#### National Center for Immunization and Respiratory Diseases



### **General Best Practices for Immunization, Part 2**

Pink Book Web-on-Demand Series July 9, 2024

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- Describe the fundamental principles of the immune response.
- Describe immunization best practices.
- Describe an emerging immunization issue.
- For each vaccine-preventable disease, identify those for whom routine immunization is recommended.
- For each vaccine-preventable disease, describe characteristics of the vaccine used to prevent the disease.
- Locate current immunization resources to increase knowledge of team's role in program implementation for improved team performance.

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#### **General Best Practices for Immunization**

- Timing and spacing
- Contraindications and precautions
- Preventing and managing adverse reactions to immunization
- Vaccine administration
- Storage and handling

- Altered immunocompetence
- Special situations
- Vaccination records
- Vaccination programs
- Vaccine information sources

### **Contraindications and Precautions**

#### Contraindication

- A condition in a recipient that increases the risk for a serious adverse reaction
- Action: Do <u>**not</u>** give the vaccine dose.</u>

#### Precaution

- A condition in a recipient that might increase the risk for a serious adverse reaction, might cause diagnostic confusion, or might compromise the ability of the vaccine to produce immunity
- Action: <u>Defer</u> the vaccine dose.

## Screening

### Screening

- Specific questions intended to identify contraindications or precautions to vaccination.
- Use of a standardized form will facilitate effective screening.
- Screening must occur at every vaccination encounter (not just before the first dose).
- The following questions are written from the perspective of the pediatric visit, but can be adjusted for an adult visit.



- Is the child sick today?
- Does the child have an allergy to any medications, food, latex, or any vaccine?
- Has the child had a serious reaction to a vaccine in the past?

- Has the child had a seizure, brain, or nerve problem?
- Has the child had a long-term problem with heart, kidney, lung (including asthma), no spleen, cochlear implant, spinal fluid leak, regular aspirin or salicylate medication, metabolic disease (such as diabetes), or a blood disorder?
- Has the child had a history of intussusception?

- Does the child have cancer (e.g., leukemia), HIV/AIDS, or any other immune system problem?
- Has the child taken prednisone, other steroids, or anticancer medications, or had radiation treatments in the past 3 months?
- Has the child taken medications for rheumatoid arthritis, Crohn's disease, or psoriasis?
- Has the child had Multisystem Inflammatory Syndrome in children (MIS-C)?
- Has the child had myocarditis or pericarditis?

- Has the child received a transfusion of blood or blood products, or been given a medicine called "immune (gamma) globulin" in the past year?
- Is the child/teen pregnant or is there a chance they could become pregnant during the next month?
- Has the child received vaccinations in the past 4 weeks?

Screening Checklist

DATE OF BIRTH

#### for Contraindications to Vaccines for Children and Teens

For parents/guardians: The following questions will help us determine which vaccines your child may be given today. If you answer "yes" to any question, it does not necessarily mean your child should not be vaccinated. It just means additional questions must be asked. If a question is not clear, please ask your healthcare provider to explain it.

PATIENT NAME .

