General Best Practice Guidelines for Immunization, Part 2 Vaccine Safety

Pink Book Web-on-Demand Series
July 19, 2022

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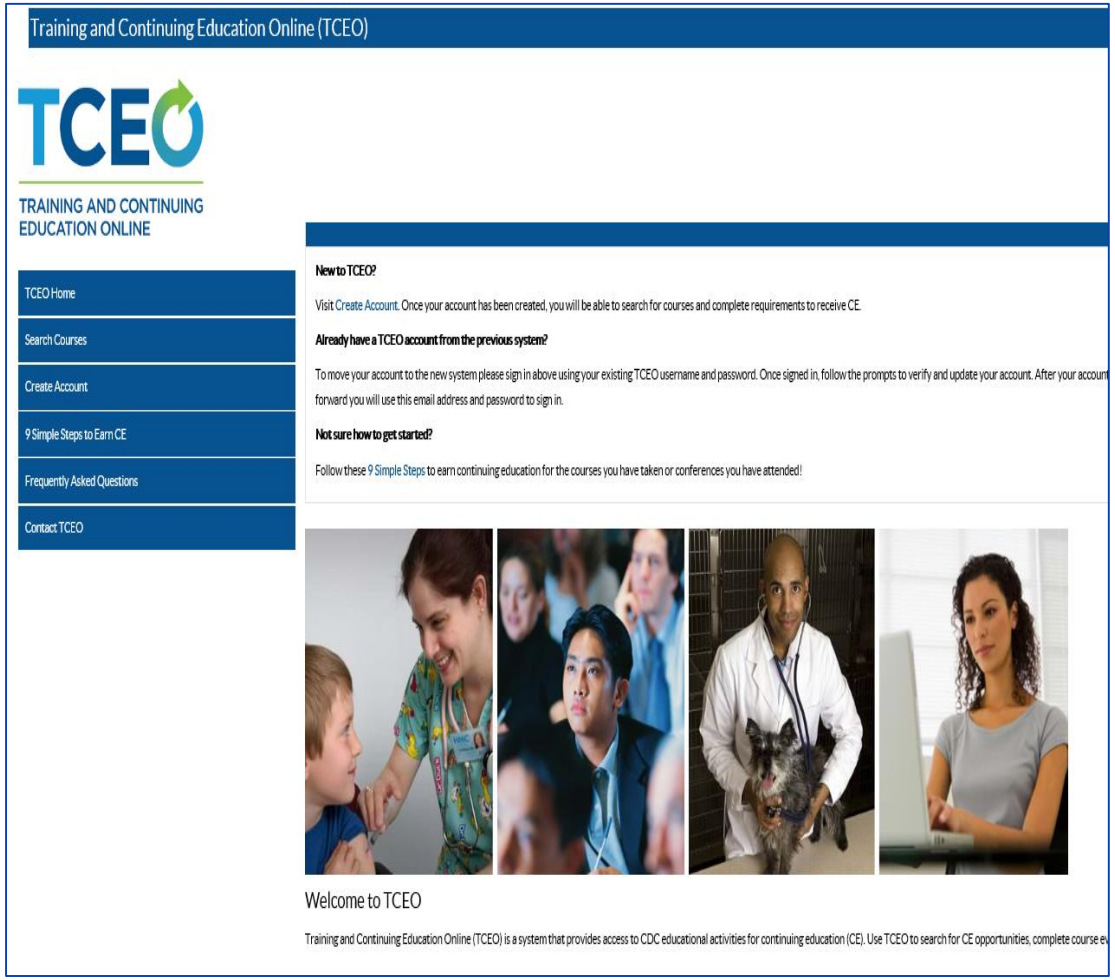
Learning Objectives

- Describe the Advisory Committee on Immunization Practices General Best Practice Guidelines on Immunization.
- 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.
- Implement disease detection and prevention health care services (e.g., smoking cessation, weight reduction, diabetes screening, blood pressure screening, immunization services) to prevent health problems and maintain health.

Continuing Education Information

- **CE credit, go to**: https://tceols.cdc.gov/
- **Search course number: WD4564-071922**
- **CE credit expires: July 1, 2024**
- **CE instructions are available on the Pink Book Web-on-Demand Series web page**
- **Questions and additional help with the online CE system, e-mail** CE@cdc.gov



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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 Practice Guidelines for Immunization

- **ACIP Table of Contents**
  - Introduction
  - Methods
  - 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

General Best Practice Guidelines for Immunization

- **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

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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)
- Following questions written from the perspective of the pediatric patient, but can be adjusted for the adult patient

Screening Questions

- 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?

Screening Questions

- **Has the child had a seizure, brain, or nerve problem?**

- **Has the child had a long-term problem with heart, kidney, lung (including asthma) or metabolic disease (such as diabetes), or a blood disorder?**

Screening Questions

- 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 x-ray treatments in the past 3 months?

Screening Questions

- 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 she 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

PATIENT NAME _____

DATE OF BIRTH ____/____/____ (month / day / year)

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	don't know
1. Is the child sick today?	☐	☐	☐
2. Does the child have allergies to medications, 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 lung, heart, kidney or metabolic disease (e.g., diabetes), asthma, a blood disorder, no spleen, complement component deficiency, a cochlear implant, or a spinal fluid leak? Is he/she on long-term aspirin therapy?	☐	☐	☐
5. If the child to be vaccinated is 2 through 4 years of age, has a healthcare provider told you that the child had wheezing or asthma in the past 12 months?	☐	☐	☐
6. If your child is a baby, have you ever been told he or she has had intussusception?	☐	☐	☐
7. Has the child, a sibling, or a parent had a seizure; has the child had brain or other nervous system problems?	☐	☐	☐
8. Does the child have cancer, leukemia, HIV/AIDS, or any other immune system problem?	☐	☐	☐
9. Does the child have a parent, brother, or sister with an immune system problem?	☐	☐	☐
10. In the past 3 months, has the child taken medications that affect the immune system such as prednisone, other steroids, or anticancer drugs; drugs for the treatment of rheumatoid arthritis, Crohn's disease, or psoriasis; or had radiation treatments?	☐	☐	☐
11. In the past year, has the child received a transfusion of blood or blood products, or been given immune (gamma) globulin or an antiviral drug?	☐	☐	☐
12. Is the child/teen pregnant or is there a chance she could become pregnant during the next month?	☐	☐	☐
13. Has the child received vaccinations in the past 4 weeks?	☐	☐	☐

FORM COMPLETED BY _____ DATE _____

FORM REVIEWED BY _____ DATE _____

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.

