed by heat, chemicals, or radiation; or pieces of microorganisms that still elicit an immune response.
Pros	<ul style="list-style-type: none"> Gets a strong immune response. The stronger the response, the longer lasting and more effective the immunity (More Effective) 	<ul style="list-style-type: none"> Incapable of causing disease Easy to produce More easily stored
Cons	<ul style="list-style-type: none"> Small chance that the live microbe could evolve and regain some pathogenic trait Must be refrigerated to preserve More difficult to produce 	<ul style="list-style-type: none"> Gets a weaker immune response – usually requires multiple doses or “booster shots” to get full immunity

Table 1
Common Vaccines and Type of Virus Contained

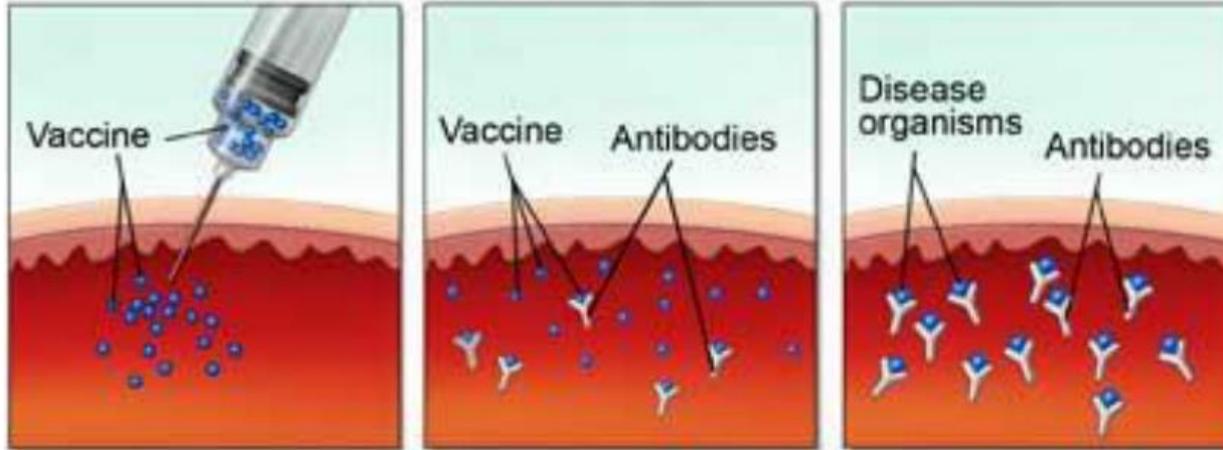
Vaccine	Live or Inactivated
Influenza	Inactivated
Pneumococcal (PCV13/PPSV23)	Inactivated
Tetanus	Inactivated
Diphtheria	Inactivated
Pertussis	Inactivated
Hepatitis B	Inactivated
Human papillomavirus	Inactivated
Measles/mumps/rubella	Live
Zoster	Live

— MDC

How do vaccines (generally) work ...

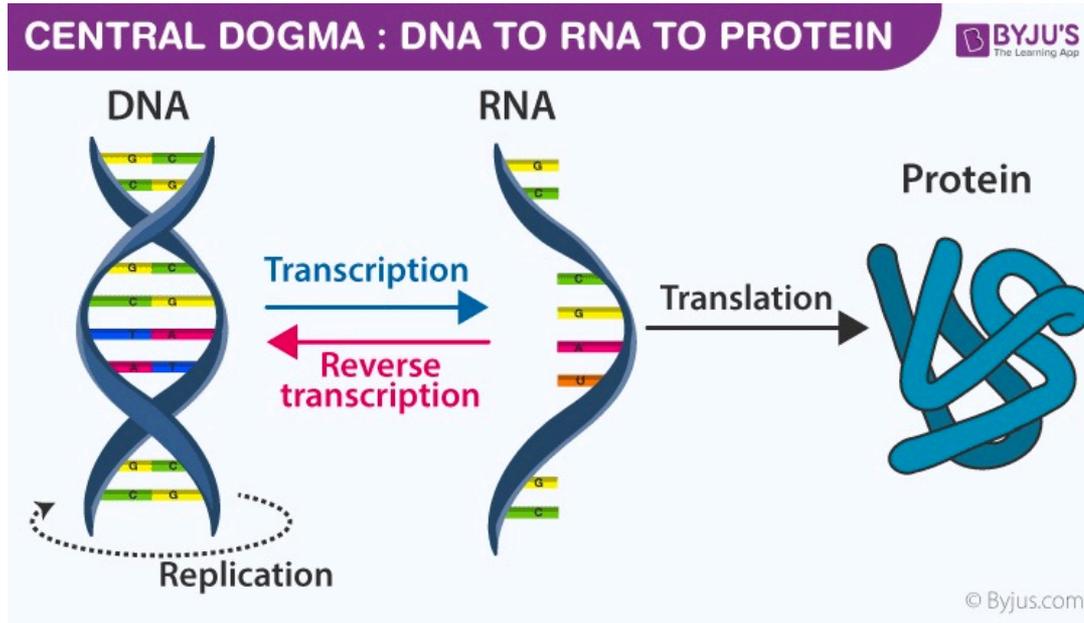


Vaccine Immunity



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Central Dogma of Biology



Three types of COVID19 Vaccines



1. Protein subunit vaccines

- harmless pieces (proteins) of COVID-19 instead of the entire virus

2. mRNA vaccines

- contain nucleic acid from the virus that causes COVID-19 that gives our cells instructions for how to make a harmless protein that is unique to the virus

