

Understanding COVID-19 Vaccines and Clinical Research

Dr. Brittany Ober-Shepherd, MD

Research Physician
Emerging Infectious Diseases Branch
Walter Reed Army Institute of Research

WRAIR

Walter Reed Army
Institute of Research

September 24th, 2021



Presentation Overview

- Information on COVID vaccines
- Vaccine development process
- Myths and misconceptions about COVID vaccines
- Why we still need COVID-19 research

COVID-19 Vaccine Basics



Current Vaccines Available

mRNA Vaccines

Moderna, Pfizer-BioNTech



Booster: 65+, Immunocompromised

DNA Vaccines

Johnson & Johnson



Booster: Under discussion

Moderna and J&J have EUA from the FDA for ages 18+.

Pfizer has FULL FDA approval for ages 16+ and EUA for ages 12-15.

63%

of the United States has had at least 1 dose

of doses in U.S.

Moderna	Phase 3 clinical trial	30,351
	Public health rollout	146 million
Pfizer	Phase 3 clinical trial	43,661
	Public health rollout	213 million
J&J	Phase 3 clinical trial	44,325
	Public health rollout	14.5 million

Are there any common/uncommon side effects?

MODERNA

Pain at injection site

Fatigue

Headache

Muscle pain

Joint pain

Chills

Swollen Lymph Nodes

Facial Swelling
in people with facial fillers

Bell's Palsy

Myocarditis

Allergic Reactions

Anaphylaxis

PFIZER

Injection site pain

Fatigue

Headaches

Muscle soreness

Chills

Nausea

Fevers

Bell's Palsy

Allergic Reactions

Dizziness/Vertigo

Guillan-Barre Syndrome

Anaphylaxis

J&J

Injection site pain

Rash

Headaches

Muscle soreness

Fevers

Immune mediated
thrombocytopenia

Guillan-Barre Syndrome

Blood Clots

Anaphylaxis

3.1 cases per 1 million

More likely

Less Likely

4.7 cases per 1 million

Are there any common/uncommon side effects?

Anaphylaxis: 4.7 cases per 1 million

Blood Clots (J&J): 3.1 cases per 1 million

Pain at injection site

Injection site pain

Injection site pain

Fatigue

Fatigue

Rash

More

Muscle pain

Muscle soreness

Muscle soreness

Joint pain

Chills

Fevers

Chills

Swollen Lymph Nodes

Nausea

Immune mediated thrombocytopenia

Facial Swelling

Fevers

Guillan-Barre Syndrome

in people with facial fillers

Bell's Palsy

Blood Clots

Bell's Palsy

Allergic Reactions

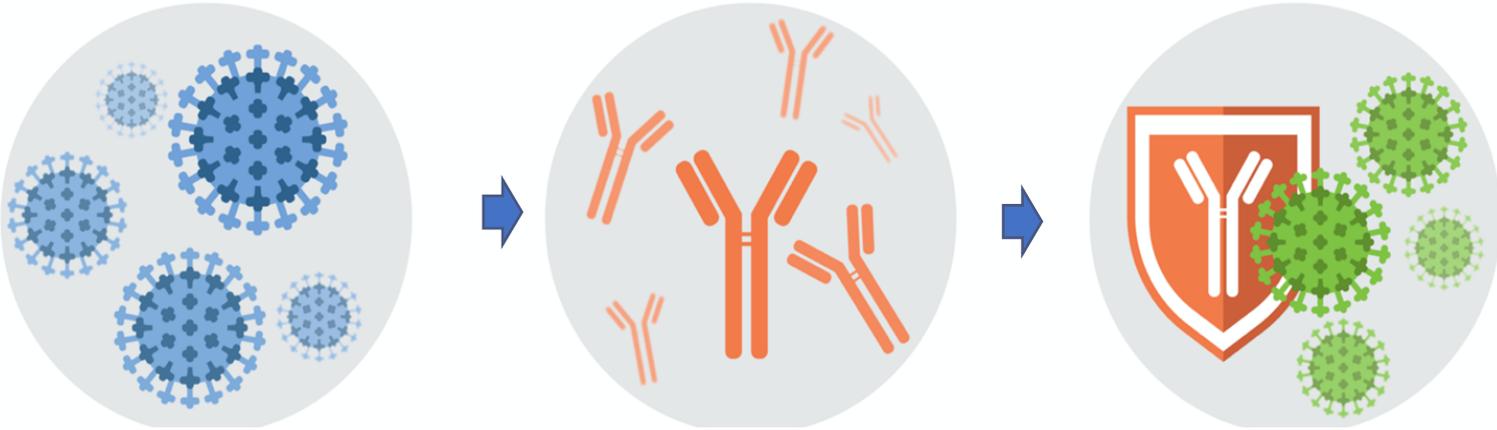
Anaphylaxis

Less Likely

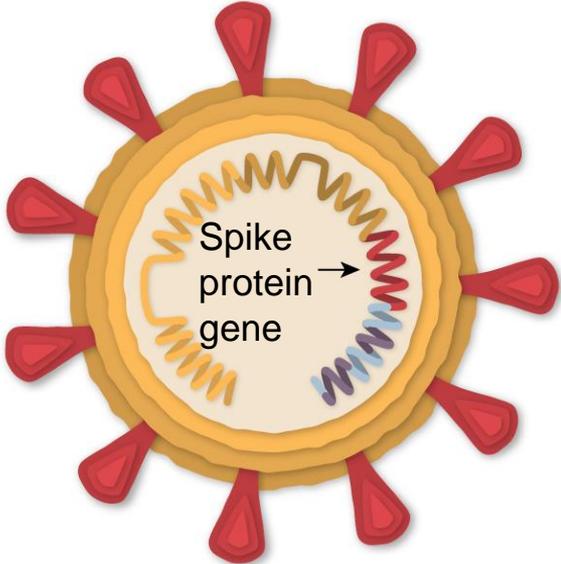
Death from COVID-19:

