MA PTA Health, Safety, and Wellness Webinar Series: Engaging Together To Be Healthy

Building Vaccine Confidence to Ensure Optimal Health for You and Your Families

Richard Moriarty, MD FAAP
Professor of Clinical Pediatrics, UMass Medical School
MA Chapter American Academy of Pediatrics Immunization Initiative

Life Before Vaccines

DIPHTHERIA

DATE	MATERIAL	DOSE	PHYSICIAN

TUBERCULIN

DATE	RESULT	PHYSICIAN

WHOOPING COUGH

TYPHOID

DATE	MATERIAL	DOSE	PHYSICIAN

TETANUS

Booster	March	29	1957
Booster	June	6	1959 -

OTHER IMMUNIZATIONS

DESCRIPTION	DATE	PHYSICIAN
Booster	Jan 27 1949	Dr. Crosley
Polio	Spring 55	4th booster June 6 1959
"	Fall 55	5th " " " 196
" Booster	June 29 1956	

SMALLPOX

DATE	RESULT	PHYSICIAN
May 19 49	(first one didn't take)	
19 ?	Booster	

DATE CONTAGIOUS DISEASES CONTRACTED

DISEASE	DATE	DISEASE	DATE
Measles	Jan. 1952	Mumps Dec.	1960
German Measles	Sept. '45 Sept. '51	Scarlet Fever	
Whooping Cough		Other:	
Diphtheria			
Chicken Pox	March 3 1953		

SCHICK TEST

Flu shot	Sept. 1957	

BLOOD GROUP: _____ Rh: _____

DRUG IDIOSYNCRASY _____

Life Before Vaccines

- diphtheria: in 1921 >15,000 deaths; toxoid vaccine in 1920's
- polio 1952: 21,000 paralyzed and 3100 died/year; vaccine: 1955
- measles 1950's and 1960's: 750,000 cases & 500 deaths/year; vaccine: 1963
- rubella 1964-5: 12 million infections, 20,000 babies born, 2100 deaths, 11,000 abortions; vaccine: 1969
- HIB: 1 out of every 200 children < age 5 had invasive disease; 1000 children per year died; vaccines 1985-7
- chickenpox: 100 deaths, 10,000 hospitalized; 30% get shingles later in life; vaccine: 1995
- rotavirus: severe diarrhea, ER visits, hospitalization; vaccines: 2006-8
- HPV: cervical cancer; head/neck cancer; vaccine: 2006
- Many physicians now are going through training without seeing these diseases

Life Since Vaccines

- Smallpox has been eradicated
- Polio is near to being eradicated
- Rubella & congenital rubella rare in US
- Invasive HIB disease rare
- Chickenpox much less common; outbreaks among unimmunized clusters; shingles will be less common
- Invasive pneumococcal pneumonia less common in children AND adults
- Rotavirus less common in children and adults
- HPV: dramatic falls in cervical pre-cancers and cervical cancers

Every $ spent on vaccines save about $10 in health care costs

https://www.nationalgeographic.com/culture/2019/08/cannot-forget-world-before-vaccines/#close
https://www.idsociety.org/news--publications-new/articles/2019/lower-health-care-costs-act-highlights-the-value-of-vaccines/

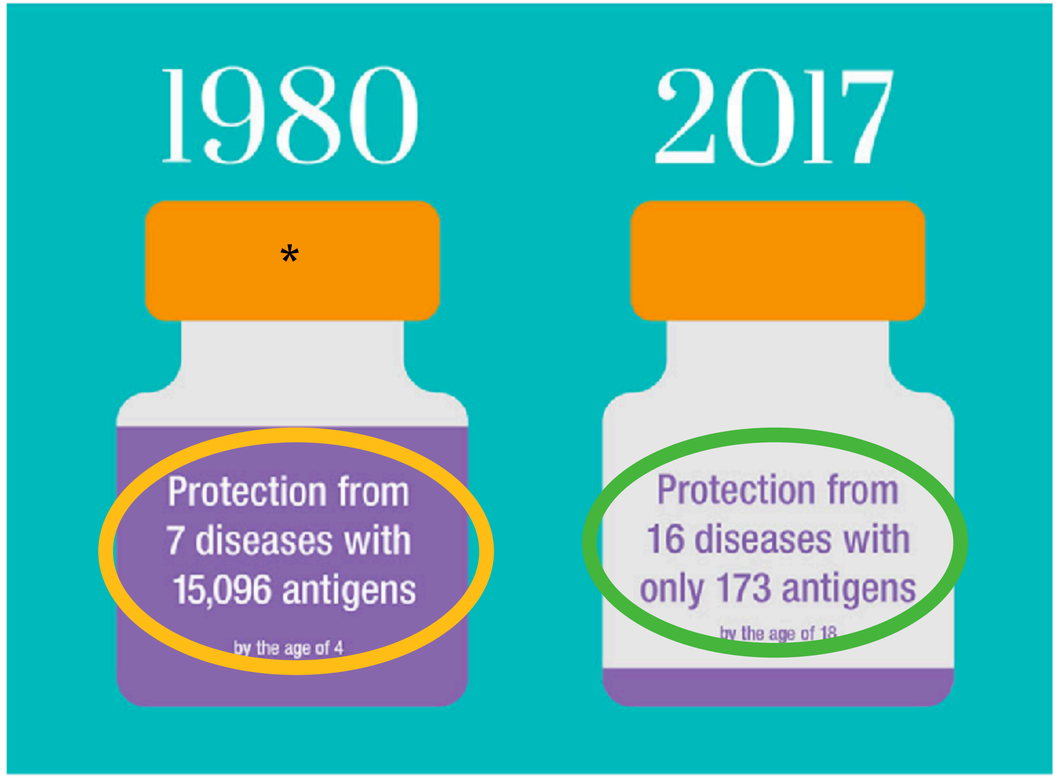
Today Children are Safer and Healthier

Diphtheria *
Tetanus *
Pertussis *
Polio *
HIB
Chickenpox
Hepatitis A
Hepatitis B
Pneumonia
Meningitis
Rotavirus
Measles*
Mumps*
Rubella*
Influenza
HPV

Combination vaccines minimize the number of injections

Vaccines Today Work Better Than Ever

Since 1980: More protection, fewer antigens.

