Vaccines, Variants and the Road Ahead

April 12, 2021
Presentation to the Eastern Pennsylvania Conference

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Disclosures

- Elsen Jacob and Susan Jacob have no financial disclosures
- The speakers are not representing their organizations for purposes of this talk
- Please seek the advice of your personal healthcare provider for specific decisions related to your health

Objectives

- Describe COVID-19, transmission, and clinical presentation
- Summarize vaccines, their development, and approval process
- Understand available COVID vaccines and how to prepare for the future

A Case

- Your 70 year old neighbor Robert who has diabetes sees you on the sidewalk. He asks for your advice on the COVID-19 vaccine.

- “Should I get it? I hear it hurts”
- “What are my chances of getting COVID anyway?”
- “It seems the vaccine came out too fast!”
- “Will it affect my DNA?”
- “How do I sign up for it?”

Audience Question

- How many of you know someone who had COVID-19?
- Who here has received the vaccine?
- Who plans to receive the vaccine?

COVID-19 Overview

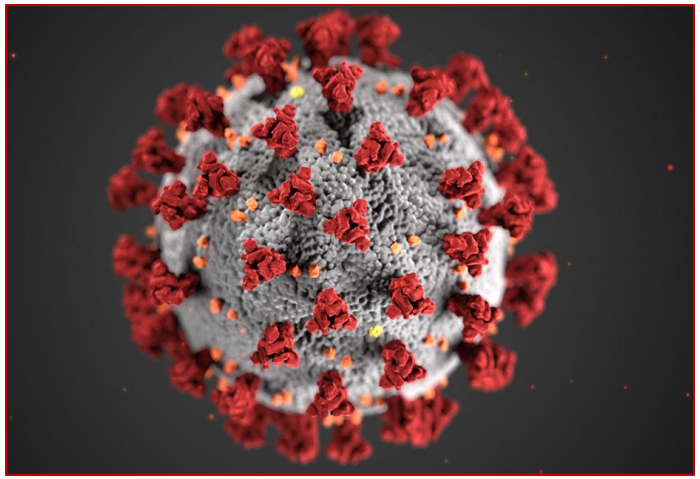
COVID-19

Pandemic vs. epidemic

Transmission

Presentation

Coronavirus Disease-19 (COVID-19)



Caused by SARS Coronavirus 2 (SARS-CoV-2)

- Novel coronavirus, first identified in Wuhan, China in 2019
- One of 7 coronaviruses known to infect humans

Coronavirus

- Named for crown-like spikes on surface
- >135 million global cases, and >2.9 million global deaths
  - >31 million US cases, and >561,000 US deaths (3rd leading cause of death in 2020)

U.S. National Institutes of Health; Centers for Disease Control and Prevention; World Health Organization; John Hopkins Coronavirus Center

Epidemic vs. Pandemic

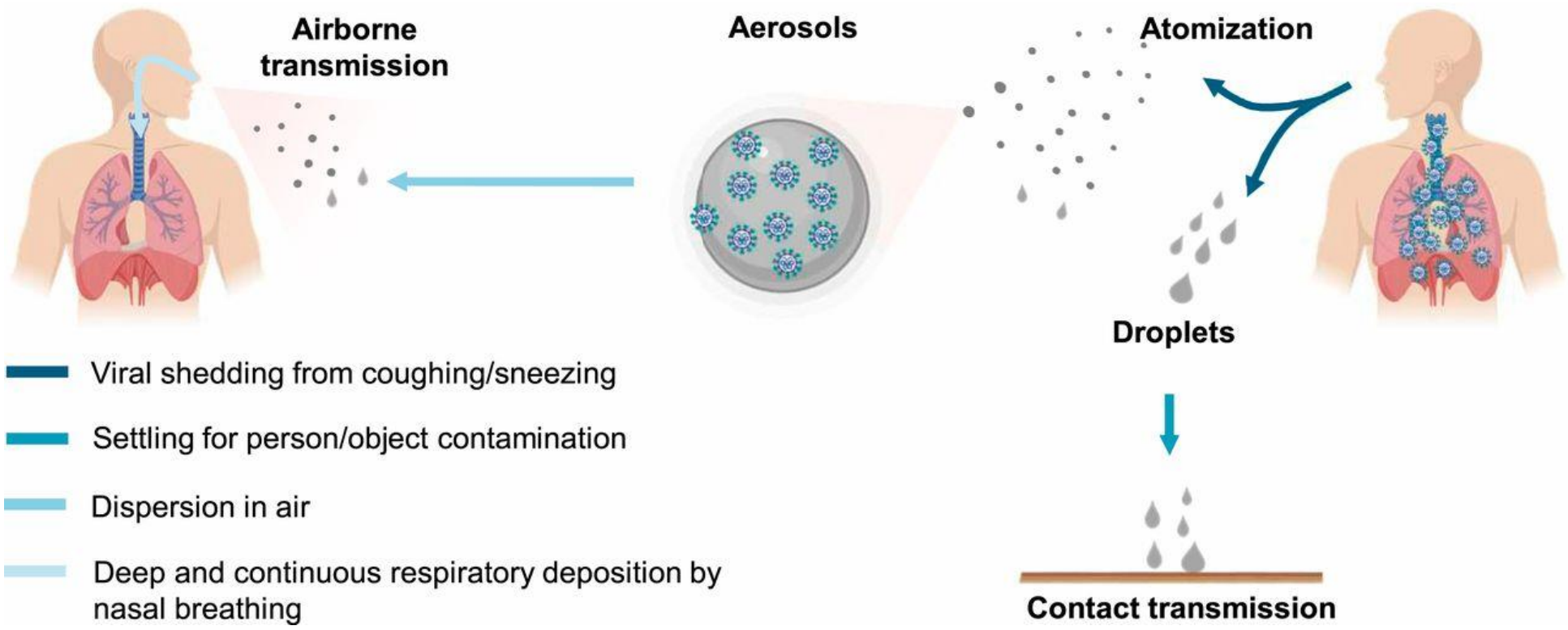
- On March 11, 2020 World Health Organization (WHO) declared COVID-19 a pandemic

- ***Epidemic***: "Increase, often sudden, in the number of cases of a disease above what is normally expected in that population in that area; agent and susceptible hosts are present in adequate numbers, and the agent can be effectively conveyed from a source to the susceptible hosts”

- ***Pandemic***: "Epidemic that has spread over several countries or continents, usually affecting a large number of people"

Centers for Disease and Prevention; World Health Organization

Modes of Transmission



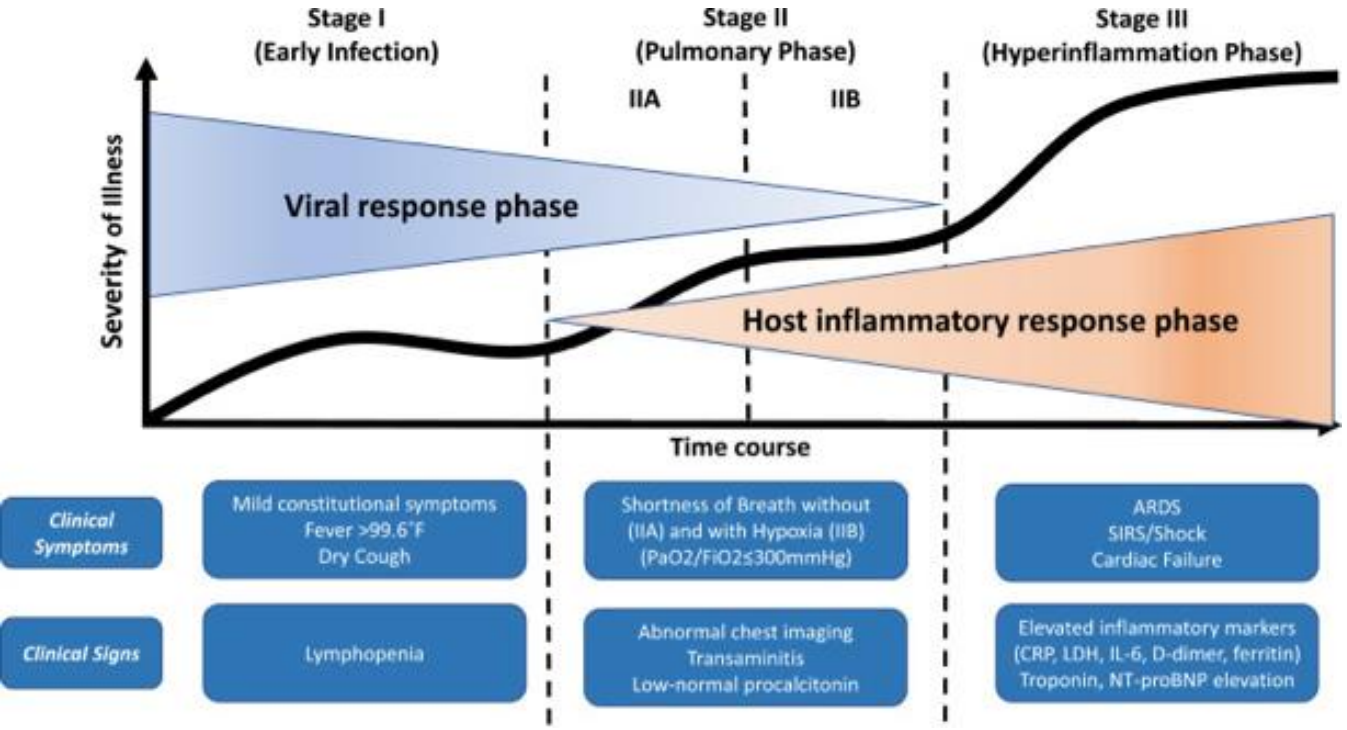
Highlights the need for social distancing, masks, & proper hand washing

