



IDPH Region One COVID-19 Vaccine Education

MERCYHEALTH, OSF, UW SWEDISHAMERICAN, NW KISHWAUKEE
EMS SYSTEMS

Objectives

- ▶ Review New IDPH 515.865 Regulations
- ▶ Review COVID-19 Signs/Symptoms/Statistics/Transmission
- ▶ Discussed COVID-19 vaccine development
- ▶ Discuss Different COVID-19 Vaccines
- ▶ Review COVID-19 Vaccine Benefits/Effectiveness
- ▶ Review COVID-19 Vaccine Risks and Common Side Reactions
- ▶ Discuss commonly asked questions regarding COVID-19 vaccines including hesitancy and misinformation

IDPH EMS Administrative Code

515.865- COVID-19 Vaccination of Provider Personnel

- ▶ a, 1) "Staff means any licensed, employed or volunteer, public or private EMS Provider....."
- ▶ a, 2) "Provider means any individual, groups of individuals, corporation, partnership, association, trust joint venture, unit of local government or other public or private ownership entity that owns and operated one of more **ambulances or EMS vehicles** for the **transportation or care** of emergency patients."

IDPH EMS Administrative Code

515.865- COVID-19 Vaccination of Provider Personnel

- ▶ Responsibility of EMS Agencies (transport/non-transport)
 - ▶ Receive First of Single Dose of COVID-19 Vaccine by 9/19/21
 - ▶ Maintain Records
 - ▶ Vaccination
 - ▶ Declination of COVID-19 Vaccine
 - ▶ Testing*
 - ▶ COVID-19 Vaccine Education***

IDPH EMS Administrative Code

515.865- COVID-19 Vaccination of Provider Personnel

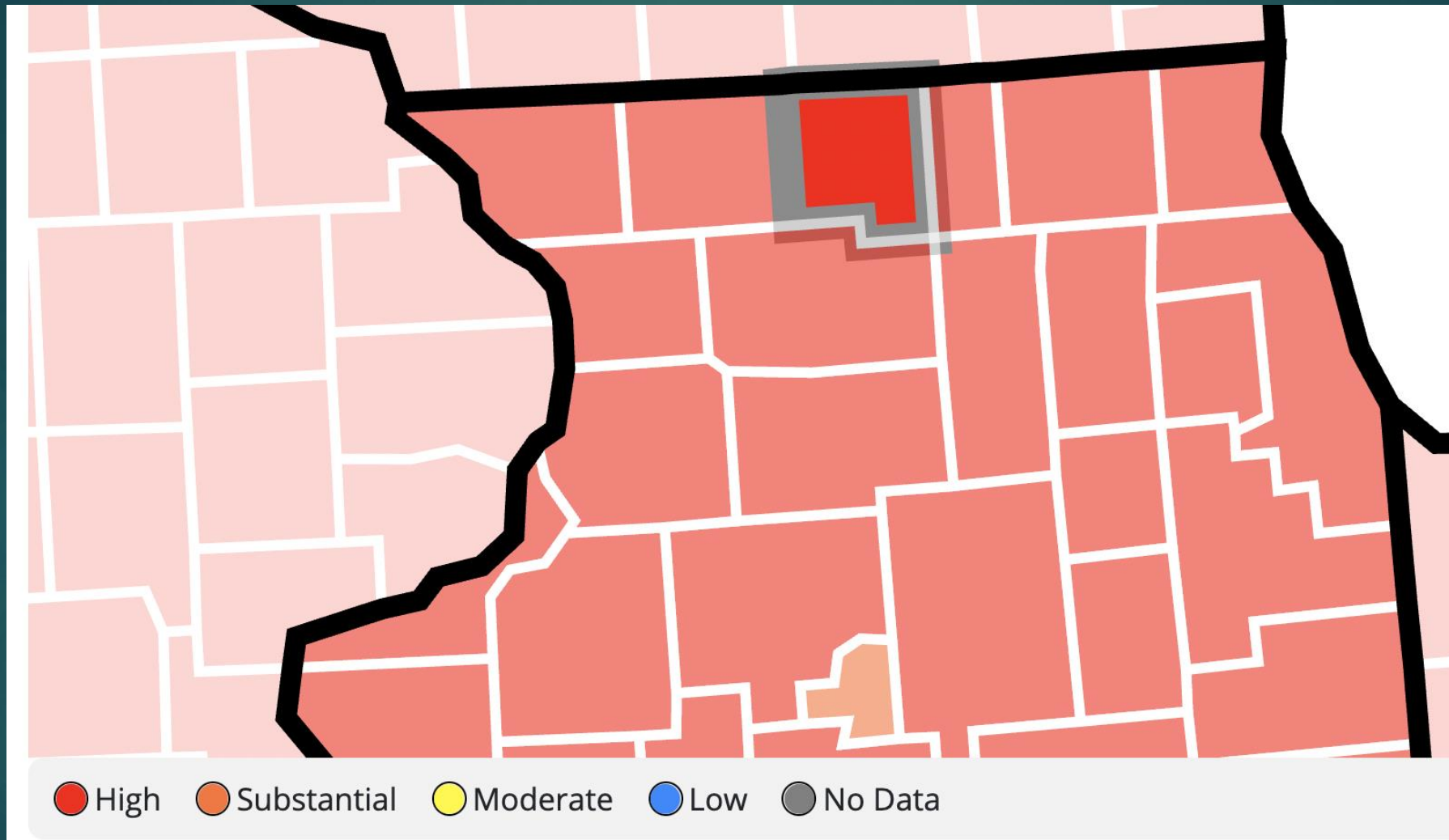
- ▶ IDPH Exemptions for COVID-19 Vaccination
 - ▶ Medical Contraindication
 - ▶ Accommodations under ADA/Disability related reasonable accommodation
 - ▶ Vaccination would require individual staff member to violate or forgo a sincerely held religious belief, practice of observation
- ▶ EMS personnel who meet criteria for an exemption are required to undergo COVID-19 testing

IDPH EMS Administrative Code

515.865- COVID-19 Vaccination of Provider Personnel

- ▶ C) Beginning 9/9/21 each EMS provider shall require its staff who are not full vaccinated to undergo testing for COVID-19
 - ▶ If staff tests positive, they are subject to facility isolation and quarantine rules
 - ▶ Frequency of Testing
 - ▶ High or Substantial COVID-19 Transmission = Twice Weekly Testing separated by at least two days
 - ▶ Any other amount of COVID-19 Transmission – Once Weekly Testing

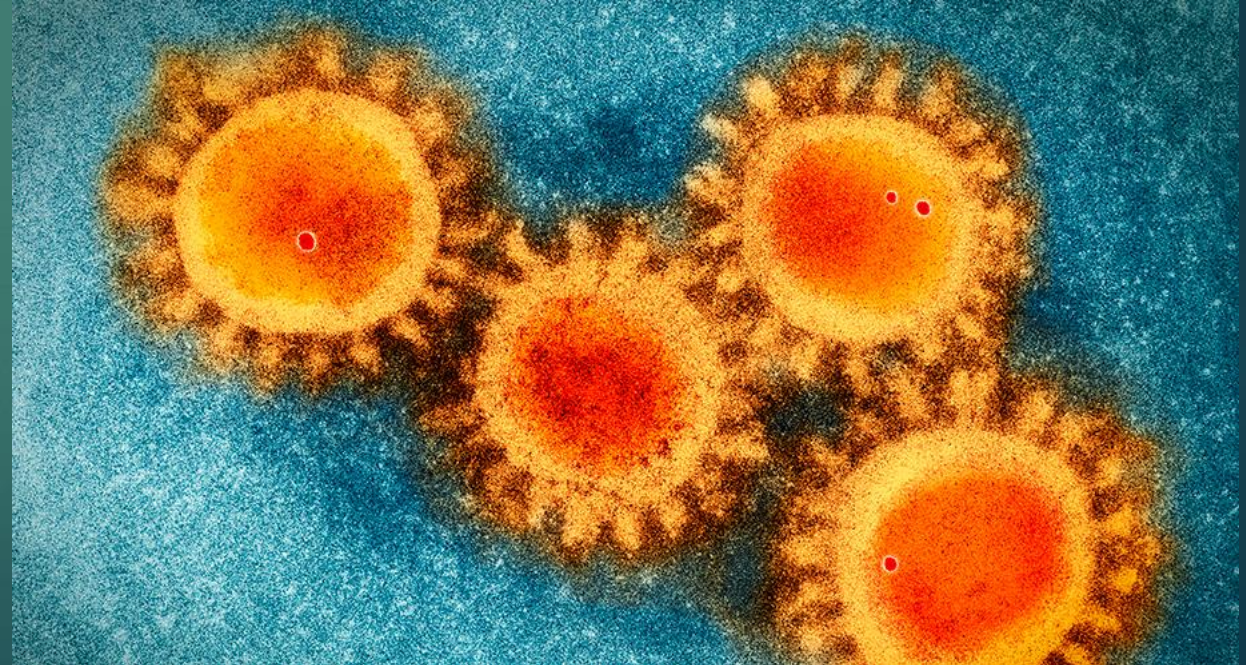
COVID Data Tracker



<https://covid.cdc.gov/covid-data-tracker/#county-view> | Illinois | 17201 | Risk | community_transmission_level

COVID-19-Background

- ▶ SARS-CoV2 = Virus
- ▶ Coronovirus Disease 2019 – COVID-19
- ▶ Coronaviruses
 - ▶ Corona mean crown
 - ▶ Spike Proteins
 - ▶ Family of Viruses
 - ▶ Severe Acute Respiratory Syndrome
 - ▶ Middle East Respiratory Syndrome
 - ▶ Seasonal Variation



