COVID-19 Vaccine Update

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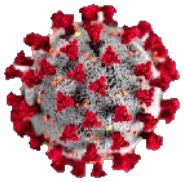
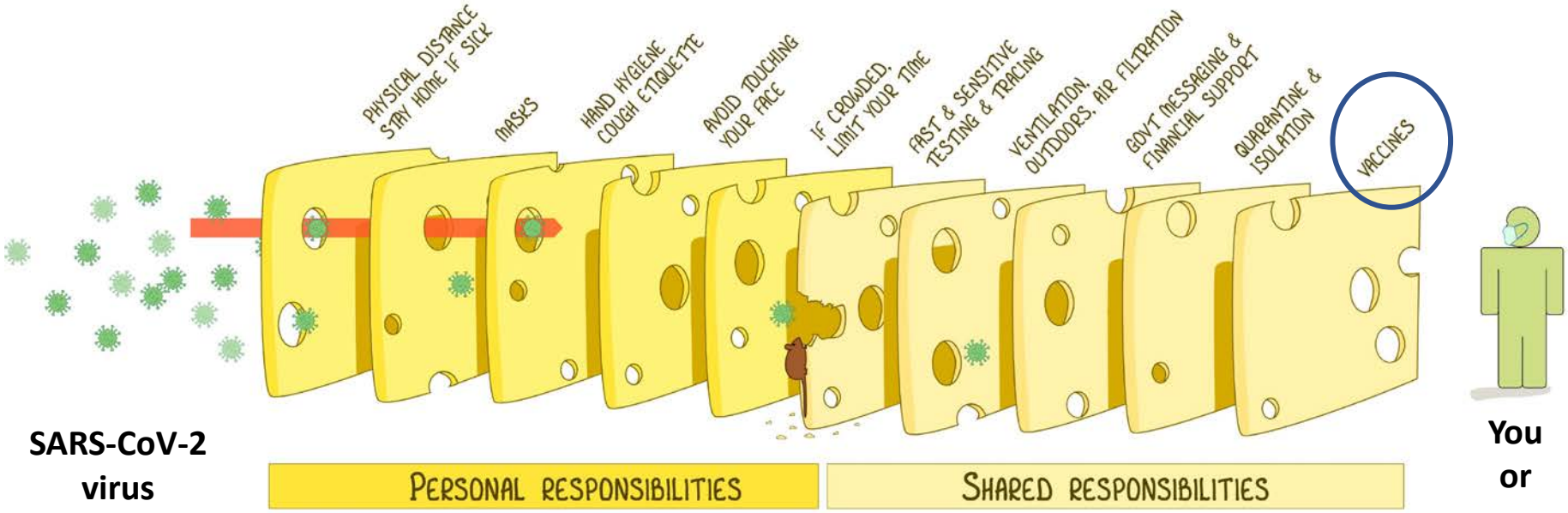
VANDERBILT HEALTH



Prevention

The Swiss Cheese Respiratory Virus Defense

Recognizing that No Single Intervention is Perfect



SARS-CoV-2 virus

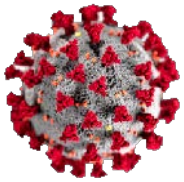
You or me

Each intervention (layer) has failings (holes)
Multiple layers reduce their impact

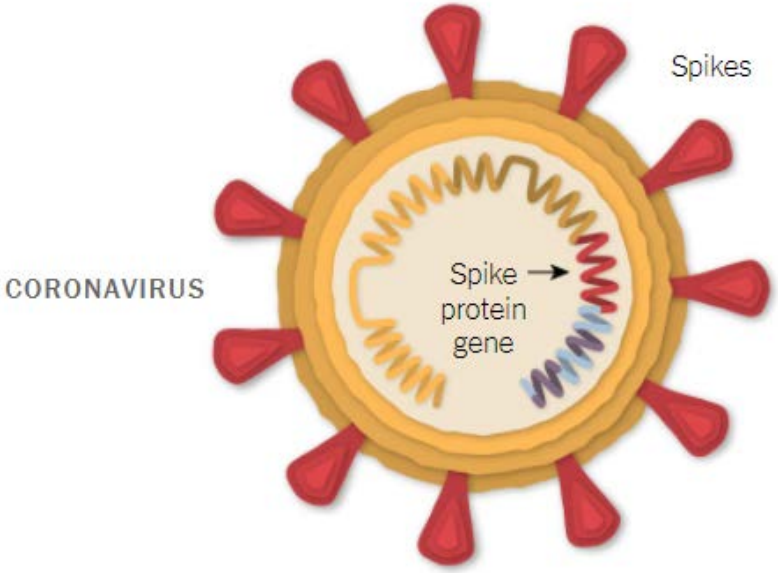
Figure drawn by Dr. Ian M. Mackay (2020)

VANDERBILT HEALTH

How Does a COVID Vaccine Work?