Key takeaway: avoid being indoors without a mask

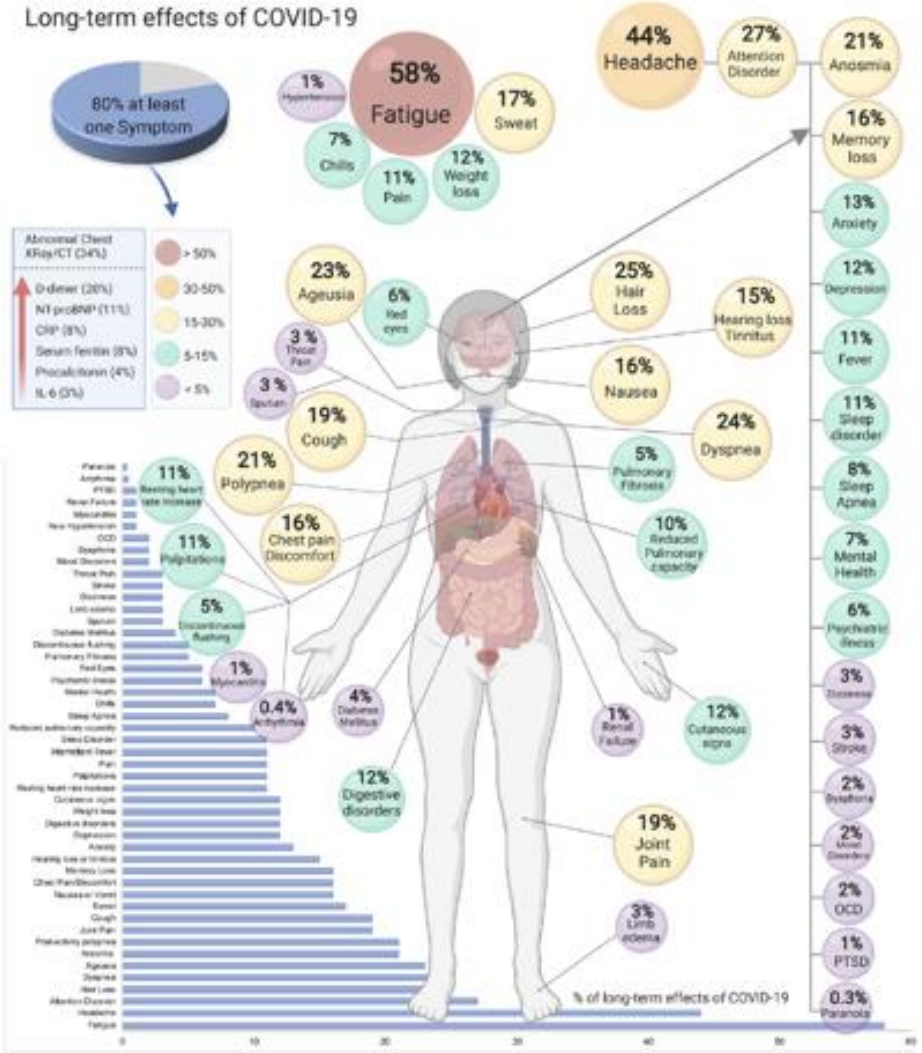
Centers for Disease Control and Prevention; Zhang R et al (2020) *PNAS*. **117 (41)**: 14857–14863.

COVID-19 Presentation

Acute illness (1-3 weeks)



Late sequelae (>3 weeks)



Siddiqi H, et al (2020) *J Heart Lung Transplant*. **39(5)**:405-407;
Amenta EM, et al (2020) *Open Forum Infectious Diseases*. **7(12)**:1-7;
Lopez-Leon et al. medRxiv preprint

‘Long-Haulers’

- Can affect anyone, not just at risk members of society
- ‘Young, healthy people are safe’ = wrong

I’m a COVID-19 long-hauler and an epidemiologist – here’s how it feels when symptoms last for months

August 11, 2020 8.10am EDT

U.S.News NEWS » News Best Countries Best States Healthiest Communities Cities Elections The Racial Divide Photos Events

COVID-19 Vaccine Distribution: » How Many People in Your State Are Vaccinated? >>

Home / News / Health News

They Got COVID-19. Months Later, They’re Still Sick. Who Are the COVID Long-Haulers?

Many people are still sick months after getting COVID-19. Here’s who they are, and who is trying to help.

For Long-Haulers, Covid-19 Takes a Toll on Mind as Well as Body

“It makes you depressed, anxious that it’s never going to go away.”

Inside the 'cyclone' of brain fog many COVID-19 long-haulers are still experiencing

A new study found some survivors are suffering from ongoing neurological issues.

By Sasha Pezenik

March 24, 2021, 6:02 AM • 7 min read

NEWS FEATURE · 14 SEPTEMBER 2020

The lasting misery of coronavirus long-haulers

Months after infection with SARS-CoV-2, some people are still battling crushing fatigue, lung damage and other symptoms of ‘long COVID’.

Michael Marshall

HEALTH

‘A shadow of what I was’: COVID-19 ‘long-haulers’ shed light on brain-related symptoms


By Daina Goldfinger & Jasmine Pazzano · Global News

Posted November 16, 2020 5:30 pm · Updated November 17, 2020 2:54 pm

Who is most at risk

- Older adults (65+)
- Frontline workers
- Patients with conditions affecting their immune system
  - Diabetes, chronic kidney disease, chronic lung disease, heart conditions, liver disease, cancer, immunocompromised, etc (per CDC)
- Pregnancy
- Long term care facilities, assisted living facilities

Back to Robert

- Your **70** year old neighbor Robert who has **diabetes** sees you on the sidewalk. He asks for your advice on the COVID-19 vaccine.

- **"What are my chances of getting COVID anyway?"**

Audience: Should Robert be concerned?
Please type your response in the Zoom chat

Vaccine Development Overview

Brief History and the importance of vaccines

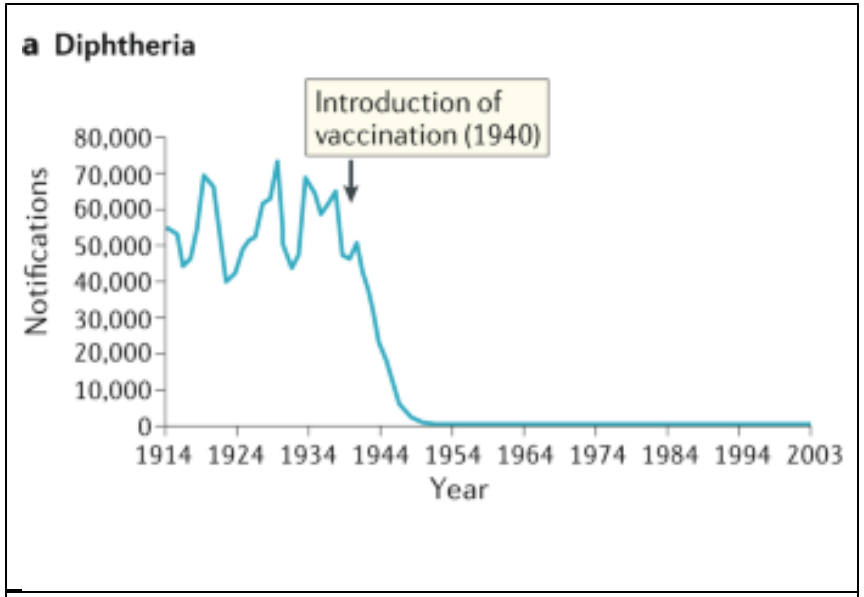
Components of Vaccines and how they work

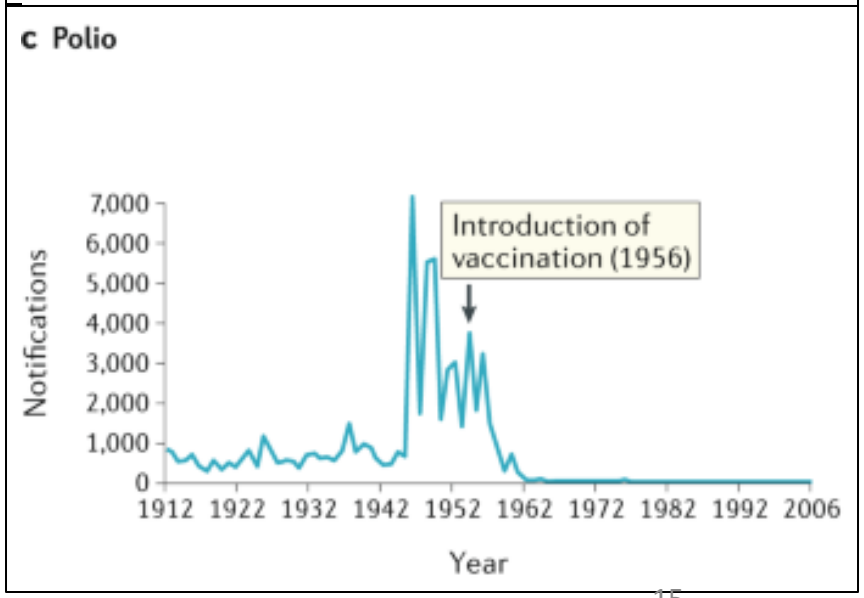
Vaccine Testing

Emergency Use Authorization

Brief History of Vaccines

- Modern vaccination started with smallpox in 1796
  - ~300 million deaths due to smallpox In the 20th century
  - Smallpox is the only infectious disease eradicated in 1980
- Vaccines prevented disease, saved millions of lives
- Many vaccines available
- Depending on travel and risk factors, other vaccines might be recommended