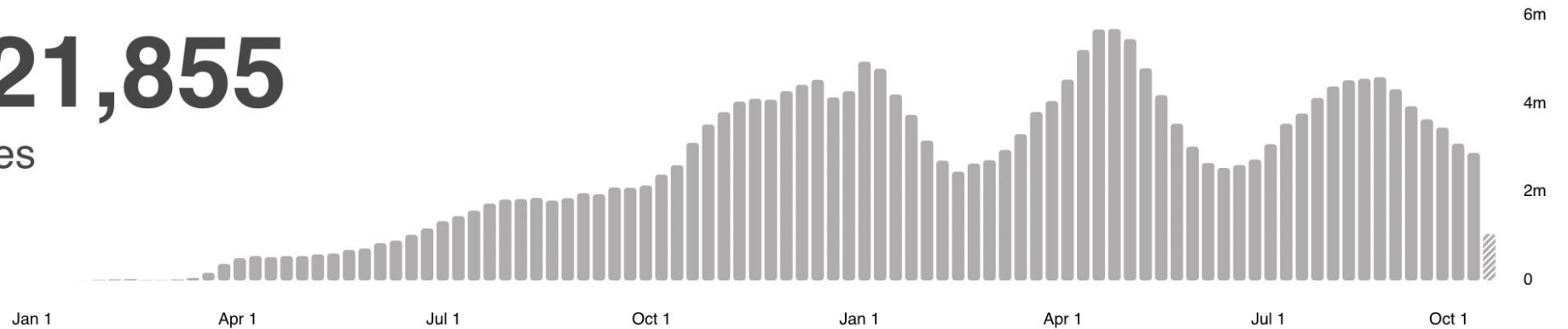
COVID-19 Background

- ▶ First discovered in Humans in Wuhan, China in late 2019
- ▶ 1/7/20- Chinese Isolate SARS-coV-2 as virus Causing Outbreak
- ▶ 1/17/20 Flight Screening Begins in the US
- ▶ 1/20/20 First Case in the US is Identified in Washington State
- ▶ 3/11/20 WHO Declares COVID-19 a Pandemic
- ▶ 3/13/20 US Declares Nationwide Emergency
- ▶ 3/17/20 First Human Vaccine Trial Begins (Moderna)
- ▶ 5/28/20 US deaths reach 100,000
- ▶ 12/11/20 Pfizer Vaccine receives EUA
- ▶ 12/16/20 IDPH Region One Receives Pfizer Vaccines

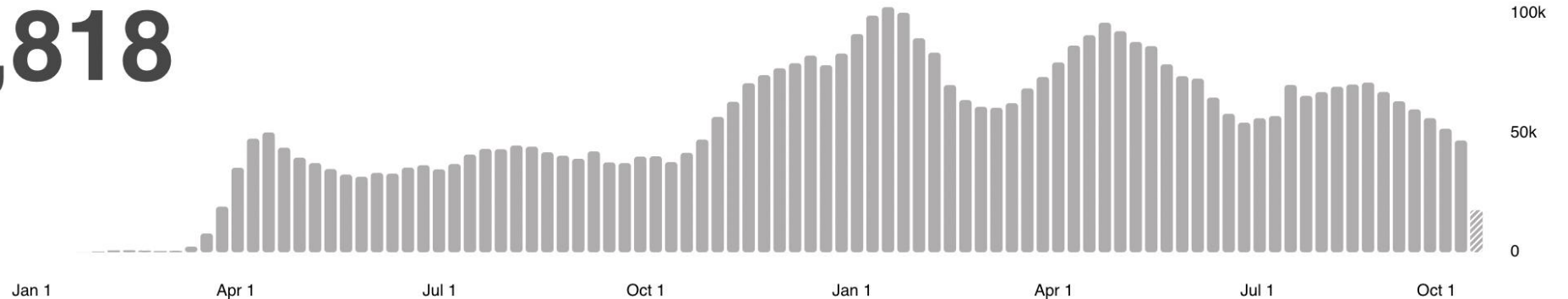
World COVID-19 Pandemic Statistics- WHO 8/13/21

Global Situation

238,521,855
confirmed cases



4,863,818
deaths



Source: World Health Organization

▨ Data may be incomplete for the current day or week.

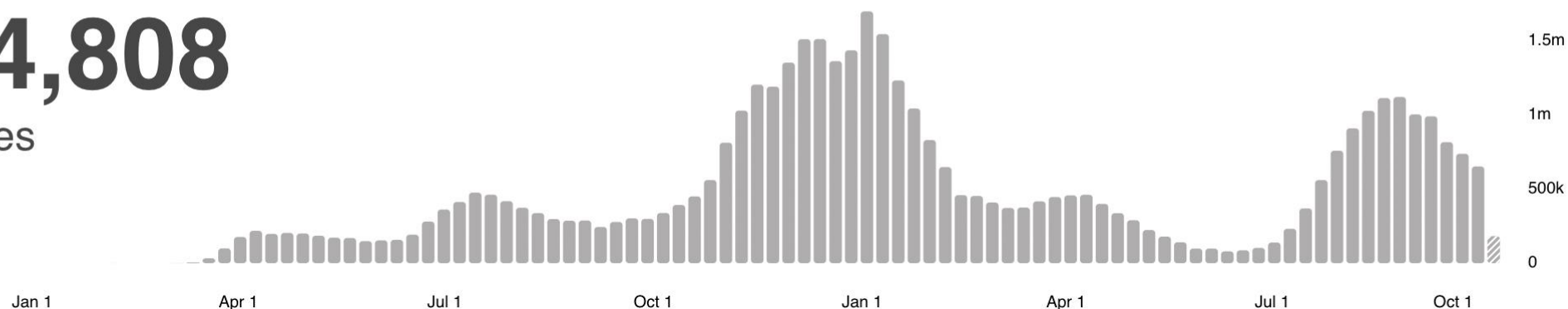
US- COVID-19 Pandemic Statistics

WHO 8/08/21

United States of America Situation

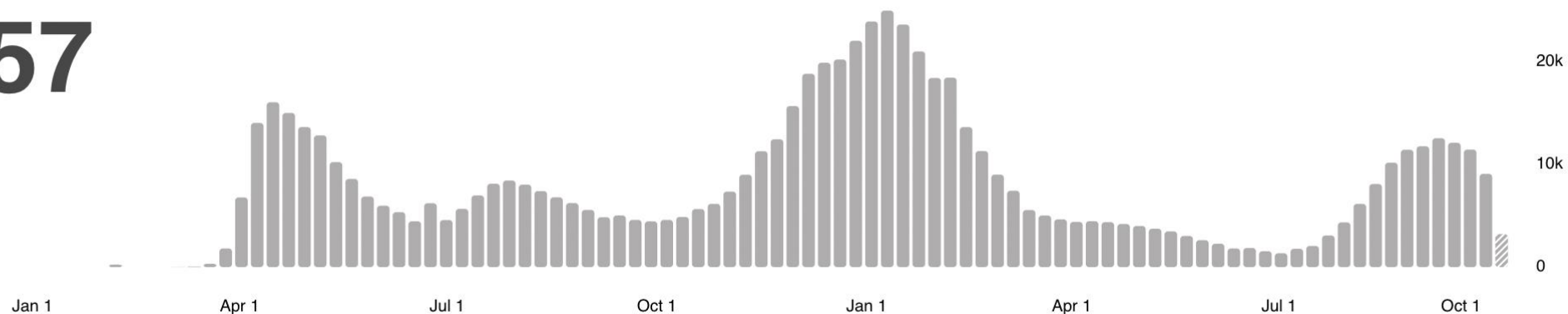
44,194,808

confirmed cases



710,757

deaths



Source: World Health Organization

▨ Data may be incomplete for the current day or week.

COVID-19 Transmission -CDC

- ▶ The principal mode by which people are infected with SARS-CoV-2 (the virus that causes COVID-19) is through exposure to respiratory fluids carrying infectious virus.



COVID-19 Transmission -CDC

- ▶ Exposure occurs in three principal ways:
 - ▶ Inhalation of very fine respiratory droplets and aerosol particles
 - ▶ Deposition of respiratory droplets and particles on exposed mucous membranes in the mouth, nose, or eye by direct splashes and sprays, and
 - ▶ Touching mucous membranes with hands that have been soiled either directly by virus-containing respiratory fluids or indirectly by touching surfaces with virus on them.