3. Vector vaccines

- use weakened/inactivated version of a different virus to carry a small amount of genetic material from COVID-19 inserted in it (this is called a viral vector)

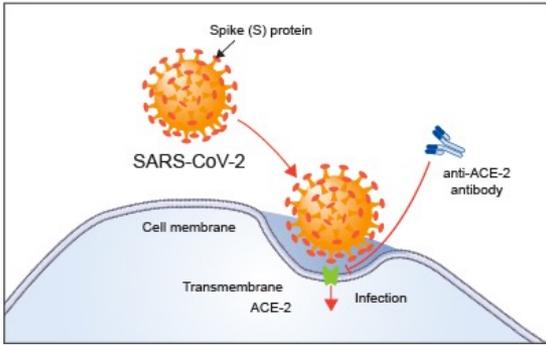
To Help Ease Concerns Regarding Viral Vector Vaccine



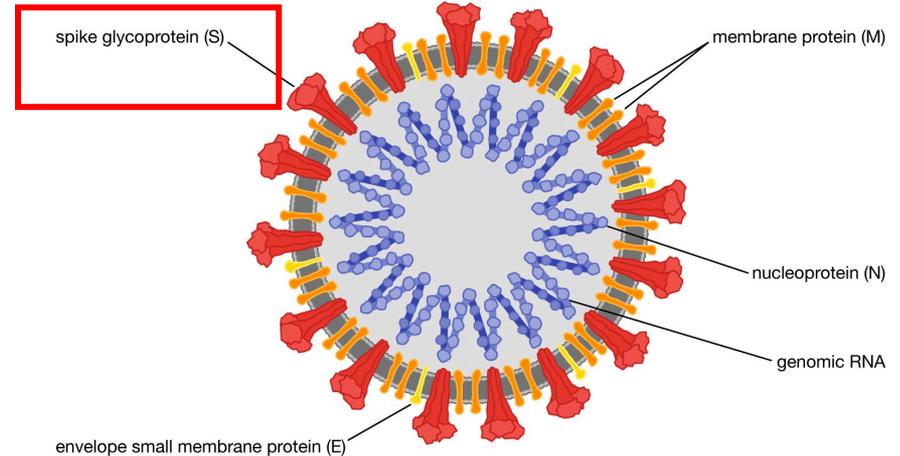
- Use an adenovirus
 - Common cold viruses that can cause illnesses ranging from cold-like symptoms to bronchitis, gastroenteritis, and conjunctivitis
 - For the vaccine, the virus has been engineered to be incapable of replicating and causing disease
 - Used as a delivery shuttle to deliver the genes for making the SARS-CoV-2 spike protein that in turn elicits an immune response and provides protection against the coronavirus
 - Do not carry the enzymatic machinery necessary for integration into the host cell's DNA
 - Engineered adenoviruses used in vaccines have been further crippled by deleting chunks of their genome so that they cannot replicate, further increasing their safety



SARS-CoV-2



Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)



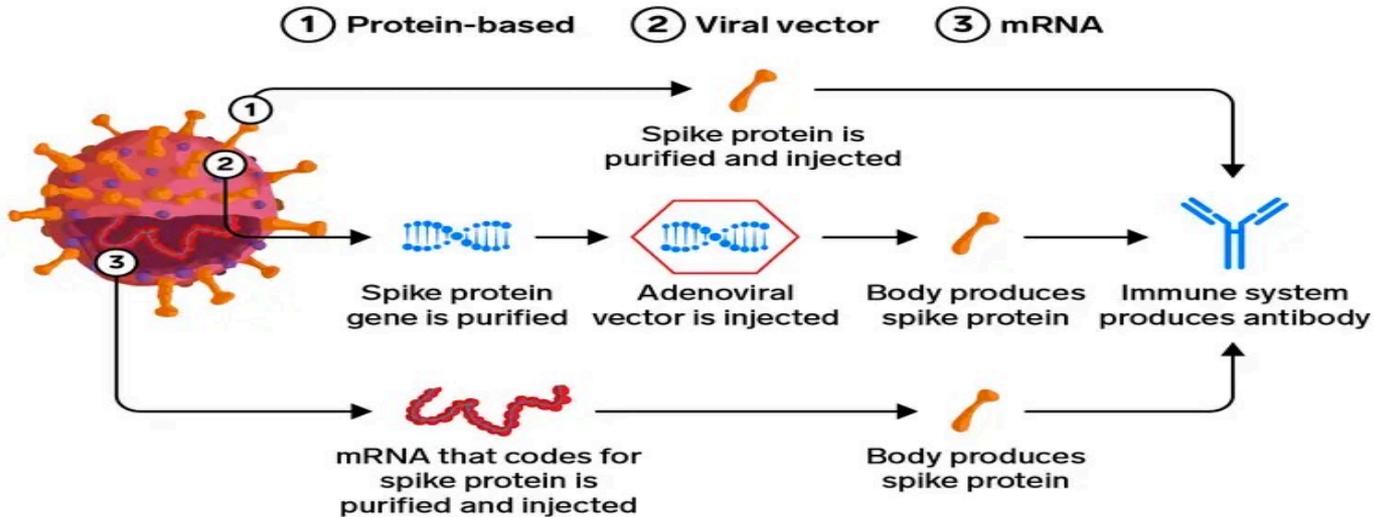
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- Spike protein plays a crucial role in penetrating host cells and initiating infection
- Without the spike protein, the virus cannot interact with and infect host cells
- Ideal target for vaccines