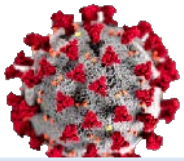


- The COVID-19 virus is covered in spikes that allow the virus to attach to a cell. Once it is attached, the virus can damage the cell & begin to make the body sick. **Antibodies should stop the virus from attaching to cells & making you sick.**



https://www.nytimes.com/interactive/2020/health/pfizer-biontech-covid-19-vaccine.html

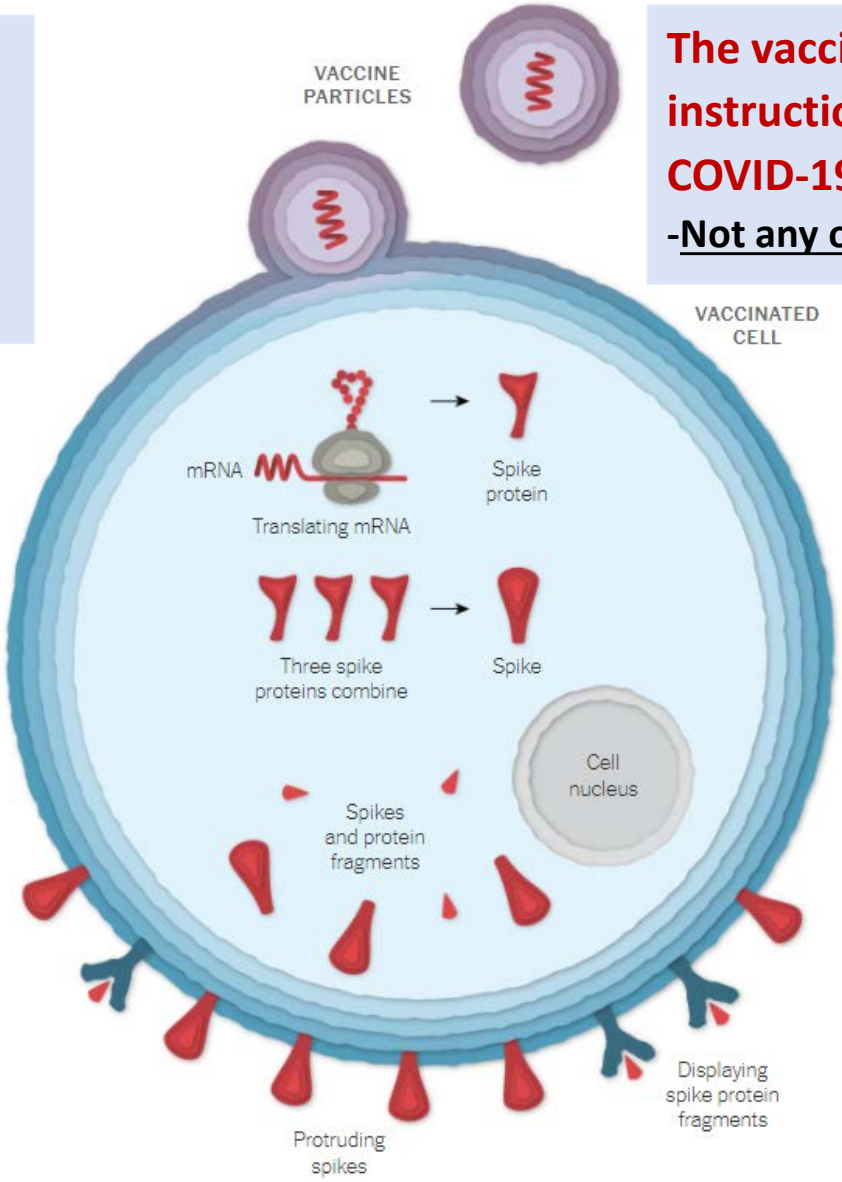
How Does an mRNA Vaccine Work?



Uses a small portion of the virus's messenger RNA (mRNA) - an instruction manual used by cells to build different types of proteins.

The vaccines contain only the instructions for creating the COVID-19 spike protein

-<u>Not any other part of the virus</u>

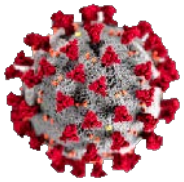


The mRNA causes muscle cells to produce spike proteins, which enter the blood stream. The immune system recognizes that the spike proteins are foreign and makes specific antibodies to block the spikes.