60k cases per 1 million if unvaccinated

HOW DO VACCINES WORK?

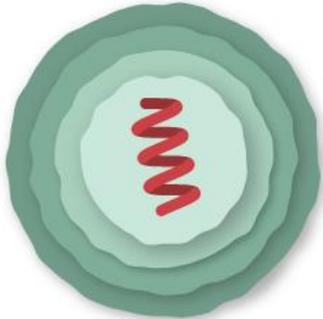


mRNA vaccines (Moderna and Pfizer)

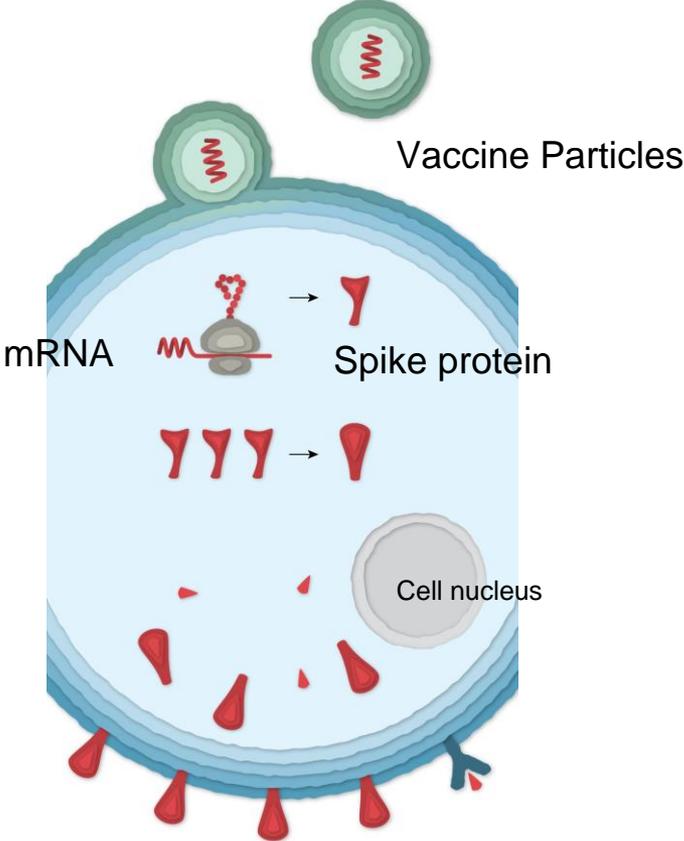


SARS-CoV-2

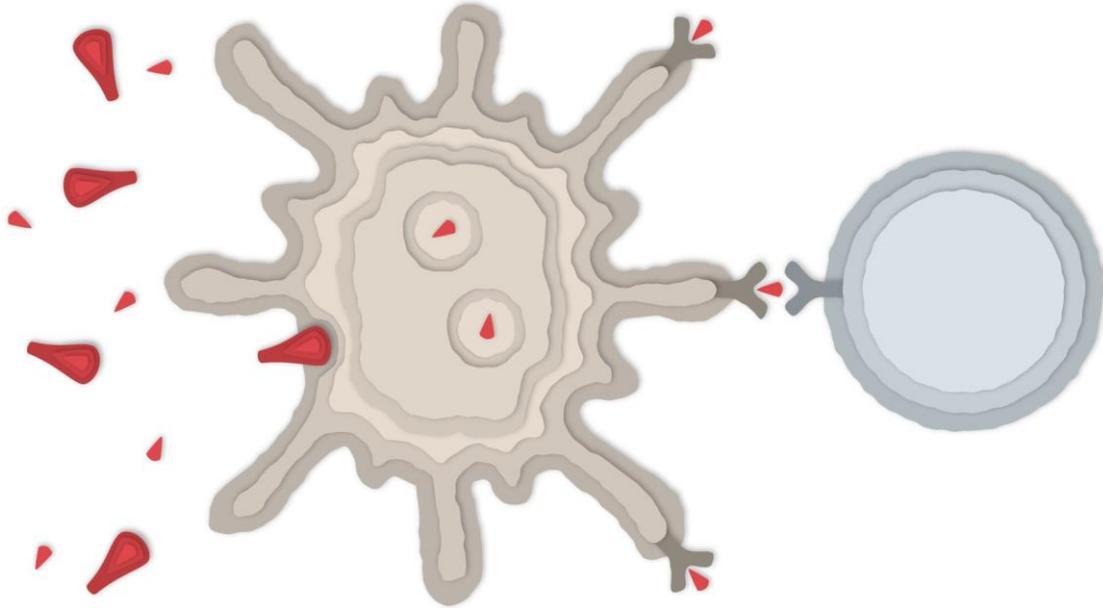
mRNA is tucked inside an oily or "lipid" bubble
→



mRNA vaccines (Moderna and Pfizer)