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www.immunize.org/catg.d/p4060.pdf • Item #P4060 (10/20)

Information for Healthcare Professionals about the Screening Checklist for Contraindications to Vaccines (Children and Teens)

Are you interested in knowing why we included a certain question on the screening checklist? If so, read the information below. If you want to find out even more, consult the references in ***Notes*** *below.*

NOTE: For supporting documentation on the answers given below, go to the specific ACIP vaccine recommendation found at the following website: www.cdc.gov/vaccines/hcp/acip-recs/index.html

1. Is the child sick today? *[all vaccines]*

There is no evidence that acute illness reduces vaccine efficacy or increases vaccine adverse events. However, as a precaution with moderate or severe acute illness, all vaccines should be delayed until the illness has improved. Mild illnesses (such as otitis media, upper respiratory infections, and diarrhea) are NOT contraindications to vaccination. Do not withhold vaccination if a person is taking antibiotics.

2. Does the child have allergies to medications, food, a vaccine component, or latex? *[all vaccines]*

An anaphylactic reaction to latex is a contraindication to vaccines that contain latex as a component or as part of the packaging (e.g., vial stoppers, prefilled syringe plungers, prefilled syringe caps). If a person has anaphylaxis after eating gelatin, do not administer vaccines containing gelatin. A local reaction to a prior vaccine dose or vaccine component, including latex, is not a contraindication to a subsequent dose or vaccine containing that component. For information on vaccines supplied in vials or syringes containing latex, see www.cdc.gov/vaccines-pubs/pinkbook/downloads/appendices/B/latex-table.pdf, for an extensive list of vaccine components, see www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf. People with egg allergy of any severity can receive any recommended influenza vaccine (i.e., any IIV, RIV, or LAIV) that is otherwise appropriate for the patient's age and health status. With the exception of ccIIV and RIV (which do not contain egg antigen), people with a history of severe allergic reaction to egg involving any symptom other than hives (e.g., angioedema, respiratory distress), or who required epinephrine or another emergency medical intervention, the vaccine should be administered in a medical setting, such as a clinic, health department, or physician office; vaccine administration should be supervised by a healthcare provider who is able to recognize and manage severe allergic conditions.

3. Has the child had a serious reaction to a vaccine in the past? *[all vaccines]*

History of anaphylactic reaction (see question 2) to a previous dose of vaccine or vaccine component is a contraindication for subsequent doses. History of encephalopathy within 7 days following DTP/DTaP is a contraindication for further doses of pertussis-containing vaccine. There are other adverse events that might have occurred following vaccination that constitute contraindications or precautions to future doses. Under normal circumstances, vaccines are deferred when a precaution is present. However, situations may arise when the benefit outweighs the risk (e.g., during a community pertussis outbreak).

4. Does the child have a long-term health problem with lung, heart, kidney, or metabolic disease (e.g., diabetes), asthma, a blood disorder, no spleen, complement component deficiency, a cochlear implant, or a spinal fluid leak? Is he/she on long-term aspirin therapy? *[MMR, MMRV, LAIV, VAR]*

A history of thrombocytopenia or thrombocytopenic purpura is a precaution to MMR and MMRV vaccines. The safety of LAIV in children and teens with lung, heart, kidney, or metabolic disease (e.g., diabetes), or a blood disorder has not been established. These conditions, including asthma in children ages 5 years and older, should be considered precautions for the use of LAIV. Children with functional or anatomic asplenia, complement deficiency, cochlear implant, or CSF leak should not receive LAIV. Children on long-term aspirin therapy should not be given LAIV; instead, they should be given IIV. Children with CSF leak, anatomic or functional asplenia, or cochlear implant, or on long-term aspirin therapy should not be given LAIV; instead, they should be given IIV. Aspirin use is a precaution to VAR.

5. If the child to be vaccinated is 2 through 4 years of age, has a healthcare provider told you that the child had wheezing or asthma in the past 12 months? *[LAIV]*

Children ages 2 through 4 years who have had a wheezing episode within the past 12 months should not be given LAIV. Instead, these children should be given IIV.

6. If your child is a baby, have you ever been told that he or she has had intussusception? *[Rotavirus]*

Infants who have a history of intussusception (i.e., the telescoping of one portion of the intestine into another) should not be given rotavirus vaccine.

7. Has the child, a sibling, or a parent had a seizure; has the child had brain or other nervous system problem? *[DTaP, Td, Tdap, IIV, LAIV, MMRV]*

DTaP and Tdap are contraindicated in children who have a history of encephalopathy within 7 days following DTP/DTaP. An unstable progressive neurologic problem is a precaution to the use of DTaP and Tdap. For children with stable neurologic disorders (including seizures) unrelated to vaccination, or for children with a family history of seizures, vaccinate as usual (exception: children with a personal or family [i.e., parent or sibling] history of seizures generally should not be vaccinated with MMRV; they should receive separate MMR and VAR vaccines). A history of Guillain-Barré syndrome (GBS) is a consideration with the following: 1) Td/Tdap: if GBS has occurred within 6 weeks of a tetanus-containing vaccine and decision is made to continue vaccination, give Tdap instead of Td if no history of prior Tdap;

NOTE: For summary information on contraindications and precautions to vaccines, go to the ACIP's General Best Practice Guidelines for Immunization at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html

2) influenza vaccine (IIV, LAIV, or RIV): if GBS has occurred within 6 weeks of a prior influenza vaccination, vaccinate with IIV if at high risk for severe influenza complications.