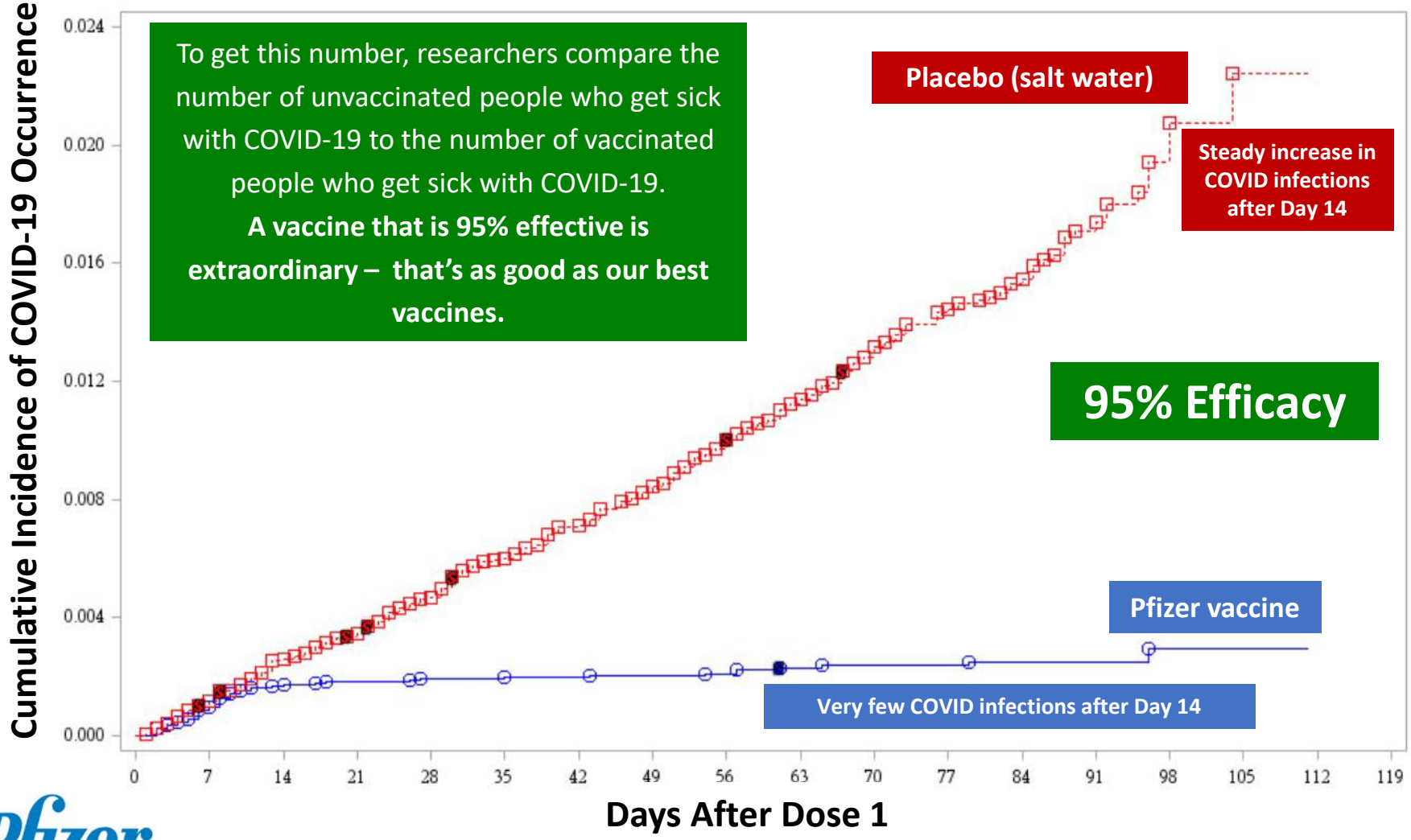
This mRNA is rapidly degraded in the cell and **never enters the nucleus of the cell & does not affect or interact with a person's DNA (genetic code).**

https://www.nytimes.com/interactive/2020/health/pfizer-biontech-covid-19-vaccine.html

How Effective are the mRNA Vaccines?