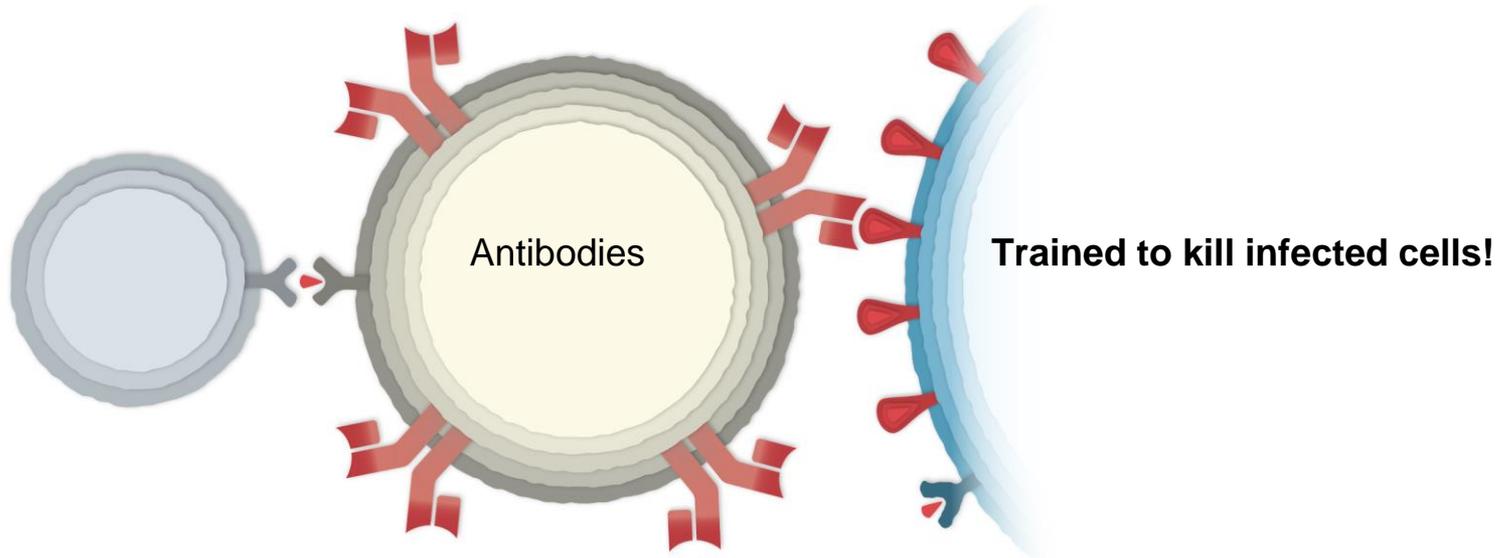


mRNA vaccines (Moderna and Pfizer)



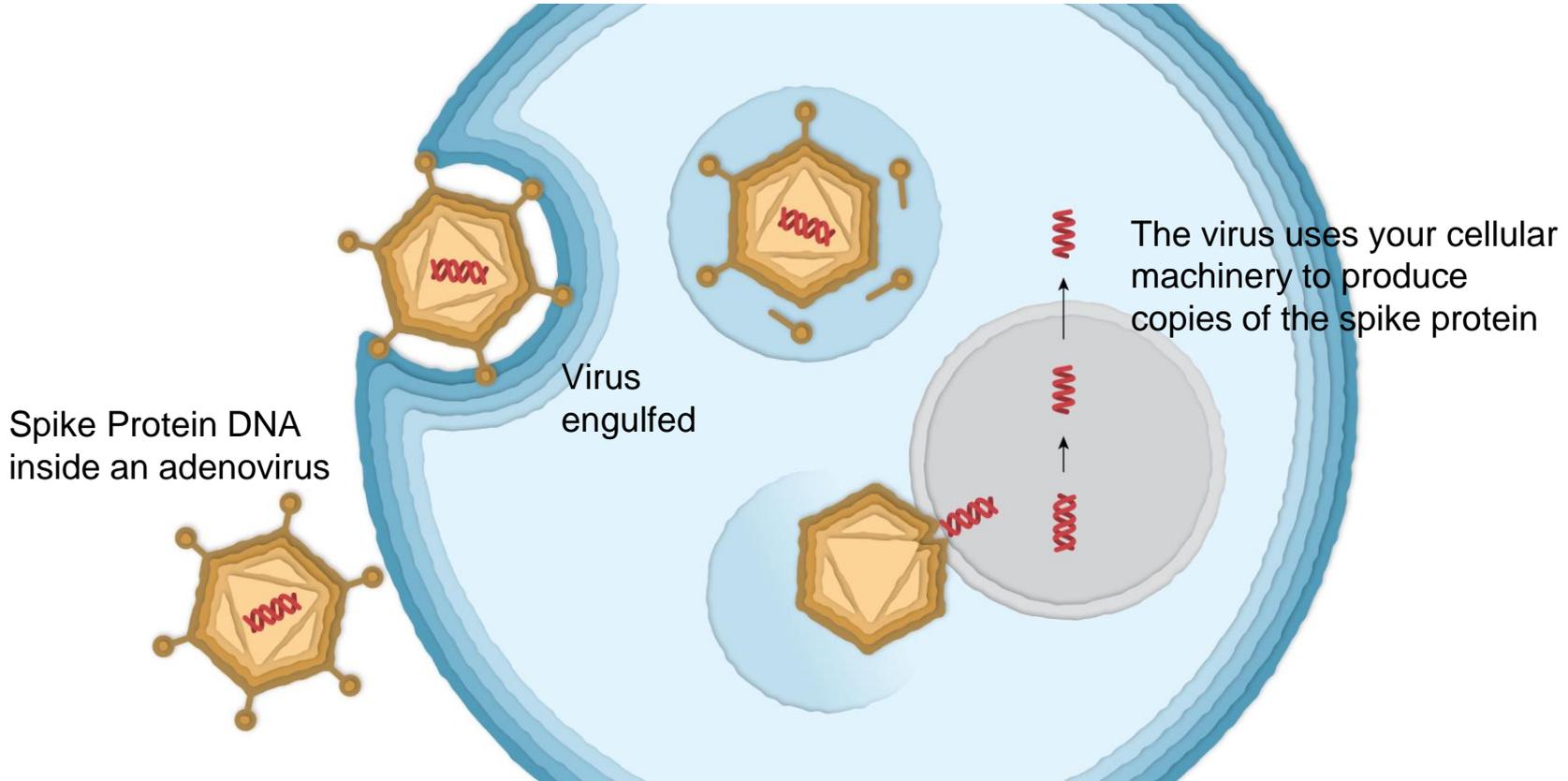
Antigen presenting cells capture the intruder and notify Helper T-Cells that backup is needed!