Three types of COVID19 Vaccines



Three types of coronavirus vaccines in development



Source: National Institutes of Health presentation at Senate hearing on September 9, 2020

INSIDER

COVID-19 Vaccines



- Three vaccines have received Emergency Use Authorization from the Food and Drug Administration
 - Pfizer
 - Moderna
 - Janssen (Johnson & Johnson)
- 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

Pfizer COVID-19 Vaccine

- Type of Vaccine: [mRNA](#)
- Number of Shots: 2 shots, 21 days apart
- Recommended for people aged **16 years and older**
- Side effects (such as fever, chills, tiredness, and headache) throughout the body were more common after the second dose of the vaccine
 - Mild to moderate
- **95% effective** at preventing laboratory-confirmed COVID-19 illness in people without evidence of previous infection

REAL-WORLD EVIDENCE CONFIRMS HIGH EFFECTIVENESS OF PFIZER-BIONTECH COVID-19 VACCINE AND PROFOUND PUBLIC HEALTH IMPACT OF VACCINATION ONE YEAR AFTER PANDEMIC DECLARED



March 11, 2021- a year after WHO pandemic declared



- Real-world roll-out data from Ministry of Health Israel, Pfizer vaccine
- 94% of asymptomatic infection prevented
- 97% effective against symptomatic COVID-19 cases, hospitalizations, severe and critical hospitalizations, and deaths
- Unvaccinated individuals 44 times more likely to develop symptomatic COVID-19 and 29 times more likely to die from COVID-19



April 1 press release, 100% effectiveness in real-world against severe disease even against B.1.351

Pfizer and BioNTech Confirm High Efficacy and No Serious Safety Concerns Through Up to Six Months Following Second Dose in Updated Topline Analysis of Landmark COVID-19 Vaccine Study

- *Analysis of 927 confirmed symptomatic cases of COVID-19 demonstrates BNT162b2 is highly effective with 91.3% vaccine efficacy observed against COVID-19, measured seven days through up to six months after the second dose*
- *Vaccine was 100% effective in preventing severe disease as defined by the U.S. Centers for Disease Control and Prevention and 95.3% effective in preventing severe disease as defined by the U.S. Food and Drug Administration*
- *Vaccine was 100% effective in preventing COVID-19 cases in South Africa, where the B.1.351 lineage is prevalent*
- *Vaccine safety now evaluated in more than 44,000 participants 16 years of age and older, with more than 12,000 vaccinated participants having at least six months follow-up after their second dose*

Moderna COVID-19 Vaccine



- Type of Vaccine: [mRNA](#)
- Number of Shots: 2 shots, 1 month (28 days) apart
- Recommended for people aged **18 years and older**
- Side effects (such as fever, chills, tiredness, and headache) throughout the body were more common after the second dose of the vaccine (mild to moderate)
- **94.1% effective** at preventing laboratory-confirmed COVID-19 illness in people who received two doses who had no evidence of being previously infected
 - High effectiveness in clinical trials among people of diverse age, sex, race, and ethnicity categories and among persons with **underlying medical conditions**

Reactions to the mRNA vaccines

Adverse Effects (reactogenicity)

- Local reactions: pain, swelling, erythema at the injection site, localized axillary lymphadenopathy on the same side as vaccinated arm
- Systemic: fever, fatigue, headache, chills, myalgia, arthralgia
 - Most are mild to moderate in severity, occur within the first three days of vaccination, and resolve within 1–3 days of onset
 - More frequent and severe following 2nd dose and among younger persons compared to older persons (i.e., >55 or ≥65 years [for Pfizer-BioNTech or Moderna vaccines, respectively]).
- ~80–89% of vaccinated persons develop at least 1 local symptom
- ~55–83% develop at least 1 systemic symptom



Vaccine Safety, cont'd

- Hypersensitivity-related adverse events in trials
 - 0.63% of Pfizer-BioNTech (0.51% placebo)
 - 1.5% of Moderna (1.1% placebo)
 - **No anaphylaxis**
- Rare reports of anaphylaxis
- 15 min observation period (30 min if history of allergic reaction/anaphylaxis)
- Primary ingredients of concern—lipid nanoparticles
- Acute Allergic Reaction Protocol for management on site
- UCSF experience to date – **no anaphylaxis after thousands**

Warnings and contraindications



■ Warnings and precautions

- Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration
- **Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response**

■ Contraindications

- Should not be administered to individuals with known history of a severe allergic reaction (e.g., anaphylaxis) to any component in the vaccine
- Those with an allergy to **polyethylene glycol (and polysorbate)** may need additional monitoring in a facility that is equipped to care for a severe allergic reaction