COVID-19 Signs and Symptoms

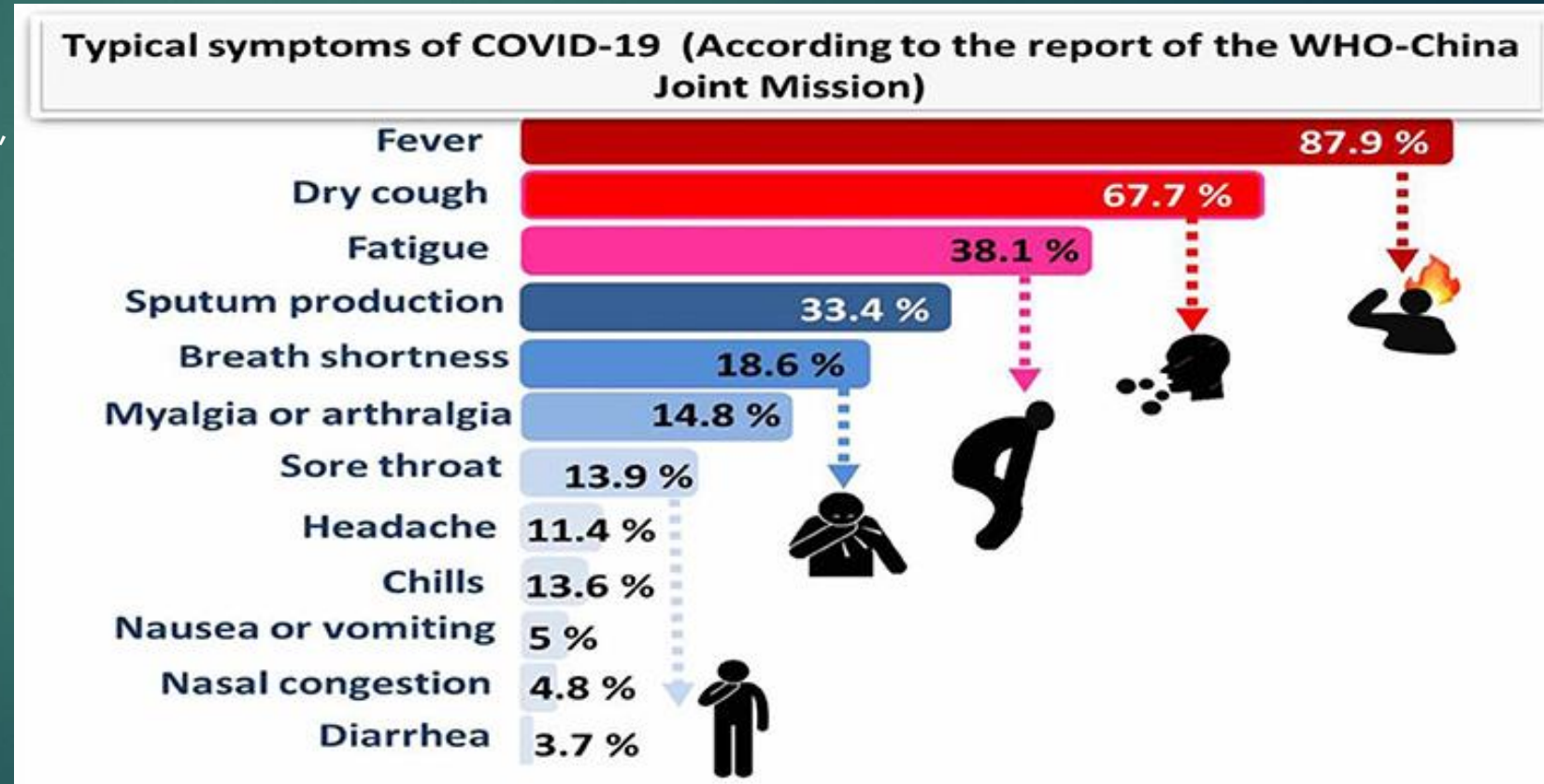
- ▶ Mild to Severe Illness
- ▶ Symptoms Typically Occur 2-14 day following exposure
- ▶ Most Common Symptoms
 - ▶ Fever
 - ▶ Cough
 - ▶ Fatigue



COVID-19 Signs and Symptoms

► Other Symptoms

- Loss of taste or smell,
- Nasal congestion,
- Conjunctivitis
- Sore throat,
- Headache
- Muscle or joint pain,
- Nausea or vomiting,
- Diarrhea,
- Chills or dizziness.



COVID-19 Progression- WHO

- ▶ Among those who develop symptoms
 - ▶ 80% Recover
 - ▶ 15% Become Seriously Ill and require hospitalization or oxygen
 - ▶ 5% Require Intensive Care Resources

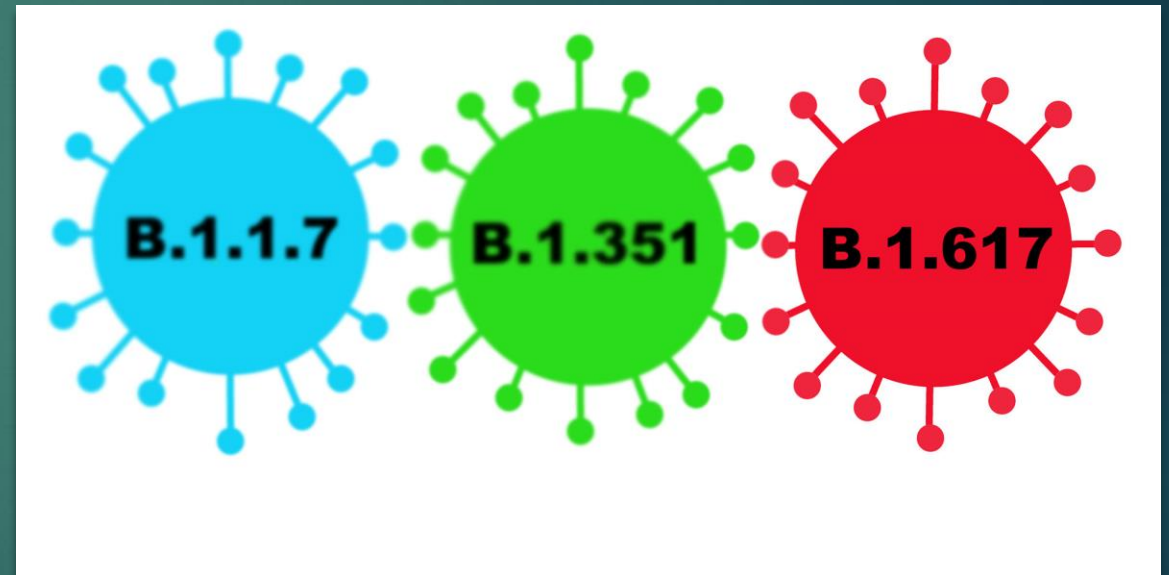


COVID-19 Who is at Risk to Progress to severe Disease

- ▶ 29.9% of inpatients and 74.9% of outpatients diagnosed with COVID-19 had no comorbidities¹
- ▶ Common Risk Factors
 - ▶ Age over 60***
 - ▶ Cancer
 - ▶ Cerebrovascular disease
 - ▶ Chronic kidney disease*
 - ▶ COPD (chronic obstructive pulmonary disease)
 - ▶ Diabetes mellitus, type 1 and type 2
 - ▶ Heart conditions (such as heart failure, coronary artery disease, or cardiomyopathies)
 - ▶ Obesity (BMI ≥ 30 kg/m²)
 - ▶ Pregnancy and recent pregnancy
 - ▶ Smoking, current and former

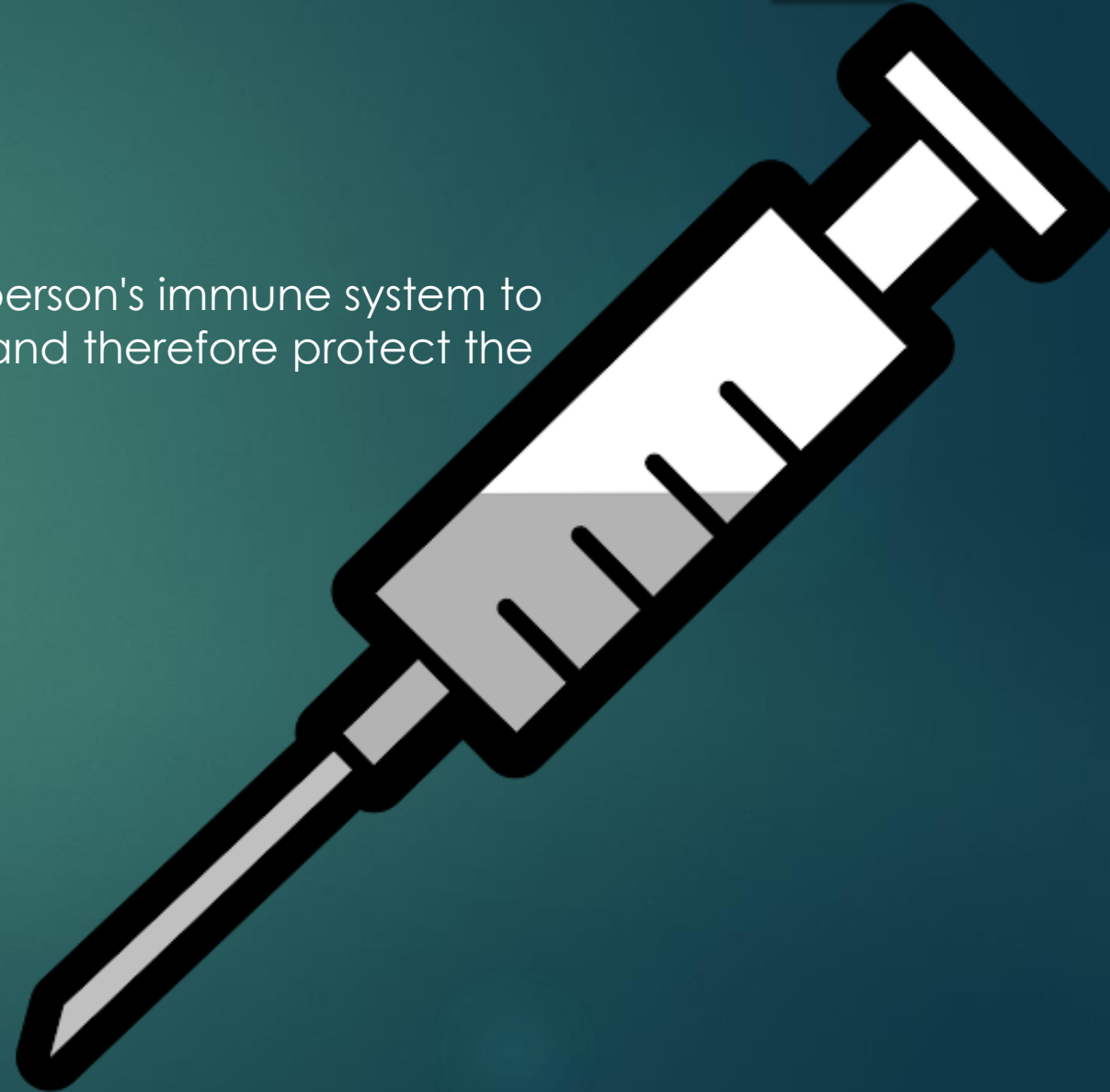
COVID-19 Variants

- ▶ Virus are expected to change/mutate as they circulate
- ▶ When a virus has one or more new mutations it's called a variant of the original virus. (Mayo)
- ▶ **Delta (B.1.617.2).**
 - ▶ Most common variant in the US
 - ▶ 2x as contagious as other variants