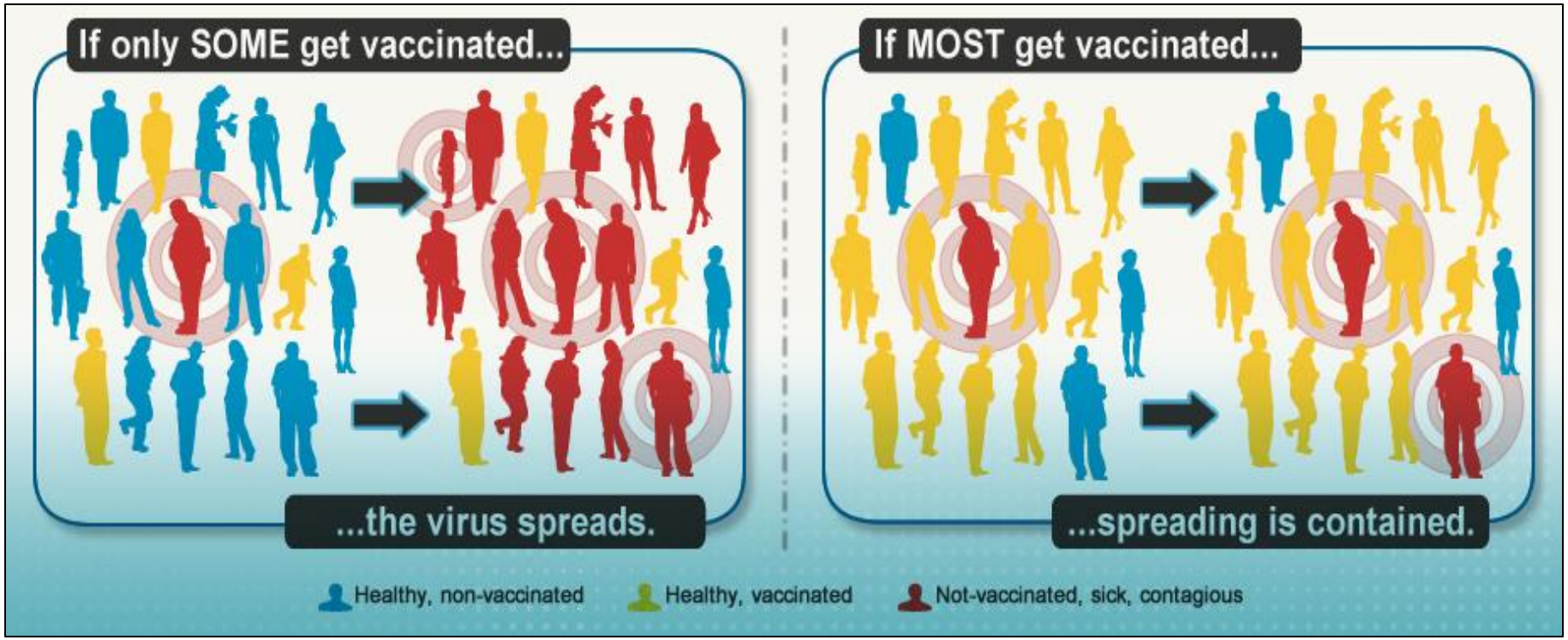
Centers for Disease Control and Prevention
Pollard AJ, et al (2020). *Nature Reviews Immunology*. 21; 83-100

The Importance of Vaccines

- Protects against mortality (death) and disease
- Prevents spread of disease
- Adds to number vaccinated and contributes to herd immunity

https://www.mayoclinic.org/diseases-conditions/coronavirus/in-depth/coronavirus-vaccine/art-20484859

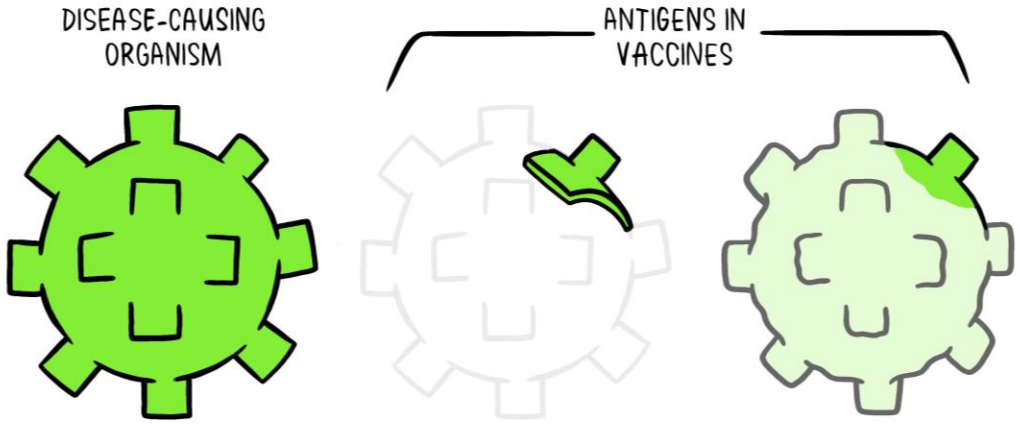
Herd Immunity

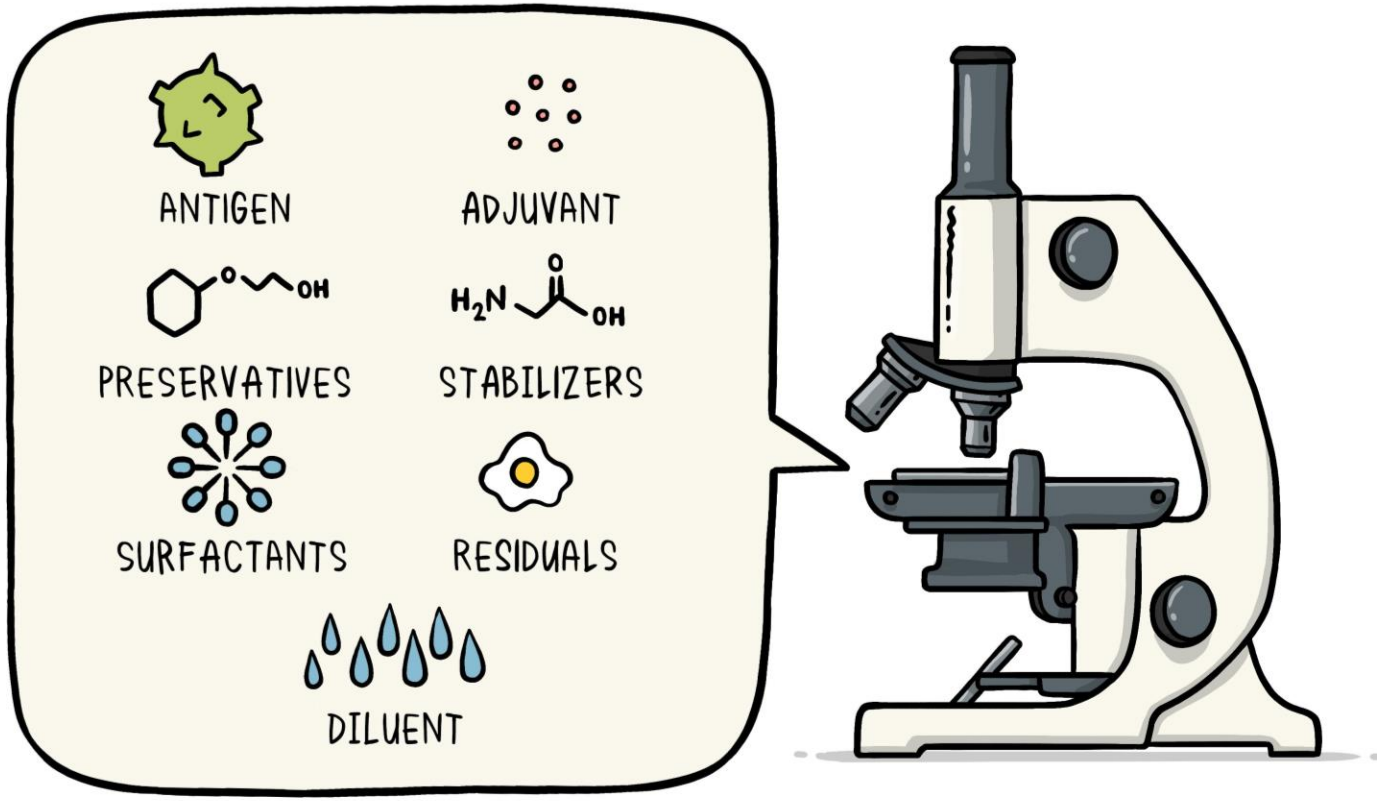


- **Indirect protection to unvaccinated people**
- **Depending on how contagious, 50-90% of population needs immunity**
- **At least 70% vaccination/immunity to SARS-CoV-2 needed for herd immunity**

Centers for Disease Control and Prevention; Johns Hopkins School of Public Health