8. Does the child have cancer, leukemia, HIV/AIDS, or any other immune system problem? *[LAIV, MMR, MMRV, RV, VAR]*

Live virus vaccines (e.g., MMR, MMRV, VAR, RV, LAIV) are usually contraindicated in immunocompromised children. However, there are exceptions. For example, MMR is recommended for asymptomatic HIV-infected children who do not have evidence of severe immunosuppression. Likewise, VAR should be considered for HIV-infected children age 12 months through 8 years with age-specific CD4+ T-lymphocyte percentage at 15% or greater, or for children age 9 years or older with CD4+ T-lymphocyte counts of greater than or equal to 200 cell/μL. VAR should be administered (if indicated) to persons with isolated humoral immunodeficiency. Immunosuppressed children should not receive LAIV. Infants who have been diagnosed with severe combined immunodeficiency (SCID) should not be given a live virus vaccine, including RV. Other forms of immunosuppression are a precaution, not a contraindication, to RV. For details, consult ACIP recommendations (see references in **Notes** above).

9. Does the child have a parent, brother, or sister with an immune system problem? *[MMR, MMRV, VAR]*

MMR, VAR, and MMRV vaccines should not be given to a child or teen with a family history of congenital or hereditary immunodeficiency in first-degree relatives (i.e., parents, siblings) unless the immune competence of the potential vaccine recipient has been clinically substantiated or verified by a laboratory.

10. In the past 3 months, has the child taken medications that affect the immune system such as prednisone, other steroids, or anticancer drugs; drugs for the treatment of rheumatoid arthritis, Crohn's disease, or psoriasis; or had radiation treatments? *[LAIV, MMR, MMRV, VAR]*

Live virus vaccines (e.g., LAIV, MMR, MMRV, VAR) should be postponed until after chemotherapy or long-term high-dose steroid therapy has ended. For details and length of time to postpone, consult the ACIP statement. Some immune mediator and immune modulator drugs (especially the antitumor-necrosis factor agents adalimumab, infliximab, and etanercept) may be immunosuppressive. A comprehensive list of immunosuppressive immune modulators is available in CDC Health Information for International Travel (the "Yellow Book") available at wwwnc.cdc.gov/travel/yellowbook/2020/travelers-with-additional-considerations/immunocompromised-travelers. The use of live vaccines should be avoided in persons taking these drugs. To find specific vaccination schedules for stem cell transplant (bone marrow transplant) patients, see General Best Practice Guidelines for Immunization (referenced in **Notes** above). LAIV, when recommended, can be given only to healthy nonpregnant people ages 2 through 49 years.

11. In the past year, has the child received a transfusion of blood/blood products, or been given immune (gamma) globulin or an antiviral drug? *[MMR, MMRV, LAIV, VAR]*

Certain live virus vaccines (e.g., MMR, MMRV, LAIV, VAR) may need to be deferred, depending on several variables. Consult the most current ACIP recommendations (referenced in **Notes** above) for the most current information on intervals between antiviral drugs, immune globulin or blood product administration and live virus vaccines.

12. Is the child/teen pregnant or is there a chance she could become pregnant during the next month? *[HPV, IPV, LAIV, MenB, MMR, MMRV, VAR]*

Live virus vaccines (e.g., MMR, MMRV, VAR, LAIV) are contraindicated one month before and during pregnancy because of the theoretical risk of virus transmission to the fetus. Sexually active young women who receive a live virus vaccine should be instructed to practice careful contraception for one month following receipt of the vaccine. On theoretical grounds, IPV and MenB should not be given during pregnancy; however, it may be given if there is a risk of exposure. IIV and Tdap are both recommended during pregnancy. HPV vaccine is not recommended during pregnancy.

13. Has the child received vaccinations in the past 4 weeks? *[LAIV, MMR, MMRV, VAR, yellow fever]*

Children who were given either LAIV or an injectable live virus vaccine (e.g., MMR, MMRV, VAR, yellow fever) should wait 28 days before receiving another vaccination of this type (30 days for yellow fever vaccine). Inactivated vaccines may be given at the same time or at any spacing interval.

VACCINE ABBREVIATIONS

LAIV = Live attenuated influenza vaccine
HPV = Human papillomavirus vaccine
IIV = Inactivated influenza vaccine
ccIIV = cell culture inactivated influenza vaccine
IPV = Inactivated poliovirus vaccine
MMR = Measles, mumps, and rubella vaccine
MMRV = MMR+VAR vaccine
RIV = Recombinant influenza vaccine
RV = Rotavirus vaccine
Td/Tdap = Tetanus, diphtheria, (acellular pertussis) vaccine
VAR = Varicella vaccine

https://www.immunize.org/

Invalid Contraindications and Precautions

- 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)
- Antibiotics 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 women**
  - *Should* receive MMR, varicella, zoster, and rotavirus vaccines
  - *Should* receive either non-live influenza vaccine or LAIV

Invalid Contraindications

- **Preterm birth (less than 37 weeks)**
  - Generally, infants and children should be vaccinated 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)

Family History of Adverse Events

- **Family history of adverse events after vaccination or medical conditions are generally NOT a contraindication**

- **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 vaccine

- **Family history can be a precaution**
  - Example: Family history of seizures is a precaution to MMRV

Knowledge Check

- **A pregnant woman living in a household is a contraindication to administering measles-mumps-rubella (MMR) or varicella (VAR) vaccines to a healthy child in the same household.**