mRNA vaccines (Moderna and Pfizer)

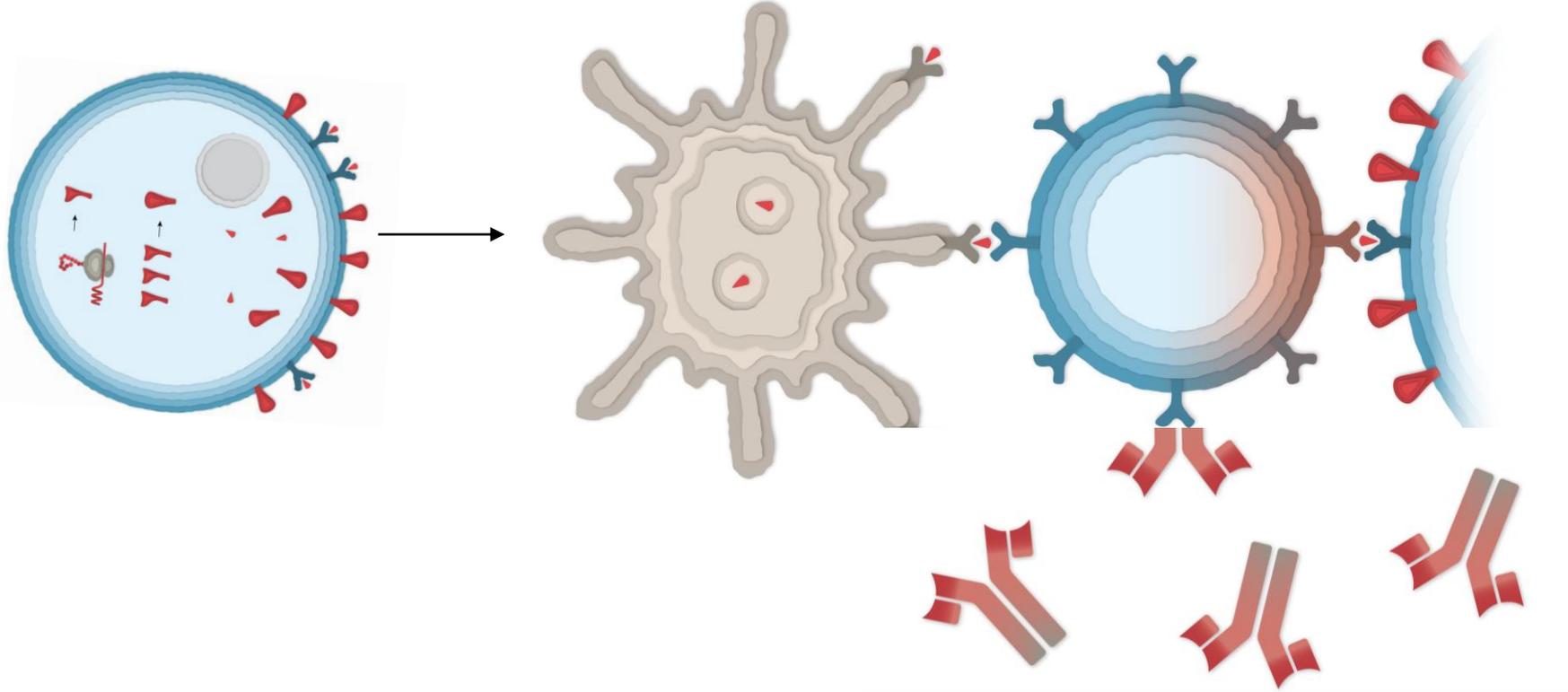


Booster shots are like a fire drill, providing practice and instilling long term memory.