Johnson & Johnson COVID-19 Vaccine



- Type of Vaccine: viral vector
- Number of Shots: **1 shot**
- Recommended for people aged **18 years and older**
- Side effects: See next slide
- **66.3% effective** at preventing laboratory-confirmed COVID-19 illness in people who had no evidence of prior infection 2 weeks after receiving the vaccine
 - High efficacy at preventing hospitalization and death in people who did get sick
 - Might provide protection against asymptomatic infection

Important message about Johnson & Johnson COVID-19 vaccine

- On 4/13, the FDA and CDC paused use of the Johnson & Johnson (J&J) COVID-19 vaccine because 6 people developed a rare but serious type of blood clot about 2 weeks after getting the vaccine
- CDC doesn't know yet if there is any link between the vaccine and the blood clots
- More than 6.8 million people have gotten the J&J vaccine in the U.S. and only a few cases of blood clots have been identified – this is a case of putting safety first and being extra-cautious
- There have not been any reports of blood clots in people who received the Pfizer or Moderna COVID-19 vaccines
- Until federal health experts have finished studying this matter, this vaccine will not be available

A pause does not mean that the vaccine is dangerous – it gives experts time to gather more information.

Source: CDC.gov

Important message about Johnson & Johnson COVID-19 vaccine



- According to the CDC, if you got the J&J COVID-19 vaccine and develop any of the symptoms below within 3 weeks after vaccination, contact your healthcare provider or seek medical care:
 - Severe headache
 - Abdominal pain
 - Leg pain
 - Shortness of breath



COVID-19 Vaccine Types

How mRNA COVID-19 Vaccines Work

Understanding the virus that causes COVID-19.

Coronaviruses like the one that causes COVID-19 are named for the crown-like spikes on their surface, called **spike proteins**. These **spike proteins** are ideal targets for vaccines.

What is mRNA?

Messenger RNA, or mRNA, is genetic material that tells your body how to make proteins.

What is in the vaccine?

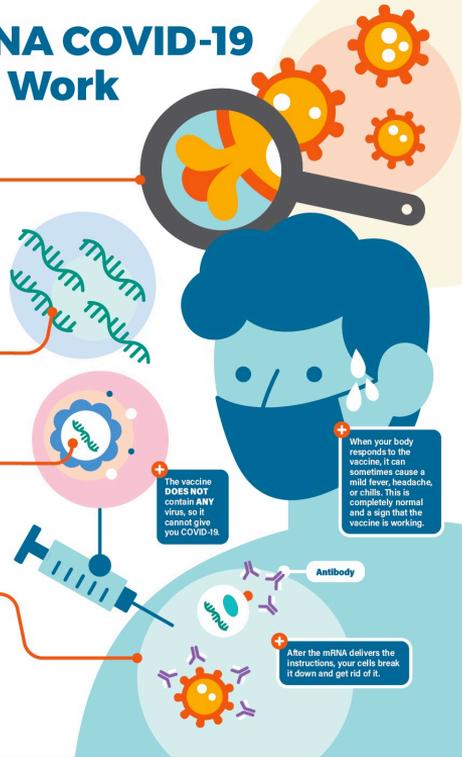
The vaccine is made of mRNA wrapped in a coating that makes delivery easy and keeps the body from damaging it.

How does the vaccine work?

The mRNA in the vaccine teaches your cells how to make copies of the **spike protein**. If you are exposed to the real virus later, your body will recognize it and know how to fight it off.

Getting vaccinated?

For information about COVID-19 vaccine, visit: [cdc.gov/coronavirus/vaccines](https://www.cdc.gov/coronavirus/vaccines)



How Viral Vector COVID-19 Vaccines Work

Understanding the virus that causes COVID-19.

Coronaviruses, like the one that causes COVID-19, are named for the crown-like spikes on their surface, called **spike proteins**. These **spike proteins** are ideal targets for vaccines.

What is a viral vector vaccine?

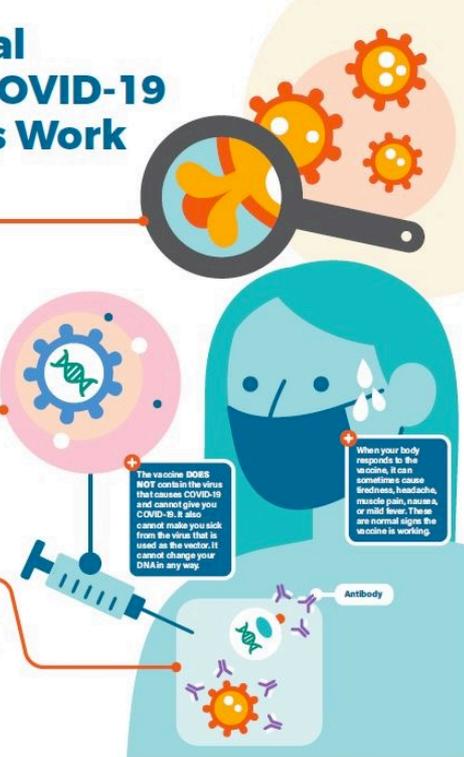
A viral vector vaccine uses a harmless version of a different virus, called a "vector", to deliver information to the body that helps it protect you.