|   | yes  | no | don't<br>know |
|---|------|----|---------------|
| 1. Is the child sick today?   |      |    |               |
| 2. Does the child have allergies to medicine, food, a vaccine component, or latex?  |      |    |               |
| 3. Has the child had a serious reaction to a vaccine in the past?   |      |    |               |
| 4. Does the child have a long-term health problem with heart, lung (including asthma), kidney, liver, nervous system, or metabolic disease (e.g., disbetes), a blood disorder, no spleen, a cochiear implant, or a spinal fluid lea Are they taking regular aspirin or salicylate medication? | sk?  |    |               |
| 5. For children age 2 through 4 years: Has a healthcare provider told you that the child had<br>wheezing or asthma in the past 12 months?   |      |    |               |
| 6. For babies: Have you ever been told the child had intussusception?   |      |    |               |
| 7. Has the child, a sibling, or a parent had a seizure; has the child had a brain or other nervous system problem?  |      |    |               |
| 8. Has the child ever been diagnosed with a heart condition (myocarditis or pericarditis) or have they had<br>Multisystem Inflammatory Syndrome (MIS-C) after an infection with the virus that causes COVID-19?   |      |    |               |
| 9. Does the child have an immune-system problem such as cancer, leukemia, HIV/AIDS?   |      |    |               |
| 10. In the past 6 months, has the child taken medications that affect the immune system such as prednisone, other<br>steroids, or anticancer drugs; drugs to treat rheumatoid arthritis, Crohn's disease, or psoriasis; or had radiation<br>treatments?                                       | r 🗆  |    |               |
| 11. Does the child's parent or sibling have an immune system problem?   |      |    |               |
| 12. In the past year, has the child received immune (gamma) globulin, blood/blood products, or an antiviral drug?   |      |    |               |
| 13. Is the child/teen pregnant?   |      |    |               |
| 14. Has the child received vaccinations in the past 4 weeks?  |      |    |               |
| 15. Has the child ever felt dizzy or faint before, during, or after a shot?   |      |    |               |
| 16. Is the child anxious about getting a shot today?  |      |    |               |
| FORM COMPLETED BY   | DATE |    |               |
| FORM REVIEWED BY  | DATE |    |               |

#### Did you bring your immunization record card with you? yes D no D

It is important to have a personal record of your child's vaccinations. If you don't have one, ask the child's healthcare provider to give you one with all your child's vaccinations on it. Keep it in a safe place and bring it with you every time you seek medical care for your child. Your child will need this document to enter day care or school, for employment, or for international travel.



### **Invalid Contraindications**

- Disease exposure
- Mild illness or convalescence
- Preterm birth
- Breastfeeding
- Allergy to products not present in vaccine or allergy that is not severe (e.g., anaphylactic)

- Antibiotic therapy
- Pregnant woman in the household
- Family history of adverse events after vaccination
- Tuberculin skin testing

### **Invalid Contraindications**

#### • Mild illness

- Vaccinate with
  - Low-grade fever
  - Upper respiratory infection
  - Otitis media
  - Mild diarrhea

#### **Household Contacts and Pregnancy**

- Susceptible household contacts of pregnant women:
  - Should receive all recommended vaccines, including MMR, varicella, and rotavirus vaccines if indicated
  - Can receive either non-live influenza vaccine or LAIV

#### **Invalid Contraindications**

- Preterm birth (less than 37 weeks)
  - Generally, infants and children should be immunized according to chronologic age (not gestational age)
  - Use full recommended dose
  - Birth weight and size not factors but, as with all rules, there are exceptions (HepB, nirsevimab)

#### **Family History of Adverse Events or Medical Conditions**

- A family history of adverse events after vaccination or medical conditions is generally <u>not</u> a contraindication.
- A family history of a congenital immunosuppressive condition is a temporary contraindication to MMR and varicella vaccines.
  - Requires screening to assure the condition is not inherited prior to receipt of MMR and varicella vaccines
- Family history can be a precaution.
  - Example: Family history of seizures is a precaution to MMRV.



A healthy child who lives in a household with a pregnant woman should be administered measles-mumps-rubella (MMR) vaccine.

A. True

B. False



A healthy child who lives in a household with a pregnant woman should be administered measles-mumps-rubella (MMR) vaccine.



B. False



### **Vaccine Safety**

#### **Comparison of 20th Century Annual Morbidity and Current Morbidity:** Vaccine-preventable Diseases

| Disease                     | 20th Century<br>Annual Morbidity <sup>†</sup> | 2023<br>Reported Cases <sup>+ +</sup> | Percent<br>Decrease |
|-----------------------------|---|---------------------------------------|---------------------|
| Smallpox                    | 29,005  | 0                                     | 100%                |
| Diphtheria                  | 21,053  | 2                                     | >99%                |
| Measles                     | 530,217                                       | 47                                    | >99%                |
| Mumps                       | 162,344                                       | 429                                   | >99%                |
| Pertussis                   | 200,752                                       | 5,611                                 | 97%                 |
| Polio (paralytic)           | 16,316  | 0                                     | 100%                |
| Rubella                     | 47,745  | 3                                     | >99%                |
| Congenital Rubella Syndrome | 152   | 0                                     | 100%                |
| Tetanus                     | 580   | 15                                    | 97%                 |
| Haemophilus influenzae      | 20,000  | 27*                                   | >99%                |

