Back to the Basics of Immunizations

Immunization Summit

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ImmunizeAR
ARKANSAS IMMUNIZATION ACTION COALITION

Objectives

By the end of this session, participants will be able to:

- Discuss the impact and importance of vaccines on public health
    - Why do we vaccinate?
- Understand basic immunology about how vaccines work
- Describe the vaccine approval and recommendations processes
    - How are vaccines studied? How are they approved? How are they recommended?
- Describe safety of vaccines and vaccine safety monitoring systems
- More confidently recommend and discuss vaccines

Why

“Back to the Basics”?

A **strong recommendation** from a healthcare provider is an important factor for a patient's decision to vaccinate.

Why do we vaccinate?

Importance of Vaccination

- **Immunization is a global health success story, saving millions of lives every year.**
  - Vaccines reduce risks of getting a disease by working with your body's natural defenses to build protection.

- **Immunization currently prevents 3.5 million to 5 million deaths every year** from diseases like diphtheria, tetanus, pertussis (whooping cough), influenza and measles.

https://www.who.int/health-topics/vaccines-and-immunization#tab=tab_1

10 Reasons to Get Vaccinated (NFID)

1. Vaccine-preventable diseases have not gone away.
2. Vaccines help keep you healthy.
3. Vaccines are as important to your overall health as diet and exercise.
4. Vaccination can mean the difference between life and death.
5. Vaccines are safe.
6. Vaccines cannot cause the diseases they are designed to prevent.
7. Young and healthy people can get very sick, too.
8. Vaccine-preventable diseases are expensive.
9. When you get sick, your children, grandchildren, and parents may also be at risk.
10. Your family and co-workers need you.

https://www.nfid.org/immunization/10-reasons-to-get-vaccinated/

Immunology Refresher

Immunity

Immunity is the ability of the human body to tolerate the presence of material indigenous to the body and to eliminate foreign substances.

This discriminatory ability to eliminate foreign substances is performed by a complex system of interacting cells called the immune system.

https://www.cdc.gov/pinkbook/hcp/table-of-contents/chapter-1-principles-of-vaccination.html

Active Immunity vs Passive Immunity

Active Immunity	Passive Immunity
• Acquired through exposure to a disease organism, triggering the immune system to produce antibodies to that disease. • Long-lasting • Takes time to develop protection <u>Two types</u> • Natural: from exposure to the actual disease • Vaccine-induced: from introduction of a killed or weakened form of the disease through vaccination	• Acquired by being given antibodies to a disease (rather than producing them through his or her own immune system) • Short-lasting (a few weeks or months) • Immediate protection <u>Examples</u> • Newborn baby receiving antibodies through the placenta. Baby is protected after birth. • Antibody-containing blood products, such as immune globulin (may be given when immediate protection from a specific disease is needed) • Monoclonal antibodies

https://www.cdc.gov/vaccines/basics/immunity-types.html

How do vaccines work?

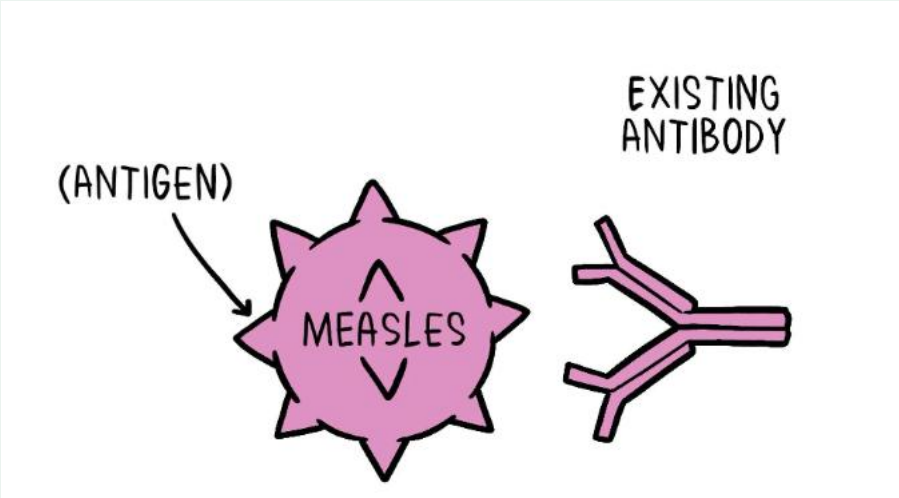
Vaccines teach your immune system to respond to a specific disease so your body can fight it off if you come into contact with it in the future.