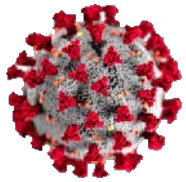


First COVID Occurrence After Dose #1

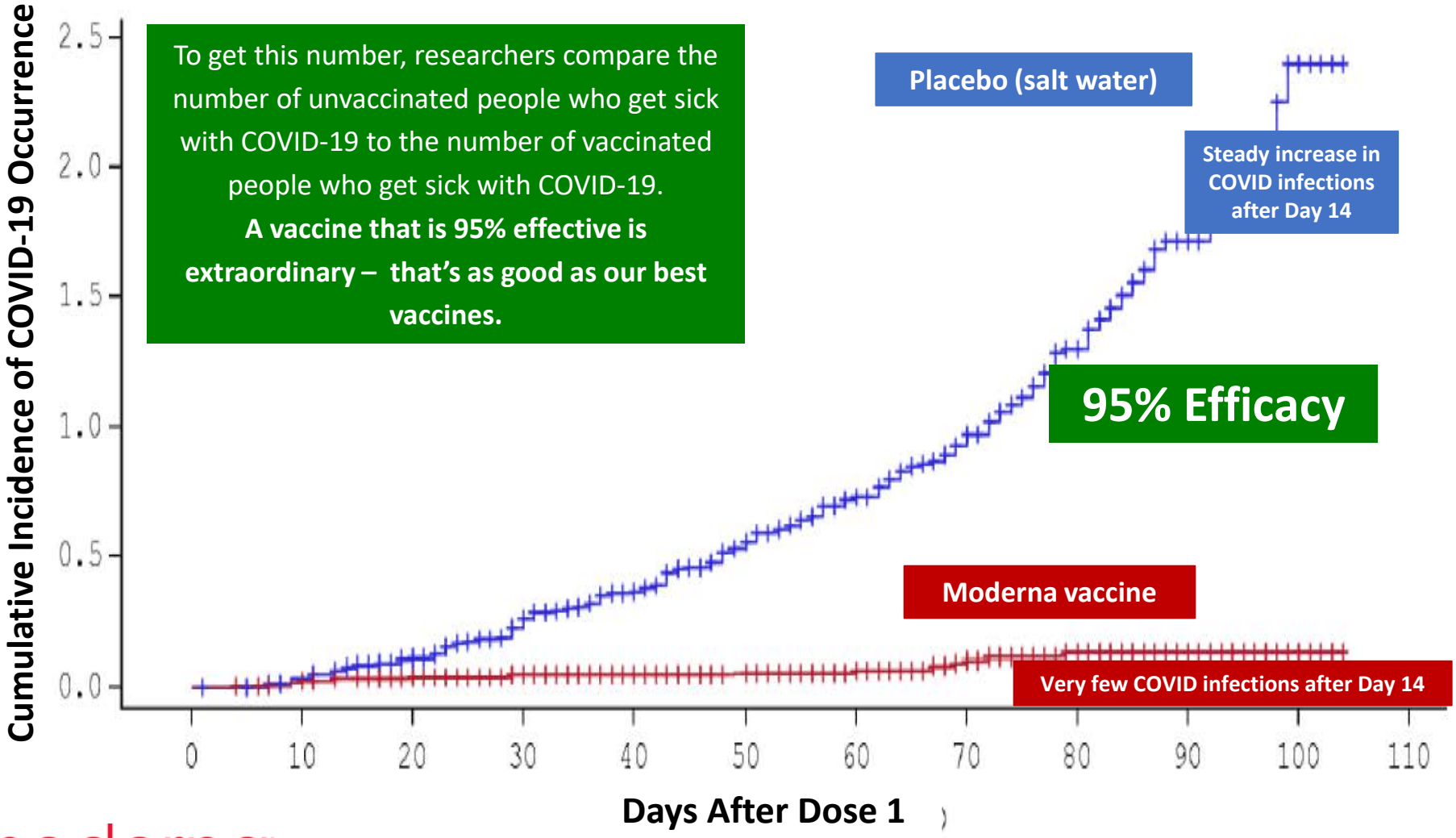


Pfizer

How Effective are the mRNA Vaccines?

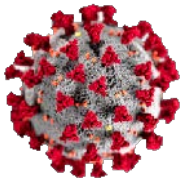


First COVID Occurrence After Dose #1



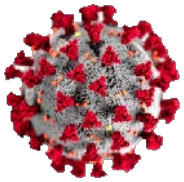
moderna

What Do We Know About the Safety of the mRNA Vaccines?



- The safety profile of the mRNA vaccines has been very good. They have been given to **over 38 million people** in the US with very few side effects.
- The participants in the clinical trials will continue to be followed for adverse events, but it is expected that these will be unlikely based on experience with other vaccines.
- Vaccines can only be given to people in the U.S. with the authorization of the Food and Drug Administration (FDA).
- The FDA has strict guidelines & requirements for ensuring that a vaccine is both safe & effective.

