Objectives

- Explain Adverse Events Following Immunizations (AEFIs)
- Understand true contraindications/precautions to vaccination
- Learn about select vaccine- and population-specific safety guidelines
- Learn about national vaccine safety regulations
- Recognize the multiple available resources to help with decision-making around vaccination
Patient & Parent Concerns
Health Concerns

- Pain of injection
- Side effects (prior history vs anecdotes)
- Currently healthy and do not want to develop new disease
- Introducing too many and/or toxic substances into body → “overwhelming the immune system”
- “Unnatural” method of developing immunity
Societal Concerns

Losing personal liberties
- e.g. parental authority over child’s healthcare decisions

Financial motives of providers and manufacturers

Conspiracy theories
- e.g. vaccine preservatives, inadequate research, experimenting on the public
US Vaccination Schedule
United States Vaccination Schedule

**Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger, United States, 2020**

### Table

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**Recommended Immunizations for Children from Birth Through 6 Years Old**

- Birth: HepB, DTaP (Hib), PCV13
- 1 month: HepB, RV, IPV
- 2 months: DTaP (Hib), PCV13
- 4 months: HepB, RV, PCV13
- 6 months: DTaP (Hib), IPV, PCV13
- 12 months: IPV, PCV13
- 24 months: IPV
- 3, 4 years: IPV
- 6 years: IPV

**Influenza (Flu) and MMR**

- Flu: Yearly
- MMR: 1st dose at 12-15 months, 2nd dose at 4-6 years

**Varicella**

- Varicella: 2 doses at 12-15 months and 4-6 years

**Hepatitis A**

- Hepatitis A: 2 doses at 12-15 months and 4-6 years

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**Provider Version**

- https://www.cdc.gov/vaccines/schedules/hcp/child-adolescent.html

**Parent-Friendly Version**

- https://www.cdc.gov/vaccines/schedules/easy-to-read/child-easyread.html
Advisory Committee on Immunization Practices (ACIP)

- US Vaccine schedule set by CDC’s ACIP recommendations
  - 15 voting members from research and medical specialties
  - 8 members representing national agencies involved in immunization policy
  - 30 liaison organizations with immunization expertise
- Meets together three times per year and in smaller working groups year-round

https://www.cdc.gov/vaccines/acip/about.html
How are vaccines chosen for the schedule?

- Latest research is reviewed year-round by working groups.
- Research on specific vaccines includes:
  - Safety, immunogenicity, effectiveness of a vaccine at a given age.
  - Severity of disease being prevented.
  - Number of children affected if no vaccine exists.

The Advisory Committee on Immunization Practices (ACIP): Questions and Answers.
How is the timing of vaccines determined?

- Research on timing of administration primarily focuses on **morbidity and mortality at different ages**
  - ACIP studies the ages at which disease rates peak
  - Balances risks of disease exposure to vaccine safety and effectiveness
- Goal is to vaccinate as early and safely as is beneficial

The Advisory Committee on Immunization Practices (ACIP): Questions and Answers
Is it safe to give so many vaccines at once?!

- YES.
- Giving multiple vaccines at a single visit
  - Improves coverage rates and individual protection
  - More convenient/cost-effective for patient
  - Does not change safety or efficacy of vaccines

CDC Pinkbook p. 27
Exceptions to multi-vaccine administration

- In general, any vaccine can be co-administered with any other vaccine except...

- **AVOID** co-administering the following:
  - PCV-13 and Menactra
    - Especially in asplenic patients
  - Combo MMRV vaccine (age <4 y or first dose)
    - Ok to give MMR and VZV at the same time but separately

http://www.immunize.org/askexperts/experts_meningococcal_acwy.asp
CDC Pinkbook p. 12
Adverse Events
Adverse Events Following Immunization (AEFI)

- What is an AEFI?
  - “An untoward effect caused by a vaccine that is extraneous to the vaccine’s primary purpose of producing immunity”
  - aka Side Effect

- Three primary types
  - Localized
  - Systemic
  - Allergic

CDC Pinkbook p. 15
Localized Reactions

- Most common type (up to 80% of vaccine doses)
- Examples: pain, swelling, redness at injection site, etc
- Occurs within hours of vaccine administration
- Usually mild, self-limited
- Rarely more severe—Arthus reaction

CDC Pinkbook pp. 15-16
Systemic Reactions

- Generalized, relatively mild symptoms
- Examples: fever, myalgias, headache, etc
- Non-specific symptoms; not always related to vaccine itself
- Somewhat more common with live-vaccines
  - Virus needs to replicate
- Occurs days to weeks after vaccination