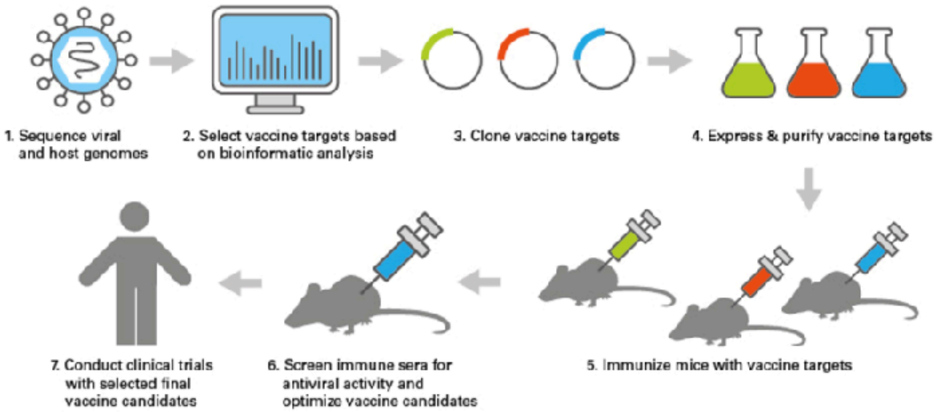


Based on CDC Recommended Vaccine Schedule U.S. for children birth to 18 years.
Source: Plotkin's Vaccines (Seventh Edition)

Source: *Plotkin's VACCINES, 7th Edition*

How Are Vaccines Developed?

- What diseases are affecting people?
- How common are those diseases?
- What diseases cause injury, disability, death?
- At what age do those diseases occur?
- Can we develop a way of detecting this disease?
- Can we detect immunity to the disease?
- Is there an animal model for the disease / vaccine?
- Attempts to develop vaccines don't always work
- Few pharmaceutical companies invest heavily in vaccines
- More $$ in drugs for cancer, immunotherapy
- Could a vaccine be improved?



How Are Vaccines Approved?

How a new vaccine is developed, approved and manufactured

The Food and Drug Administration (FDA) sets rules for the three phases of clinical trials to ensure the safety of the volunteers. Researchers test vaccines with adults first.

PHASE 1

$

20-100 healthy volunteers

- Is this vaccine safe?
- Does this vaccine seem to work?
- Are there any serious side effects?
- How is the size of the dose related to side effects?

PHASE 2

$$

several hundred volunteers

- What are the most common short-term side effects?
- How are the volunteers' immune systems responding to the vaccine?

PHASE 3

$$$

hundreds or thousands of volunteers

- How do people who get the vaccine and people who do not get the vaccine compare?
- Is the vaccine safe?
- Is the vaccine effective?
- What are the most common side effects?

FDA licenses the vaccine only if:
- It's safe and effective
- Benefits outweigh risks

Vaccines are made in batches called lots.

Manufacturers must test all lots to make sure they are safe, pure and potent. The lots can only be released once FDA reviews their safety and quality.

The FDA inspects manufacturing facilities regularly to ensure quality and safety.

FOR MORE INFORMATION, VISIT HTTPS://WWW.FDA.GOV/CBER

data & safety monitoring board (DSMB) at each phase

after licensing, vaccine is manufactured

THE PROOF of safety & efficacy is in phase 3

appropriate subjects in trials HCW, elderly, nursing home, children, essential workers, medically-at-risk

https://www.youtube.com/watch?v=Fcvgp6gNh6o and https://www.cdc.gov/vaccines/parents/infographics/journey-of-child-vaccine.html

O.W.S. $$$ for COVID Vaccine Development

data & safety monitoring board (DSMB) at each phase

Phase 2 Safety & Immunogenicity

vaccine batches concurrently made during phases 2-3 Under O.W.S

The Journey of Your Child's Vaccine

Before a new vaccine is ever given to people, extensive lab testing is done that can take several years. Once testing in people begins, it can take several more years before clinical studies are complete and the vaccine is licensed.

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government has removed the financial risks from phases 2, 3 & manufacturing

Advisory Committee on Immunization Practices

15 voting members

8 ex-officio members

30 non-voting members from various organizations

meetings open to public

If the FDA licenses a vaccine, experts may consider adding it to the recommended immunization schedule.

How a vaccine is added to the U.S. Recommended Immunization Schedule

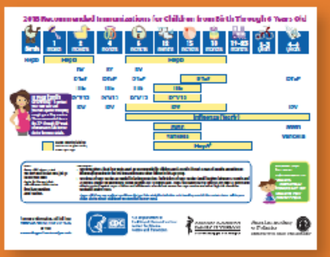
The Advisory Committee on Immunization Practices (ACIP) is a group of medical and public health experts. Members of the American Academy of Pediatrics (AAP) and American Academy of Family Physicians (AAFP) are among some of the groups that also bring related immunization expertise to the committee. This group carefully reviews all available data about the vaccine from clinical trials and other studies to develop recommendations for vaccine use. The ACIP continues to monitor vaccine safety and effectiveness data even after the vaccine's routine use and may change or update recommendations based on that data.

When making recommendations, ACIP considers:

- How safe is the vaccine when given at specific ages?
- How well does the vaccine work at specific ages?
- How serious is the disease this vaccine prevents?
- How many children would get the disease the vaccine prevents if we didn't have the vaccine?

ACIP recommendations are not official until the CDC Director reviews and approves them and they are published. These recommendations then become part of the United States official childhood immunization schedule.

New vaccine to protect your child against a disease is added to the schedule.