Vaccine Development

- ▶ What is a Vaccine?
 - ▶ Vaccines are products that stimulate a person's immune system to produce immunity to a specific disease and therefore protect the person from that disease



Vaccine Development

- ▶ Phase 1- vaccine is given to a small number of generally healthy people to assess its safety at increasing doses and to gain early information about how well the vaccine works to induce an immune response in people
- ▶ Phase 2-studies include more people, where various dosages are tested on people with varying health statuses and from different demographic groups, in randomized-controlled studies
- ▶ Phase 3- the vaccine is administered to more people in randomized, controlled studies involving broad demographic groups and generates critical information on effectiveness and additional important safety data

COVID-19 Vaccine Development

Traditional vaccine development: One step at a time



COVID-19 vaccine development: Multiple steps happening at once



COVID-19 Vaccine Development

- ▶ Following SARS/MERS outbreak we knew which area on Coronaviruses we would likely need to target
- ▶ Genomic Sequence for SARS-CoV-2 was rapidly published
- ▶ Unprecedented Funding
- ▶ Trials Overlapped
- ▶ Front End Manufacturing
- ▶ High number of cases/controls due to pandemic

Emergency Use Authorization

- ▶ An Emergency Use Authorization (EUA) is a mechanism to facilitate the availability and use of medical countermeasures, including vaccines, during public health emergencies.
- ▶ Granted by the FDA
- ▶ EUA requires data on each phase to be submitted as well as follow up data.
- ▶ Following submission data is reviewed by FDA as well as independent data safety monitoring board

mRNA Vaccines

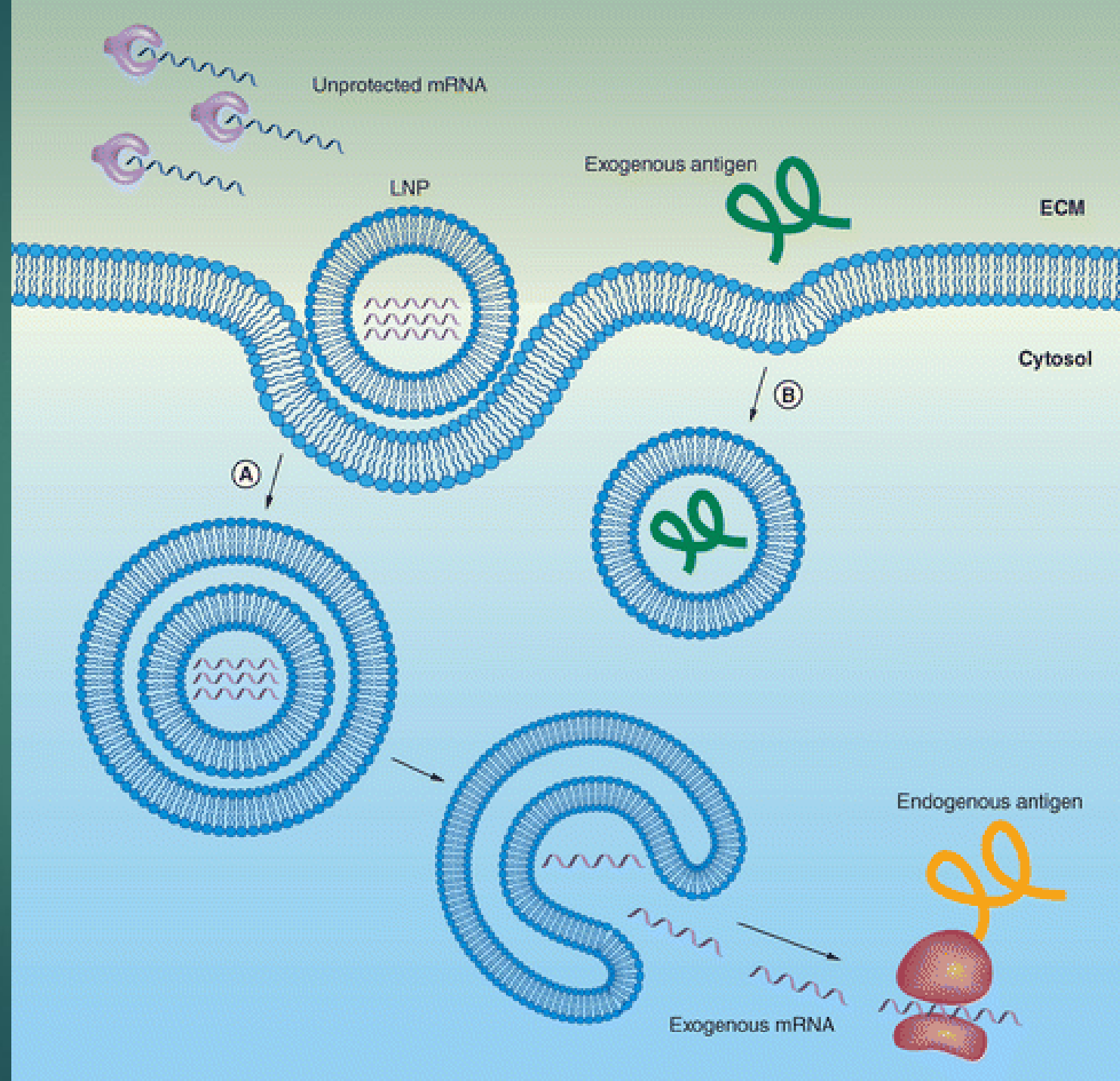
- ▶ Development for >20 years
- ▶ Other mRNA vaccines under development
 - ▶ Ebola
 - ▶ Zika
 - ▶ Rabies
 - ▶ Malaria
- ▶ mRNA do not contain and pieces of the virus
 - ▶ No weakened, dead or noninfectious portions of the virus
- ▶ Teach our own cells to make spike protein which triggers immune response

mRNA Vaccines

- ▶ mRNA is blueprint cells use to make proteins
 - ▶ SARS-coV-2 Spike Protein
- ▶ Do not incorporate into nucleus or change DNA
 - ▶ DNA is in Nucleus, mRNA is not in Nucleus
 - ▶ mRNA does not have the enzyme to be changed into DNA
 - ▶ mRNA cannot be integrated into DNA

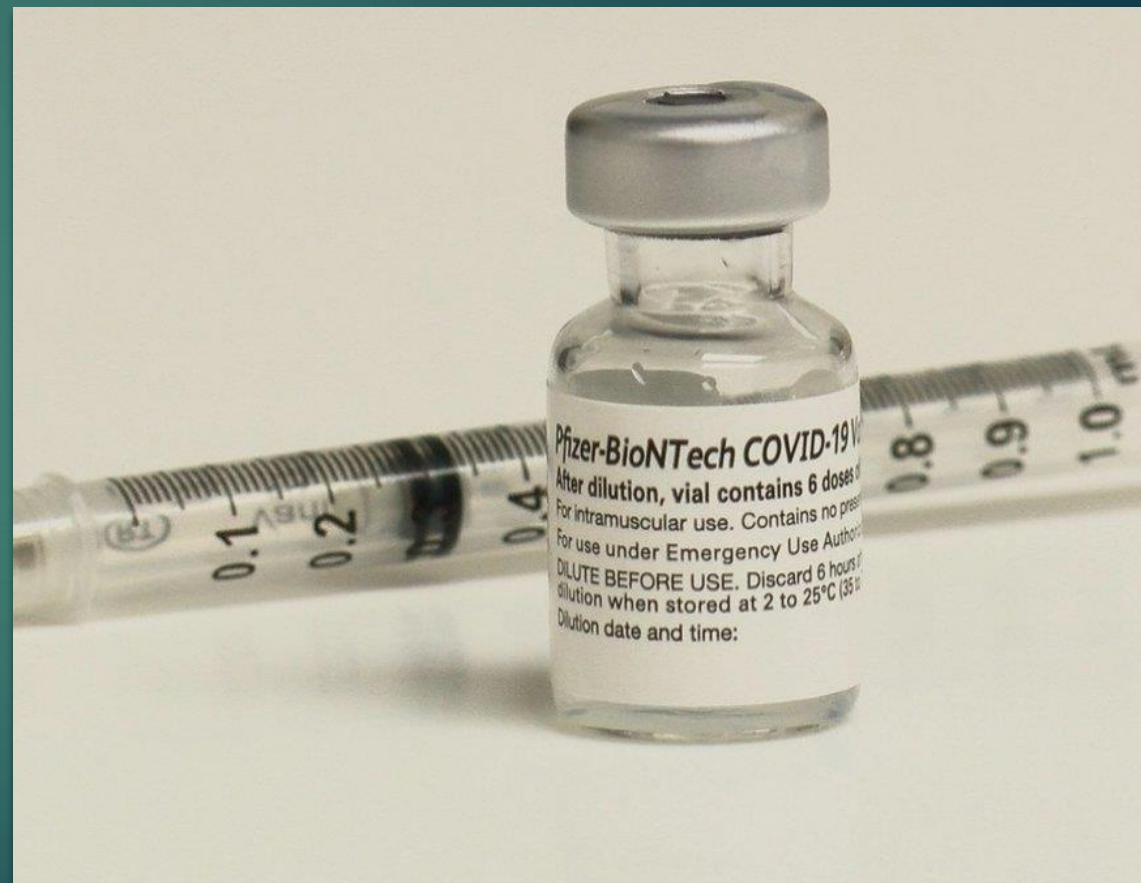
mRNA Vaccines

- ▶ Lipid Nanoparticle protects mRNA for enzymatic destruction and facilitates movement into cell cytoplasm
- ▶ mRNA is translated into protein by ribosomes
- ▶ Antigen is produced which triggers antigen response
- ▶ Reichmuth et. Al 2016²



