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

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Professor of Clinical Pediatrics, UMass Medical School
MA Chapter American Academy of Pediatrics Immunization Initiative
# Life Before Vaccines

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## Diphtheria

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## Tuberculin

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## Whooping Cough

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## Typhoid

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## Tetanus

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## Smallpox

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## Other Immunizations

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<tr>
<th>DESCRIPTION</th>
<th>DATE</th>
<th>PHYSICIAN</th>
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<tbody>
<tr>
<td>Booster</td>
<td>May 1947</td>
<td>? Boozer</td>
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<tr>
<td></td>
<td>Nov 1956</td>
<td>? Boozer</td>
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## Contagious Diseases Contracted

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<tr>
<th>DISEASE</th>
<th>DATE</th>
<th>DISEASE</th>
<th>DATE</th>
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<tbody>
<tr>
<td>Measles</td>
<td>Jan 1952</td>
<td>Mumps</td>
<td>Dec 1960</td>
</tr>
<tr>
<td>German Measles</td>
<td>Apr 1957</td>
<td>Scarlet Fever</td>
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## Smallpox

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## Schick Test

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**Image:** A black and white photograph of a young boy and girl. The boy is wearing a hat and the girl is wearing a hat and a scarf. They are both smiling. The background appears to be a rural setting with a house and a fence.
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
Today Children are Safer and Healthier

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

Combination vaccines minimize the number of injections

Vaccines Today Work Better Than Ever

1980
Protection from 7 diseases with 15,096 antigens
by the age of 4

2017
Protection from 16 diseases with only 173 antigens
by the age of 18

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

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

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.

How a new vaccine is developed, approved and manufactured

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- 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

THE PROOF of safety & efficacy is in phase 3

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

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

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?

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.

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Harvard Pilgrim Health Plan

Boston Medical Center
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.

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

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

This map was made by joining immunization records to MassGIS schools based on addresses and school IDs. There are 24 school records in the immunization data that could not be identified in the school database. This map also does not include schools that did not have data (i.e., reported fewer than 30 total students, had data discrepancies, or had a negative Crisp).

The downloadable immunization data can be found here: https://www.mass.gov/service-details/school-immunizations
Immunization Rates Have Fallen Significantly
Both in MA and around the US Due to COVID-19 Pandemic

Childhood Vaccines (4-6.9y)

Vaccines Administered at 4-6.9 Years, by Calendar Week 2020
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

50% of Americans would refuse COVID-19 Vaccine
September 2020 Pew Research Poll

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, Philippines, 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?

1. Scientists generated an mRNA sequence that codes for the virus spike protein.

2. The RNA sequence, a blueprint for making the spike, is swathed in a lipid coating for delivery.

3. Once it arrives, cells read the information in the mRNA sequence to produce millions of copies of the spike protein.

4. The protein fragments spur the immune system to produce antibodies that can protect when a real virus enters the body.
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 \( \geq 16 \)y; Moderna vaccine approved for \( \geq 18 \)y
- 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](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
- Total: 10-15 years

**Accelerated**

- Exploratory/Pre-clinical: 3-6 months
- Clinical Development: Phase 1, 2, 3 (0.5-1.5 years)
- Registration: 2-4 months
- Launch: 2-6 months
- Total: 1-2 years

Phases done simultaneously rather than sequentially
COVID-19 Dashboard by the Center for Systems Science and Engineering (CSSE) at Johns Hopkins University

Global Cases: 103,992,501

Global Deaths: 2,255,867

US: 26,437,262

Other countries: India, Brazil, United Kingdom, Russia, France, Spain, Italy, etc.

Last Updated: 2/3/2021, 9:22 AM

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
Modern & 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
  - 50-69 years old: 5000/million
  - 70+ years 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