+ JAMA. 2007;298(18):2155-2163

+ + Centers for Disease Control and Prevention. National Notifiable Diseases Surveillance System, Weekly Tables of Infectious Disease Data. Atlanta, GA. CDC Division of Health Informatics and Surveillance. Available at:

https://wonder.cdc.gov/nndss/mdss weekly tables menu.asp?mmwr year=2020&mmwr week=53. Available at: Weekly statistics from the National Notifiable Diseases Surveillance System (NNDSS). (cdc.gov). Data submitted through Dec 31, 2023; accessed on Jan 24, 2024; diptheria and polio case counts reported by CDC Program. \* Haemophilus influenzae type b (Hib) < 5 years of age. An additional 12 cases of Hib are estimated to have occurred among the 257 notifications of Haemophilus influenzae (< 5 years of age) with unknown serotype.

#### **Importance of Vaccine Safety**

- Vaccines have a long history of successfully protecting people and communities against infectious diseases.
- FDA regulates vaccines to make sure they are safe and effective.
- CDC provides clinical guidance for vaccine use.
- Before a vaccine can be approved, it must go through years of testing to show it is safe, effective, and its benefits outweigh the risks.
- Once a vaccine is approved for use, FDA and CDC continue to monitor its safety.

#### What is "Safe"...What is "Effective"?

- No vaccine is 100 percent safe.
- No vaccine is 100 percent effective.

### **Pre-clinical Vaccine Safety Studies**

- Laboratory
- Animals





### **Prelicensure Human Studies**

- Phase I, II, III trials
- Phase I trials 20-100 individuals (safety)
- Phase II trials several hundred (dose ranging, immunogenicity, safety)
- Phase III trials (safety, efficacy) usually include a control group that receives a placebo.
- Common adverse reactions are identified.
- Most Phase III trials include 2,000 to 5,000 participants.
- Largest recent Phase III trial was REST (rotavirus) around 70,000 infants

### **Post-licensure Vaccine Safety Monitoring**

- Identify rare adverse reactions after vaccine administered to millions of persons
- Monitor increases in known adverse reactions—identify risk factors for reactions
- Identify vaccine lots with increased rates of reactions





## Federal Vaccine Safety Monitoring

#### VAERS is the nation's early warning system for vaccine safety



VAERS

#### Vaccine Adverse Event Reporting System

Primarily a safety signal detection and hypothesis generating system

http://vaers.hhs.gov





VAERS accepts all reports from everyone, regardless of the plausibility of the vaccine causing the event or the clinical seriousness of the event.

#### **Key Strengths**

- Can rapidly detect potential safety problems
- Can detect rare adverse events

#### **Key Limitations**

- Inconsistent quality and completeness of information
- Generally, cannot determine cause and effect

#### **Limitations of VAERS Database**



#### VAERS only contains partial data in pink cell (incomplete population data)

Not able to calculate rates of occurrence of adverse events Not able to determine increased risk for adverse events

### Which Adverse Events Should be Reported to VAERS?

- Required reporting for health care providers<sup>1</sup>:
  - Any adverse event listed by the vaccine manufacturer as a contraindication to further doses of the vaccine
  - Any adverse event listed in the VAERS Reportable Events Table<sup>2</sup> following vaccination that occurs within the specified time period after vaccination
- Healthcare providers are encouraged to report any clinically significant or unexpected adverse events (AEs) following any vaccination.
- With the COVID-19 vaccination program, vaccines under emergency use authorization have different reporting requirements.