Components of Vaccines

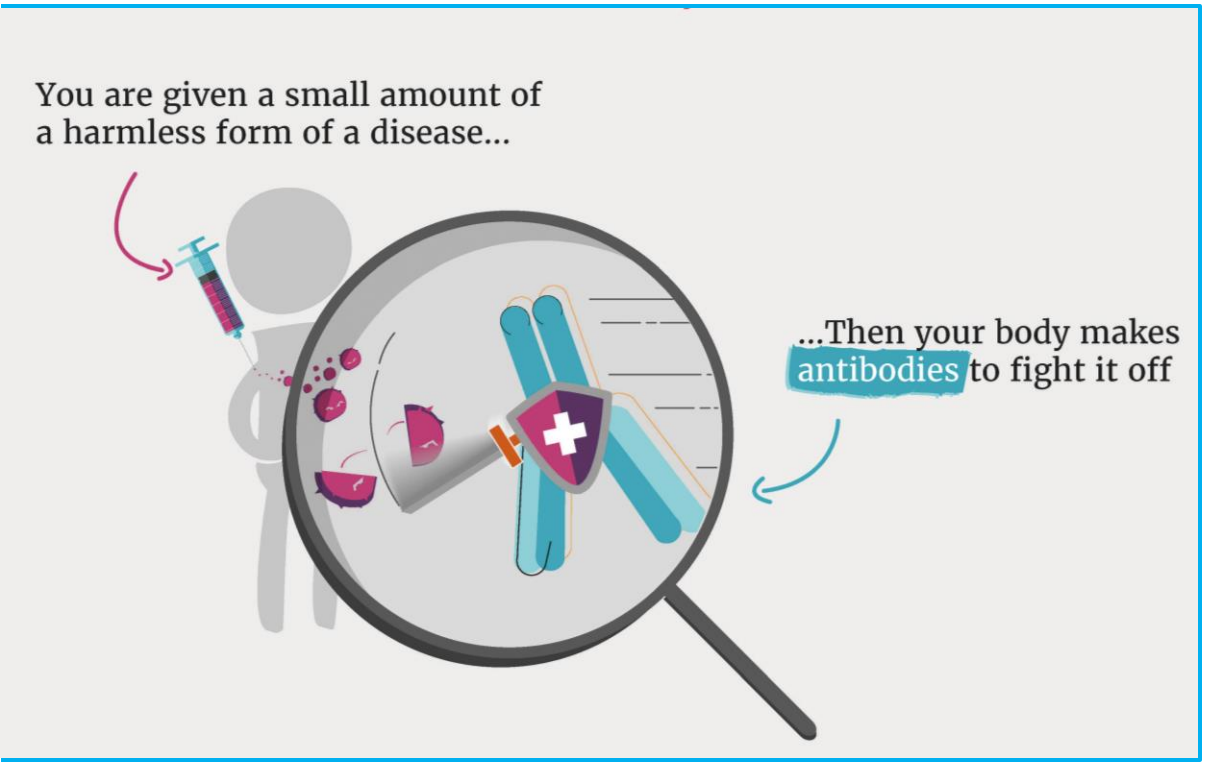




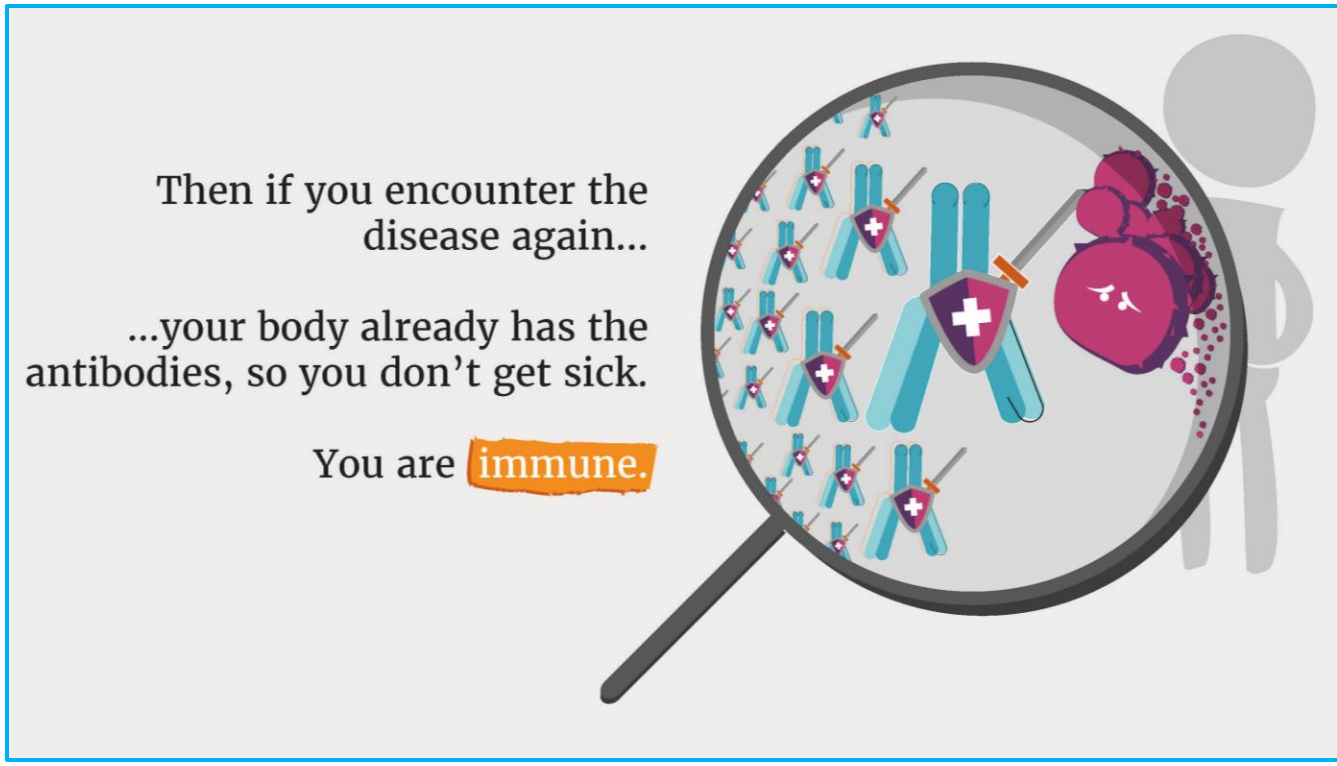
Images: https://www.who.int/news-room/feature-stories/detail/how-are-vaccines-developed

How Vaccines Work

Comparison: Training for the battle



Comparison: Ready for the battle



Important fact: COVID-19 vaccines will not cause COVID-19

Image: https://www.immunology.org/celebrate-vaccines/public-engagement/infographics

Vaccine Testing

- Pre-Clinical Phase
- Phase 1
- Phase 2
- Phase 3

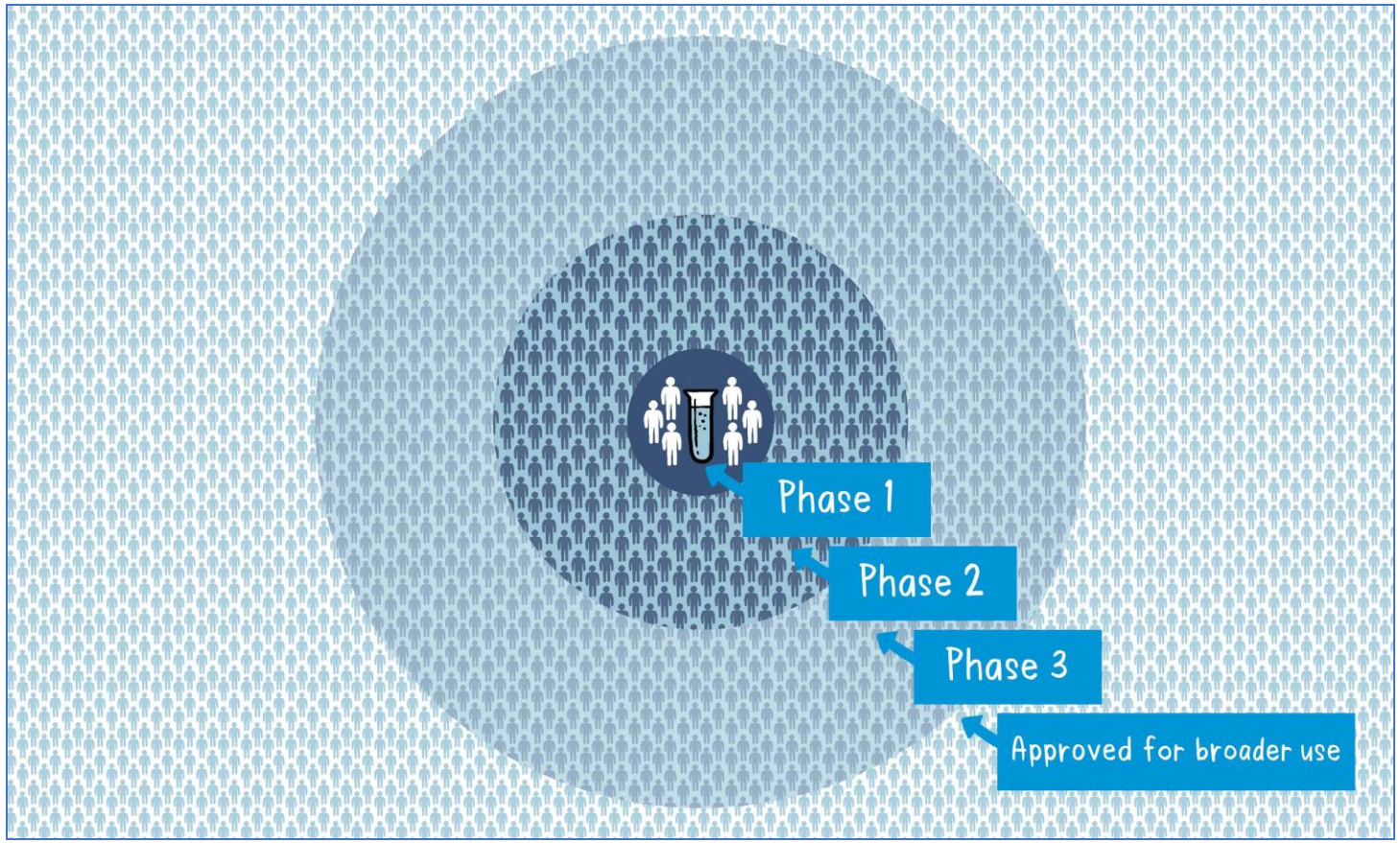


Image: https://www.who.int/news-room/feature-stories/detail/how-are-vaccines-developed