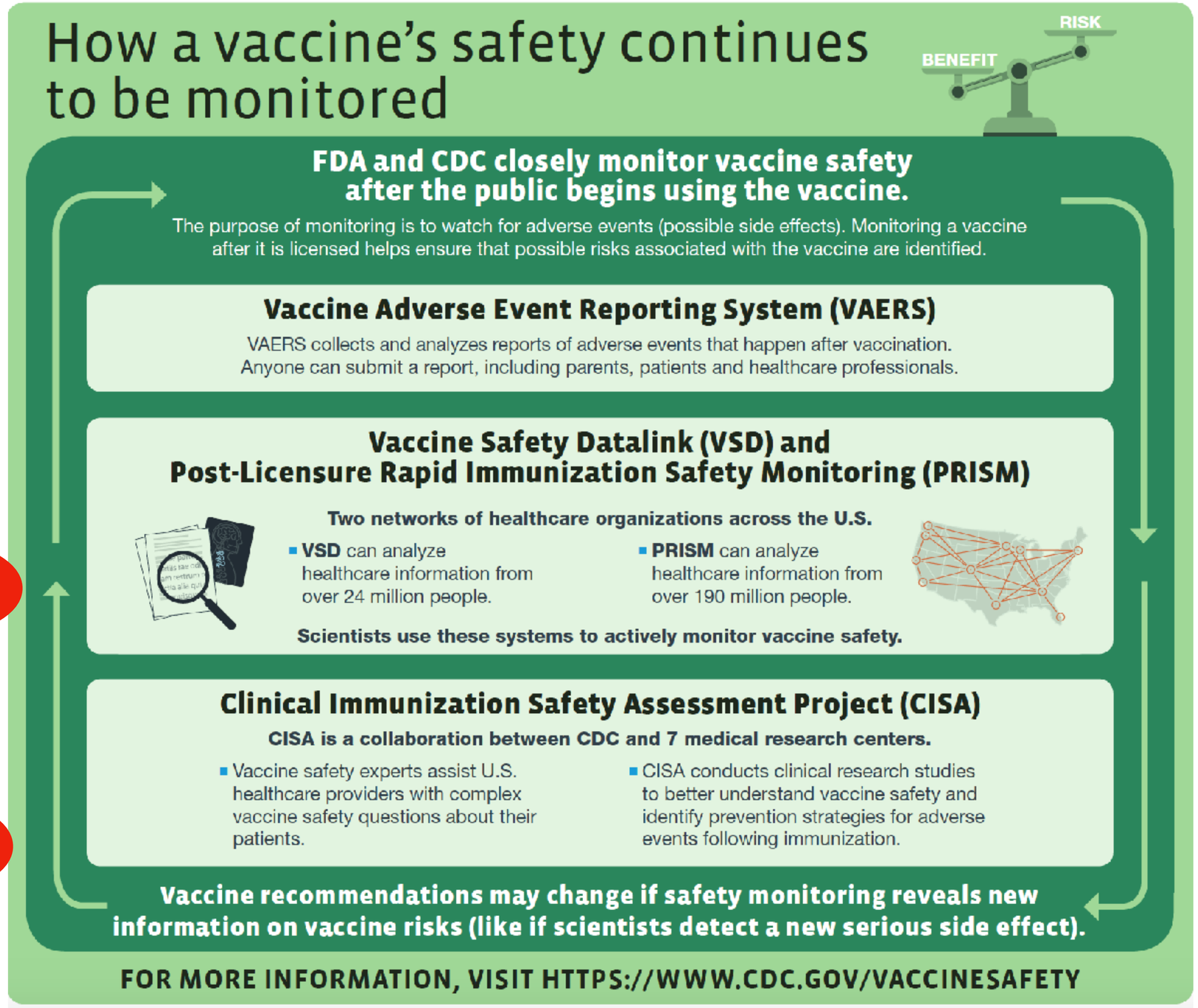
FOR MORE INFORMATION, VISIT HTTPS://WWW.CDC.GOV/VACCINES

Vaccine Adverse Events Reporting System is a sentinel system and does not prove cause and effect

Harvard Pilgrim Health Plan

Boston Medical Ceneter

After being added to the U.S. Recommended Immunization Schedule, health experts continue to monitor the vaccine's safety and effectiveness.



Additional Monitoring System for COVID-19 Vaccines

V-safe is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after you receive a COVID-19 vaccination. Through **v-safe**, you can quickly tell CDC if you have any side effects after getting the COVID-19 vaccine. Depending on your answers, someone from CDC may call to check on you and get more information. And **v-safe** will remind you to get your second COVID-19 vaccine dose if you need one

Aim your smartphone's camera at this code

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

How Is The Vaccine Schedule Developed?

- Vaccines are developed to prevent illnesses
- Vaccines should be given **before** diseases are likely to happen or before the diseases are known to cause problems
- The vaccines should be safe and cost-effective
- Pertussis: severe problem for children less than 6-12 months of age
- Pneumonia, HIB, rotavirus affect children before age 2
- Measles, chickenpox not a problem until after age 1 year
- Hepatitis B for neonates 90% chance of long term liver disease

How Are Vaccine Studies Set Up?

- Each added vaccine is tested in conjunction with the current schedule
  - no interference with development of immunity
  - no increased risk of side effects
- Placebo-controlled studies in children
  - Polio vaccine
  - Danish study MMR & autism

Polio Vaccine trial 1954
440,000 received vaccine
220,000 received placebo
1.2 million "observed controls

https://www.historyofvaccines.org/content/blog/vaccine-randomized-clinical-trials

Why Are Some Vaccines Required for School?

- DTaP: diphtheria, tetanus, pertussis
- HIB: *Haemophilus influenzae*
- MMR: measles, mumps, rubella
- Varicella: chickenpox
- Influenza
- Men ACWY: meningitis
- Polio
- Hepatitis B