CDC Pinkbook p. 16
Allergic Reactions

- Rare, require medical attention
- Occur within minutes to hours of receiving vaccine
- Examples: diffuse urticaria, wheezing, anaphylaxis, etc
- Reaction may be to any vaccine component: antigen, preservative, cell culture medium, etc
- Risk can be reduced with pre-vaccine screening

CDC Pinkbook pp. 16-18
AEFI and Causality

- AEFI can fit into multiple other categories besides extent of effects
  - Severity, frequency, disease, age
  - Vaccine-induced, programmatic, idiosyncratic, coincidental
- Difficult to assess causality
  - More likely if: occurs on repeat administration, observed in prior studies, timing plausible, * biologically plausible
  - *Note: timing does NOT necessarily indicate causality

CDC Pinkbook pp. 49-50
The Provider’s Responsibility

- Product Management (storage, handling, administration)
- Patient Care
  - Screening for precautions and contraindications
  - Timing and spacing of vaccines
  - Managing AEFI
  - Reporting AEFI to Vaccine Adverse Events Reporting System
  - Communicating risks/benefits to patients

CDC Pinkbook p. 55
National Vaccine Safety Regulations
Vaccine Safety & Monitoring

- **National Childhood Vaccine Injury Act (NCVIA) (1986)**
  - Spurred by increase in lawsuits against manufacturers
  - Mandated providers, manufacturers to report adverse events after vaccination

- **Vaccine Adverse Event Reporting System (VAERS) (1990)**
  - Administered by the CDC and FDA
  - May be confirmed adverse reactions or coincidental events
  - Receives 30,000 reports/year (41% providers, 29% manufacturers, 14% patients/parents)
Vaccine Adverse Effects Monitoring System

- VAERS is able to detect
  - New or rare adverse events
  - Increase in rates of AEFIs
  - Patient risk factors for AEFIs
- Further studies needed to clarify adverse event signals
- Not all reported adverse events are causal effects

CDC Pinkbook pp. 52
Vaccine Adverse Effects Monitoring System

- Providers are required to report some adverse events following specific vaccinations to VAERS
- Encouraged to report any clinically significant event after vaccination if unsure about causality
- Manufacturers required to submit any adverse effects of which they become aware

CDC Pinkbook pp. 52
Vaccine Information Statements

- Vaccine information statements (VIS) must be given to patients prior to vaccination
- Mandated by National Childhood Vaccine Injury Act
- Available from CDC website, multiple languages
- Can use as a starting point in addressing patient concerns or screening for contraindications

CDC Pinkbook pp. 59
Table of mandated reportable events available online

| Measles, mumps and rubella in any combination; MMR, MR, M, MMRV, R | A. Anaphylaxis or anaphylactic shock (7 days)  
B. Encephalopathy or encephalitis (15 days)  
C. Any acute complications or sequelae (including death) of above events (Interval - not applicable)  
D. Events described in manufacturer’s package insert as contraindications to additional doses of vaccine (Interval - see package insert) |
|-----------------|--------------------------------------------------------------------------------------------------|
| Rubella in any combination; MMR, MMRV, MR, R | A. Chronic arthritis (42 days)  
B. Any acute complications or sequelae (including death) of above event (interval - not applicable)  
C. Events described in manufacturer’s package insert as contraindications to additional doses of vaccine (interval - see package insert) |
| Measles in any combination; MMR, MMRV, MR, M | A. Thrombocytopenic purpura (7-30 days)  
B. Vaccine-strain measles viral infection in an immunodeficient recipient (6 months)  
C. Any acute complications or sequelae (including death) of above events (interval - not applicable)  
D. Events described in manufacturer’s package insert as contraindications to additional doses of vaccine (interval - see package insert) |

https://vaers.hhs.gov/resources/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf
More Vaccine Safety & Monitoring

- Vaccine Safety Datalink (VSD) (1990)
  - Partnership between CDC and large health plans to monitor rare and serious adverse events
  - Allows rapid cycle analysis of events in close to real time

- Vaccine Injury Compensation Program (VICP) (1986)
  - “No fault” program
  - Covers routine childhood vaccines (adults can file claims too)
  - Uses vaccine injury table

CDC Pinkbook p. 53
CDC Pinkbook pp. 54-55
CISA Program

- Clinical Immunization Safety Assessment Program (CISA)
  - CDC-supported program focusing on vaccine safety at individual patient level
  - Works on strategies to detect and prevent adverse events especially in special populations
- Provides free consult service to providers
  - Phone: 1-800-CDC-INFO
  - Email: CISAeval@cdc.gov
Contraindications and Precautions
When NOT to Vaccinate

- **Contraindication**
  - A condition that increases the risk of a patient developing a serious AEFI
  - Do not administer the vaccine

- **Precaution**
  - A condition that might increase the risk or severity of an AEFI or compromise vaccine’s effectiveness
  - Avoid administering unless benefits >> risks