COVID-19 Vaccine Development

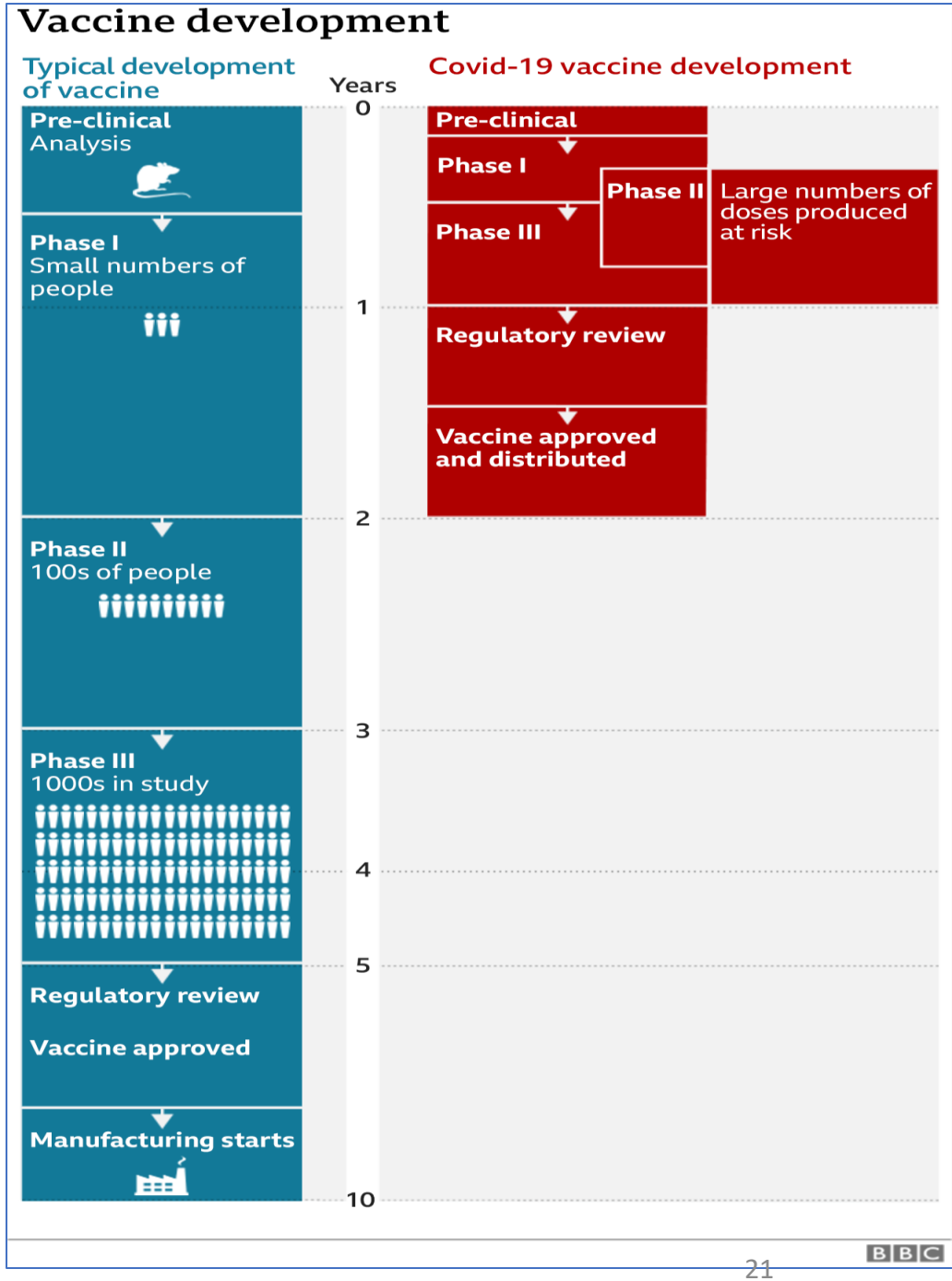
- Normal vaccine development takes 5-20 years
- Usual delays are due to
  - Funding
  - Patient enrollment
  - Administrative approval
  - Manufacturing

Original studies

>30K volunteers for Moderna trial

>43K volunteers for Pfizer/BioNTech trial

>43K volunteers for J&J/Janssen trial



https://www.bbc.com/news/health-54027269
https://www.mayoclinic.org/diseases-conditions/coronavirus/in-depth/coronavirus-vaccine/art-20484859

Emergency Use Authorization (EUA)

- Food and Drug Administration (FDA) evaluates medical products
- In emergencies such as COVID-19, the FDA can issue an EUA to strengthen protection against chemical, biological, radiological and nuclear threats
- EUAs evaluate risk versus benefit of products to allow for faster approval
  - Allow access to drugs, tests, critical medical products when no approved options

U.S. FOOD & DRUG ADMINISTRATION

EUA Process

1. Vaccine manufacturer conducts lab research
2. Manufacturer submits Investigational New Drug application
3. Clinical trials conducted (Phase 1, 2, 3)
4. Drug Safety Monitoring Board evaluates Phase 3 trial data
5. Company determines if FDA safety + efficacy requirements are met
6. Company submits request for EUA
7. FDA's Center for Biologics Evaluation and Research (CBER) evaluates EUA request
8. FDA convenes public meeting of its Vaccines and Related Biological Products Advisory Committee
9. CBER considers Committee input to determine if safety, effectiveness, and manufacturing data support authorization of EUA
10. FDA authorizes vaccine for emergency use if CBER deems that benefits outweigh risks and manufacturing information is adequate to ensure quality and consistency
11. FDA informs the company that EUA has been authorized

Food and Drug Administration (FDA)

Back to Robert

- Your 70 year old neighbor Robert who has diabetes sees you on the sidewalk. He asks for your advice on the COVID-19 vaccine.

- **“It seems the vaccine came out too fast!”**

Audience: Should Robert be concerned about the speed of the vaccine development?
Please type your response in the Zoom chat

The COVID-19 Vaccine

Components of Vaccines

Vaccine Testing

What Should Matter in COVID-19 Vaccines

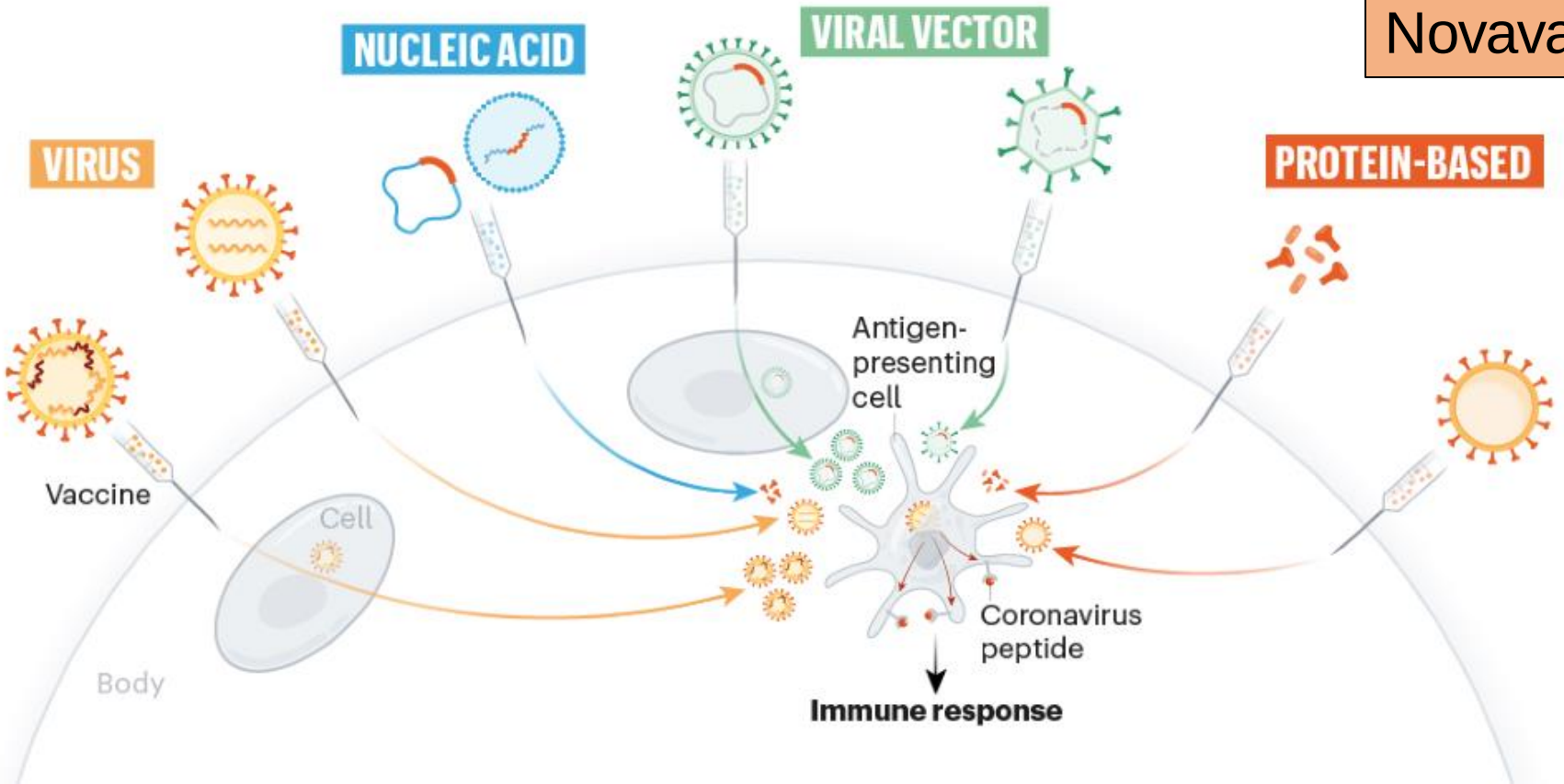
- Clinical
  - ***Prevention of death***
  - ***Prevention of hospitalizations***
  - Overall efficacy
- Number of doses