spread by respiratory droplets

spread by contact

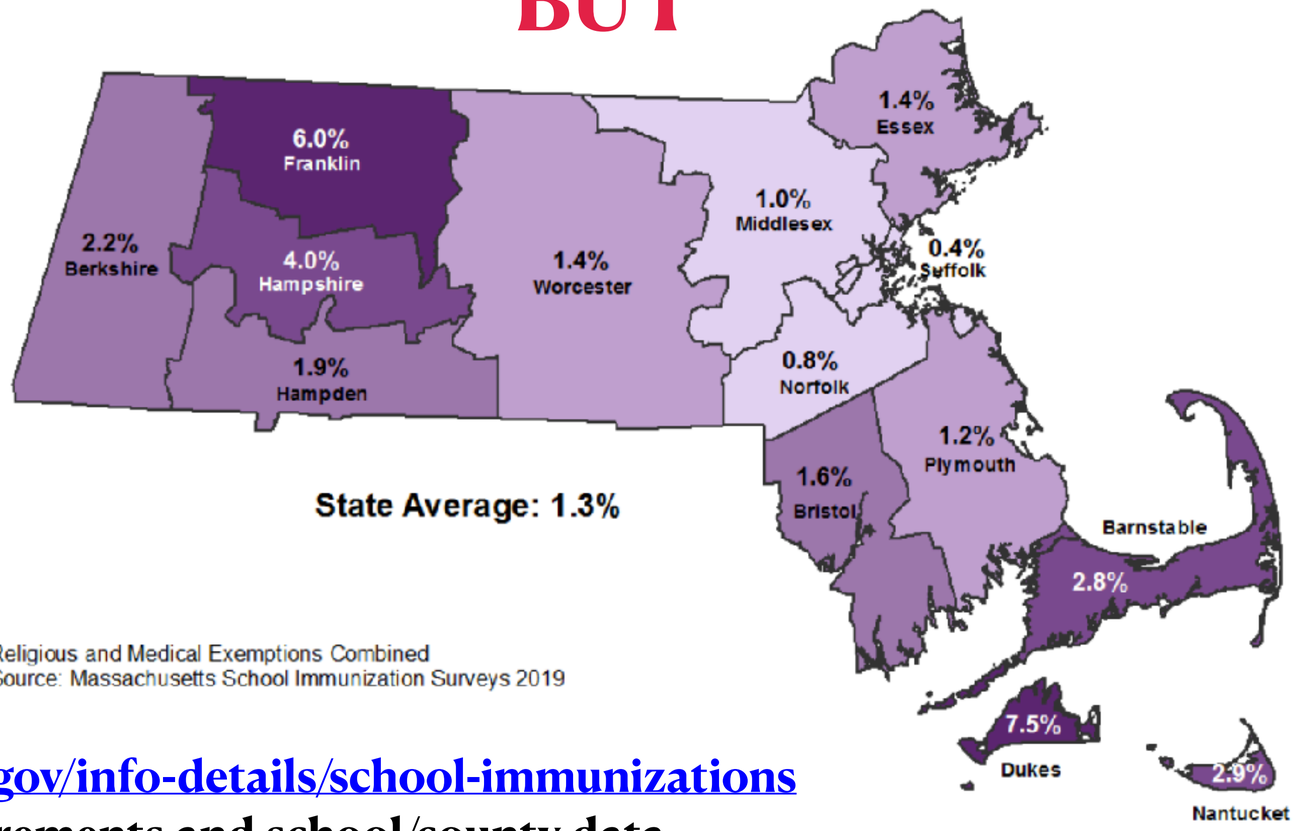
https://www.mass.gov/info-details/school-immunizations

school requirements and school/county data

How Are School Immunization Rates in MA?

- Based on 2019-2020 kindergarten immunization data reported to DPH for the 2019-2020 school year
- DTaP: 97%
- Polio: 97%
- MMR: 97%
- Hep B: 98%
- Varicella: 98%
- Average exemptions: 1.3%

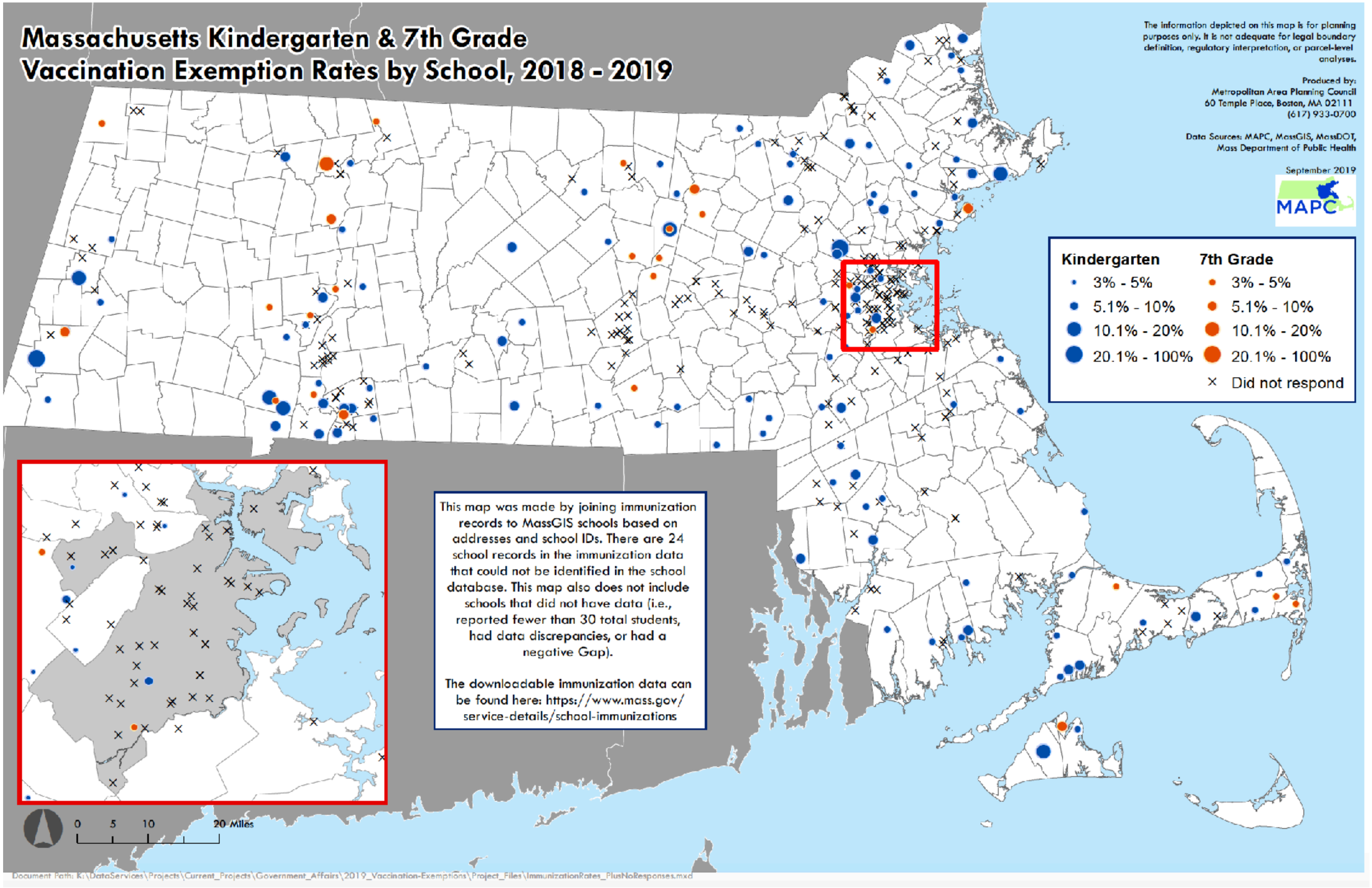
BUT



Religious and Medical Exemptions Combined
Source: Massachusetts School Immunization Surveys 2019

