National Center for Immunization and Respiratory Diseases



General Best Practices for Immunization, Part 2

Pink Book Web-on-Demand Series
July 11, 2024

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Learning Objectives

- 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.

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> or CE Coordinator, Melissa Barnett, at <u>MBarnett2@cdc.gov</u>



https://www.train.org/cdctrain/welcome

Disclosure Statements

- In compliance with continuing education requirements, all planners and presenters must disclose all financial relationships, in any amount, with ineligible companies during the previous 24 months as well as any use of unlabeled product(s) or products under investigational use.
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Disclosure Statements

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

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 **not** give the vaccine dose.

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: **Defer** 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 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.

	yes	no	knov
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., diabetes), a blood disorder, no spleen, a cochlear implant, or a spinal fluid leak? Are they taking regular aspirin or salicytate medication?			
5. For children age 2 through 4 years: Has a healthcare provider told you that the child had 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 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 steroids, or anticancer drugs; drugs to treat rheumatoid arthrifts, Crohn's disease, or psoriasis; or had radiation treatments?			
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 DA	TE		
FORM REVIEWED BY DA	TE.		

Did you bring your immunization record card with you? yes ☐ no ☐

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.



FOR PROFESSIONALS www.immunize.org / FOR THE PUBLIC www.vaccineinformation.org



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 person 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 people:
 - 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.



Knowledge Check

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.

A. True

B. False

Vaccine Safety

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

Disease	20th Century Annual Morbidity [†]	2023 Reported Cases † †	Percent 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

https://wonder.cdc.gov/nndss/nndss 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; ightheria and polic case counts reported by CDC Program. * Haemophilus influenzae (< 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.

^{† †} 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:

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



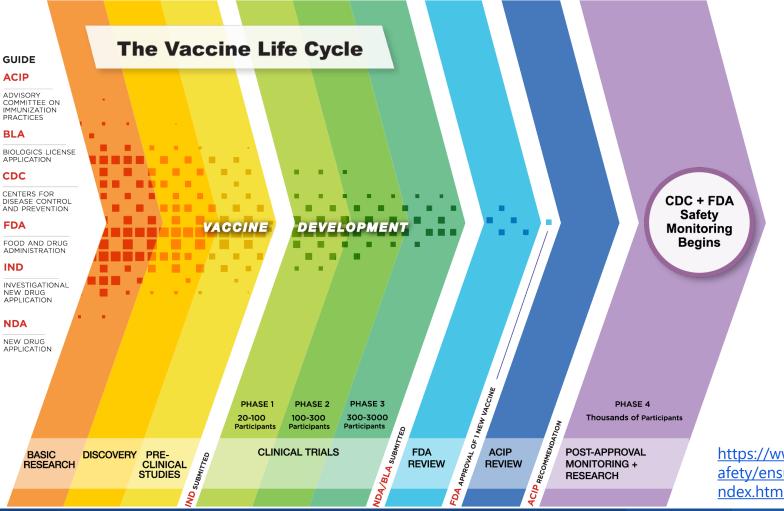


Prelicensure Human Studies

- 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



GUIDE

ACIP ADVISORY COMMITTEE ON **IMMUNIZATION**

PRACTICES BLA

APPLICATION CDC CENTERS FOR

FDA

IND

NEW DRUG APPLICATION NDA NEW DRUG APPLICATION

ADMINISTRATION

BASIC

Safety is Part of **Every Vaccine**

https://www.cdc.gov/vaccines afety/ensuringsafety/history/i ndex.html

3

Federal Vaccine Safety Monitoring

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





Vaccine Adverse Event Reporting System

Primarily a safety signal detection and hypothesis generating system

http://vaers.hhs.gov



VAERS

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

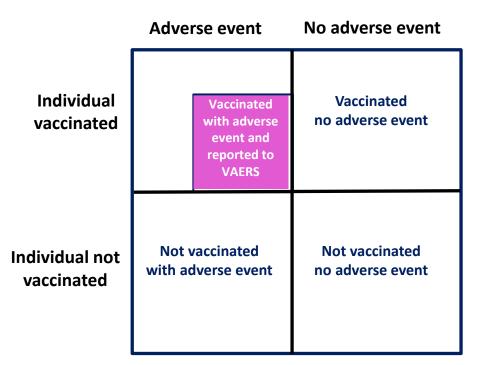
Key Strengths

- 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 providers¹:
 - 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 Table² 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.