DNA vaccines (J&J)



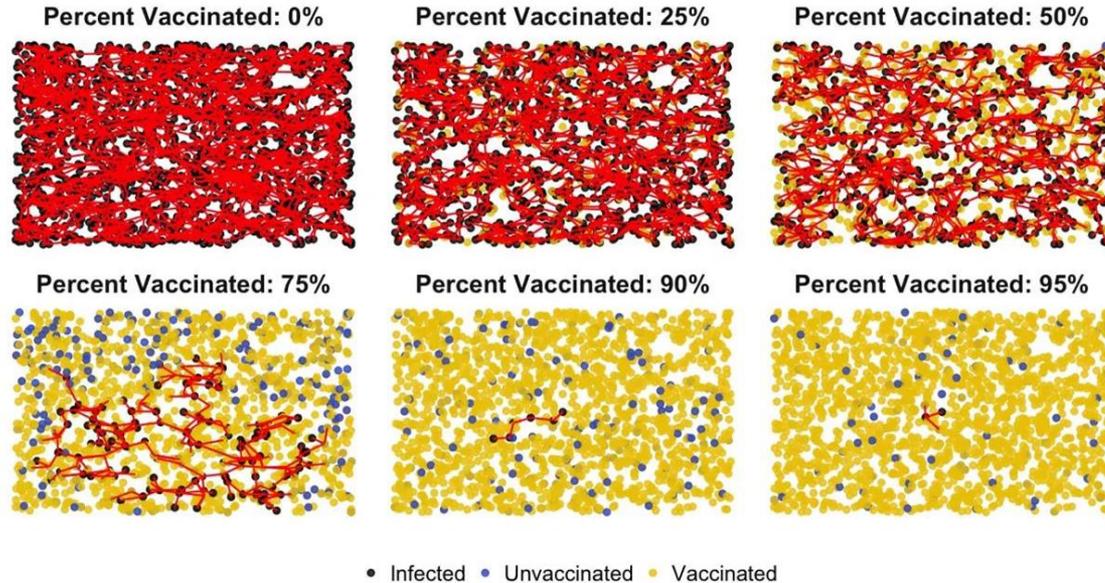
DNA vaccines (J&J)



How vaccines protect the community

- Vaccines work by creating herd immunity without people getting sick... **BUT** if they're less effective (or unused) in any community, they're less effective for everybody.

Herd Immunity from Vaccines: How it Works



Vaccine Development Process

Development of new vaccines

STEP 1: laboratory research “Preclinical Phase”

After creating a new vaccine product, researchers need to:

- Determine its structure
- Test whether it will stimulate the immune system in the right way



Laboratory studies with animals are used to:

- Demonstrate that the vaccine can stimulate the immune system
- Show that it can protect against disease
- Check for any safety issues or adverse effects

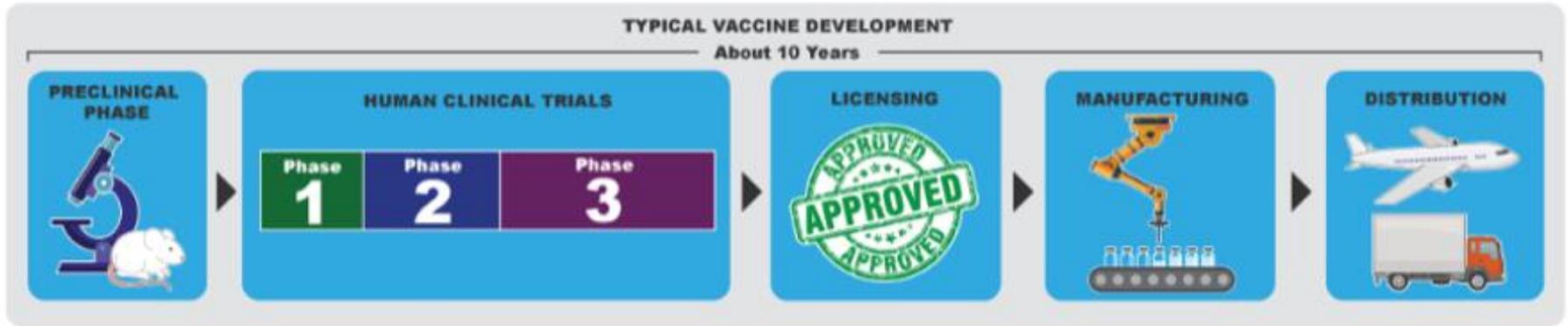
Manufacturing quality: COVID-19 vaccines

FDA requires that manufacturing quality is verified before any human trials are done

- **Identity** – verify the product is present, how much, and absent any adulteration
- **Purity** – check to ensure no impurities have been introduced
- **Potency** – verifies the product does what is expected, i.e. still works to stimulate the immune system in the correct way