COVID-19 Vaccines-Pfizer

- ▶ mRNA Vaccine
- ▶ Phase 3 trial had over 40,000 participants
- ▶ Phase 3 Data 95% effective against preventing severe disease



COVID-19 Vaccines-Pfizer

Indications

- ▶ EUA for 12-15 y/o
- ▶ Approved for >15 y/o under name COMIRNATY
- ▶ 2 Doses 21 Days Apart
- ▶ 3rd Dose- Immunocompromised- EUA
 - ▶ >28 days following initial 2 dose series

COVID-19 Vaccines-Pfizer

Indications

- ▶ Booster Dose- EUA for > 18 y/o
 - ▶ Completed initial 2 dose series > 6 months prior
 - ▶ >65 y/o
 - ▶ 18-64 with underlying medical conditions that puts recipient at high risk for severe COVID-19
 - ▶ 18 y/o + who live in an institutional setting
 - ▶ Frontline workers 18 years and older whose occupation increases my exposure to the COVID-19 virus, such as **healthcare workers or first responders**, education staff, food and agriculture, manufacturing, corrections workers, U.S Postal Service, public transit or grocery store workers

COVID-19 Vaccines-

Pfizer/Moderna Contraindications

- ▶ Severe allergic reaction (e.g., anaphylaxis) to a previous dose or component of Pfizer/Moderna vaccine.
 - ▶ Persons with contraindications to mRNA COVID-19 vaccines may be able to receive Janssen COVID-19 Vaccine.
- ▶ Immediate allergic reaction of any severity to a previous dose or component of an mRNA COVID-19 vaccine (including polyethylene glycol [PEG])
 - ▶ An immediate allergic reaction is defined as any hypersensitivity related signs or symptoms such as urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within 4 hours following exposure to a vaccine or medication.

COVID-19 Vaccines-Pfizer

Contraindications

- ▶ A list of ingredients can be found on CDC website or the vaccines' package insert
- ▶ None of the vaccines contain (including J+J)
 - ▶ Eggs
 - ▶ Gelatin
 - ▶ Latex

COVID-19 Vaccines-Pfizer

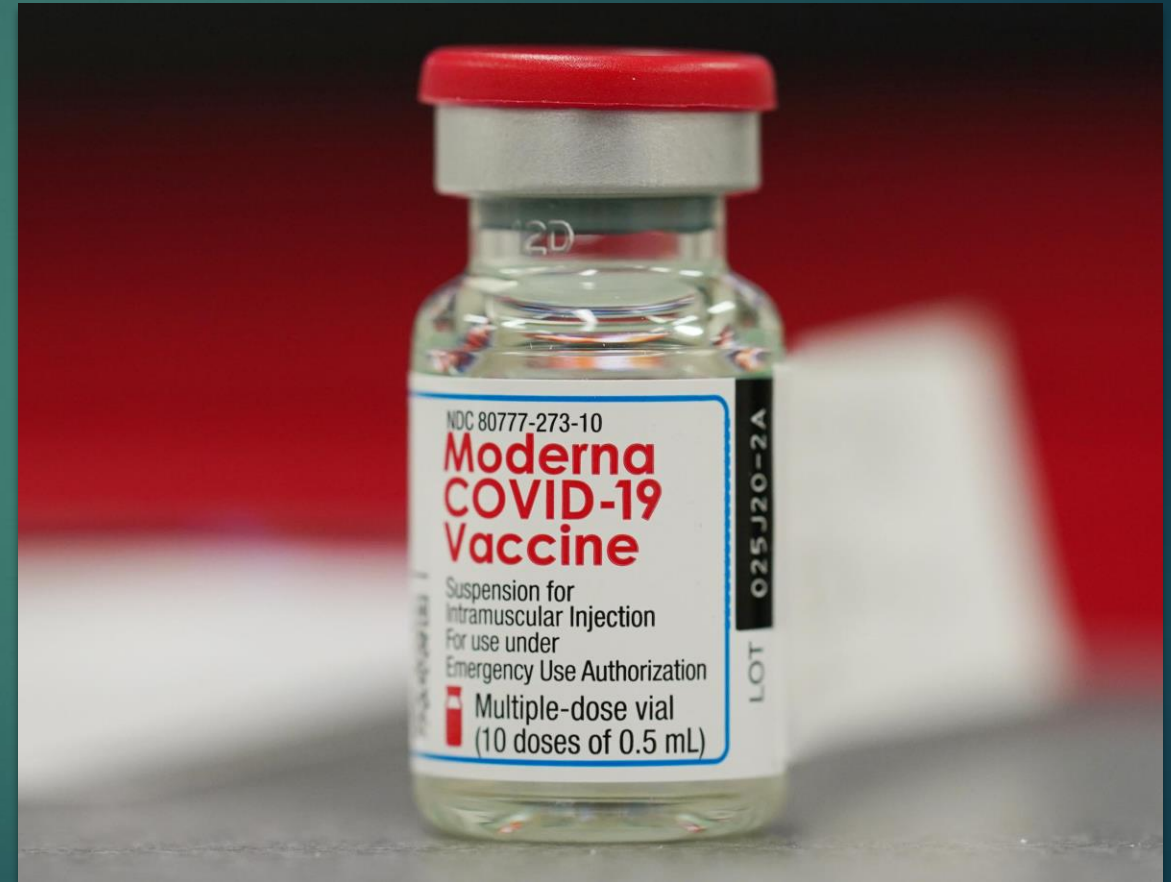
- ▶ UK Study Pfizer vaccine was 88% effective against symptomatic disease from the B.1.617.2 variant, compared to 93% effectiveness against the B.1.1.7 variant³
- ▶ Being Administered in 136 Countries
- ▶ Per Pfizer As of 10/13/21 nearly 236 Million doses of the Pfizer Covid-19 vaccine had been administered in the US

COVID-19 Vaccine Side Effects Pfizer

SIDE EFFECT	FIRST DOSE	SECOND DOSE
Injection site pain	83%	78%
Fatigue	47%	59%
Headache	42%	52%
Muscle pain	21%	37%
Chills	14%	35%
Diarrhea	11%	10%
Joint pain	11%	22%
Fever	4%	16%
Vomiting	1%	2%

COVID-19 Vaccine-Moderna

- ▶ mRNA Vaccine
- ▶ Phase 3 Trial had over 30,000 participants
- ▶ Indications
 - ▶ EUA for >18 y/o
 - ▶ 2 Doses 28 days apart
- ▶ Phase 3 Data 94% effective against preventing severe disease



COVID-19 Vaccine-Moderna

- ▶ 10/14/21 FDA Panel votes to support Moderna Booster Dose
 - ▶ Final Recommendations pending
 - ▶ Likely will be similar high risks groups as Pfizer
 - ▶ CDC will meet week of 10/18

COVID-19 Vaccine-Moderna

- ▶ The [New England Journal of Medicine](#) found Moderna vaccine to be 96.3% effective in preventing symptomatic illness in health care workers compared to 88.8% for Pfizer.⁴
- ▶ Per Moderna As of 10/13/21 more than 153 Million doses of the Moderna Covid-19 vaccine had been administered in the US