<sup>&</sup>lt;sup>1</sup> National Childhood Vaccine Injury Act

<sup>&</sup>lt;sup>2</sup> The Reportable Events Table reflects what is reportable by law (42 USC 300aa-25) to the Vaccine Adverse Event Reporting System (VAERS). https://vaers.hhs.gov/resources/VAERS\_Table\_of\_Reportable\_Events\_Following\_Vaccination.pdf

### **VAERS Reporting Form**

- VAERS reporting methods
  - Option 1: online reporting tool (preferred)
  - Option 2: writable PDF form combined with electronic document upload capability

|  |   |   | ity is kept | confidential. Instruct   | ions are provide  | s on the last to   |   |
|--|---|---|-------------|--|---|--|---|
| INFORMATION ABOUT THE PATIEN   | T WHO RECEIV  | ED THE VACO   | INE (Use (  | Continuation Page  | if needed)  |  |   |
| 1. Patient name: (first) (last)  |   |   | 9. Prescr   | iptions, over-the-cou  | nter medication   | s, dietary suppl   | ements, or  |
| Street address:  |   |   | herbal      | remedies being take  | n at the time of  | vaccination:   |   |
| City: State: County  | c   |   |             |  |   |  |   |
| ZIP code: Phone: () Email:   |   |   | 10. Aller   | gies to medications,   | food, or other p  | roducts:   |   |
| 2. Date of birth: (mm(dd)yyyy) _/ / 🏥 3. Sex: 🗆 Male   | e 🗆 Female  | Unknown   |             |  |   |  |   |
| <ol> <li>Date and time of vaccination: (mm(dd/yyyy) / / </li> </ol>  | Time:   |   | 11. Other   | r illnesses at the tim   | e of vaccination  | and up to one  | month prior   |
| 5. Date and time adverse event started: (mm/dd/yyyy) / /   | 🛗 Time:   |   |             |  |   |  |   |
| 6. Age at vaccination: Years Months 7. Today's date: (mm)d   | dimmi _/ /  | <u> </u>  | 12. Chro    | nic or long-standing I   | health condition  | s:   |   |
| 8. Pregnant at time of vaccination?:  Yes No Unk (If yes, describe the event, any pregnancy complications, and estimated due dat   | nown<br>te if known in item   | 18)   |             |  |   |  |   |
| INFORMATION ABOUT THE PERSON COMPLETING THIS FOR   | RM  | INFORM  | IATION A    | BOUT THE FACILIT   | Y WHERE VAC   | CINE WAS GIV   | /EN   |
| 13. Form completed by: (name)  | 15.   | Facility/clinic i   | name:       |  | 16. Type of f   | acility: (Check o  | ne)   |
| Relation to patient: 🗆 Healthcare professional/staff 🔅 Patient (yours  | elf) —  |   |             |  | Doctor's o  | office, urgent ca  | are, or hospi   |
| Parent/guardian/caregiver     Other:   | Fax   | : ( )   |             |  | Pharmacy  | or store   |   |
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| City: State: ZIP code:   | -   |   |             |  | Public hea  | ith clinic   |   |
| Phone: ( ) Email:  |   |   |             |  | Nursing h   | ame or senior li   | ang facility  |
| 14. Best doctor/healthcare Name:   | Lity  | r   |             |  | C Others  | student health   | clinic  |
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### **VAERS Additional Information**

- Instructions for reporting to VAERS: <u>https://vaers.hhs.gov/reportevent.html</u>
- Additional assistance:
  - Email at info@vaers.org
  - Phone at 1-800-822-7967



The Vaccine Adverse Event Reporting System (VAERS) can be used to establish a causal association between a vaccine and an adverse event.

- A. True
- B. False



The Vaccine Adverse Event Reporting System (VAERS) can be used to establish a causal association between a vaccine and an adverse event.



### **Post-Licensure Vaccine Safety Activities**

- Phase IV trials
  - ~10,000 participants
  - Studies safety and effectiveness over longer time period
- Vaccine Safety Datalink (VSD)
- Clinical Immunization Safety Assessment Project (CISA)
- V-safe



VSD Vaccine Safety Datalink Sites that do not provide data are denoted with an asterisk(\*).