Immunity is gained without risk of infection.

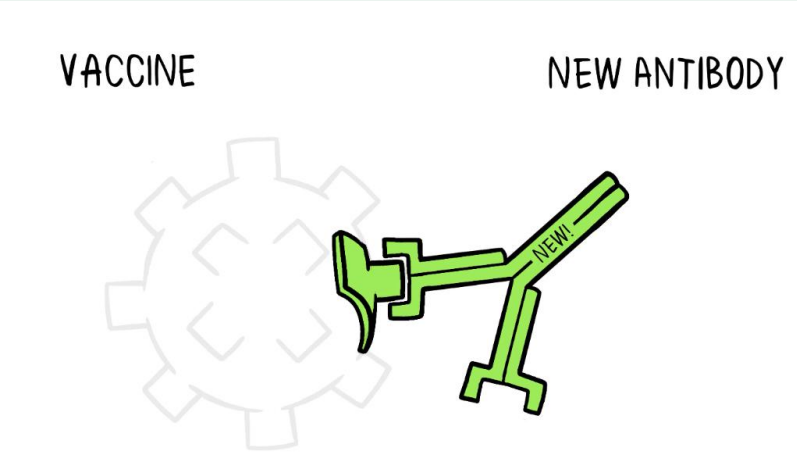
https://www.chop.edu/vaccine-education-center/science-history/vaccine-science/how-do-vaccines-work

How do vaccines work?

- The subpart of a pathogen that causes the formation of antibodies is called an antigen.
  - The antibodies produced in response to the pathogen's antigen are an important part of the immune system.
- Vaccines trigger an immune response within the body.
  - Antibodies are produced without the risk of infection.
- **Vaccines prompt the immune system to respond, much as it would have on its first reaction to the actual pathogen.**



When a new pathogen or disease enters our body, it introduces a new antigen. For every new antigen, our body needs to build a specific antibody that can grab onto the antigen and defeat the pathogen.



https://www.who.int/news-room/feature-stories/detail/how-do-vaccines-work

How do vaccines work?

- Vaccines produce an immune response without the risks of natural infection.
- The differences between a vaccine and getting the disease naturally are the dose, the known time of exposure, and the potential severity of the pathogen.
- Vaccines offer us protection with lesser quantities of virus or bacteria, the control of scheduling the exposure, and the knowledge that immunity will be gained without experiencing severe illness.

https://www.chop.edu/vaccine-education-center/science-history/vaccine-science/how-do-vaccines-work

Herd Immunity

Not everyone **can** be vaccinated.

- People with certain underlying health conditions, certain age groups, and those who have allergies to certain vaccine components may not be able to get vaccinated with some vaccines.
- These people can still be protected if they live in and amongst others who are vaccinated.

When a lot of people in a community are vaccinated, the pathogen has a hard time circulating because most of the people it encounters are immune.

- So, the more that others are vaccinated, the less likely people who are unable to be protected by vaccines are at risk of even being exposed to the harmful pathogens.

This is called herd immunity.

https://www.chop.edu/vaccine-education-center/science-history/vaccine-science/how-do-vaccines-work

Herd Immunity

This is especially important for those people who not only can’t be vaccinated but may be more susceptible to the diseases we vaccinate against.

No single vaccine provides 100% protection.

Herd immunity does not provide full protection to those who cannot safely be vaccinated. However, these people will have more substantial protection if those around them are vaccinated.

Think about…

- Babies
- Pregnant people
- Elderly people
- People with cancer
- People with diseases that suppress their immune system
- People that take medications that suppress their immune system

https://www.who.int/news-room/feature-stories/detail/how-do-vaccines-work

Vaccine Ingredients

Every vaccine ingredient serves a purpose

To provide immunity

We become immune to (or protected from) a disease when our bodies create specific antibodies to fight that disease. Vaccines contain ingredients that help your body build this immunity.

To keep the vaccine safe and long-lasting

Vaccines need to be safe and effective. Certain ingredients help keep vaccines safe from contamination and toxins. Others, like stabilizers, help vaccines stay effective for a long time.