Why Were They Able to Make These Vaccines So Quickly? Did They Cut Corners or Take More Risks?

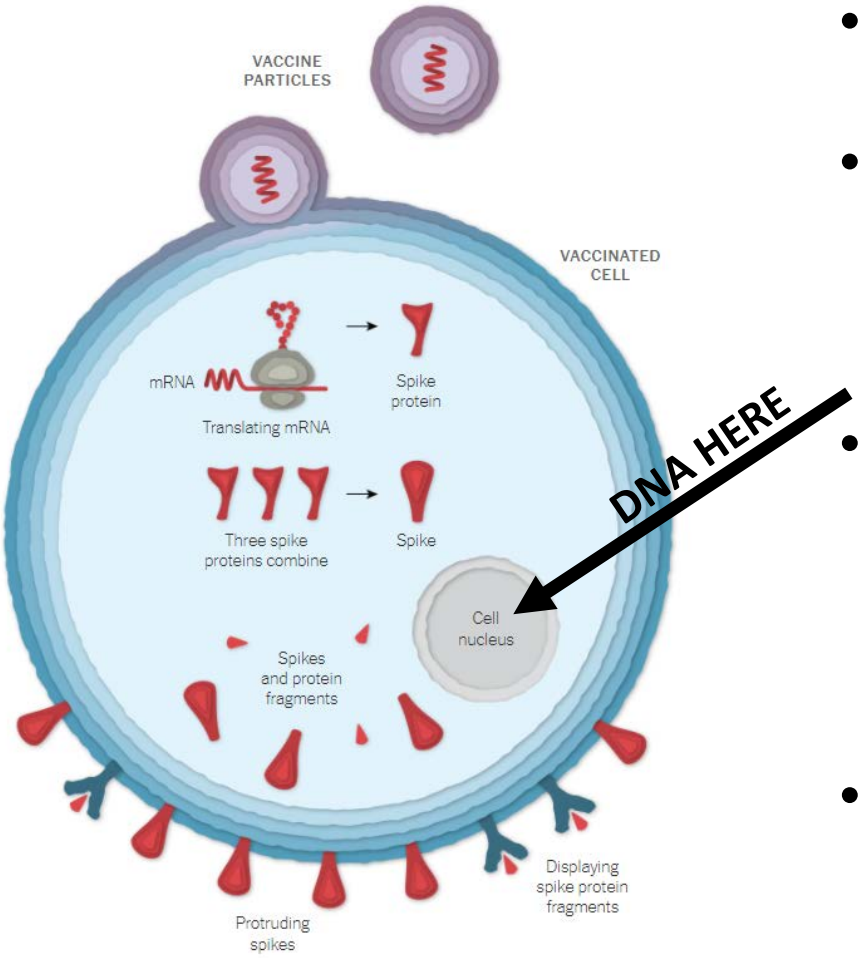


Both Pfizer & Moderna used similar processes to develop the vaccines & had two advantages to speed up this process:

1. Even though COVID-19 is a new virus, scientists have been studying these types of viruses for over 15 years & so had a head start on research
    - Researchers here at Vanderbilt have been at the forefront of coronavirus vaccine development over the past decade
2. Some of the steps were completed at the same time, instead of one after the other
    - For example, through Operation Warp Speed, the US government funded large scale manufacturing before anyone knew the vaccines would work

- Despite this speed it is important to understand that there were **no corners cut** in the processes of reviewing & approving the vaccine
    - They were subject to the same standards of safety as other drugs & vaccines

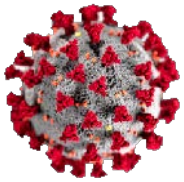
Will this mRNA Vaccine Affect My DNA or Cause Changes in My Genes?



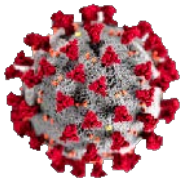
- No, these vaccines cannot affect or change your DNA.
- The mRNA message **never enters the nucleus of the cell & does not affect or interact with a person's DNA (genetic code).**
- After the piece of the spike protein is made, the cell breaks down the mRNA strand & disposes of them using enzymes in the cell.
- Humans also don't have enzymes to turn RNA into DNA.

https://www.nytimes.com/interactive/2020/health/pfizer-biontech-covid-19-vaccine.html

Who Should Not Get the mRNA COVID Vaccine?