**13** participating integrated health care organizations

#### **VSD Electronic Files + Chart Review**





## CISA

Clinical Immunization Safety Assessment (CISA) Project

8 participating medical research centers with vaccine safety experts



Clinical consult services\*

CISAeval@cdc.gov

Clinical research

Clinical Immunization Safety Assessment (CISA) Project | CISA | Monitoring | Ensuring Safety | Vaccine Safety | CDC





- V-safe is a vaccine safety monitoring system that lets vaccination recipients share with CDC how they feel after getting a participating vaccine.
- Originally launched in December 2020 to monitor the safety of COVID-19 vaccines.
- V-safe sends personalized and confidential health check-ins via text messages or emails.
- Currently, 2023-2024 updated COVID-19 and RSV vaccines are being monitored in V-safe.



### **National Vaccine Injury Compensation Program**

- Established by National Childhood Vaccine Injury Act (1986)
- "No fault" program
- Covers all routinely recommended childhood vaccines
- Vaccine Injury Table
  - <u>https://www.hrsa.gov/sites/default/files/hrsa/vaccine-compensation/vaccine-injury-table.pdf</u>

| للله Health Resources & Servi                                 | es Administration Call or Text the Maternal Mental Health Hotlin   |
|---|--|
| HRSA<br>Health Resources & Services Administration            | Bureaus and Offices   Newsroom   Contact HRSA   Recursos en esp  |
| Home Grants ~ Loans &   | Scholarships v Data Warehouse v About HRSA v   |
| Home » National Vaccine Injury Co                             | mpensation Program   |
| VICP Home<br>About the Program<br>Covered Vaccines            | National Vaccine Injury Compensation<br>Program  |
| Who Can File a<br>Petition                                    | COVID-19 claims  |
| How to File a Petition<br>Vaccine Injury<br>Compensation Data | For claims associated with the COVID-19 vaccine or other COVID-19 related<br>countermeasures, please file your Request for Benefits with<br>the <u>Countermeasures Injury Compensation Program</u> . |
| Questions   |  |
| Resources   | Electronic filing now available for  |
| Advisory Commission<br>on Childhood<br>Vaccines (ACCV)        | HRSA Injury Compensation Programs  |
|   | Visit Injury Compensation Program's New Site!  |

### **The Provider's Role**

- Immunization providers can help ensure the safety and effectiveness of vaccines through proper:
  - Vaccine storage and administration
  - Timing and spacing of vaccine doses
  - Screening for contraindications and precautions
  - Management of adverse reactions
  - Reporting to VAERS
  - Benefit and risk communication

### **Benefit and Risk Communication**

- Opportunities for questions should be provided before each vaccination.
- Vaccine information statements (VISs)
  - The National Childhood Vaccine Injury Act (Federal law) requires VISs be provided to the patient, parent, or their legal representative before each dose of vaccine.
  - Required for public and private providers
- For vaccines covered under Emergency Use Authorization (EUA) (e.g., COVID-19 vaccines for children 6 months through 11 years) FDA requires that recipients or their caregivers receive Fact Sheets, which have content similar to VISs, are developed by the vaccine manufacturer, and are approved by FDA.
- CDC provides English versions at <u>Vaccine Information Statement | Current VISs |</u>
   <u>https://www.cdc.gov/vaccines/hcp/vis/index.html</u>
   CDC and Translations | Immunize.org

#### **Continuing Education Information**

- To claim continuing education (CE) for this course, please follow the steps below by July 2, 2026.
- Search and register for course **WD4810-071124** in **CDC TRAIN**.
- Pass the post-assessment at 80%.
- Complete the evaluation.
- Visit "Your Learning" to access your certificates and transcript.
- If you have any questions, contact **CDC TRAIN** at <u>train@cdc.gov</u> <u>https:@rwCE.Coordina</u>tor, Melissa Barnett, at <u>MBarnett2@cdc.gov</u>

#### CDC TRAIN

HOME COURSE CATALOG CALENDAR RESOURCES HELF



#### **E-mail Your Immunization Questions to us**



# ONIPINFO@cdc.gov

#### **Thank You From Atlanta!**

For more information, contact CDC 1-800-CDC-INFO (232-4636) TTY: 1-888-232-6348 www.cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.