To make the vaccine more effective

All vaccine ingredients help to make a vaccine as effective as possible, while being safe. Ingredients like aluminum salt help boost the body's response to the vaccine.

https://www.cdc.gov/vaccines/basics/index.html

Vaccine Ingredients

Antigens	Adjuvants	Stabilizers	Preservatives	Manufacturing Byproducts
• The part of the vaccine that generates an immune response	• Enhances the immune response to the vaccine • Can decrease the quantity of vaccine needed for immunity	• Protects the integrity of the vaccine • Keeps the vaccine effective after manufacturing	• Prevents bacterial or fungal contamination • Required for vaccines in multi-dose vials (some exceptions)	• Small quantities of chemicals and cell byproducts used during vaccine production may remain in final preparation
• Whole viruses or bacteria • Parts of the viruses or bacteria • Products made by the bacteria (toxins) • Nucleic acids	• Aluminum salts • Monophosphoryl lipid A • QS21 • MF59 • CpG	• Gelatin • Polysorbate 80	• Thimerosal	• Antibiotics • Egg proteins • Formaldehyde • Yeast

This table does not include every ingredient in vaccines.
This is meant to be a guide if asked about certain components of a vaccine and their purpose.

https://www.chop.edu/vaccine-education-center/vaccine-safety/vaccine-ingredients/types-of-vaccine-ingredients

Vaccine Ingredients

Helpful Resources

- https://www.chop.edu/vaccine-education-center/vaccine-safety/vaccine-ingredients
- https://vaccinateyourfamily.org/questions-about-vaccines/whats-in-a-vaccine/
- https://www.healthychildren.org/English/safety-prevention/immunizations/Pages/Vaccine-Ingredients-Frequently-Asked-Questions.aspx
- https://www.immunize.org/clinical/vaccine-confidence/topic/adjuvants/
- https://www.immunize.org/ask-experts/topic/vaccine-safety/
- https://www.cdc.gov/vaccines/basics/index.html
- https://www.vaccinesafety.edu/components-excipients/

Children's Hospital of Philadelphia® Vaccine Education Center

VACCINATE YOUR FAMILY

healthychildren.org Powered by pediatricians. Trusted by parents. from the American Academy of Pediatrics

Immunize.org

Johns Hopkins Bloomberg School of Public Health | IVS Institute for Vaccine Safety

CDC

Vaccine Approval Process

Definitions

FDA: The U.S. Food and Drug Administration

- The regulatory authority that has oversight of the safety, effectiveness, and quality of vaccines that are used in the United States.

CBER: FDA's Center for Biologics Evaluation and Research

- Ensures that FDA's rigorous scientific and regulatory process are followed by those who pursue the development of vaccines.

VRBPAC: FDA's Vaccines and Related Biological Products Advisory Committee

- Provides input on scientific data to look at safety, effectiveness, and use of the vaccine.