How does the vaccine work?

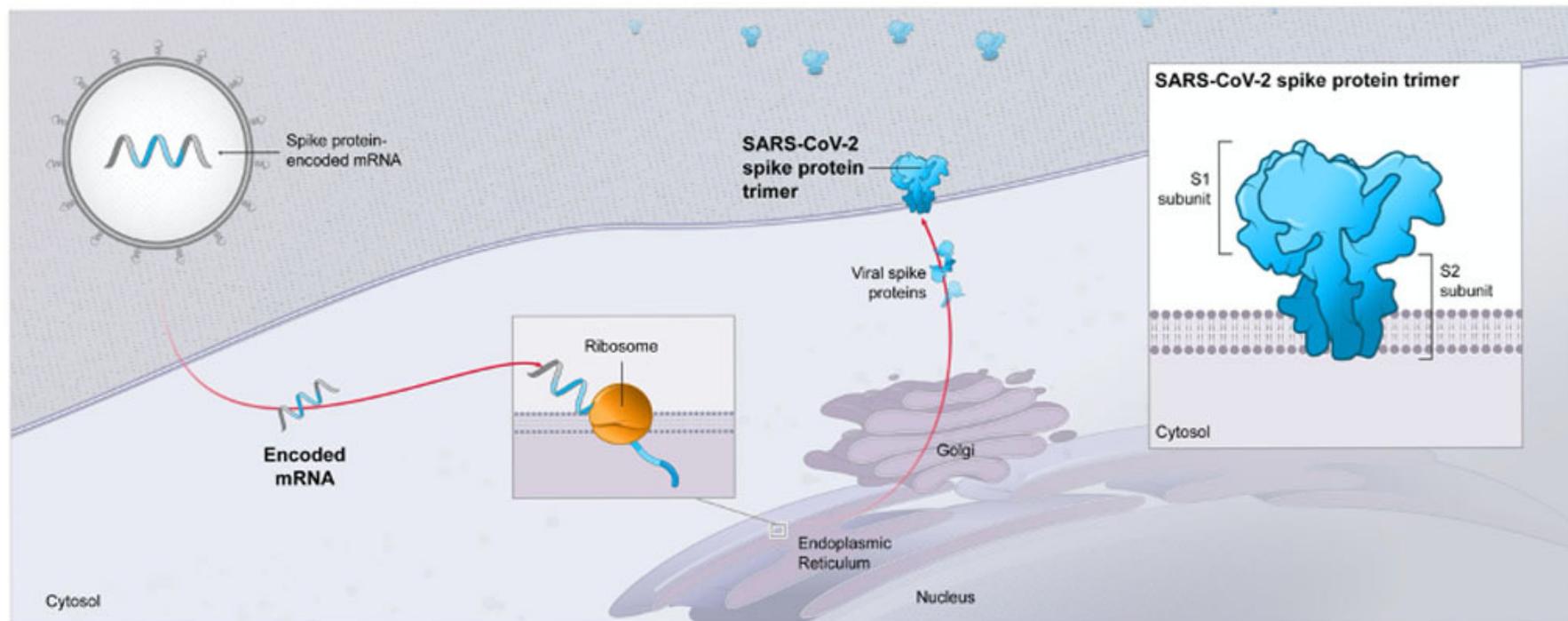
The vaccine teaches your body how to make copies of the **spike proteins**. If you are exposed to the real virus later, your body will recognize it and know how to fight it off.

GETTING VACCINATED?

For information about COVID-19 vaccine, visit: [cdc.gov/coronavirus/vaccines](https://www.cdc.gov/coronavirus/vaccines)



mRNA-1273 encodes for the full-length Spike Protein in the Pre-fusion Conformation (S-2P)

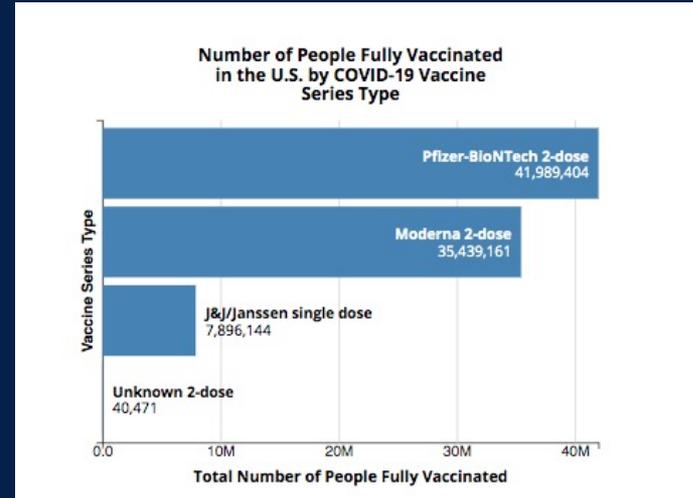
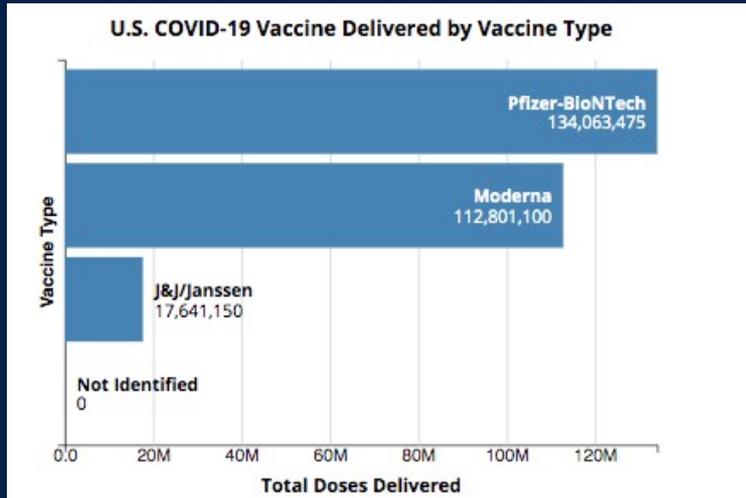