- **Almost everyone should get the vaccine**
- Very **few people should not**:
  - If you are **under the age of 16**
  - If you are **allergic to components** of the vaccine (see later slides)
  - If you have **received COVID antibody or plasma** therapy in the 90 days before planned vaccination



Allergies & the mRNA Vaccines (I)

- Concerns raised with initial vaccination roll out -

INDIA TOP NEWS DECEMBER 9, 2020 / 9:31 PM / UPDATED 2 MONTHS AGO

UK issues anaphylaxis warning on Pfizer vaccine after adverse reactions

NATIONAL

2nd likely anaphylactic reaction to Pfizer COVID-19 vaccine in Alaska reported in Fairbanks

Pfizer

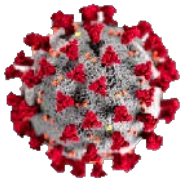
During December 14–23, 2020, monitoring by the Vaccine Adverse Event Reporting System detected 21 cases of anaphylaxis after administration of a reported 1,893,360 first doses of the Pfizer-BioNTech COVID-19 vaccine (11.1 cases per million doses); 71% of these occurred within 15 minutes of vaccination.

moderna

During December 21, 2020–January 10, 2021, monitoring by the Vaccine Adverse Event Reporting System detected 10 cases of anaphylaxis after administration of a reported 4,041,396 first doses of Moderna COVID-19 vaccine (2.5 cases per million doses administered). In nine cases, onset occurred within 15 minutes of vaccination. No anaphylaxis-related deaths were reported.

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

Allergies & the mRNA Vaccines (II)



COVID-19 Vaccine Components

Description	Pfizer-BioNTech COVID-19 vaccine	Moderna COVID-19 vaccine
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	PEG2000-DMG: 1,2-dimyristoyl-rac-glycerol, methoxypolyethylene glycol
	1,2-distearoyl-sn-glycero-3-phosphocholine	1,2-distearoyl-sn-glycero-3-phosphocholine
	Cholesterol	Cholesterol
	(4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl) bis(2-hexyldecanoate)	SM-102: heptadecane-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate
Salts, sugars, buffers	Potassium chloride	Tromethamine
	Monobasic potassium phosphate	Tromethamine hydrochloride
	Sodium chloride	Acetic acid
	Dibasic sodium phosphate dihydrate	Sodium acetate
	Sucrose	Sucrose

- Also, allergy to polysorbates (could cross-react with PEG)
- Polysorbates: Widely used; emulsifiers that make incompatible substances, like oil and water, stick together

Allergies & the mRNA Vaccines (III)

- No current evidence suggests those with food or seasonal allergies are at higher risk for allergies to drugs and vaccines. You are recommended to be vaccinated.

ALLERGIES

PROCEED WITH VACCINATION

- ❑ Do you have food, pet, insect, seasonal or latex allergies?
- ❑ Are you allergic to oral medications?
- ❑ Have you had a mild allergic reaction (i.e. no EpiPen required/non-anaphylactic) to other vaccines or injected medications?
- ❑ Do you have a family history of anaphylaxis?

Yes

- ❑ Proceed with vaccination.
- ❑ Provide a 15-minute observation period.

PRECAUTION TO VACCINATION

- ❑ Do you have a history of anaphylaxis to another vaccine, injectable medication or unknown product?

Yes

- ❑ Contact Allergy on-call provider for guidance . If clearance is given, observe patient for 30 minutes.

OR

- ❑ Do you have a history of anaphylaxis that is not related to a vaccine or injectable therapy?

Yes

- ❑ Proceed with vaccination.
- ❑ Provide a 30-minute observation period.

DO NOT VACCINATE

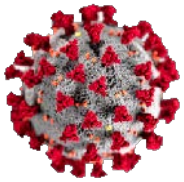
- ❑ Do you have a history of anaphylaxis to any component of the Pfizer-BioNTech vaccine?

Yes

- ❑ Do NOT proceed with vaccination.

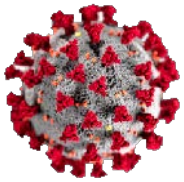
CDC Pre-Vaccination Checklist: https://www.cdc.gov/vaccines/covid-19/downloads/pre-vaccination-screening-form.pdf

I Have Already Had COVID-19. Do I Need to Get the Vaccine?



- **Yes, but wait 90 days after infection**
  - While we suspect you might have some protection against future infections, we do not know how long the protection will last (& that may be related to the severity of the initial infection)
- The vaccine should provide a more robust immune response
  - **The vaccine induces strong & specific immunity** to block the virus from sticking to cells & infecting us
  - Data from clinical trials indicate that mRNA COVID-19 vaccines can safely be given to persons with evidence of a prior SARS-CoV-2 infection.