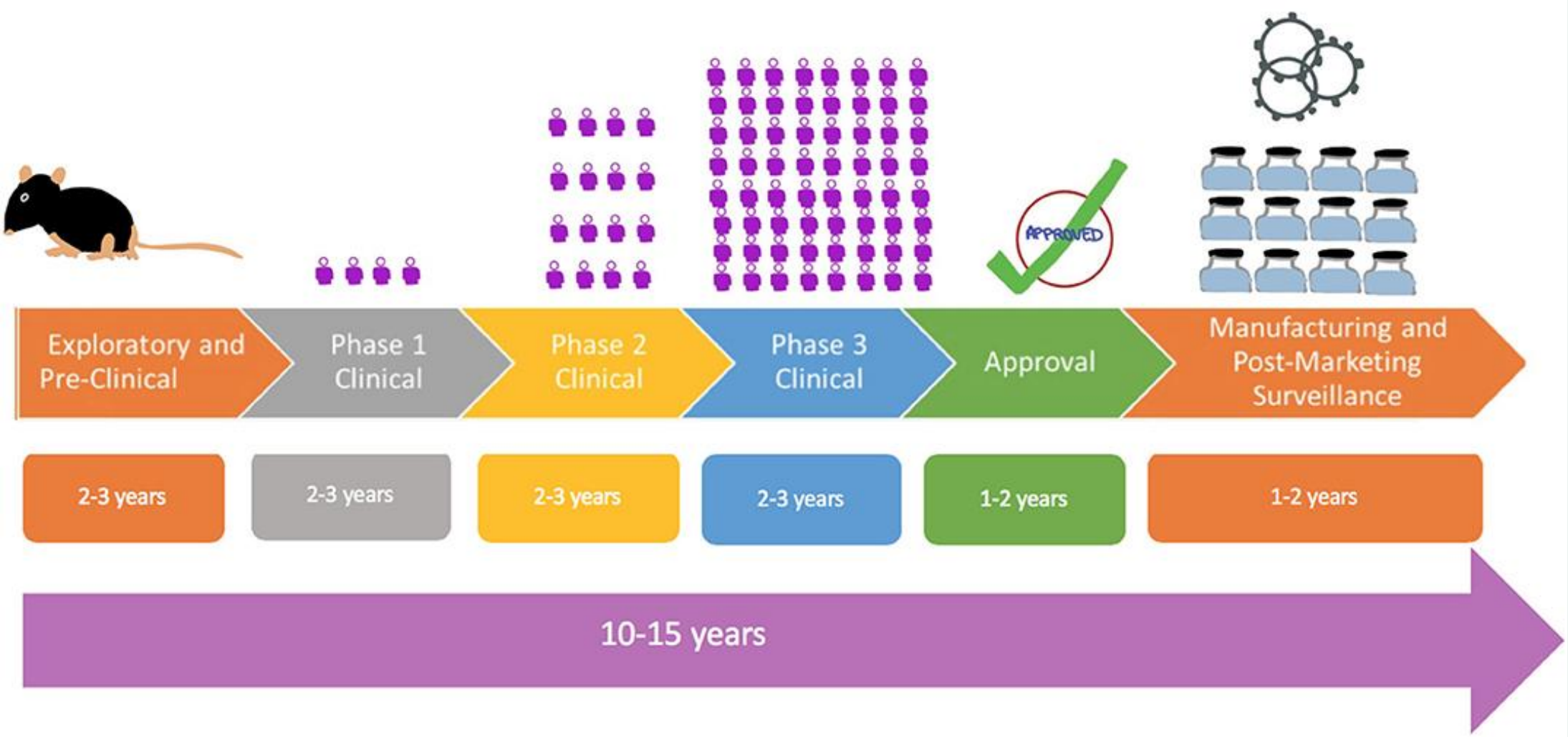
Vaccine Approval Process

General Stages of Vaccine Development

- Research and discovery
- Proof of concept
- Testing the vaccine
  - Clinical Trials (phases 1-3)
- The manufacturing process
- Approving the vaccine
- Recommending the vaccine for use
- Monitoring safety after approval

https://www.cdc.gov/vaccines/basics/test-approve.html

Vaccine Approval Process



Citation: Sharma O, Sultan AA, Ding H and Triggle CR (2020) A Review of the Progress and Challenges of Developing a Vaccine for COVID-19. *Front. Immunol.* 11:585354. doi: 10.3389/fimmu.2020.585354

Placebo Controlled Trials

In vaccine trials, appropriate placebos can include:

- Saline (a salt solution)
- Diluent or culture medium (ingredients in the vaccine without the actual components of the pathogen)
- An existing vaccine that protects against the same pathogen
- Other vaccines that would be given to the types of people in the trial

American Academy of Pediatrics

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FACT CHECKED

Fact Checked

Fact Checked: Childhood Vaccines Are Carefully Studied—Including with Placebos—to Ensure They're Safe and Effective

Evidence Snapshot

New vaccines for newly identified pathogens and diseases are tested through randomized controlled trials, comparison groups, and placebos. All existing vaccines have been through this process, as well as ongoing safety monitoring that can identify even very rare side effects. Leading medical organizations including the World Health Organization (WHO) and the American Academy of Pediatrics (AAP) emphasize that childhood vaccines are thoroughly tested to ensure safety and effectiveness.

https://www.aap.org/en/news-room/fact-checked/fact-checked-childhood-vaccines-are-carefully-studiedincluding-with-placebosto-ensure-theyre-safe-and-effective/?srsltid=AfmBOoplrCNb0aom5hyERSO4-NOu9oX8dCUyFZXoMENe6OV9-_0uvpjD

https://www.chop.edu/vaccine-education-center/science-history/vaccine-science/process-vaccine-development

Vaccine Recommendation Process

Definitions

CDC: U.S. Centers for Disease Control and Prevention

- Sets the U.S. adult and childhood immunization schedules based on recommendations from the Advisory Committee on Immunization Practices (ACIP).
- Monitors safety data after vaccines are approved and recommended.

ACIP: CDC's Advisory Committee on Immunization Practices

- A group of medical and public health experts who develop recommendations for use of a vaccine in the United States.