COVID-19 Vaccine- Moderna Side Effects

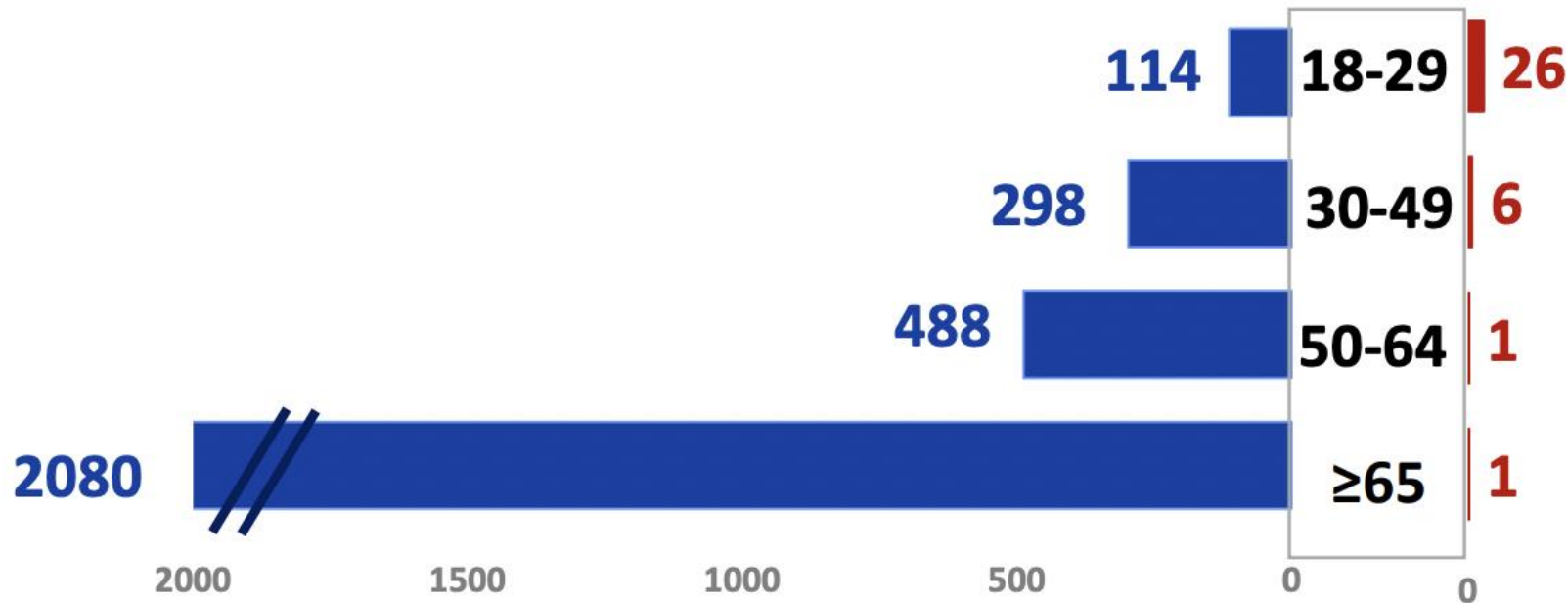
SIDE EFFECT	FIRST DOSE	SECOND DOSE
Injection site pain	<div><div></div><div>87%</div></div>	<div><div></div><div>90%</div></div>
Fatigue	<div><div></div><div>39%</div></div>	<div><div></div><div>68%</div></div>
Headache	<div><div></div><div>35%</div></div>	<div><div></div><div>63%</div></div>
Body/muscle aches	<div><div></div><div>24%</div></div>	<div><div></div><div>61%</div></div>
Joint pain	<div><div></div><div>17%</div></div>	<div><div></div><div>45%</div></div>
Nausea/vomiting	<div><div></div><div>9%</div></div>	<div><div></div><div>21%</div></div>
Chills	<div><div></div><div>9%</div></div>	<div><div></div><div>48%</div></div>
Fever	<div><div></div><div>1%</div><div>9%</div></div>	<div><div></div><div>17%</div></div>

COVID-19 Vaccine mRNA FDA Warning- Myocarditis/Pericarditis

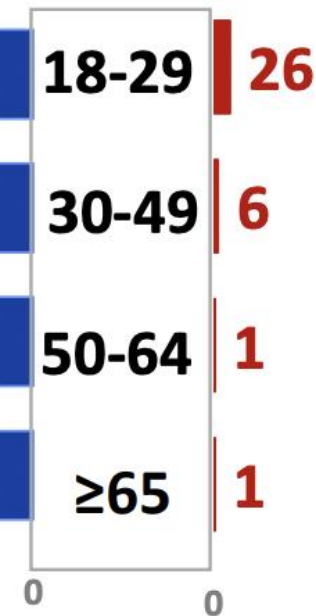
- ▶ Cases of Myocarditis and Pericarditis have been reported following administration of the Pfizer-and Moderna vaccine.
 - ▶ Predominantly Males
 - ▶ Aged 12-29
 - ▶ Typically Occur withing a few days of receiving the 2nd dose
- ▶ Recommended to not receive subsequent dose mRNA vaccine if myocarditis or pericarditis occurs after previous dose
- ▶ People who have a history of myocarditis or pericarditis unrelated to mRNA COVID-19 vaccination may receive any currently FDA-approved or FDA-authorized COVID-19 vaccine after the episode of myocarditis or pericarditis has completely resolved.

COVID-19 Vaccine mRNA FDA Warning- Myocarditis/Pericarditis

COVID-19-Associated Hospitalizations
Prevented per Million Doses



Cases of Myocarditis
Expected per Million Doses



Myocarditis with COVID-19

**Myocarditis (inflammation of part of the heart muscle)
occurs more frequently among COVID-19 patients**

16x higher risk
of myocarditis among patients with COVID-19*



**Vaccination is the best way to protect against
COVID-19-related complications**



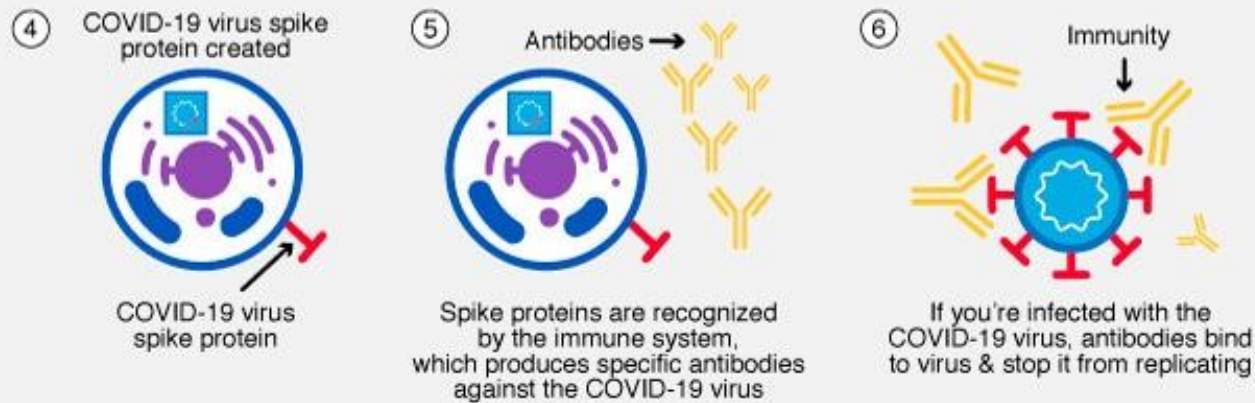
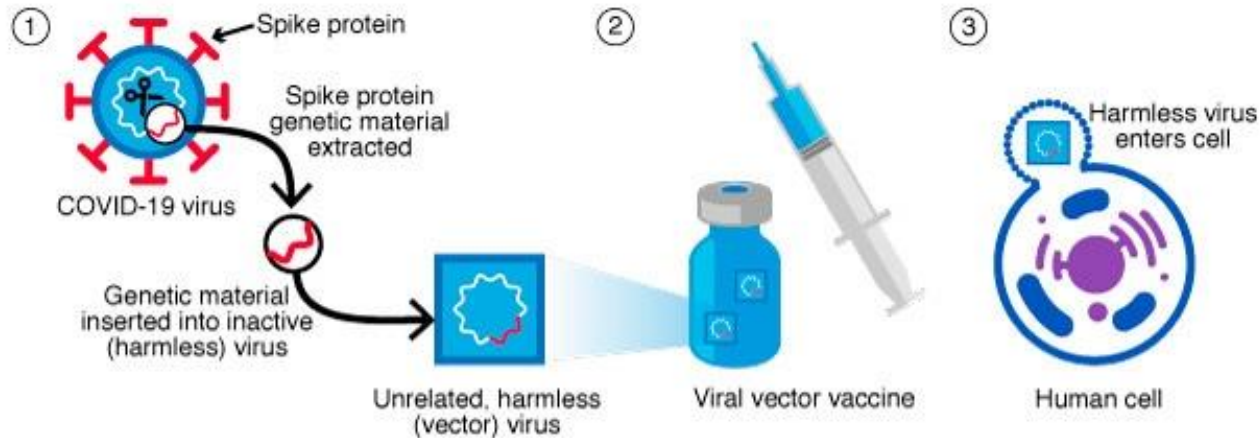
*Premier Healthcare Database Special COVID-19 Release

bit.ly/MMWR83121b

MMWR

COVID-19 Vaccine J + J

- ▶ EUA for 18 y/o +
 - ▶ Single Dose
- ▶ Recombinant Vector Vaccine- Disabled Adenovirus
 - ▶ Pink Eye, Common Cold
 - ▶ Delivers genetic code the codes for Spike Protein of SARS CoV-2
- ▶ Phase 3 Trial
 - ▶ 43,000 Participants
 - ▶ 66% Effective in preventing moderate and severe COVID-19
 - ▶ Study included Variants, occurred later in the pandemic