COVID-19 Vaccine Candidates

-Pfizer/BioNTech
-Moderna

-J&J/Janssen

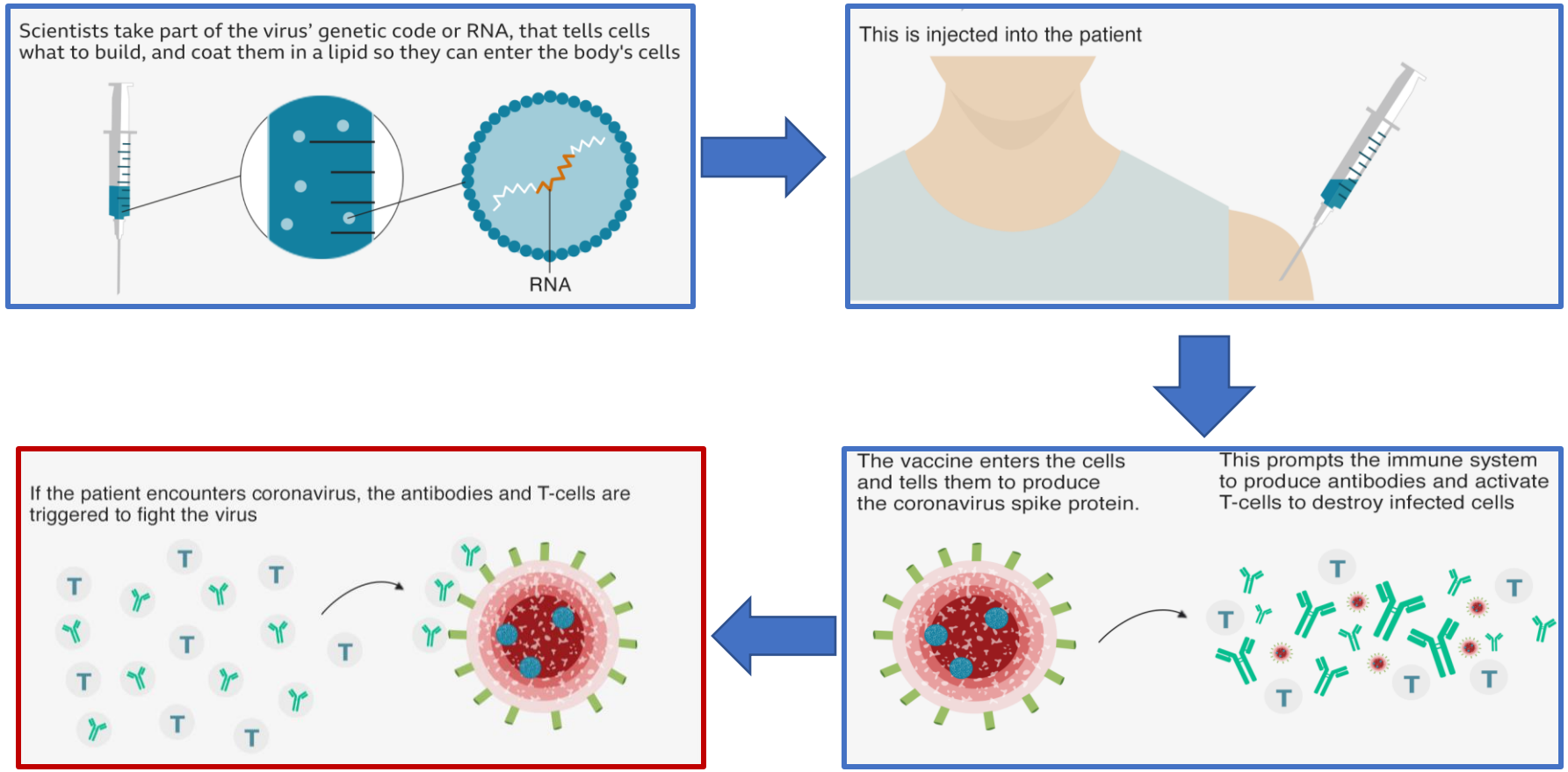
Novavax



Nature

mRNA Vaccines

- mRNA biology and potential for use as a vaccine, studied for decades
- mRNA is the genetic material telling our body how to make proteins
- Does not use weakened or inactivated virus
- Cells are instructed to make the harmless 'spike protein'
- Does not integrate with our DNA

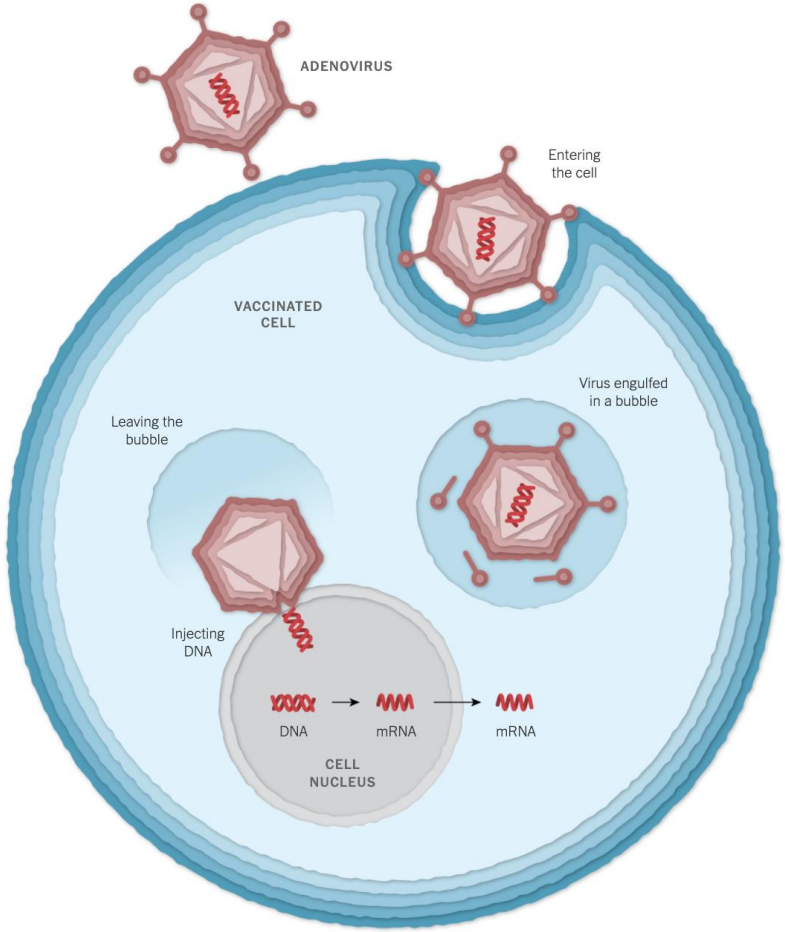


Centers for Disease Control and Prevention
https://www.bbc.com/news/health-54986208
Nature


COVID-19
The mRNA vaccine is like a most wanted poster that tells your body how to recognize COVID-19. It can't and won't change your DNA.
COURTESY OF THE mRNA VACCINE
MOST WANTED
BY THE IMMUNE SYSTEM
COVID-19
SPIKE PROTEIN
ARMED AND DANGEROUS
WATERLOO
5in5

Viral Vector Vaccines

- Adenovirus-based vaccine
- Modified cold virus that cannot cause cold or flu-like symptoms
- Used successfully for Ebola
- DNA is not as fragile as RNA; adenovirus' protein coat protects genetic material.
  - Adenovirus and DNA degraded after delivering message
- Can be stored for longer



New York Times

COVID Vaccines – Overview

Vaccine	Origin	Type	# of Doses	FDA Status	Ages
Pfizer/BioNTech	USDE	mRNA	2 shots 21 days apart	EUA	16 and older
Moderna	US	mRNA	2 shots 28 days apart	EUA	18 and older
Johnson &Johnson/Janssen	USBE	Viral vector	1 shot	EUA	18 and older

Over 183 million doses of COVID-19 vaccines as of April 10,2020
'Fully vaccinated' 2 weeks after last dose
No evidence that vaccination caused any death

Centers for Disease Control and Prevention

Back to Robert

- Your 70 year old neighbor Robert who has diabetes sees you on the sidewalk. He asks for your advice on the COVID-19 vaccine.

- **“Will it affect my DNA?”**

Please type your response in the Zoom chat

Pfizer-BioNTech

Type	mRNA
Approval status; Age **Upcoming trials**	EUA December 11th, 2020; 16+ Adolescent completed, child started
Number of shots	2 (3 weeks apart)
Overall Efficacy	95% (clinical trial) 91% (real world)
Protection severe disease, hospitalizations, death	100%, 100%, 100%
Side Effects	Injection site pain, fatigue, headache, muscle pain, chills, fever, joint pain

Polack FP, et al (2020) *NEJM*. **383**:2603-2615; Image: aarp.org

Moderna

Type	mRNA
Approval status; Age **Upcoming trails**	EUA December 18th, 2020; 18+ Adolescent ongoing, child started
Number of shots	2 (4 weeks apart)
Overall Efficacy	94.1% (clinical trial)
Protection severe disease, hospitalizations, death	100%, 100%, 100%
Side Effects	Injection site pain, fatigue, headache, muscle pain, chills, fever, joint pain

Baden LR , et al (2020) *NEJM*. **384**:403-416; Image: Npr.org

Johnson &Johnson/Janssen

Type	Viral Vector
Approval status; Age	EUA Feb 27, 2021; 18+
Number of shots	1
Overall Efficacy	72% (clinical trial)
Protection from severe disease, hospitalizations, death	85%, 100%, 100%
Side Effects	Injection site pain, headache, fatigue, myalgias, nausea