Immunization Recommendations

- The ACIP makes recommendations for use of vaccines then the CDC Director must approve the recommendation.
- After the CDC Director approves the recommendation, it becomes “official”.
- Recommendations are published yearly.
  - Addendums can be made throughout the year.

IMPORTANT NOTE…

Insurance plans are **not required** to pay for vaccines if they are administered outside of the ACIP/CDC guidelines.

NOTE: FDA approval and package inserts may not be the same as ACIP/CDC guidelines.

If you prescribe and/or administer an immunization outside of ACIP/CDC guidelines…

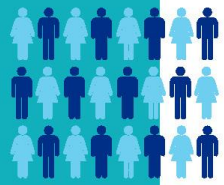
- Please document the clinical reason for prescribing outside of guidelines
- Counsel the patient on why you recommend it
- Counsel the patient that they may have to pay out of pocket

Vaccine Safety

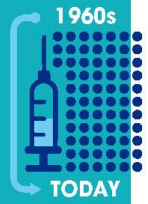
VACCINES ARE SAFE:

5 phases of research and development that can take **up to 15 years** are completed before a vaccine can be approved by the US Food & Drug Administration for public use[1]

4 separate surveillance systems are used to oversee and monitor vaccine efficacy and safety in the US[2]



3 phases of clinical trials involving THOUSANDS of volunteers are required to ensure the safety of vaccines prior to approval for public use in the US[3]



BILLIONS of vaccine doses have been safely administered in the US for more than **50** years and serious adverse events are rare[4]

Recommended childhood immunizations in the US protect against **16** dangerous vaccine-preventable diseases[5]

Sources: 1. The History of Vaccines **2.** Centers for Disease Control and Prevention **3.** US Food and Drug Administration **4.** Centers for Disease Control and Prevention **5.** American Academy of Pediatrics

National Foundation for Infectious Diseases

nfid.org/vaccine-science

#ShotOfScience

https://www.nfid.org/immunization/vaccine-science-safety/

Vaccine Safety Monitoring Systems

Vaccine Safety Monitoring Systems *After* Vaccine Approval

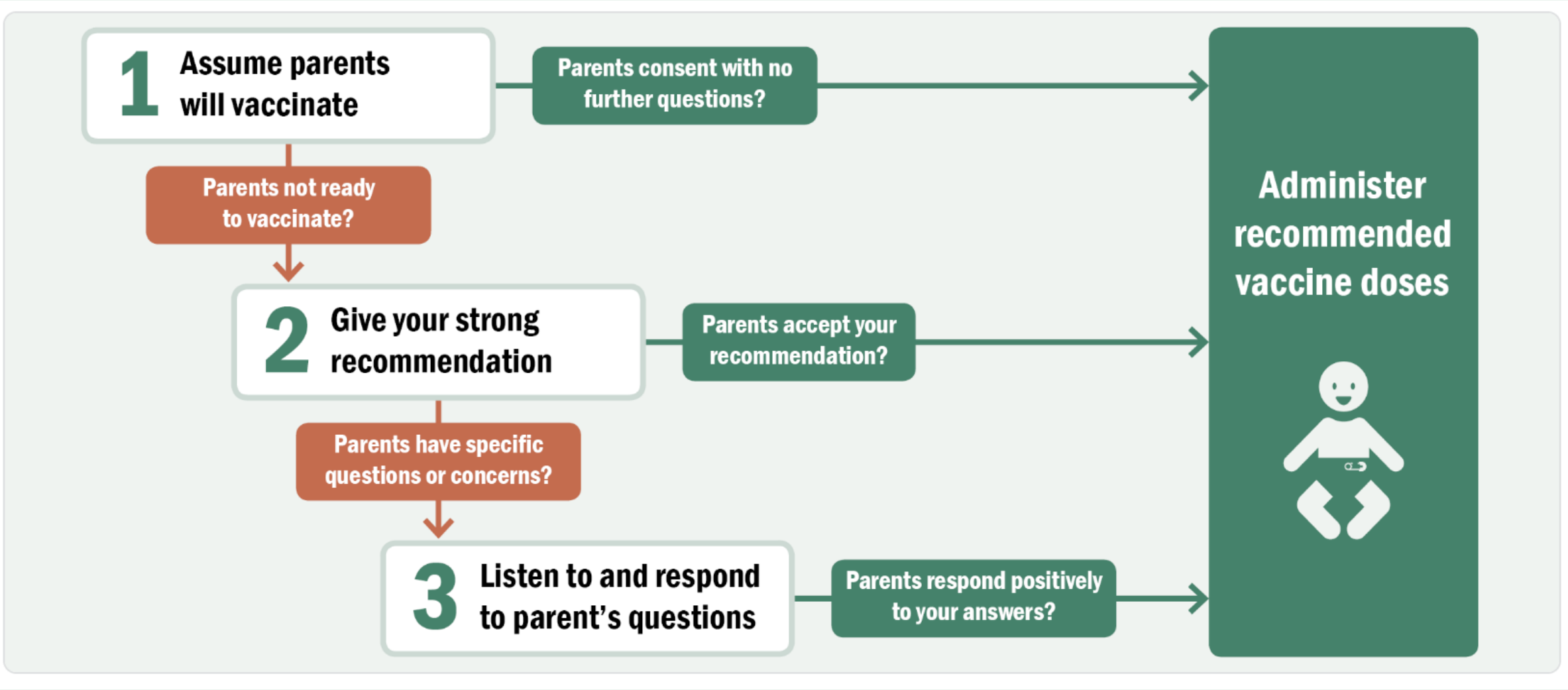
- Vaccine Adverse Event Reporting System (VAERS)
- Vaccine Safety Datalink (VSD)
- Clinical Immunization Safety Assessment (CISA)
- Biologic Effectiveness and Safety System (BEST)