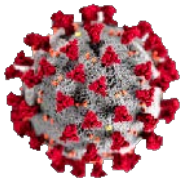
I am at Low Risk from Severe COVID Infection. Why Shouldn't I Just Rely on Natural Immunity from Infection?



- You **may not mount** as strong an immune response
- You **may get very sick** from a natural infection
- You **may have lingering health effects** after infection
- You **may transmit the virus** to others

In a CDC study of 513 adults aged 18–49 years without underlying medical conditions hospitalized, 22% were admitted to intensive care unit; 10% required mechanical ventilation; and three patients died (0.6%).

Can I Get Infected from the COVID Vaccine? Should People with Weak Immune Systems Avoid the Vaccine?



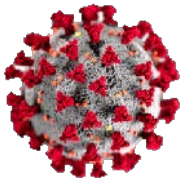
- **No**
- The vaccine does **not** contain live virus & only encodes the RNA for the single spike protein of the virus
- **You cannot contract COVID from the vaccine**.

No other parts of the COVID-19 virus are present

*Patients with a weaker immune system should get vaccinated, as they may be at **higher risk** for severe COVID-19 infection.*
*They **may not** be able to mount as strong an immune response, but there is no risk of acquiring a vaccine-related infection.*

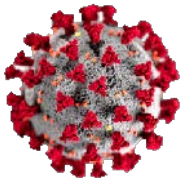
https://www.nytimes.com/interactive/2020/health/pfizer-biontech-covid-19-vaccine.html

I'm Planning to Try & Get Pregnant Sometime in the Next Year. Should I Avoid Vaccination?



- Limited data on mRNA vaccine safety during pregnancy
  - Animal developmental & reproductive toxicity (DART) studies for Pfizer & Moderna reported no harms
  - Not a live vaccine & does not enter cell DNA
- Pregnant people are at ↑ risk of severe illness from COVID & COVID can also ↑ risk of adverse pregnancy outcomes.
- **CDC: Pregnant persons may choose to be vaccinated**
- **ACOG: Should not be withheld from pregnant individuals**
- Routine testing for pregnancy prior to receipt of a COVID-19 vaccine is not recommended by the CDC

Can the COVID-19 Vaccine Make Me Infertile/Sterile?



- **No**
- There is an internet claim that the vaccine spike protein cross reacts to another protein (syncytin-1) that is important to placenta formation.
- The COVID vaccines also do not contain syncytin-1 protein or mRNA encoding syncytin-1.
- These vaccine spike protein and syncytin-1 are very different from each other. There is no evidence that the vaccine response creates cross-reacting antibodies to syncytin-1.


No evidence that COVID-19 vaccine results in sterilization

By BEATRICE DUPUY December 8, 2020

https://apnews.com/article/fact-checking-afs:Content:9856420671

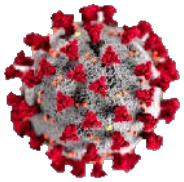

The New York Times

Tracking Viral Misinformation

No, there isn't evidence that Pfizer's vaccine causes infertility.

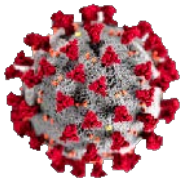
https://www.nytimes.com/2020/12/10/technology/pfizer-vaccine-infertility-disinformation.html

Will the Vaccine will be Offered or Recommended for Nursing Mothers?

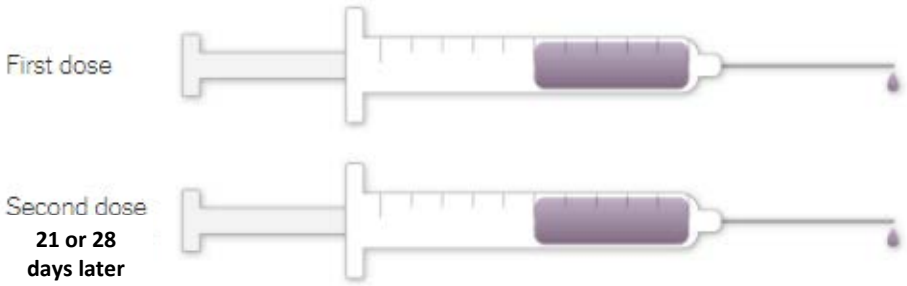


- There are no data on the safety of COVID-19 vaccines in lactating persons; however, RNA vaccines are not live virus vaccines & are not thought to be a risk to the breastfeeding infant
- **Lactating persons may choose to be vaccinated per the CDC and American College of Obstetrics and Gynecology**

How Long After Vaccination Will I be Protected?