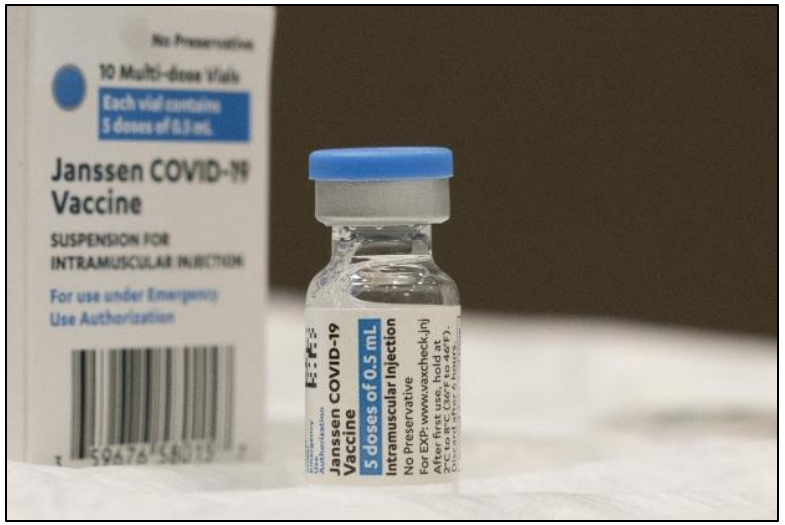


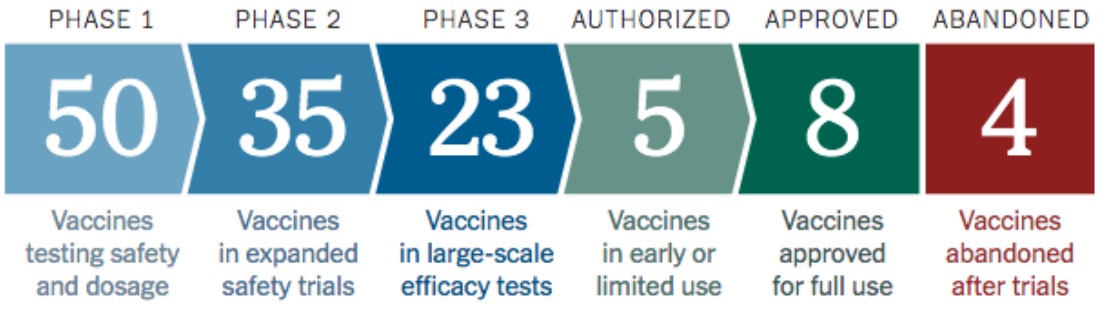
Image: wpr.org

ENSEMBLE Trial NCTO4505722

In the Pipeline & Around the World

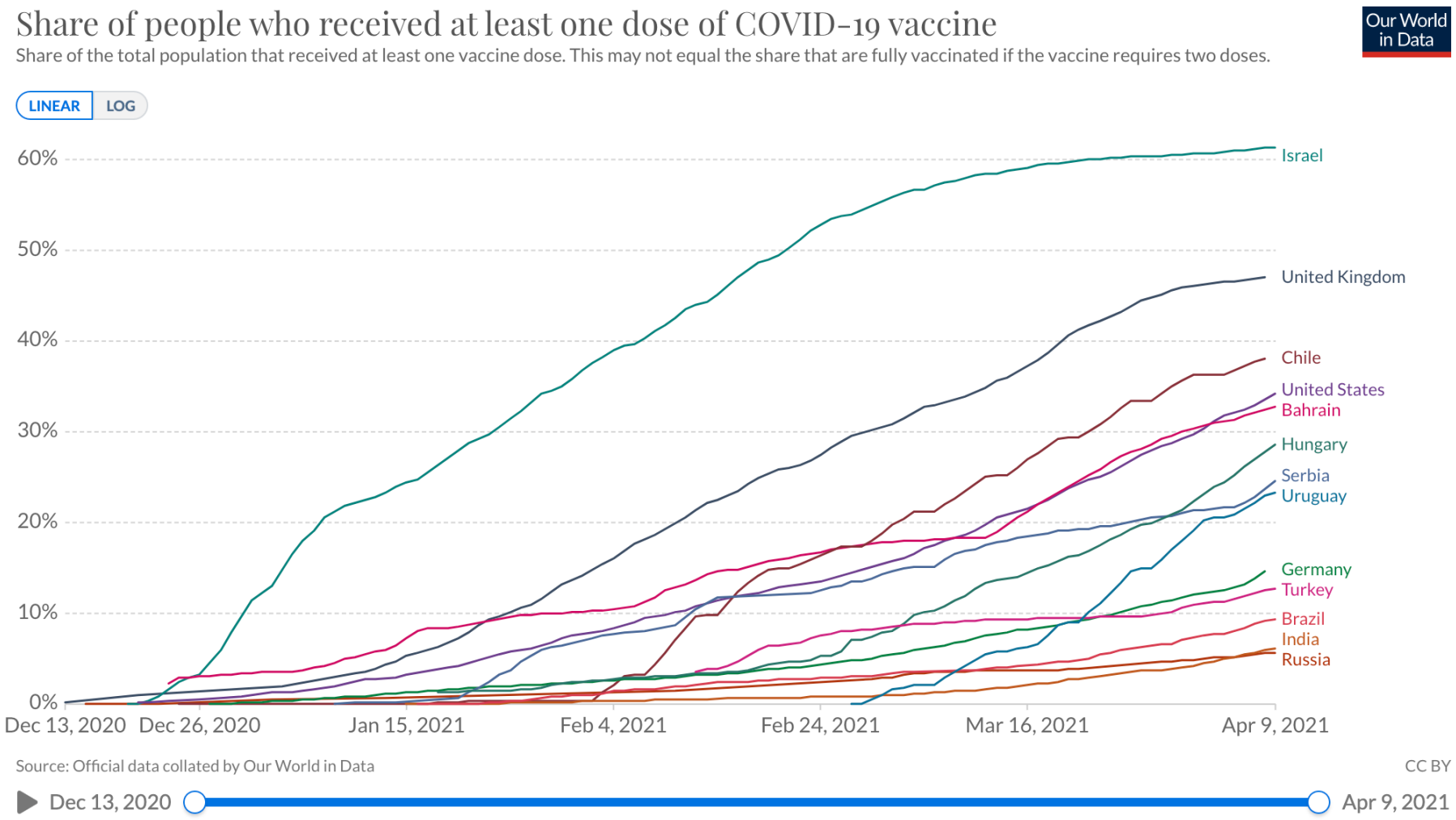
Leading vaccines

Developer	How It Works	Phase	Status
Pfizer-BioNTech	mRNA	2 3	Approved in several countries. Emergency use in U.S., E.U., other countries.
Moderna	mRNA	3	Approved in Switzerland. Emergency use in U.S., E.U., other countries.
Gamaleya	Ad26, Ad5	3	Early use in Russia. Emergency use in other countries.
Oxford-AstraZeneca	ChAdOx1	2 3	Approved in Brazil. Emergency use in U.K., E.U., other countries.
CanSino	Ad5	3	Approved in China. Emergency use in other countries.
Johnson & Johnson	Ad26	3	Emergency use in U.S., E.U., other countries.
Vector Institute	Protein	3	Early use in Russia. Approved in Turkmenistan.
Novavax	Protein	3	
Sinopharm	Inactivated	3	Approved in China, U.A.E., Bahrain. Emergency use in other countries.
Sinovac	Inactivated	3	Approved in China. Emergency use in other countries.
Sinopharm-Wuhan	Inactivated	3	Approved in China. Limited use in U.A.E.
Bharat Biotech	Inactivated	3	Emergency use in India, other countries.



New York Times

Vaccinations around the world



In the U.S.: 34.2% of people received at least received 1 dose (178 million doses)

Back to Robert

- Your 70 year old neighbor Robert who has diabetes sees you on the sidewalk. He asks for your advice on the COVID-19 vaccine.

- **“Should I get it? I hear it hurts”**

Audience: Should Robert get the vaccine?
Please type your response in the Zoom chat

Special Considerations

Children

Older Adults

Pregnancy and Lactation

COVID-19 Vaccine in Children

- Children are ~20% of U.S. population
- Symptomatic infection uncommon and generally mild; rare severe cases/hospitalizations
  - Rare Multisystem Inflammatory Syndrome in Children (MIS-C)
- Pfizer/BioNTech EUA approved in children 16+
- Several promising studies underway
  - Pfizer/BioNTech vaccine studied in >1000 12-15 yo, 100% effective; Moderna trial ongoing
  - Studies started for younger children (6 months – 11 yo) - Pfizer/BioNTech, Moderna
- Children could be eligible by the 2021-2022 school year

Older Adults

- Severe illness from COVID-19 increases with age
- Adults 65+ make up 8 out of 10 deaths from COVID-19
- CDC recommends prioritizing 65+ adults for vaccination
- Older adults report fewer side effects from the vaccines

Centers for Disease Control and Prevention; AARP

COVID-19 Vaccine in Pregnancy & Lactation

- ↑ risk of severe illness & adverse pregnancy outcomes in COVID-19
- >30,000 pregnant women received the vaccine (CDC)
- Data on safety in pregnancy from studies
  - Animal studies found no safety concerns
  - Clinical trials show protection of mother, fetus
- Original studies did not include those lactating
  - Non-replicating vaccines pose no risk
  - Clinical trials show protection of child
- No evidence of adverse effects on fertility
- Recommended in pregnancy and lactation (CDC, FDA, ACOG, ABM)

Centers for Disease Control and Prevention; American College of Obstetricians and Gynecologists (ACOG)

Planning for the Future

Signing up for vaccination and preparation
Variants
Gathering (Social gatherings, Worship/Singing, School)
Travel

Back to Robert

- Your 70 year old neighbor Robert who has diabetes sees you on the sidewalk. He asks for your advice on the COVID-19 vaccine.