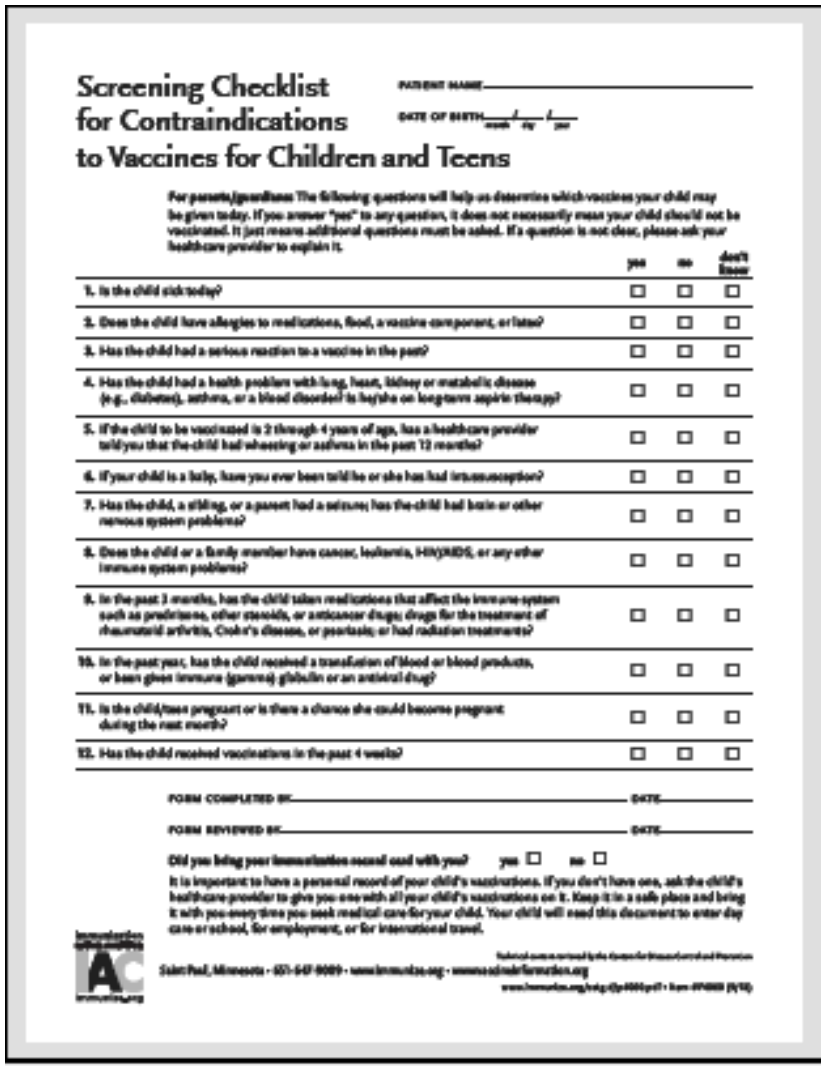
- A. True
- B. False

Answer

- A pregnant woman living in the household is a contraindication to administering measles-mumps-rubella (MMR) or varicella (VAR) vaccines for a healthy child in the same household.

- B. False

Screening Checklist



Screening Checklist for Contraindications to Vaccines for Children and Teens

PATIENT NAME _____

DATE OF BIRTH ___/___/___ (month / day / year)

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	yes	no	don't know
1. Is the child sick today?	☐	☐	☐
2. Does the child have allergies to medications, food, a vaccine component, or latex?	☐	☐	☐
3. Has the child had a serious reaction to a vaccine in the past?	☐	☐	☐
4. Has the child had a health problem with lung, heart, kidney or metabolic disease (e.g., diabetes), asthma, or a blood disorder? Is he/she on long-term aspirin therapy?	☐	☐	☐
5. If the child to be vaccinated is 2 through 4 years of age, has a healthcare provider told you that the child had wheezing or asthma in the past 12 months?	☐	☐	☐
6. If your child is a baby, have you ever been told he or she has had intussusception?	☐	☐	☐
7. Has the child, a sibling, or a parent had a seizure; has the child had brain or other nervous system problems?	☐	☐	☐
8. Does the child or a family member have cancer, leukemia, HIV/AIDS, or any other immune system problems?	☐	☐	☐
9. In the past 3 months, has the child taken medications that affect the immune system such as prednisone, other steroids, or anticancer drugs; drugs for the treatment of rheumatoid arthritis, Crohn's disease, or psoriasis; or had radiation treatments?	☐	☐	☐
10. In the past year, has the child received a transfusion of blood or blood products, or been given immune globulin or an antiviral drug?	☐	☐	☐
11. Is the child/teen pregnant or is there a chance she could become pregnant during the next month?	☐	☐	☐
12. Has the child received vaccinations in the past 4 weeks?	☐	☐	☐

FORM COMPLETED BY _____ DATE _____

FORM REVIEWED BY _____ DATE _____

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.

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www.immunize.org/catg.d/p4060.pdf • Item #P4060 (9/12)

Information for Healthcare Professionals about the Screening Checklist for Contraindications (Children and Teens)

Are you interested in knowing why we included a certain question on the screening checklist? If so, read the information below. If you want to find out even more, consult the references listed at the end.

1. Is the child sick today? (All vaccines)

2. Does the child have allergies to medications, food, a vaccine component, or latex? (All vaccines)

3. Has the child had a serious reaction to a vaccine in the past? (All vaccines)

4. Has the child had a health problem with lung, heart, kidney, HIV/AIDS, or any other immune system problem? (LAIV; MMR; MMRV; IPV; VAR)

5. Does the child have allergies to medications, food, a vaccine component, or latex? (All vaccines)

6. Has the child had a serious reaction to a vaccine in the past? (All vaccines)

7. Has the child, a sibling, or a parent had a seizure; has the child had brain or other nervous system problems? (DTaP; DT; Td; Tdap; IPV; LAIV; MMR; MMRV)

8. Does the child have a weakened immune system caused by HIV/AIDS or another disease, cancer, or treatment with drugs that affect the immune system? (LAIV; MMR; MMRV; IPV; VAR)

9. In the past 3 months, has the child taken medications that affect the immune system such as prednisone, other steroids, or anticancer drugs; drugs for the treatment of rheumatoid arthritis, Crohn's disease, or psoriasis; or had radiation treatments? (LAIV; MMR; MMRV; IPV; VAR)

10. In the past year, has the child received a transfusion of blood or blood products, or been given immune globulin or an antiviral drug? (MMR; MMRV; VAR)

11. Is the child/teen pregnant or is there a chance she could become pregnant during the next month? (DTaP; IPV; LAIV; MMR; MMRV; VAR)

12. Has the child received vaccinations in the past 4 weeks? (LAIV; MMR; MMRV; VAR; yellow fever)

REFERENCES

Immunization Action Coalition • Saint Paul, Minnesota • 651-647-9009 • www.immunize.org • www.vaccineinformation.org

www.immunize.org/catg.d/p4060.pdf • Item #P4060 — page 2 (9/12)

https://www.immunize.org/catg.d/p4060.pdf

2

Vaccine Safety

Comparison of 20th Century Annual Morbidity and Current Morbidity: Vaccine- Preventable Disease