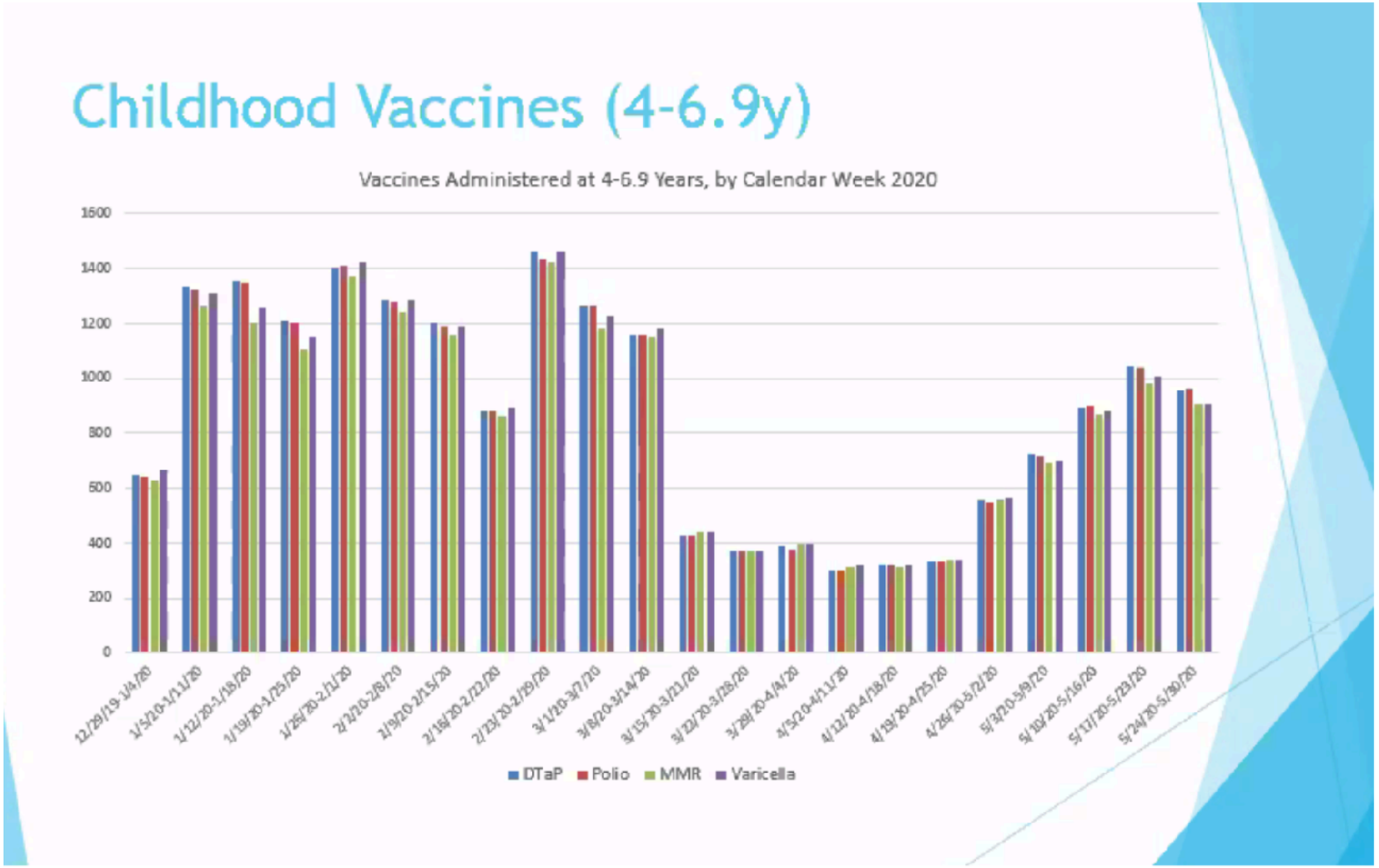
https://www.mass.gov/info-details/school-immunizations
school requirements and school/county data

Massachusetts Kindergarten & 7th Grade Vaccination Exemption Rates by School, 2018 - 2019



Immunization Rates Have Fallen Significantly

Both in MA and around the US Due to COVID-19 Pandemic



Underimmunized Communities = Potential Outbreaks

Measles is the Prime Example

- 2016 OH Amish community; 383 cases; 90% unvaccinated
- 2017 MN Somali community; 79 cases; 91 % unimmunized; $2 million
- 2019 NY religious community; 649 cases; 85% unimmunized; $8.4 million
- 2019: WA; Ukrainian/Russian Orthodox; 2 outbreaks; 87 cases; 81% 0 or 1 dose
- 2019: Samoa; vaccination rate 31%; 5700 cases, 83 deaths