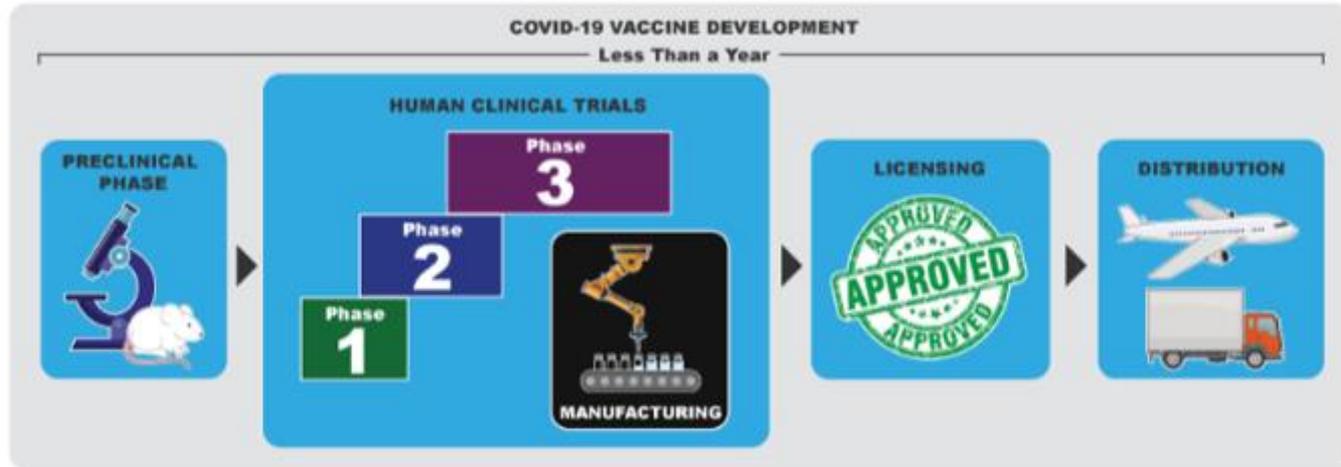
These characteristics are all verified using quality control tests

Traditional vaccine development pathway

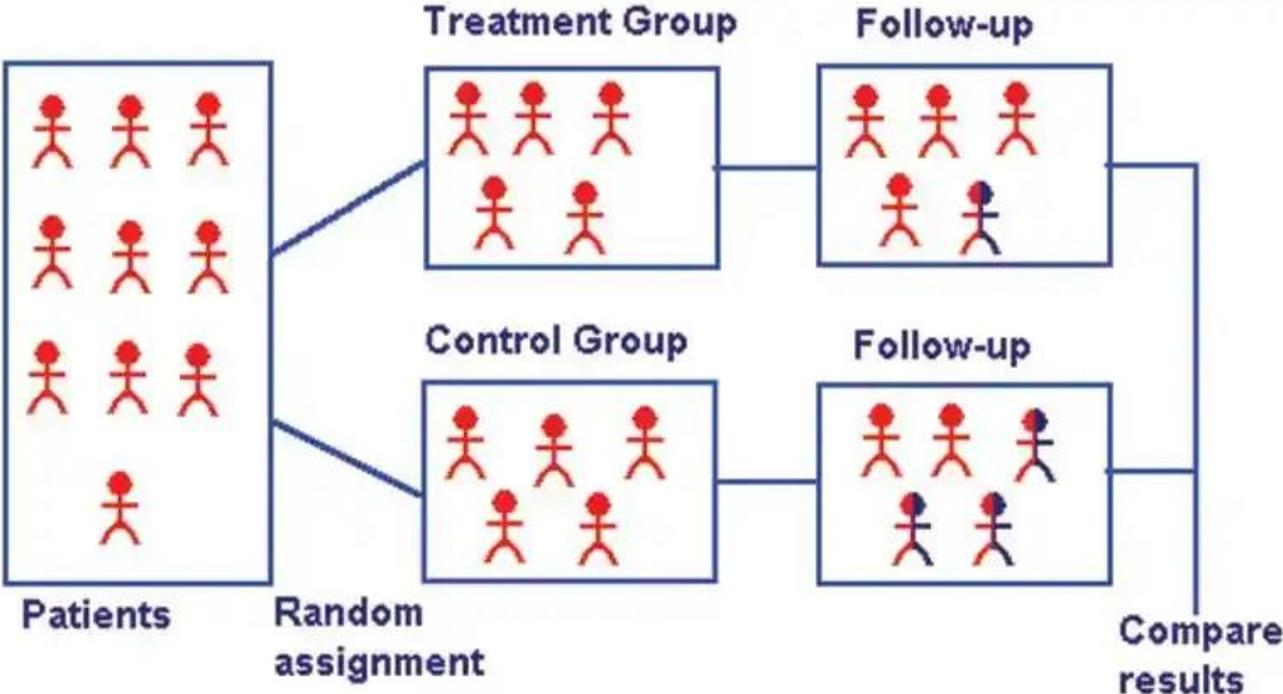


COVID-19 Vaccine Development

In the search for a COVID-19 vaccine we're **not skipping steps**. We are overlapping them instead of doing them one at a time.



How do clinical trials show whether the vaccines work and are safe?



Do the current vaccines protect against COVID variants such as the delta variant?

- **Yes!** Current vaccines provide good protection against the different variants, including the delta variant.
- While people who have been vaccinated may become infected somewhat more easily with the delta variant, they are still protected from severe disease and death.