Disease	20th Century Annual Morbidity†	2020 Reported Cases ††	Percent Decrease
Smallpox	29,005	0	100%
Diphtheria	21,053	1	> 99%
Measles	530,217	13	> 99%
Mumps	162,344	621	> 99%
Pertussis	200,752	5,398	97%
Polio (paralytic)	16,316	0	100%
Rubella	47,745	6	> 99%
Congenital Rubella Syndrome	152	0	100%
Tetanus	580	15	97%
Haemophilus influenzae	20,000	11*	> 99%

† JAMA. 2007;298(18):2155-2163

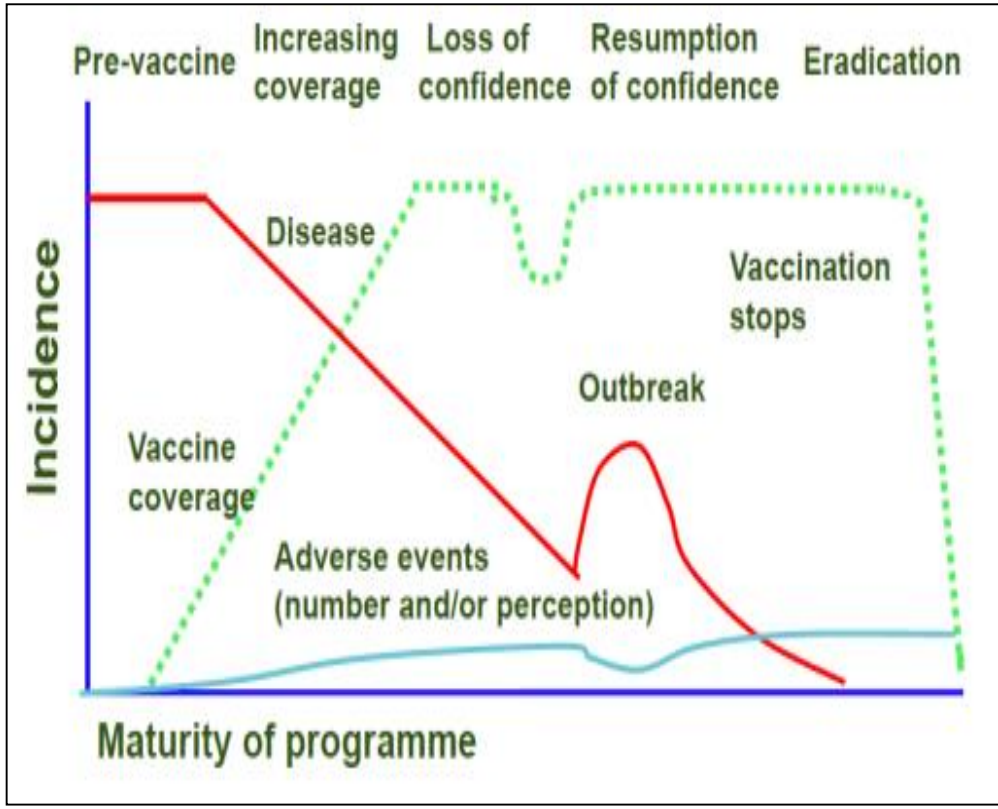
†† Centers for Disease Control and Prevention. National Notifiable Diseases Surveillance System, Weekly Tables of Infectious Disease Data. Atlanta, GA. CDC Division of Health Informatics and Surveillance. Available at: https://wonder.cdc.gov/nndss/nndss_weekly_tables_menu.asp?mmwr_year=2020&mmwr_week=53. Accessed on January 7, 2021.

* *Haemophilus influenzae* type b (Hib) < 5 years of age. An additional 7 cases of Hib are estimated to have occurred among the 136 notifications of *Haemophilus influenzae* (< 5 years of age) with unknown serotype.

Importance of Vaccine Safety

- **Decreases in disease risks and increased attention on vaccine risks**

- **Public confidence in vaccine safety is critical**
  - Higher standard of safety is expected of vaccines
  - Vaccines generally healthy (vs. ill for medications)
  - Lower risk tolerance = need to search for rare reactions
  - Vaccination universally recommended and mandated



Chen RT, et al. *Vaccine* 1994;12(6):542–50. Omer SB, et al. *N Engl J Med* 2013;368(15):1374–6

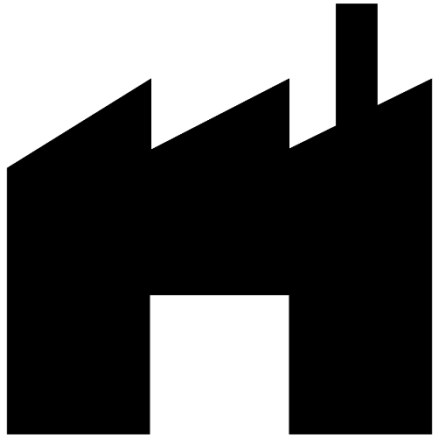
What is “Safe”?

- **SAFE = No harm from the vaccine**
  - No vaccine is 100% safe
- **SAFE = No harm from the disease**
  - No vaccine is 100% effective
- **Remind parents that to do nothing is to take a risk**