- Common factors: undervaccination, community, religious/personal exemptions

Vaccine Hesitancy: Top 10 Threat

January 2019

50% of Americans would refuse COVID-19 Vaccine

September 2020 Pew Research Poll

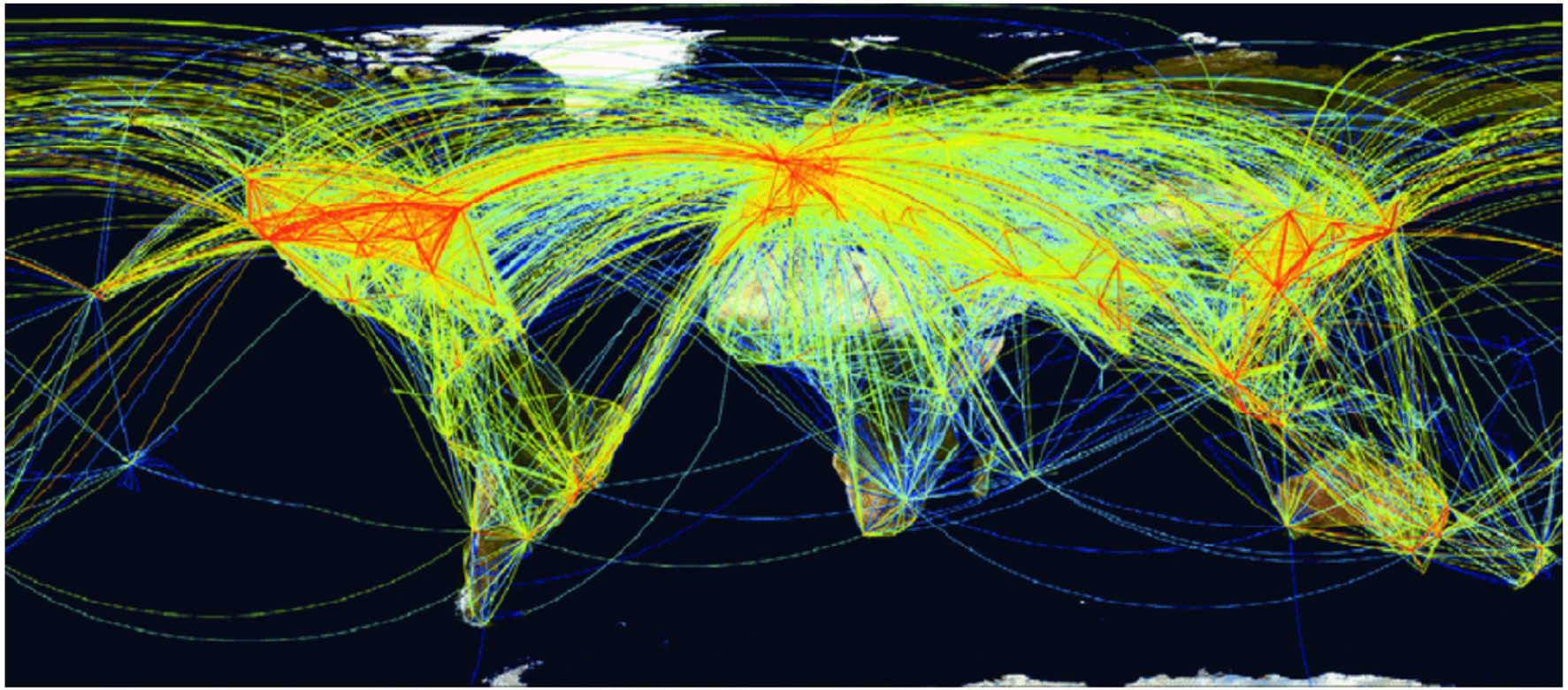
https://www.who.int/news-room/spotlight/ten-threats-to-global-health-in-2019

Pandemics + Vaccine Hesitancy + Vaccination Delays = Longer Pandemics + Other Diseases

- Mumps, pertussis, rotavirus, hepatitis A and B, pneumococcus, chickenpox, influenza, meningitis are circulating at low levels NOW
- Will they become more common in US?
- Measles and rubella are common in developing countries
  - Nigeria, India, Pakistan, Brazil, Phillippines, Israel
  - >3400 measles cases in Central and South America in 2020

At Some Point, the Pandemic Will End

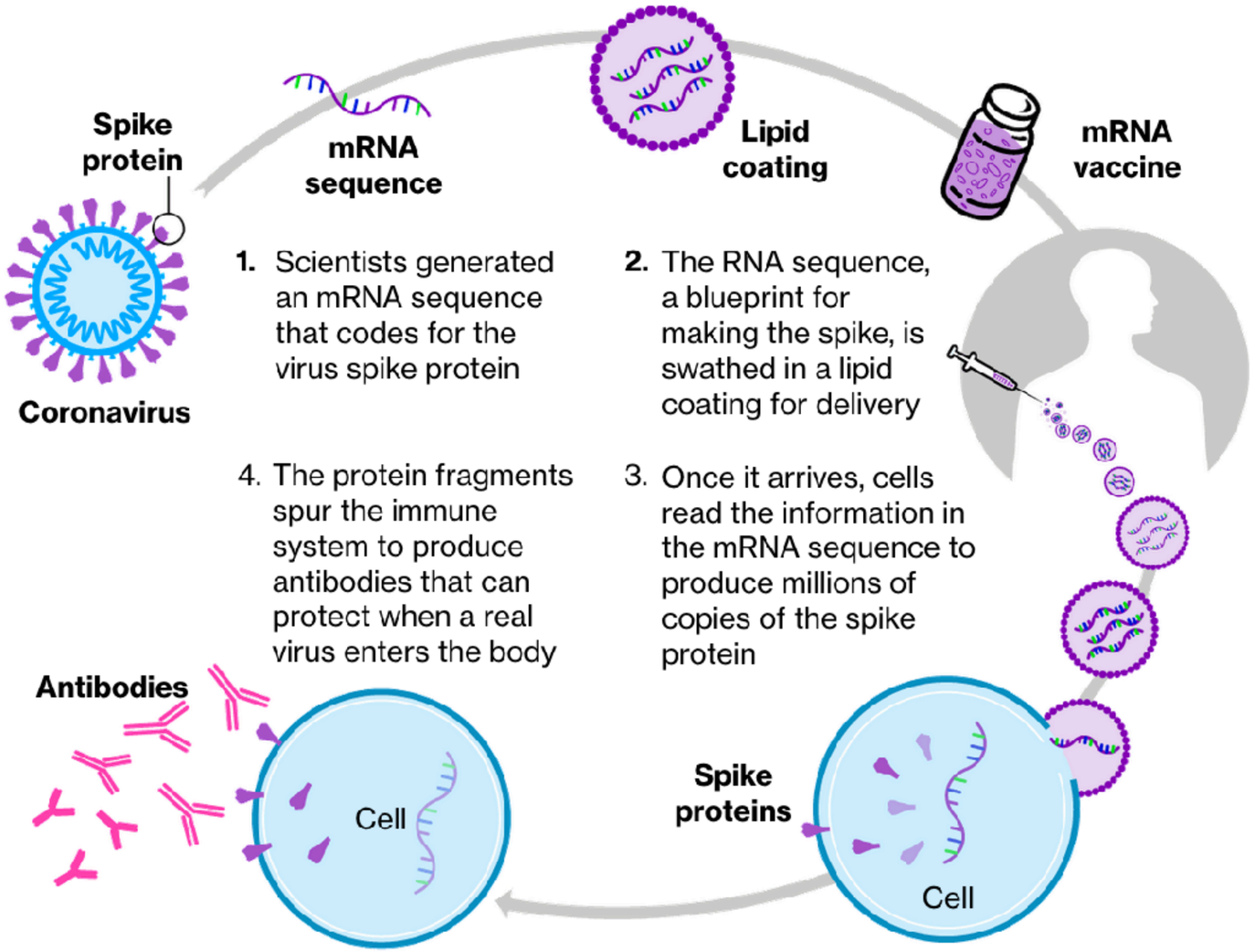
and people will travel again - YAY!



and we will be a plane ride away from outbreaks anywhere in the world.