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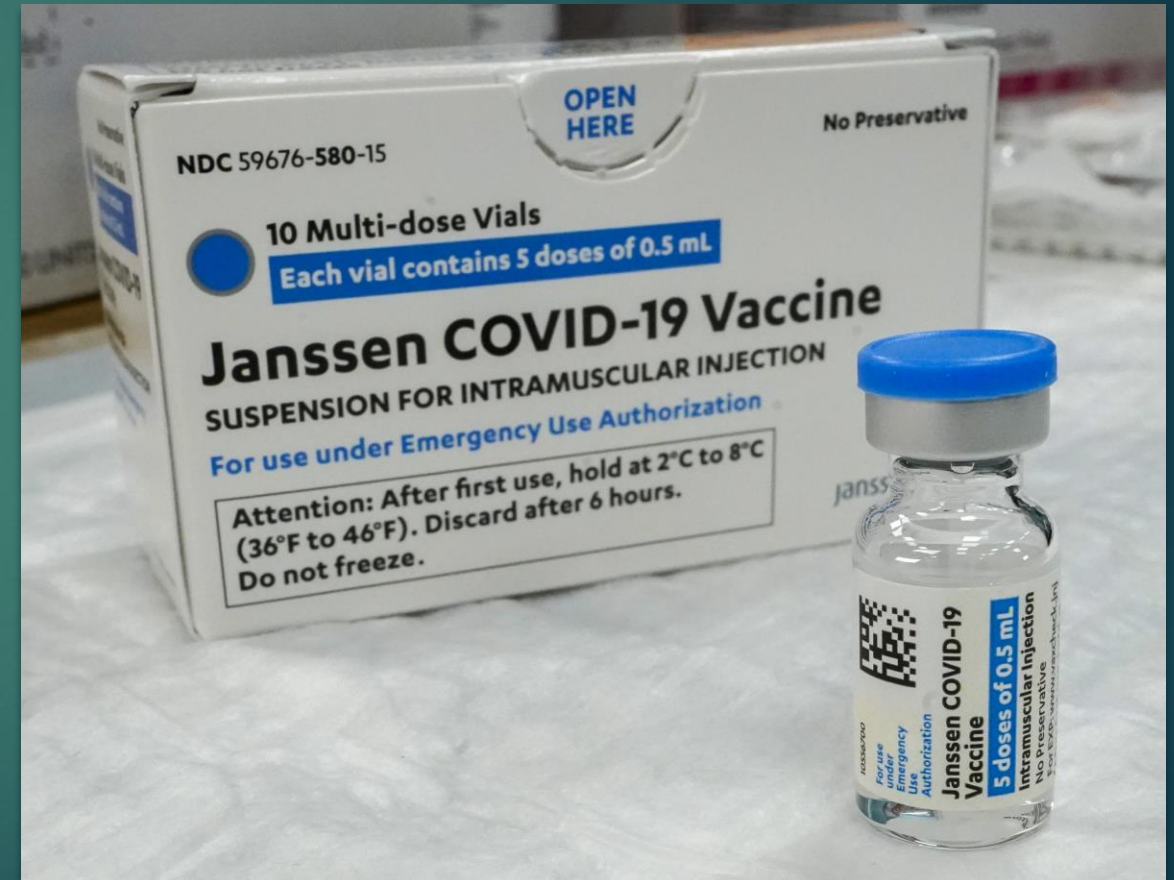
J+J COVID-19 Vaccine Mechanism of Action

COVID-19 Vaccine J + J

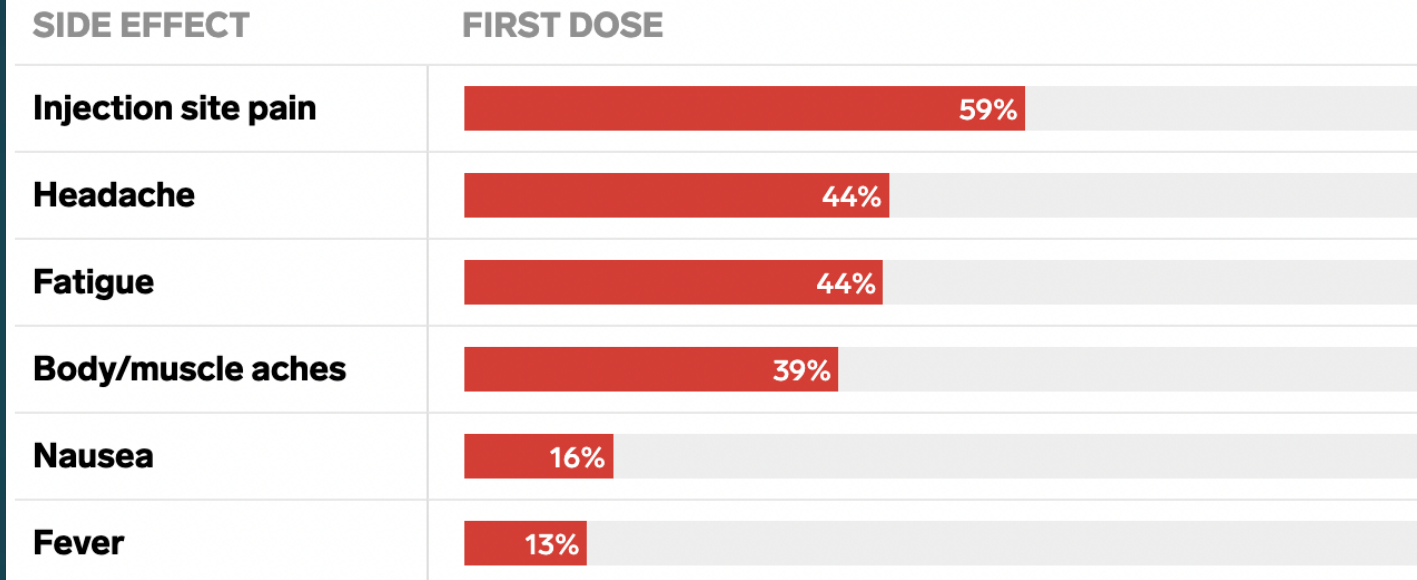
- ▶ Per J+J As of 10/13/21 nearly 15 Million doses of the Pfizer Covid-19 vaccine had been administered in the US
- ▶ Recent pre-print study from 9/21 showed: ⁵
 - ▶ 79% overall efficacy for the prevention of COVID-19
 - ▶ 81% effective for the prevention of hospitalizations associated with the virus.

COVID-19 Vaccine J + J

- ▶ 10/14/21 FDA Panel votes to support J + J Booster Dose
 - ▶ Final Recommendations pending
 - ▶ Likely will be similar high risks groups as Pfizer
 - ▶ CDC will meet week of 10/18



COVID-19 Vaccine- J+J Side Effects



COVID-19 Vaccine J + J Thrombosis with Thrombocytopenia Syndrome (TTS)

- ▶ (TTS) is a rare syndrome that involves acute venous or arterial thrombosis and new onset thrombocytopenia in patients with no recent known exposure to heparin.
 - ▶ Similar to HIT
- ▶ 1 in 500,000 doses of J + J Vaccine
 - ▶ Most Common Location = Cerebral Sinus Venous Thrombosis
 - ▶ Highest in females <50 y/o

COVID-19 Vaccine J + J

Contraindications

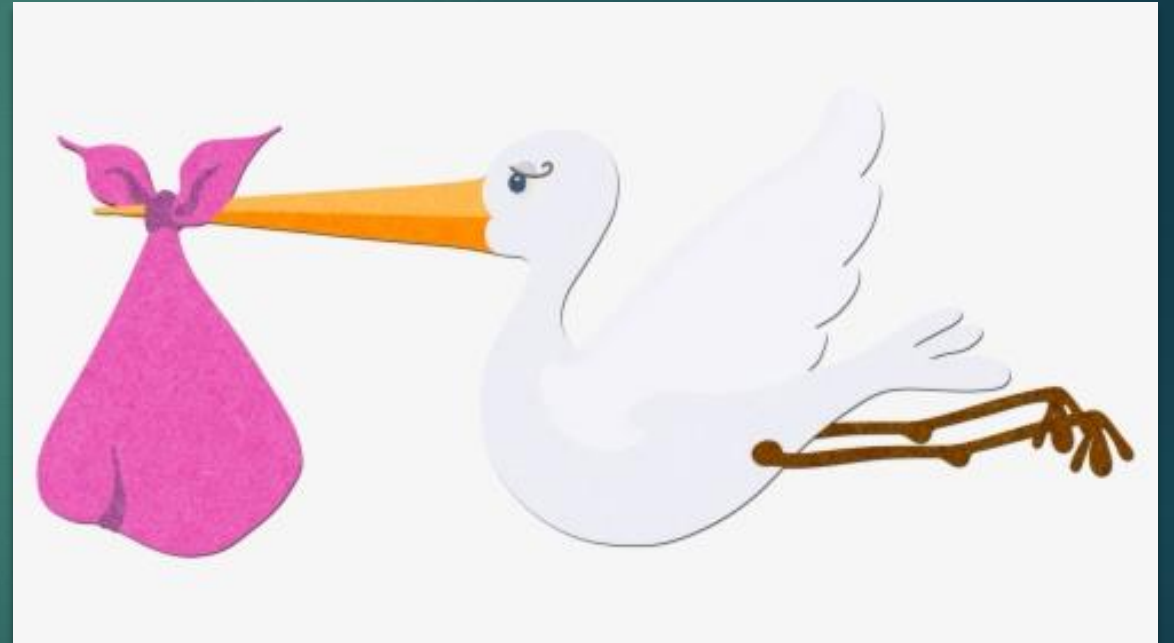
- ▶ Severe allergic reaction (e.g., anaphylaxis) to a previous dose or component of Janssen COVID-19 vaccine, including polysorbate
 - ▶ Of note the J + J vaccine does not contain:
 - ▶ Polyethylene Glycol
 - ▶ Eggs
 - ▶ Latex

COVID-19 Vaccines Guillain-Barre

- ▶ Guillain-Barré syndrome (GBS) is a neurological disorder in which the body's immune system damages nerve cells, causing muscle weakness and sometimes paralysis.
- ▶ Reports of adverse events following use of the Janssen COVID-19 vaccine under EUA suggest an increased risk of GBS during the 42 days following vaccination.
- ▶ No increased risk of GBS has been identified with mRNA vaccines during use under EUA.

COVID-19 in Pregnancy

- ▶ If you contract COVID-19 and are pregnant you are 50% more likely to end up in the ICU⁶
- ▶ A JAMA study indicates a consistent association between pregnant individuals with COVID-19 diagnosis and higher rates of adverse outcomes, including
 - ▶ maternal mortality
 - ▶ preeclampsia,
 - ▶ preterm birth.⁷



COVID-19 Vaccination in Pregnancy

- ▶ Pregnancy is not a contraindication to receive any of the 3 US COVID-19 Vaccines
- ▶ The American College of Obstetricians and Gynecologists, Society for Maternal-Fetal Medicine, American Society for Reproductive Medicine, and the CDC all recommend vaccination for pregnant people and, people who are breastfeeding and those of child-bearing age.