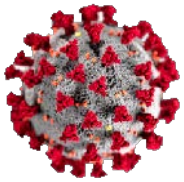


- While there are signs of immune response after just a few weeks from the first dose, vaccinated individuals are <u>not felt to be fully protected until at least 7 days after the second dose</u> of vaccine, per the manufacturer information
- So, it is very important to get **<u>both</u>** doses of the vaccine.

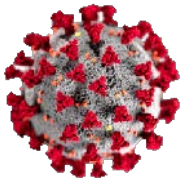


https://www.nytimes.com/interactive/2020/health/pfizer-biontech-covid-19-vaccine.html

Any Other General Advice Around mRNA Vaccination?



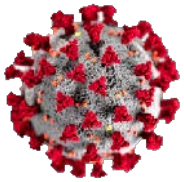
- Avoid other vaccines for 14 days before and after mRNA COVID vaccination, if possible
- Avoid mammogram, if possible, for several weeks post-vaccination (due to potentially swollen lymph nodes under arm from vaccination)
- Infrequently, persons who have received dermal fillers might experience swelling at or near the site of filler injection (usually face or lips) following administration of a dose of an mRNA COVID-19 vaccine. This appears to be temporary and can resolve with medical treatment, including corticosteroid therapy.



How Common is it to Have Symptoms After Vaccination?

- **VERY COMMON** to have vaccine symptoms, especially after 2nd dose:
  - Sore arm
  - Fatigue
  - Muscle aches
  - Fever
  - Headache
- Start 1-2 day after vax; last 1-2 days

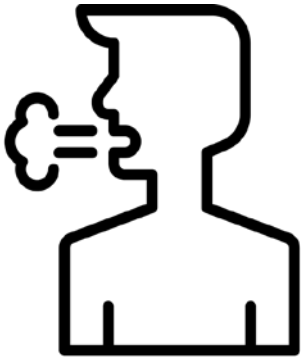
These symptoms = vaccine response!!



What Do I Do if I Have Symptoms After the Vaccination?

- Because some of the effects of the vaccine can mirror those of COVID infection, we will need to be careful to assess these symptoms after vaccination

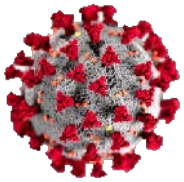
Vaccine-related



Possible COVID Infection

Vaccine-related or COVID Infection?

Can I get Facial Weakness (Bell's Palsy) from the mRNA Vaccine?



- In the Pfizer trial of >38,000 people, 4 cases of Bell's palsy among the vaccinated group and none among the placebo group; Moderna trial: 3 in vaccine group, 1 in placebo group
  - Symptoms occurred at different time points post-vaccination (3-48 days following vaccination) & lasted for < 21 days
- Because the rate of this condition was "consistent with the expected background rate in the general population," the trial ruled there was "no clear basis upon which to conclude a causal relationship" between the vaccine and the occurrence of Bell's palsy.
- FDA has recommended monitoring for this condition as more people are vaccinated; CDC: h/o Bell's Palsy is not a contraindication to receiving COVID vaccination.

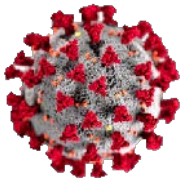
Can I Stop Wearing a Mask After I Get Vaccinated?

Nope!!!

We **know** the vaccine reduces or prevents symptoms

We **hope** it blocks infection & transmission *but do not yet know*

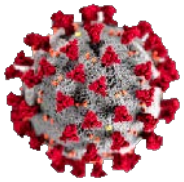
Any Changes in Other General Prevention Guidance if I am Fully-Vaccinated?



CDC quarantine change: 'Fully' vaccinated people don't have to quarantine following COVID exposure

- **Vaccinated persons with an exposure to someone with suspected or confirmed COVID-19 are not required to quarantine if they meet all of the following criteria:**
  - Are fully vaccinated (i.e., ≥2 weeks following receipt of the second dose in a 2-dose series, or ≥2 weeks following receipt of one dose of a single-dose vaccine)
  - Are within 3 months following receipt of the last dose in the series
  - Have remained asymptomatic since the current COVID-19 exposure

What About the Variant Strains of the COVID Virus? Do the Vaccines Work Against These Strains?



- New strains of the COVID virus have emerged that have changes in part of the spike protein.
- Some of these have made the virus easier to spread and may cause more severe outcomes.
- Studies of the mRNA vaccines show that there is still protection against these strains (but the antibody level may be lower vs. some strains).
- Studies of the adenovirus vaccines performed when these strains started circulating still show some protection, but this level is reduced.