- **“How do I sign up for it?”**

Signing up for Vaccinations

- The vaccine is free
- You do not need health insurance or legal documentation
- Check with your physician, pharmacist, community health center regarding vaccine availability
- State or local health departments will have more information
- Resources to sign up
  - Vaccinefinder.org
  - Local pharmacy website
  - News outlets
  - State health department

Preparation: Before during and after vaccination

Before vaccination

- Avoid NSAIDs, acetaminophen - may reduce effectiveness of vaccine
- Do not take antihistamine (e.g. Benadryl) - will mask allergic reaction

During vaccination

- Relax arm to help reduce soreness
- Stay ~15-30 minutes to get monitored

After vaccination

- Expect mild to moderate symptoms for ~48 hours after vaccination
- Can take pain medications (acetaminophen, NSAIDs) as needed if safe for you
- Risk for infection weeks after vaccine exists; unclear if exposed, can transmit virus
- CDC has recommendations of what you can do once fully vaccinated
- Keep your vaccination card, if able

WHAT YOU CAN DO ONCE YOU HAVE BEEN FULLY VACCINATED

Activity	
Visit inside a home or private setting without a mask with other fully vaccinated people of any age	✓
Visit inside a home or private setting without a mask with one household of unvaccinated people who are not at risk for severe illness	✓
Travel domestically without a pre- or post-travel test	✓
Travel domestically without quarantining after travel	✓
Travel internationally without a pre-travel test depending on destination	✓
Travel internationally without quarantining after travel	✓
Visit indoors, without a mask, with people at increased risk for severe illness from COVID-19.	✗
Attend medium or large gatherings	✗

DEPARTMENT OF HEALTH & HUMAN SERVICES · USA

CDC

cdc.gov/coronavirus

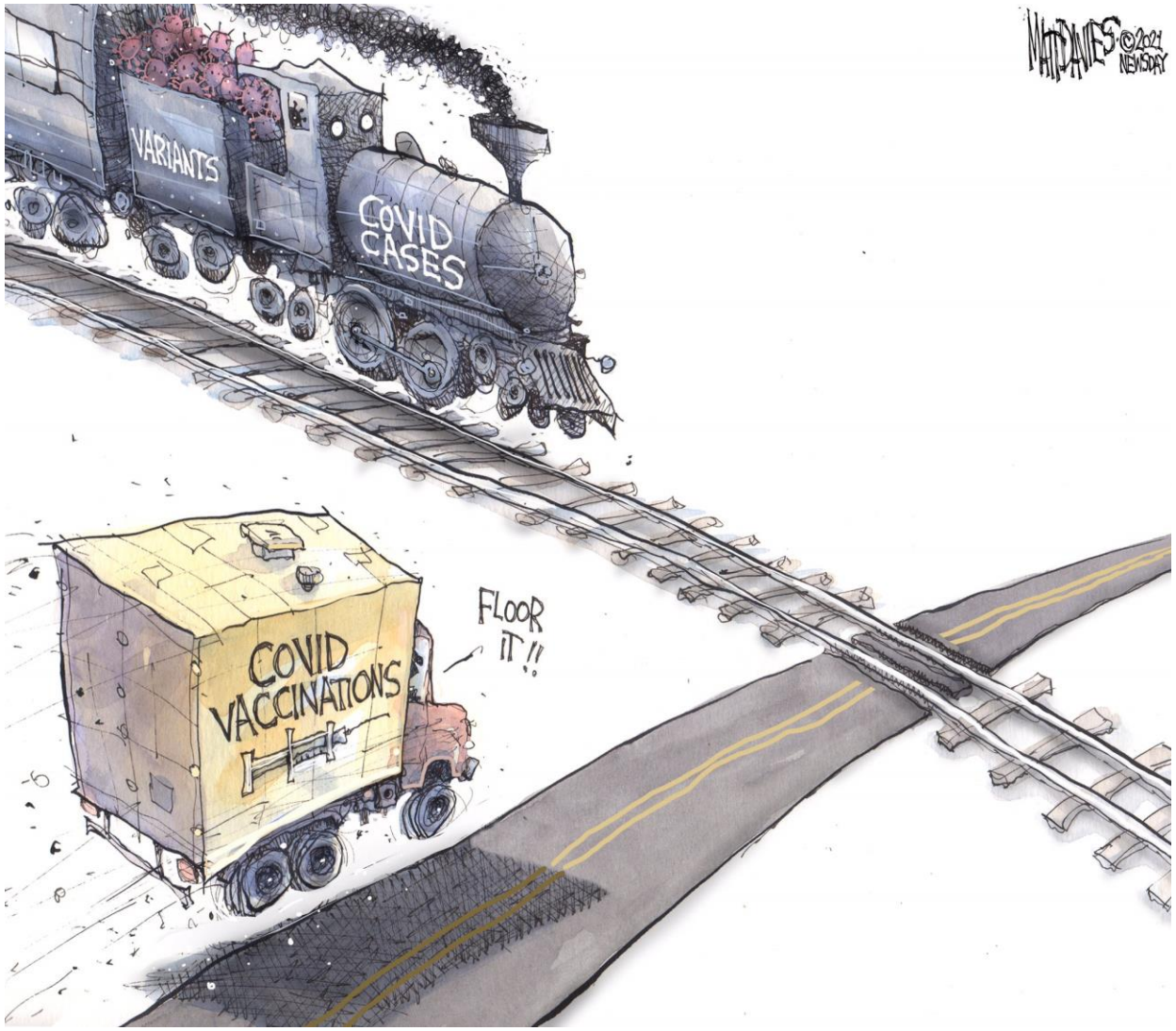
CS323698-A 04/02/2021

Planning for Church

UNSAFE TO GATHER	MAKE IT SAFER	SAFEST
Vaccination rate <50%	Vaccination rates 50-70+%	Vaccination rates 70-85+%
Viral Transmission • Cases >10/100K • Positive Tests >10%	Viral Transmission • Cases 5-10/100K • Positive Tests <10%	Viral Transmission • Cases <1/100K • Positive Tests <5%
• All at Once • Unmasked • No distancing • Full capacity • Assembly singing • Eating together	• Face masks mandatory • Physical distancing • Low-touch environment • Outdoors or increased air exchange • Shortened time of service • Singing by worship leaders only • Focus on sanitizing high-touch surfaces • Sign-in/attendance list	• All of the 'make it safer' plus no or minimized singing • Hybrid, phased plan • Wait 1 month + between phases • Fallback plan for outbreaks • Communication plan • Team responsibility

Centers for Disease Control and Prevention
https://www.wichurches.org/2021/01/14/returning-to-church/

Variants



The race against vaccines and variants lie ahead

Variants

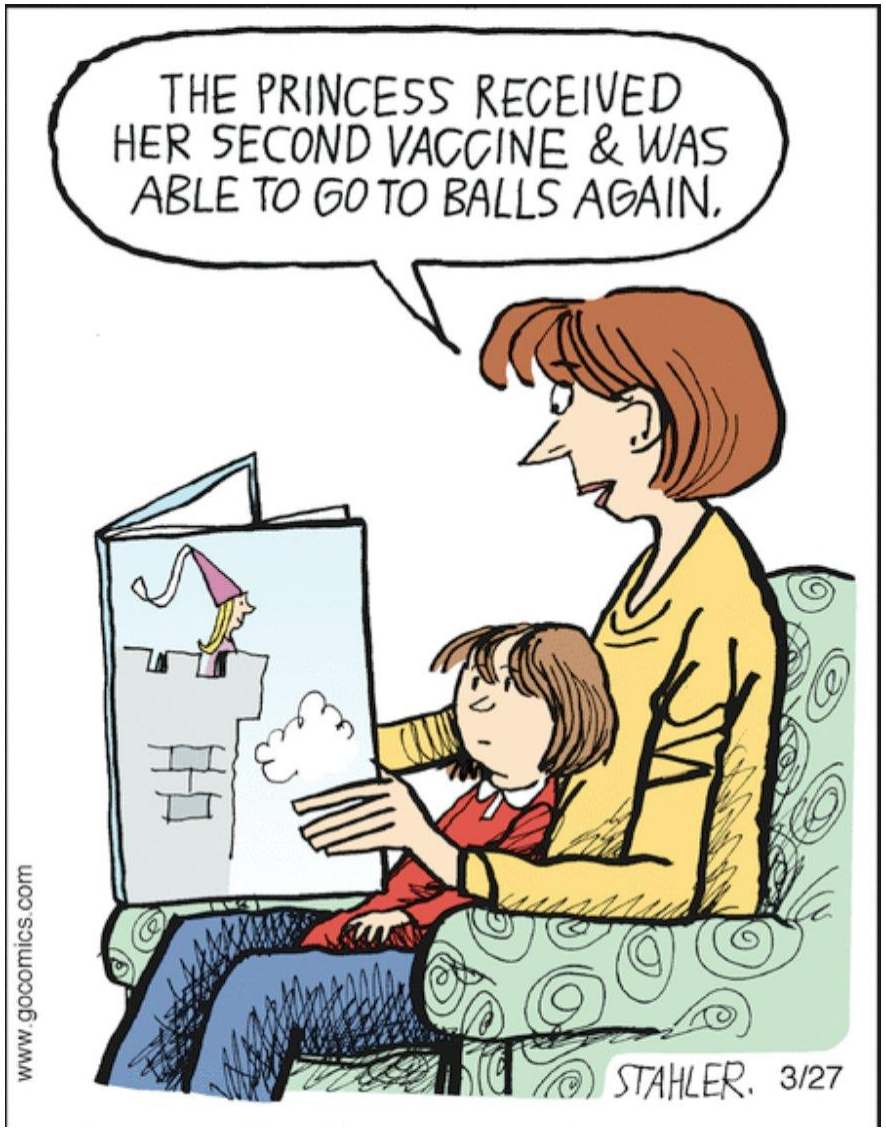
- Viruses mutate (changes genetic sequence) causing variants
- Multiple COVID-19 variants circulating affecting even young/healthy persons
- 5 Variants of Concern (VOCs) classified that spread easily, quickly, can cause severe disease
- Studies still investigating their spread, pathogenicity, vaccines effect, need for booster shots

Variant	Initial detection	In the U.S.	Comments
B.1.1.7	United Kingdom	Dec 2020 (major strain now)	~70% more transmissible 55% more deadly Vaccine still effective
B.1.351	South Africa	Jan 2021	~50% more transmissible Unknown if more severe disease Reduced vaccine effectiveness
P.1	Brazil	Jan 2021	Likely more transmissible Unknown if more severe disease Reduced vaccine effectiveness
B.1.427 & B.1.429	California	Feb 2021	~20% more transmissible Unknown if more severe disease Vaccine likely still effective

5 states account for more than 45% of new overall cases in the U.S (NY, MI, FL, **PA**, NJ). These states have some of highest rates of B.1.1.7

Centers for Disease Control and Prevention

Looking to the Future



Takeaways

- COVID-19 is a preventable infectious disease
- COVID-19 can present as a serious disease and have long-term effects
- The COVID-19 vaccines have been well studied
- Vaccination will protect you and those around you
- Our understanding on the virus continues to develop
- Continue to wear your mask, social distance, wash hands, and take other precautions

Questions?

Centers for Disease Control and Prevention