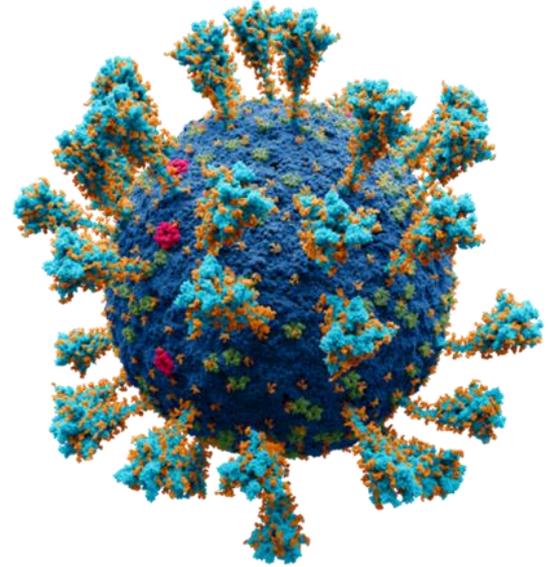


Image from <https://asm.org/Articles/2021/July/How-Dangerous-is-the-Delta-Variant-B-1-617-2>

Myths and Misconceptions

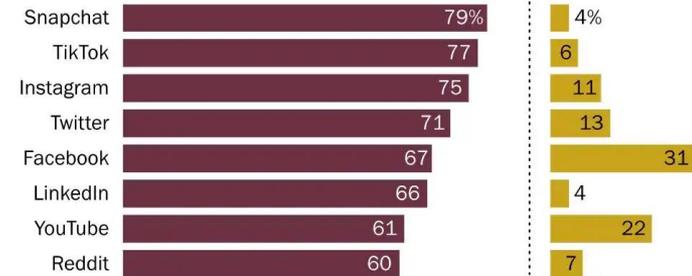
Where do misconceptions come from?

- Many people get vaccine news from social media.
- For example, 31% of US adults regularly get news on Facebook
- Of that group, most (67%) view social media as an important way to get vaccine news

Nearly 80% of Americans who regularly get news on Snapchat and on TikTok view social media as an important way of getting vaccine news

% of Americans that regularly get news on ___ who say that social media is an important way of keeping up with news about COVID-19 vaccines

% of U.S. adults who regularly get news on each site



Note: Twitch and WhatsApp not shown due to insufficient sample sizes.

Source: Survey conducted July 26-Aug. 8, 2021.

PEW RESEARCH CENTER

Myths and misconceptions: Will COVID-19 vaccines modify your DNA?

No, none of the vaccine products used for COVID vaccines are capable of modifying DNA.

- The Pfizer and Moderna vaccines use **mRNA technology** to stimulate the body to create a COVID spike protein.
- The J&J vaccine uses a **modified adenovirus** to carry the gene for the spike protein.
- Neither of these vaccine products persist in the human body or become incorporated into DNA

Can the COVID vaccines make a person infertile?

No, there is no evidence that the COVID-19 vaccines causes infertility.

There is ample evidence that women become pregnant at the same rate whether they are vaccinated or not.

For example, in a recent in vitro fertilization study, researchers compared pregnancy success rates among three groups of women. Women with:

1. Antibodies from having been vaccinated against COVID-19
2. Antibodies from having a recent infection with the virus that causes COVID-19
3. No antibodies from either having a recent infection or from having been vaccinated against COVID-19

The study found no differences in pregnancy success rates among the three groups.¹¹

Source: CDC <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/planning-for-pregnancy.html>

Antibodies from vaccines are present in breast milk.



Are there microchips in the vaccines?

No, there are no microchips in any of the COVID vaccines.

The vaccines use nanotechnology to create small particles that are suitable to stimulate the immune response.

Nanotechnology refers to the manipulation of materials

Some commentators may have been looking at *other uses of nanotechnology*, which includes microchips.

More information about nanotechnology

- Nanotechnology refers to manipulation of substances on a near-atomic level. Nanomaterials are things whose size is on a scale between 1 and 100 nanometers.
- Nanotechnology is used for many different types of applications, including medicine, consumer products, and manufacturing.
- In the case of COVID-vaccines, the vaccine products are manipulated using nanotechnology to help them enter our cells and stimulate the immune system.

It is possible to use nanotechnology to deliver microchips, but there are many other uses for nanotechnology besides this!

Was the vaccine development too rushed?

As mentioned previously, the steps in the vaccine approval process for Emergency Use Authorization included all the usual data collection activities and FDA review steps.

The steps were overlapping and conducted with huge influx of government **funds** in order to get vaccines tested more quickly.

Can a person be protected from getting sick with COVID by eating healthy foods and taking vitamins?

Healthy foods alone does not protect against COVID-19.

Unfortunately, even previously very healthy people have become very sick and even died from COVID-19 infection.

However, people who have a longstanding history of exercising and eating healthy are LESS LIKELY to be hospitalized or experience death.

Has Vitamin D been shown to be effective in treating COVID-19 infection?

No, Vitamin D has not been proven as a treatment for COVID-19 infection.

Micronutrients, such as vitamins D and C and zinc, are critical for a well-functioning immune system and play a vital role in promoting health and nutritional well-being.