CDC Pinkbook p. 57
Screening for Contraindications/Precautions

- May be temporary or permanent
  - Temporary: Moderate-severe illness, pregnant, etc
  - Permanent: Prior history of anaphylaxis after receiving vaccine, Guillain-Barre, etc

- Screening is important tool in reducing risk of AEFI
  - Immunization Action Coalition has standardized screening forms for children and adults

CDC Pinkbook p. 30
General Contraindications

- All vaccines
  - Allergy to vaccine component
  - Encephalopathy
- Live-attenuated vaccines (MMR, VZV, LAIV, typhoid)
  - Pregnancy
  - Immunosuppression

CDC Pinkbook p. 17
General Precautions

- All vaccines
  - Moderate to severe illness
  - Acutely febrile
- Live-attenuated vaccines (MMR, VZV, LAIV, typhoid)
  - Recently received blood products (MMR, VZV)
Specific Contraindications

- Rotavirus
  - SCID, Intussusception
- Tdap
  - Encephalopathy within 7 days without other clear cause
- HPV
  - Pregnancy
- Live vaccines
  - Immunosuppression, pregnancy

CDC Pinkbook pp. 17
Specific Precautions

- Guillain-Barré Syndrome
  - Tetanus, influenza

- DTaP
  - Inconsolable crying, seizure, limp/pale episode, high fevers within 48 h of administration without other known cause

CDC Pinkbook pp. 28-29
NOT a Contraindication to Vaccination

- Mild illness
- Mild self-limited localized reaction to previous dose
- Living with immunocompromised or pregnant person
- Potential exposure to infectious disease
- Current antibiotic use
- Breastfeeding
- Premature birth

CDC Pinkbook p. 24
Special Considerations
Timing/Spacing Between Doses

- Vaccines can be given up to **4 days before** minimum interval to be counted as valid per ACIP recommendations.
  - Rules may vary by organization.

- Interval between doses
  - Typically about 4 weeks
  - Increasing interval does not reduce effectiveness
  - Decreasing interval may interfere with antibody response to previous dose.

Source: CDC Pink book, pp. 9-14
Egg Allergy

- General rule: If patient can eat eggs and egg-containing products without difficulty, they can get egg-prepared vaccines (flu, yellow fever, MMR)
  - MMR ok to give with egg allergies
- If patient has history of anaphylaxis with egg products, avoid or “refer for further evaluation”

CDC Pinkbook pp. 18
Pregnancy

▪ ACOG Committee Opinion 741
  ▪ No evidence of adverse fetal effects from inactivated vaccines
  ▪ Growing evidence of safety of vaccination in pregnancy

▪ DO NOT administer
  ▪ Live vaccines (MMR, VZV, intranasal flu, typhoid) → avoid pregnancy for 4 weeks following administration
  ▪ HPV (not enough data yet)
Pregnancy

- Can give >1 vaccine at a time

- Tdap
  - Safe to give anytime
  - Preferably administer weeks 27-36 for highest chance of intrapartum transfer of passive immunity
  - Close family and caregivers should be vaccinated within 2 weeks of anticipated due date ("cocooning")

CDC Pinkbook pp. 17-19
Thimerosal

- Mercury-based antimicrobial additive used in many vaccines
  - NOT the same as toxic mercury found in fish
- Has been safely used in vaccines since the 1930s
- No longer used in childhood vaccines
  - Exception: multi-dose flu given to adults and kids
- Does NOT cause toxicity or autism

https://www.cdc.gov/vaccinesafety/concerns/thimerosal/faqs.html
Do Vaccines Cause Autism?

- NO.
  - Neither do any known additives or adjuvants (e.g. thimerosal)
  - MULTIPLE peer-reviewed studies have shown that there is NO link between autism and any vaccine, including MMR
    - See CDC website and PubMed for full papers
    - Studies include comparisons of vaccinated to unvaccinated children and those with autism compared to those without

https://www.cdc.gov/vaccinesafety/concerns/autism.html
Great Resources on Vaccines

- CDC’s Epidemiology and Prevention of Vaccine Preventable Diseases, 13th edition
  - Available for free online at cdc.gov

- Immunization Action Coalition
  - Great provider and parent resources including vaccine screening sheets free at immunize.org

- The History of Vaccines
  - Interactive educational tool for providers, parents, kids at historyofvaccines.org

- Naro, Maki. Vaccines Work: Here are the Facts.
The End

THANK YOU!
Sources


- CDC. Immunization Schedules. https://www.cdc.gov/vaccines/schedules/

- Advisory Committee on Immunization Practices. “About ACIP” and pamphlet. https://www.cdc.gov/vaccines/acip/about.html
Sources

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