COVID-19 Vaccine Trends

Total Vaccine Doses		People Vaccinated	At Least One Dose	Fully Vaccinated
Delivered	264,505,725	Total	132,321,628	85,365,180
Administered	211,581,309	% of Total Population	39.9%	25.7%
Learn more about the distribution of vaccines.		Population ≥ 18 Years of Age	130,995,636	85,060,671
		% of Population ≥ 18 Years of Age	50.7%	33%
		Population ≥ 65 Years of Age	43,826,574	35,478,824
		% of Population ≥ 65 Years of Age	80.1%	64.9%

i About these data

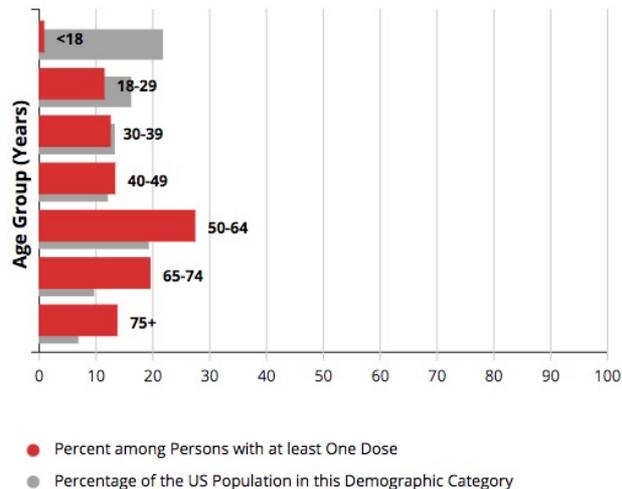
CDC | Data as of: April 19, 2021 6:00am ET. Posted: Monday, April 19, 2021 1:36 PM ET



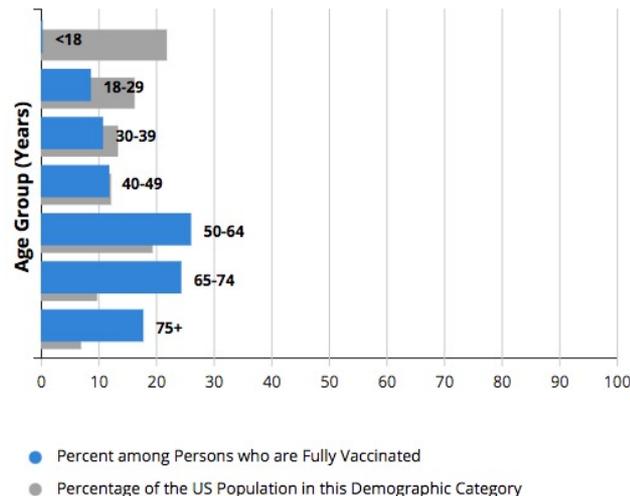
COVID-19 Vaccine Trends

Age Data of People Receiving the COVID-19 Vaccine in the US as of April 19, 2021

Data from 132,321,628 people with at least one dose administered. Age was available for 122,058,399 (92%) people with at least one dose administered.



Data from 85,365,180 people fully vaccinated. Age was available for 78,800,861 (92%) people fully vaccinated.



Source: CDC.gov

How long after getting the COVID-19 vaccine does it take to be effective? How long does it last?

- It usually takes a few weeks for the body to build immunity after vaccination
- That means it's possible a person could be infected with the virus that causes COVID-19 just before or just after vaccination and get sick. This is because the vaccine has not had enough time to provide protection
- We do not know yet how long the COVID-19 vaccines will provide protection
- Experts continue to conduct more studies about whether the vaccines also keep people from spreading COVID-19

Do I need to wear a mask and avoid close contact with others if I have been vaccinated?

- Yes. Experts continue to learn more about the protection that COVID-19 vaccines provide under real-life conditions.
- Until then it will be important for everyone to continue using all the tools available to us to help stop this pandemic, like:
 - Covering your mouth and nose with a mask
 - Washing hands often
 - Staying at least 6 feet away from others.



Wash your hands



Wear a mask



Keep your distance



Avoid groups



Can I get COVID-19 from the COVID-19 vaccines?