There is currently no guidance on the use of micronutrient supplements as a treatment of COVID-19.

WHO is coordinating efforts to develop and evaluate medicines to treat COVID-19.

FACT:
Vitamin and mineral supplements cannot cure COVID-19



World Health Organization

#Coronavirus

#COVID19

22 September 2020

Source: [https://www.who.int/images/default-source/health-topics/coronavirus/mythbusters/web-mythbusters/eng-mythbusters-covid19-\(5\)-supplements.png](https://www.who.int/images/default-source/health-topics/coronavirus/mythbusters/web-mythbusters/eng-mythbusters-covid19-(5)-supplements.png)

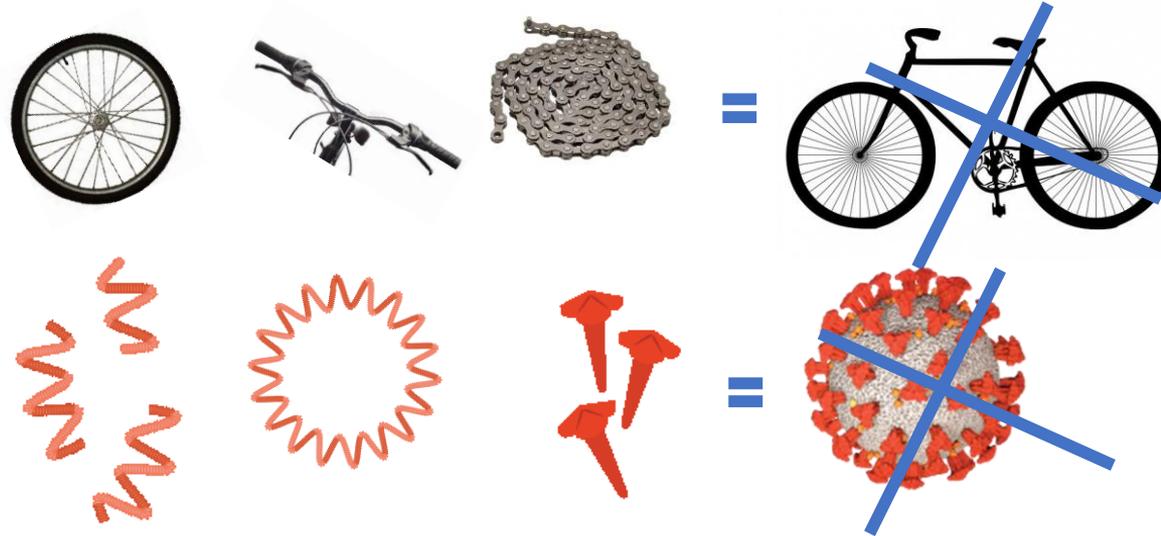
How can we tell if the pharmaceutical companies are telling the truth about the vaccines?

All clinical trials of COVID vaccines conducted by pharmaceutical companies must follow rigorous safety and data reporting standards

Pharmaceutical companies that are seeking FDA approval must submit their data for review by independent advisory committees, and by FDA scientists

Can vaccines cause COVID-19 infection or COVID-19 illness?

NO! The vaccines being tested are made from synthetic (laboratory made) pieces copied from SARS-CoV-2, not the whole virus. Therefore, the vaccines CANNOT cause infection or cause you to get COVID-19 illness.



Frequently asked questions

Should you get vaccinated if you have already had the disease?

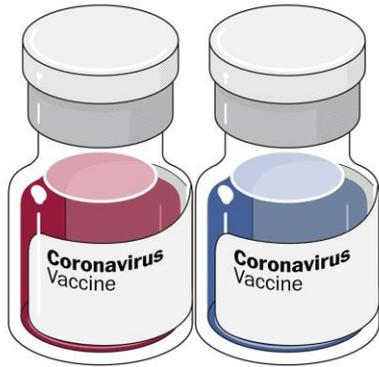
Yes!

Evidence shows that those with prior infection have a strong immune response.

Receiving the vaccine helps the immune system be even better prepared against new variants or repeat infection

How long will vaccine protection last?

The exact duration that immunity lasts is still unknown.



While more research needs to be done, experts believe you may have to receive the COVID-19 vaccine multiple times throughout your life rather than just once.

Can you get one shot of one vaccine, and a second shot of a different vaccine?

- **Yes!**
- Safety and efficacy of mixing products have not been evaluated.
- Every effort should be made to stick with the same vaccine, but getting two different shots is better than getting just one.

Do people still need to wear masks after they get vaccinated?

Yes!

The vaccines will prevent you from getting severely ill with COVID-19.

However, it is still possible to spread the virus to others even if you do not feel sick, and some people in the community may be at risk.

Why we need more clinical research on COVID-19

Why do we need another COVID vaccine?

- ✓ Current vaccines are highly effective, but may not protect against future COVID strains
- ✓ Current vaccines require ultra-cold storage which is impractical in many settings
- ✓ More vaccines are needed to cover additional populations around the world
- ✓ May improve the duration and strength of immunity of current vaccines

Ongoing vaccine research



Contact Information

- Questions? Comments? Want more information?
- Connect with a WRAIR member by sending us an email at: **Community@eidresearch.org**



THANK
YOU! 😊