Discussing Vaccines with Patients

Messaging

- **Vaccines reduce severity of disease.**
  - This does not mean you won't get the disease… but you likely won't be as sick (or die) if you get vaccinated.
- **Vaccines are worth it.**
- **You care about your patients.**
  - Your goal is to help protect your patients with the best, evidence-based practices.

Presumptive Approach



https://www.cdc.gov/vaccines-children/hcp/conversation-tips/index.html

Presumptive Approach – Step 1

Assume patients are planning to get vaccines.

Approach the conversation by stating which vaccines should be administered at that visit.

Instead of saying: “What do you think about vaccines today?”

Say: “It’s time for these shots today.”

https://www.cdc.gov/vaccines-children/hcp/conversation-tips/index.html

Presumptive Approach – Step 2

If patient or parent is not ready to vaccinate, state your **strong recommendation** for vaccination.

Share supporting reasons why you strongly recommend these vaccines.

Example:

- “I strongly recommend these vaccines today because these vaccines protect you (or your child) from serious diseases.”

https://www.cdc.gov/vaccines-children/hcp/conversation-tips/index.html

Presumptive Approach – Step 3

Encourage questions.

Listen and respond with empathy.

Example:

- “What are some questions or concerns you have? I would be glad to discuss these with you and help you feel more confident in your decision.”

https://www.cdc.gov/vaccines-children/hcp/conversation-tips/index.html

If patients have questions and you don't know the answers?

- Do NOT make up answers.
- Do NOT google in front of them.
- Offer to look up those questions and get back with them.
  - Set a timeline and method for follow-up.
- This will build trust.
  - It will not make you sound incompetent.

Example:
"That is a really great question. Honestly, I haven't had that question before and I don't know the answer to that off the top of my head. I don't want to make something up to make me sound smart, you deserve honest answers. I'd like to do some research on this and get back with you. Do you mind if I follow-up with you about this in the next day or two? I'll give you a call after I've had the opportunity to do some research."

If patients refuse to vaccinate?

Be respectful and empathetic.

Let them know you've documented the discussion and will follow-up with them at future visits.

Inform them of symptoms of illnesses of the diseases those vaccines would protect against.

Remind patients (and parents) to call ahead if they have symptoms before coming to a clinic visit or inside a pharmacy.

Do not make them feel angry or as though you don't care about them because of their decision.

https://www.cdc.gov/vaccines-children/hcp/conversation-tips/index.html

DON'T FORGET!

A strong recommendation from a healthcare provider is important!

Patients are more likely to choose to vaccinate if their healthcare providers make a **strong** recommendation for vaccination.

Credible Immunization Resources

- https://www.immunize.org/
- https://www.aap.org/en/
- https://www.chop.edu/vaccine-education-center
- https://www.nfid.org/immunization/
- https://www.immunizear.org/
- https://www.cdc.gov/vaccines/index.html
- https://www.voicesforvaccines.org/
- https://vaccinateyourfamily.org/
- https://www.vaccinesafety.edu/

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World Health Organization

voices for vaccines
credible vaccine information for families, from families

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CDC

Thank you!

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