No!! The vaccines do not contain the live virus that causes COVID-19. This means that you can't catch COVID-19 from the vaccine

- Cells breaks down and get rid of mRNA soon after it is finished using the instructions
- Genetic material delivered by viral vectors does not integrate into a person's DNA



Are there certain people that shouldn't get them?



- **People with history of severe allergic reaction (e.g., anaphylaxis) to a component in the vaccine**
 - Those with an allergy to polyethylene glycol (and polysorbate) may need additional monitoring in a facility that is equipped to care for a severe allergic reaction
 - ***Just being allergic to other things is NOT a contraindication***
- ***What about immunocompromised people?***
 - ***Recommend it!***

COVID-19 Vaccine and the Immunocompromised Host?



- People with HIV infection or other immunocompromising conditions or people who take immunosuppressive medications or therapies might be at increased risk for severe COVID-19
- No data are available to establish COVID-19 vaccine safety and efficacy in these groups
- The currently authorized COVID-19 vaccines are not live vaccines and therefore can be safely administered to immunocompromised people

Source: CDC.gov

COVID-19 Vaccine and the Immunocompromised Host?



- Data are currently insufficient to inform optimal timing of COVID-19 vaccination among people who are planning to receive immunosuppressive therapies
- Based on [general best practices for vaccination of immunocompromised people](#), ideally COVID-19 vaccination should be completed at least two weeks before initiation of immunosuppressive therapies. When it is not possible to administer a complete COVID-19 vaccine series in advance, people on immunosuppressive therapy can still receive COVID-19 vaccination

Source: CDC.gov

COVID-19 Vaccine and the Immunocompromised Host?



- Several recent studies found that immunocompromised patients may have reduced protection from vaccines
- One study examined the antibody response of 432 organ transplant recipients without prior COVID-19 infection after 1 dose of vaccine (52% Pfizer, 48% Moderna)
- Only 17% of participants had detectable antibodies to spike protein at a median of 20 days after the first vaccine dose
- Older age and receipt of antimetabolite immunosuppression were associated with reduced likelihood of developing antibody response

COVID-19 Vaccine and the Immunocompromised Host?



- Another study assessed immune response among patients with chronic inflammatory diseases after second vaccine dose
- Compared to immunocompetent controls, there was a 3-fold decrease in anti-spike IgG titers ($p=0.009$), with **greatest decrease amongst patients on steroids (10-fold)**
- Conclusion: Protective efficacy of the vaccines likely varies across different immunocompromised populations
 - Patients receiving corticosteroids may be at highest risk for reduced vaccine efficacy
 - Continued masking and distancing should be advised for vaccinated immunocompromised patients when around non-vaccinated persons
 - Utility of testing for anti-spike IgG to determine immunity requires further investigation

Other populations?



- Children?

- YES should get, but we need to study first ...
- Less potential benefit (kids generally do well, small number get sick) so safety study important
- Studies planned over next 6 months

Are the COVID-19 vaccines safe for children?

- The Pfizer vaccine is authorized for people ages 16 and older
- The Moderna and Johnson & Johnson vaccines are authorized for people ages 18 and older
- Younger children and adolescents should not get the COVID-19 vaccine right now



COVID-19 Vaccine for Children



- Given the relatively low risk of significant COVID-19 infection in children, it is important to establish the safety of pediatric vaccines
- Currently, **Pfizer** is the only COVID-19 vaccine **approved for children but limited to those 16-18 years old**
- A recent press release provided the first data about Pfizer vaccine in children ages 12 to <16 years old
 - 18 cases of COVID-19 in placebo arm (n=1,129), compared to 0 cases in the vaccine arm (n=1,131)
 - Side effects were reported “consistent” with adults but no data were shared
- Results from a study of Moderna vaccine in 12 to <18 years old are anticipated soon
- For children 6 mo to <12 years old, similar trials have recently begun for both Pfizer and Moderna vaccines; Johnson & Johnson studies in children are currently on hold
- Conclusion: COVID-19 vaccine studies in children 6 mo of age and older are now underway
 - Early data are very limited but encouraging, with high efficacy and no safety concerns in middle- and high-school age children

What if you have had COVID-19?



- Yes, ideally 90 days later ...
- People who have had COVID-19 should still receive the vaccine after they have recovered from their illness, and their isolation period has ended (minimum of 14 days at UCSF). Current evidence suggests that reinfection is uncommon in the 90 days after initial infection. *Thus, persons with documented COVID-19 infection in the previous 90 days can delay vaccination until near the end of this period*

How to address vaccine hesitancy?



- **Reassure patients that “no corners were cut”**
- **Confront misconceptions**
- **Share size of studies, multiple studies, from people like them ..**
- **Stay up with what is in the news that day!**
- **Check out the CDC toolkit!**

<https://www.cdc.gov/vaccines/covid-19/health-systems-communication-toolkit.html>

COVID-19 Return to School



Return to School for Pediatric Solid Organ Transplant Recipients in the United States During the Coronavirus Disease 2019 Pandemic: Expert Opinion on Key Considerations and Best Practices FREE

Kevin J Downes ✉, Lara A Danziger-Isakov, Melissa K Cousino, Michael Green, Marian G Michaels, William J Muller, Rachel C Orscheln, Tanvi S Sharma, Victoria A Statler, Rachel L Wattier, Monica I Ardura

Journal of the Pediatric Infectious Diseases Society, Volume 9, Issue 5, November 2020, Pages 551–563, <https://doi.org/10.1093/jpids/piaa095>

Published: 04 August 2020 **Article history** ▼

COVID-19 Return to School

- Children of any age can get COVID-19
 - Milder disease than adults
 - Pediatric SOT recipients do not seem to get COVID-19 more often than other children
- Siblings encouraged to return to school with infection prevention measures

Back to School Safety Tips

for Pediatric Solid Organ Transplantation (SOT) Recipients



Protect yourself and your school from COVID-19.