Pre-clinical Vaccine Safety Studies

- Laboratory
- Animals

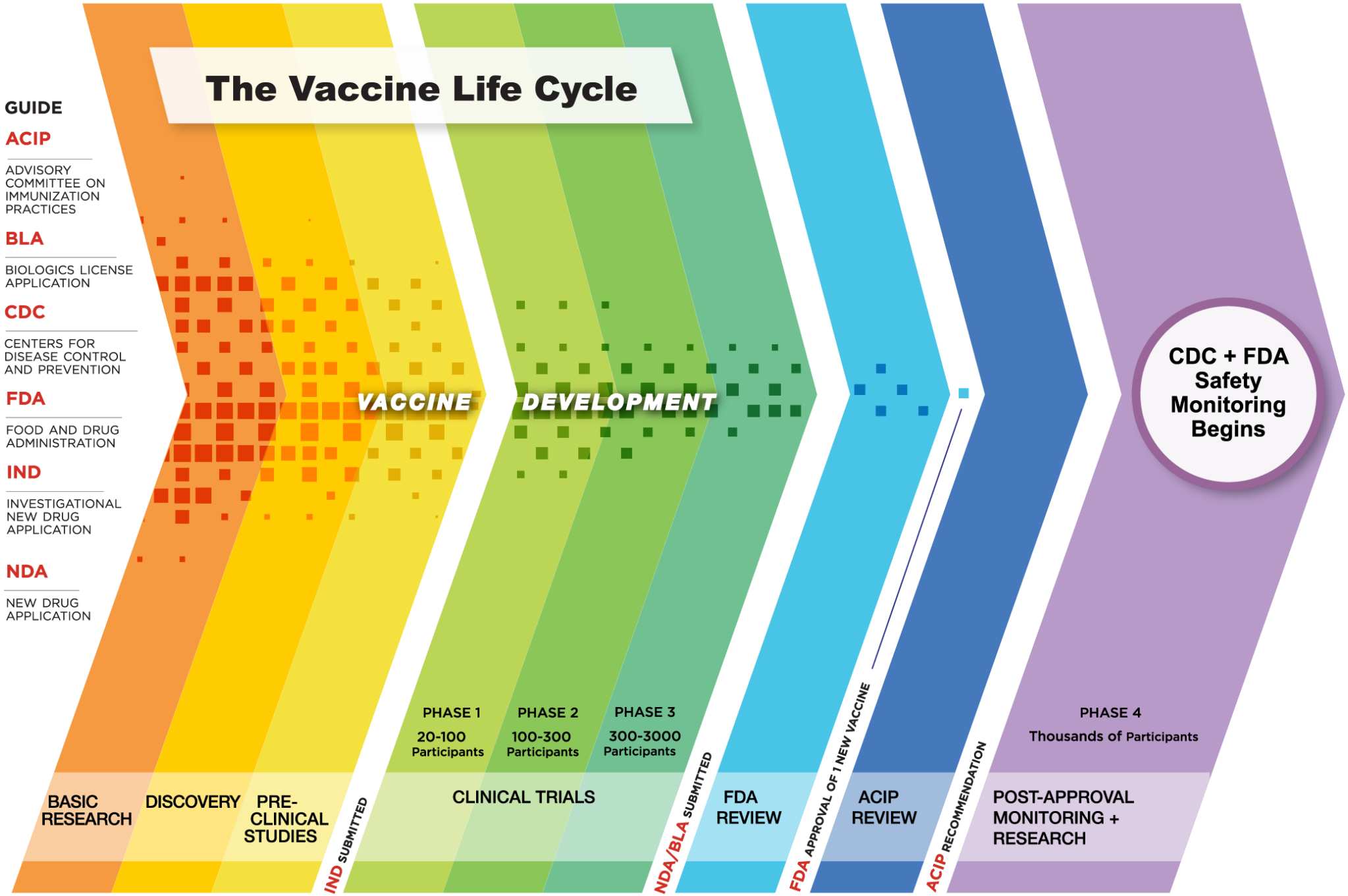
Prelicensure Human Studies



- Phase I, II, III trials
- Phase III trials 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
- Monitor increases in known adverse reactions—identify risk factors for reactions
- Identify vaccine lots with increased rates of reactions
- Identify “signals”–reports of adverse events more numerous than would be expected



Safety is Part of Every Vaccine

3

Federal Vaccine Safety Monitoring

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

CDC + FDA

VAERS

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

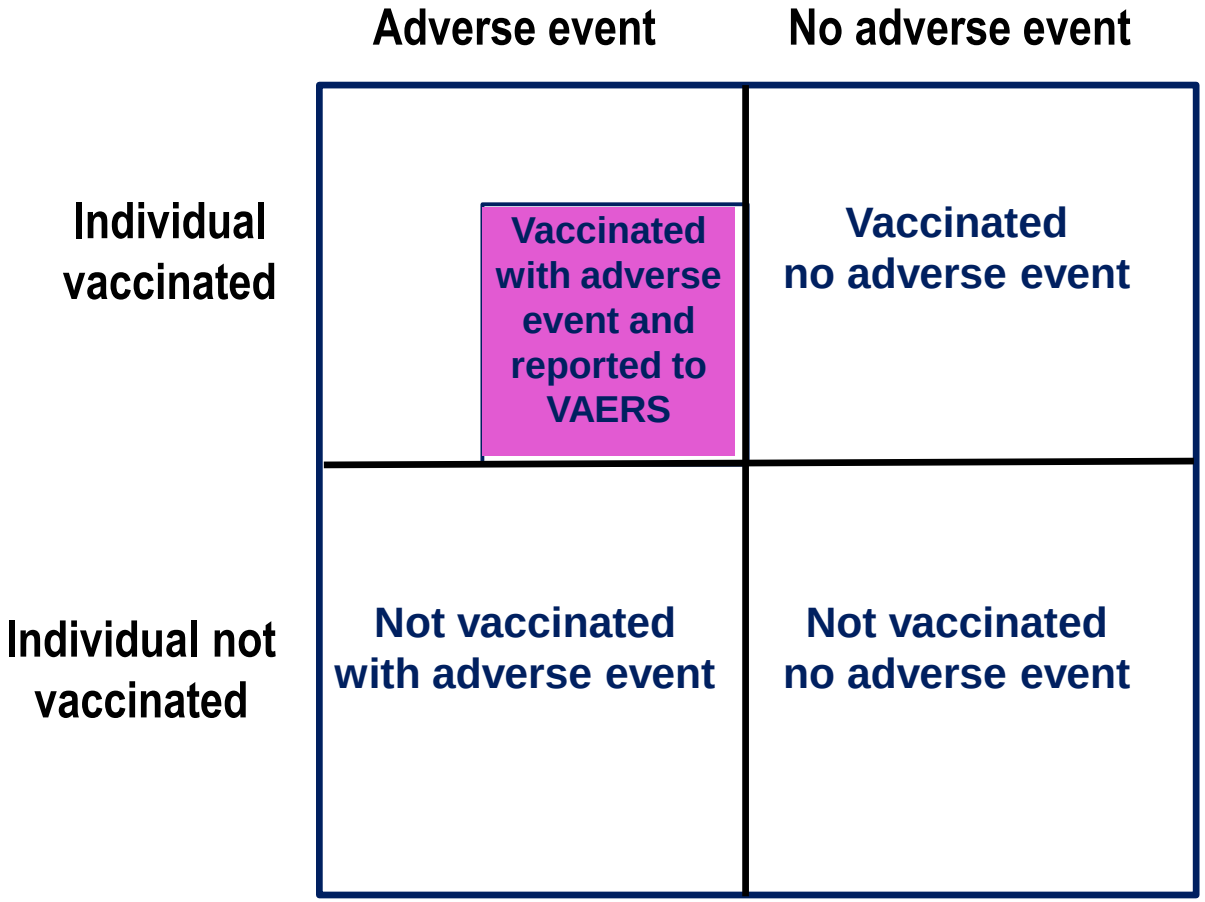
key strengths

- Rapidly detects 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?