We must keep our immunization coverage up to date!

How Does mRNA Vaccine Work?



https://www.bloomberg.com/news/articles/2020-11-16/moderna-pfizer-vaccines-look-strong-here-s-how-they-stack-up

COVID-19 Disease in Children

- Children can get COVID-19; they can spread it
- Children can be symptomatic or asymptomatic
- Children can get sick from COVID-19
- Children can develop severe COVID-19 disease
- Underlying respiratory, cardiac, oncologic diseases, obesity are risk factors
- MIS-C multi-system inflammatory syndrome in children
- Deaths reported

Pediatric COVID-19 Deaths
as of 1/2/2021

0-4y	55
5-14y	55
15-24y	510

What About COVID-19 Vaccine for Children?

- Vaccine has not been tested in children
- Pfizer vaccine approved for ≥16y; Moderna vaccine approved for ≥18y
- Both companies are starting trials for younger children
- Will side effects be the same in children?
- Will children need more than 2 doses?
- Might different COVID-19 vaccine work better for children?
- Several different types of COVID-19 vaccine are being tested now

Important Points to Know About the Vaccines

- Reactions to vaccines are normal: soreness, fatigue, malaise, fever, headache
- Reactions are a good indication that your immune system is working
- COVID—19 vaccines approved to date are NOT live COVID-19 viruses
- COVID-19 vaccines DO NOT change your DNA
- NO evidence that COVID-19 vaccines affect fertility
- NO evidence that COVID-19 vaccine causes long term effects on health
- You CAN'T get COVID-19 or "the flu" from the vaccine
- COVID-19 vaccines DO NOT contain microchips or tracking devices
- Countermeasures Injury Compensation Program*
- NO preservatives, NO adjuvants, NO fetal cells, NO eggs

* https://www.hrsa.gov/cicp/about

Vaccine Development Timeline

Typical

Pre-clinical Proof of Concept (POC)