COVID-19 Vaccination in Pregnancy

- ▶ Preliminary findings did not show obvious safety signals among pregnant persons who received mRNA Covid-19 vaccines.⁸
- ▶ A recent retrospective cohort study of pregnant women mRNA vaccination compared with no vaccination was associated with a significantly lower risk of SARS-CoV-2 infection⁹

COVID-19 Vaccination in Pregnancy- Benefits to Newborns

- ▶ A recent JAMA study found vaccinating pregnant mothers may potentially protect infants from COVID-19 infection¹⁰
- ▶ Another JAMA study showed that vaccinating pregnant mothers secrete protective antibodies in their breast milk¹¹
- ▶ Another study published in the American Journal of Obstetrics and Gynecology showed that for mothers who received either the Pfizer–BioNTech or Moderna COVID-19 vaccine during pregnancy 100% of their infants had protective antibodies at birth. ¹²

COVID-19 Vaccine vs Natural Infection

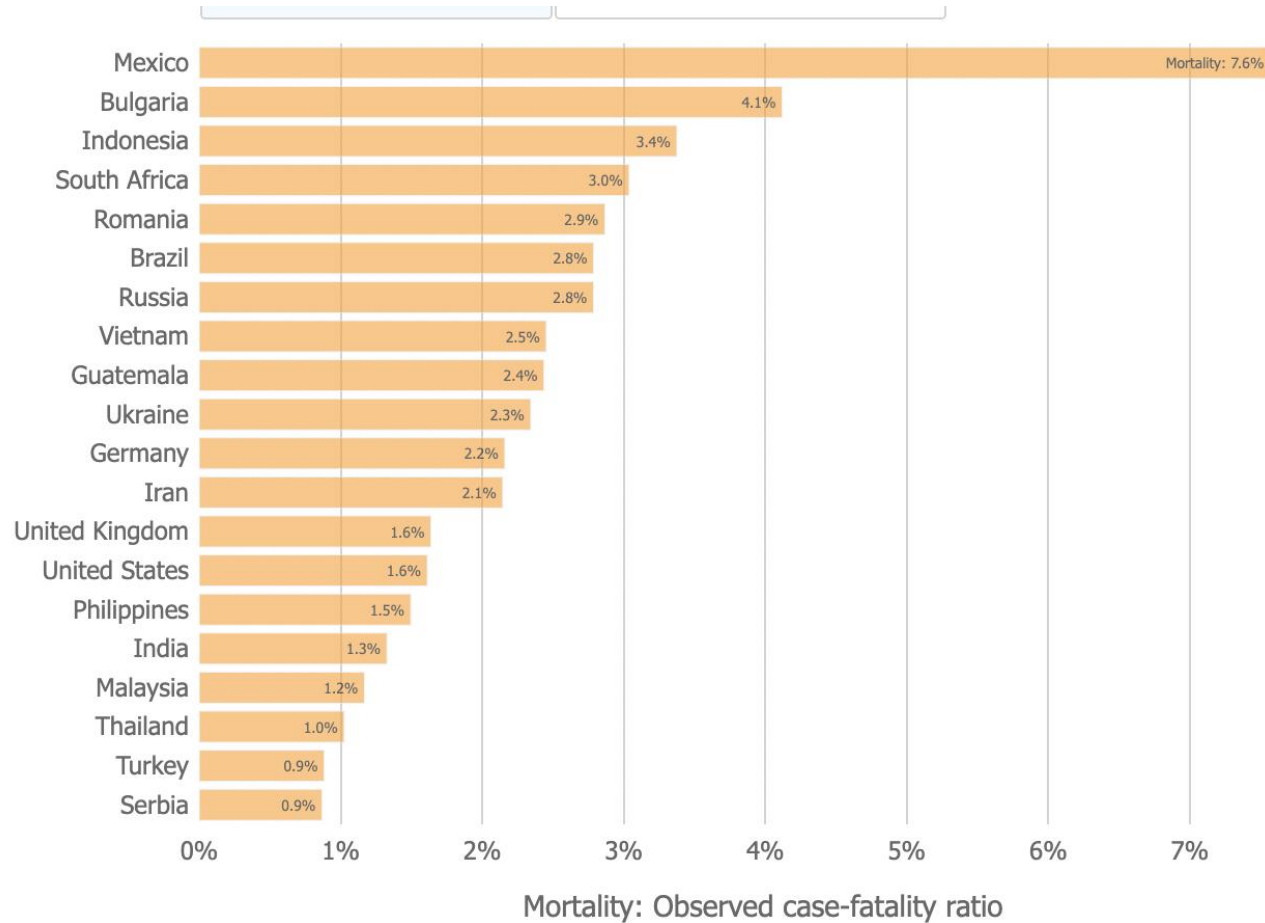
- ▶ There are benefits to natural immunity
- ▶ A recent publication (not yet peer reviewed) out of Israel showed¹⁴:
 - ▶ Natural immunity provides stronger protection against COVID-19 than the Pfizer vaccine
 - ▶ This was in patients who had previously survived a previous SARS-coV-2 infection
 - ▶ Also study found even greater immunity against the delta variant for people who got a single shot of the Pfizer vaccine and had an infection with the novel coronavirus that causes COVID-19

COVID-19 Vaccine vs Natural Infection

- ▶ However natural immunity can be messy
 - ▶ More than 1/3 of COVID-19 infections results in zero protective antibodies(36%)¹³
 - ▶ Natural immunity alone is less than half as effective than natural immunity plus vaccination¹⁴
 - ▶ 65% of people with natural immunity lost their antibodies by 60 days¹⁵
- ▶ Health Care Workers are 7x as likely to have **Severe** COVID-19 infections as other workers¹⁷
- ▶ As of May 2021 more than 115,000 health care workers have died of COVID-19^{WHO}

COVID-19 Vaccine vs Natural Infection

- ▶ COVID-19 infections have a high morbidity and mortality
 - ▶ Half of those hospitalized have at least one symptom at one year¹⁶
 - ▶ Fatigue
 - ▶ Myalgias
 - ▶ Anxiety
 - ▶ Chest Tightness
 - ▶ Case Fatality rate of confirmed cases in the US 1.6% (John Hopkins)
 - ▶ 1:100-1:250 with confirmed COVID-19 die¹⁸
 - ▶ 1:1000 with confirmed Influenza die
 - ▶ 1:500 Americans have died of COVID-19 since the start of the pandemic (Johns Hopkins)



COVID-19 Case Fatality Rates John Hopkins

COVID-19 Vaccine Protecting Infrastructure

- ▶ COVID-19 vaccines have prevented nearly 280,000 deaths and 1.25 million hospitalizations in the U.S. according to estimates at the Yales School of Public Health
 - ▶ July 2021

Transmission Post COVID-19 Vaccines

- ▶ The initial way all of the COVID-19 vaccines were studied was to prevent severe symptoms and death
- ▶ The mRNA COVID-19 vaccines reduce the risk of testing positive for COVID-19 by 91%¹⁹
- ▶ The Vaccine Can help you from bringing home COVID-19 to your family
 - ▶ A Netherlands study showed a 71% protection from the transmission was granted by vaccination (Health Care Workers Families)²⁰
 - ▶ Another study showed vaccination reduced transmission by 61%²¹

COVID-19 Administration Timing

- ▶ COVID-19 vaccines **may be administered without regard to timing of other vaccines**. This includes simultaneous administration of COVID-19 vaccine and other vaccines on the same day.
 - ▶ Administer at different site
- ▶ Flu Season!

COVID-19 Administration Timing

- ▶ If individual was recently ill with COVID-19
 - ▶ Delay vaccination until individual COVID-19 infection is resolved, and they have completed their isolation period.
- ▶ If the individual was exposed to someone with COVID-19
 - ▶ Defer vaccination until the person's quarantine period has ended.
- ▶ If individual was previously ill with COVID-19 and received monoclonal antibodies or convalescent plasma as part of COVID-19 treatment.
 - ▶ Defer vaccination until 90 days from date of last treatment.


COVID-19 Vaccine Administration Observation Period

- ▶ CDC recommends the following observation periods after COVID-19 vaccination:
- ▶ 30 minutes:
 - ▶ History of an immediate allergic reaction of any severity to other vaccines or injectable therapies
 - ▶ People with a contraindication to a different type of COVID-19 vaccine (for example, people with a contraindication to mRNA COVID-19 vaccines who receive Janssen viral vector vaccine should be observed for 30 minutes following Janssen vaccination).
 - ▶ History of anaphylaxis due to any cause
- ▶ 15 minutes: All other people

References

- ▶ 1) Rosenthal, N et al. Risk Factors Associated with In-Hospital Mortality in a US National Sample of Patients With COVID-19. *JAMA Network Open*.2020;3(12):e2029058. [doi:10.1001/jamanetworkopen.2020.29058](https://doi.org/10.1001/jamanetworkopen.2020.29058)[external icon](#)
- ▶ <https://www.mayoclinic.org/diseases-conditions/coronavirus/expert-answers/covid-variant/faq-20505779>
- ▶ 2) Reichmuth AM, Oberli MA, Jaklenec A, Langer R, Blankschtein D. mRNA vaccine delivery using lipid nanoparticles. *Ther Deliv*. 2016;7(5):319-34. doi: 10.4155/tde-2016-0006. Erratum in: *Ther Deliv*. 2016 Jun;7(6):411. PMID: 27075952; PMCID: PMC5439223.
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