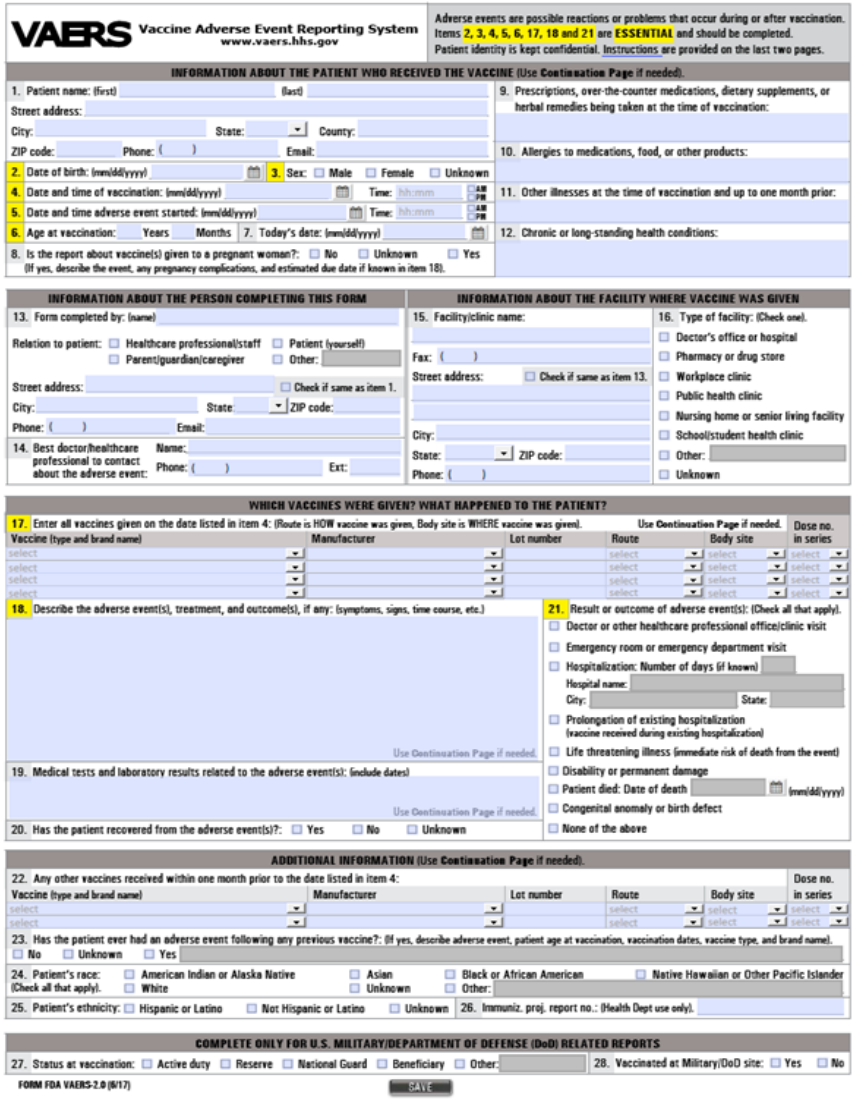
- Required reporting for healthcare providers[1]:
  - Any adverse event listed by the vaccine manufacturer as a contraindication to further doses of the vaccine
  - Any adverse event listed in the VAERS Reportable Events Table[2] following vaccination that occurs within the specified time period after vaccination

- Healthcare providers are encouraged to report any clinically significant or unexpected adverse events (AEs) following any vaccination

[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

Vaccine Adverse Event Reporting System (VAERS) and 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

Adverse events are possible reactions or problems that occur during or after vaccination. Items 2, 3, 4, 5, 6, 17, 18 and 21 are ESSENTIAL and should be completed. Patient identity is kept confidential. Instructions are provided on the last two pages.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE (Use Continuation Page if needed).

1. Patient name: (first) (last)
Street address:
City: State: County:
ZIP code: Phone: ( ) Email:
2. Date of birth: (mm/dd/yyyy) 3. Sex: Male Female Unknown
4. Date and time of vaccination: (mm/dd/yyyy) Time: hh:mm AM PM
5. Date and time adverse event started: (mm/dd/yyyy) Time: hh:mm AM PM
6. Age at vaccination: Years Months 7. Today's date: (mm/dd/yyyy)
8. Is the report about vaccine(s) given to a pregnant woman?: No Unknown Yes
(If yes, describe the event, any pregnancy complications, and estimated due date if known in item 18).
9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:
10. Allergies to medications, food, or other products:
11. Other illnesses at the time of vaccination and up to one month prior:
12. Chronic or long-standing health conditions:

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

13. Form completed by: (name)
Relation to patient: Healthcare professional/staff Patient (yourself)
Parent/guardian/caregiver Other:
Street address: Check if same as item 1.
City: State: ZIP code:
Phone: ( ) Email:
14. Best doctor/healthcare professional to contact about the adverse event: Name:
Phone: ( ) Ext:

INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN

15. Facility/clinic name:
Fax: ( )
Street address: Check if same as item 13.
City:
State: ZIP code:
Phone: ( )
16. Type of facility: (Check one).
Doctor's office or hospital
Pharmacy or drug store
Workplace clinic
Public health clinic
Nursing home or senior living facility
School/student health clinic
Other:
Unknown

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given). Use Continuation Page if needed.