¹ National Childhood Vaccine Injury Act

² 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

VAERS Vaccine Adverse Event Reporting System www.vaers.hhs.gov	Items 2, 3, 4	nts are possible reactions or problems that occur during or after vaccinati 4, 5, 6, 17, 18 and 21 are ESSENTIAL and should be completed. tity is kept confidential. Instructions are provided on the last two pages.	1911.
INFORMATION ABOUT THE PATIENT WHO RI	CEIVED THE VAC	CINE (Use Continuation Page if needed)	
Patient name: (first) (last)		9. Prescriptions, over-the-counter medications, dietary supplements, or	
Street address:		herbal remedies being taken at the time of vaccination:	
County: State: County:			
TIP code: Phone: ()		10. Allergies to medications, food, or other products:	
t. Date of birth: (mm(dd)yyyy) _ / /			
L. Date and time of vaccination: (mm/dd/yyyy) / / Time:	O AM	11. Other illnesses at the time of vaccination and up to one month prior	c
i. Date and time adverse event started: (mm/dd/yyyy) / / mm:_			
i. Age at vaccination: Years Months 7. Today's date: (mm/dd/yyyy) /	/ m	12. Chronic or long-standing health conditions:	
Pregnant at time of vaccination?: Yes	n item 18)		
INFORMATION ABOUT THE PERSON COMPLETING THIS FORM	INFORM	MATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN	
3. Form completed by: (name)	15. Facility/clinic		
Relation to patient: Healthcare professionalistaff Patient (yourself)		☐ Doctor's office, urgent care, or hosp	pital
□ Parent/guardian/caregiver □ Other:	Fax: ()	□ Pharmacy or store	
	Street address:	☐ Check if same as item 13 ☐ Workplace clinic	
Street address: Check if same as item 1		□ Public health clinic	
State: ZIP code:		□ Nursing home or senior living facility	v I
Phone: () Email:	City:	School or student health clinic	
4. Best doctor/healthcare Name:	State:	ZIP code: Other:	
about the adverse event: Phone: () Ext:	Phone: ()	□ Unknown	
WHICH VACCINES WERE GIVE			_
17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was give faccine (type and brand name) Manufacturer		RE vaccine was given) Use Continuation Page if needed Dose numb Lot number Route Body site in series	ber
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VAERS Additional Information

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



Knowledge Check

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.

- A. True
- B. <u>False</u>

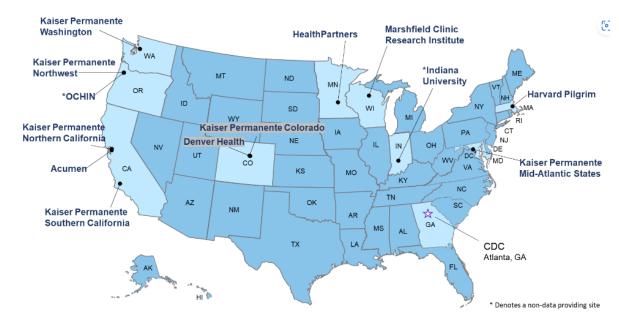
Post-Licensure Vaccine Safety Activities

- 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



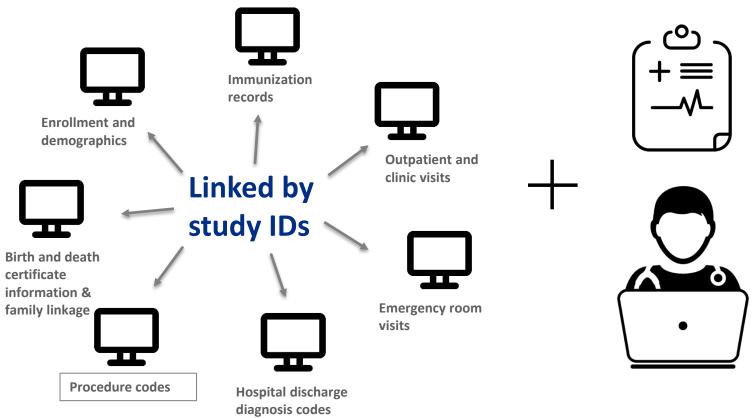
VSD

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

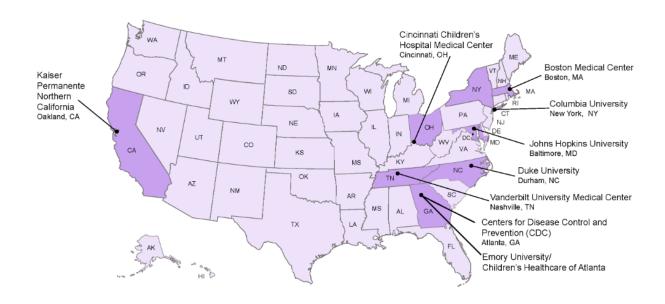




CISA

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
 - https://www.hrsa.gov/sites/default/files/hrsa/vaccinecompensation/vaccine-injury-table.pdf



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>CDC</u> and <u>Translations | Immunize.org</u>

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 or CE Coordinator, Melissa Barnett, at MBarnett2@cdc.gov



https://www.train.org/cdctrain/welcome 47

E-mail Your Immunization Questions to us



NIPINFO@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.