EXPLORATORY

? years

PRE-CLINICAL

2-4 years

CLINICAL DEVELOPMENT
Phase 1, 2, 3

6-8 years

File
REGISTRATION

1 -2 years

Launch

2 - 6 months

10-15 years

Accelerated

EXPLORATORY/PRE-CLINICAL

3-6 months

CLINICAL DEVELOPMENT
Phase 1, 2, 3

0.5 – 1.5 yrs

REGISTRATION

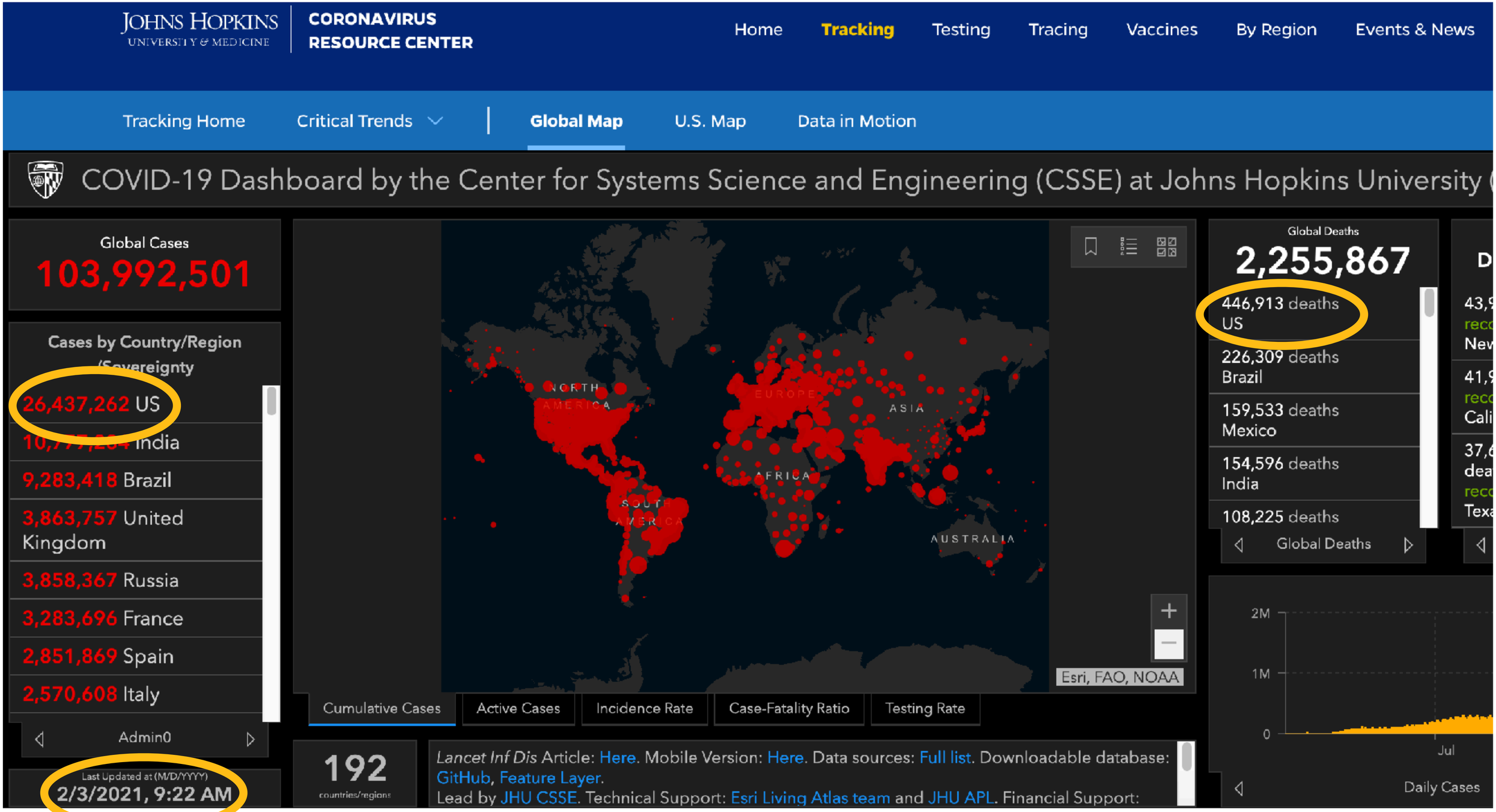
2-4 months

Launch

2 - 6 months

Phases done simultaneously rather than sequentially

1-2 years



https://coronavirus.jhu.edu/map.html

Many Superb Resources are Available for Providers, Patients, and Parents About Vaccines

- https://immunize.org/
- https://www.voicesforvaccines.org/
- https://www.cdc.gov/vaccines/
- https://www.chop.edu/centers-programs/vaccine-education-center
- https://www.vaccinateyourfamily.org/
- youtube: how mRNA vaccines work

COVID-19 Vaccines and Pregnancy

- COVID-19 causes more severe disease in pregnant women
- No fetal anomalies have been found in babies whose mothers had COVID-19 during pregnancy
- Historically vaccines have not caused problems that the disease doesn't cause
- No indication that these COVID-19 vaccines will cause harm to a pregnant woman
- Who is in your bubble?
- Discuss vaccine with your doctor - American College of Obstetrics & Gynecology
- https://www.acog.org/advocacy/advocacy-and-covid-19/covid-19-vaccines-and-pregnancy

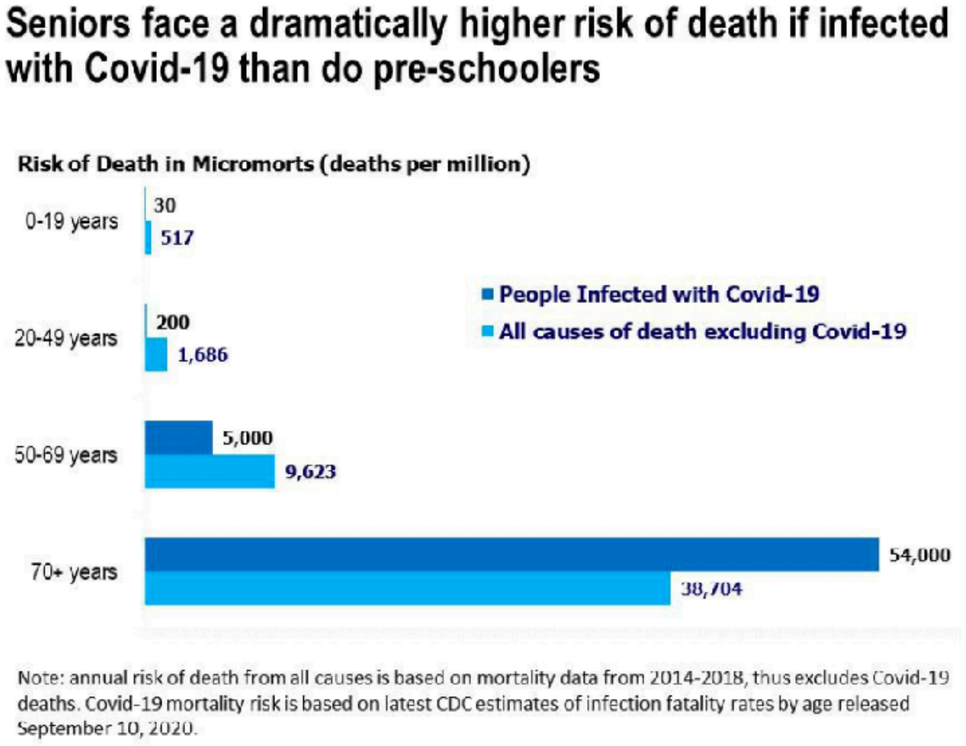
Moderna & Pfizer Vaccines Can’t Change Your DNA

- mRNA goes into the cell but can’t get into the nucleus because it lacks a nuclear access signal
- even if it could get into the nucleus, it lacks the enzyme to make itself into DNA that needs an enzyme called reverse transcriptase
- even if it could turn itself into DNA, it would need an enzyme to integrate itself into the host’s DNA; that requires an enzyme called integrate

- this mRNA does just one thing: it teaches a cell how to make the spike protein

Anaphylaxis & COVID-19 Vaccines

- Pfizer vaccine: 11.1/million doses
- Moderna vaccine: 2.5/million doses
- No anaphylaxis deaths reported as of 1/10/21
- Chance of being hit by lightning: 1/500,000
- Chances of Dying from COVID-19
  0-19 years old: 30/million
  20-49 year old: 200-/million
  years old: 5000/million
  old: 54,000/million



“Long COVID”

- Severe headaches, fatigue, “brain fog” (mild cognitive impairment) >4 weeks after acute illness
- Persistent symptoms common in up to 87% of people who have had COVID infection.
- 75% of those hospitalized had at least 1 ongoing symptom 6 months after acute illness.
- 20% of patients who **didn’t** require oxygen during their acute COVID had decreased lung function 6 months later.
- Up to 54% of people who had mild COVID symptoms and **didn’t require hospitalization** had persistent symptoms after 2-4 months.
- 25% of patients developed NEW neurologic symptoms after their acute illness was over (cognitive or sensory problems, headaches, problems with taste or smell).
- Children with long COVID symptoms have been reported

https://emergency.cdc.gov/coca/calls/2021/callinfo_012821.asp

News Items

- People who have had COVID-19 disease may have a more vigorous reaction to the first dose of vaccine; perhaps they will need only one dose of vaccine https://www.medrxiv.org/content/10.1101/2021.01.29.21250653v1

- 15% of people with people hospitalized with severe COVID-19 disease are developing diabetes https://doi.org/10.1111/dom.14269