SOT recipients may feel scared to go back to school during an ongoing pandemic. Here are the most important tips for students in K-12. Everyone is different, so SOT recipients are encouraged to consult their care team.



Keep a safe distance.

If you spend more than 15 minutes with other people at school, stay 6 feet apart.



Clean your hands frequently.

Hand hygiene is very important. Wash your hands with soap and water for 20 seconds or use hand gel with at least 60% ethanol.



Ask your school questions.

Make sure your school's cleaning and disinfection procedures comply with local health department and CDC guidelines.



Stay home if you're sick.

You must stay home if you feel sick or have been exposed to a person with known COVID-19.



Know which mask to wear.

Surgical Mask (3-ply disposable mask)

Wear a 3-ply, disposable mask or a cloth face covering with a plastic face shield if other students and staff don't have masks on.

Cloth Mask

Cloth masks are okay if all students and staff are also wearing masks or cloth face coverings.

If you are a higher risk SOT recipient, wear a 3-ply disposable mask ALL the time.

Tell your school that you are a transplant recipient!

Specific support or accommodations may be available. Helpful COVID-19 resources for pediatric SOT recipients can be found at pids.org.

CDC breakthrough data



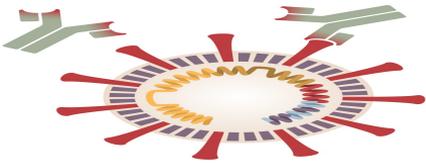
- Out of 77 million Americans who are fully vaccinated against COVID-19
 - 5,800 infections (0.008%) – 0.005% who were symptomatic (29% asymptomatic)
 - 396 hospitalizations (0.0005%)
 - Deaths 0.0001%
- Of those who died, Dr. Fauci told NPR they were elderly frail with other health problems



	Pfizer-BioNTech	Moderna	Johnson & Johnson
Type	mRNA	mRNA	Viral vector
Doses	2 (21 days apart)	2 (28 days apart)	1
Age	≥16 years	≥18 years	≥18 years
Efficacy	95%	94.1% (100% against severe disease)	66% (mod/severe) 85% (severe/critical)
Contract COVID-19 from Vaccine	No	No	No
Safe for Immunocompromised	Yes	Yes	Yes
Studies in Children	Yes (6 mo -)	Yes (6 mo -)	N/A
Not interchangeable			
Co-administration with other vaccines: not within 14 days			

A 3D rendering of a virus particle, likely a coronavirus, shown from a top-down perspective. The central core is a grey, textured sphere. The surface is covered with numerous red, crown-shaped proteins (spikes) and smaller orange and yellow particles. The background is plain white.

Thank you!



References



- CDC COVID-19 Science Updates
 - <https://www.cdc.gov/library/covid19/scienceupdates.html?Sort=Date%3A%3Adesc>
 - <https://www.cdc.gov/coronavirus/2019-nCoV/index.html>

- IDSA COVID-19 Real Time Learning Network
 - https://www.idsociety.org/covid-19-real-time-learning-network/?utm_source=IDSA%20Twitter&utm_medium=post&utm_campaign=RTLN

- Pediatric Infectious Disease Society COVID-19 Resources
 - <https://pids.org/resources/covid-19-resources/>
 - Multicenter Interim Guidance on Antiviral Use for Children with COVID-19 (<https://doi.org/10.1093/jpids/piaa115>)

- UCSF COVID-19 Resources
 - <https://coronavirus.ucsf.edu/>
 - <https://infectioncontrol.ucsfmedicalcenter.org/coronavirus>
 - <https://idmp.ucsf.edu/pediatric-guidelines-covid-19>

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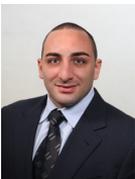
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Q&A



Vaccine Ingredients

Description	Pfizer-BioNTech	Moderna
mRNA	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2
Lipids	2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide	Polyethylene glycol (PEG) 2000 dimyristoyl glycerol (DMG)
	1,2-distearoyl-sn-glycero-3-phosphocholine	1,2-distearoyl-sn-glycero-3-phosphocholine
	Cholesterol	Cholesterol
	(4-hydroxybutyl)azanediylbis(hexane-6,1-diyl)bis(2-hexyldecanoate)	SM-102 (Proprietary to Moderna)
Salts, sugars, buffers	potassium chloride	Tromethamine
	Monobasic potassium phosphate	Tromethamine hydrochloride
	Sodium chloride	Acetic acid
	Dibasic sodium phosphate dihydrate	Sodium acetate
	Sucrose	Sucrose