Vaccine (type and brand name)	Manufacturer	Lot number	Route	Body site	Dose no. in series
select			select	select	select
select			select	select	select
select			select	select	select
select			select	select	select

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)
Use Continuation Page if needed.
19. Medical tests and laboratory results related to the adverse event(s): (include dates)
Use Continuation Page if needed.
20. Has the patient recovered from the adverse event(s)?: Yes No Unknown
21. Result or outcome of adverse event(s): (Check all that apply).
Doctor or other healthcare professional office/clinic visit
Emergency room or emergency department visit
Hospitalization: Number of days (if known)
Hospital name:
City: State:
Prolongation of existing hospitalization (vaccine received during existing hospitalization)
Life threatening illness (immediate risk of death from the event)
Disability or permanent damage
Patient died: Date of death (mm/dd/yyyy)
Congenital anomaly or birth defect
None of the above

ADDITIONAL INFORMATION (Use Continuation Page if needed).

22. Any other vaccines received within one month prior to the date listed in item 4:

Vaccine (type and brand name)	Manufacturer	Lot number	Route	Body site	Dose no. in series
select			select	select	select
select			select	select	select

23. Has the patient ever had an adverse event following any previous vaccine?: (If yes, describe adverse event, patient age at vaccination, vaccination dates, vaccine type, and brand name).
No Unknown Yes
24. Patient's race: (Check all that apply). American Indian or Alaska Native Asian Black or African American Native Hawaiian or Other Pacific Islander
White Unknown Other:
25. Patient's ethnicity: Hispanic or Latino Not Hispanic or Latino Unknown
26. Immuniz. proj. report no.: (Health Dept use only).

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at vaccination: Active duty Reserve National Guard Beneficiary Other:
28. Vaccinated at Military/DoD site: Yes No

FORM FDA VAERS-2.0 (6/17)
SAVE

VAERS (Additional Information)

- **Instructions for reporting to VAERS at**
  - 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

Answer

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

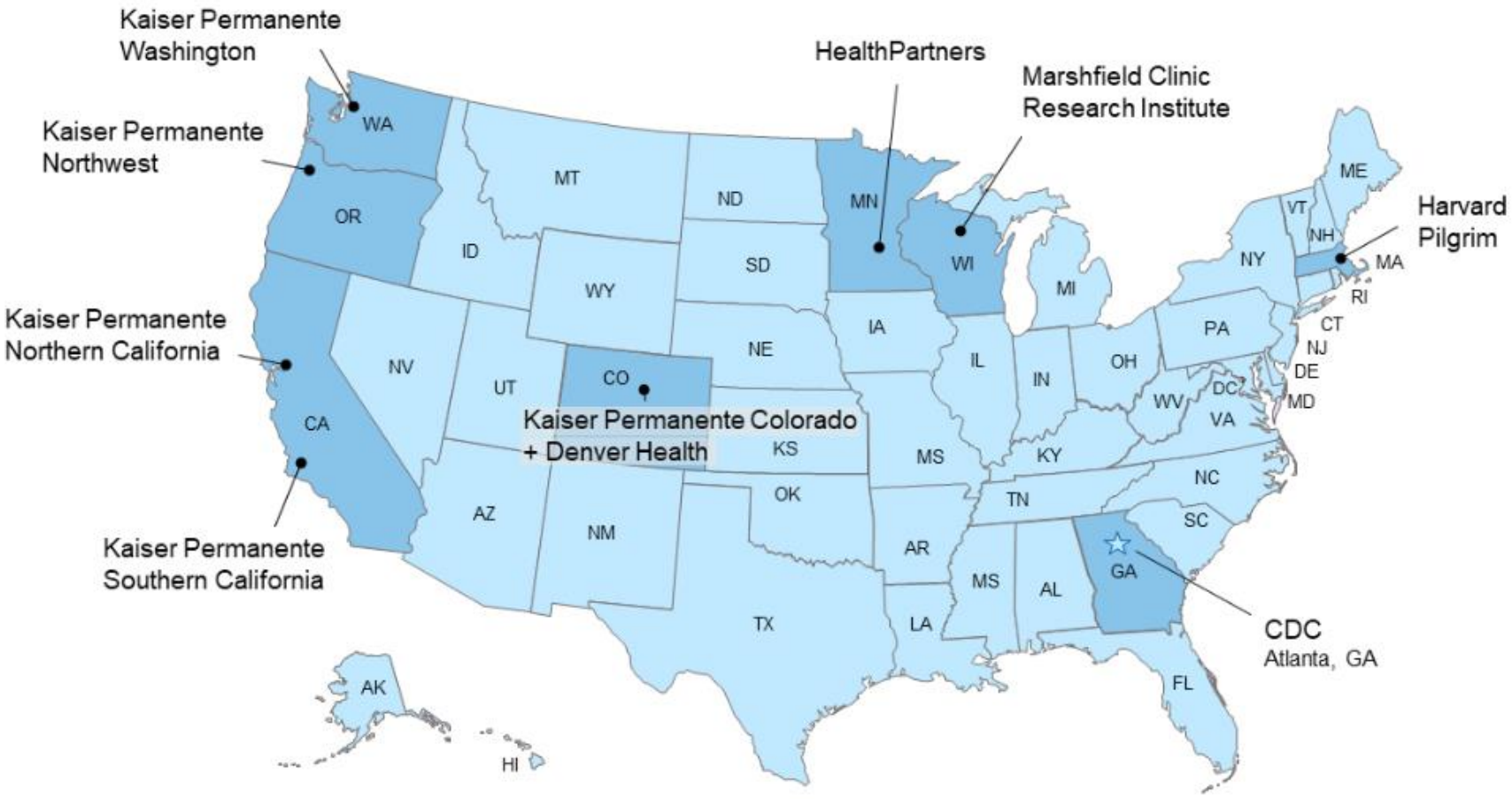
- B. False

Post-Licensure Vaccine Safety Activities

- **Phase IV trials**
  - ~10,000 participants
  - Better but still limited
- **Vaccine Safety Datalink (VSD)**
- **Clinical Immunization Safety Assessment Project (CISA)**

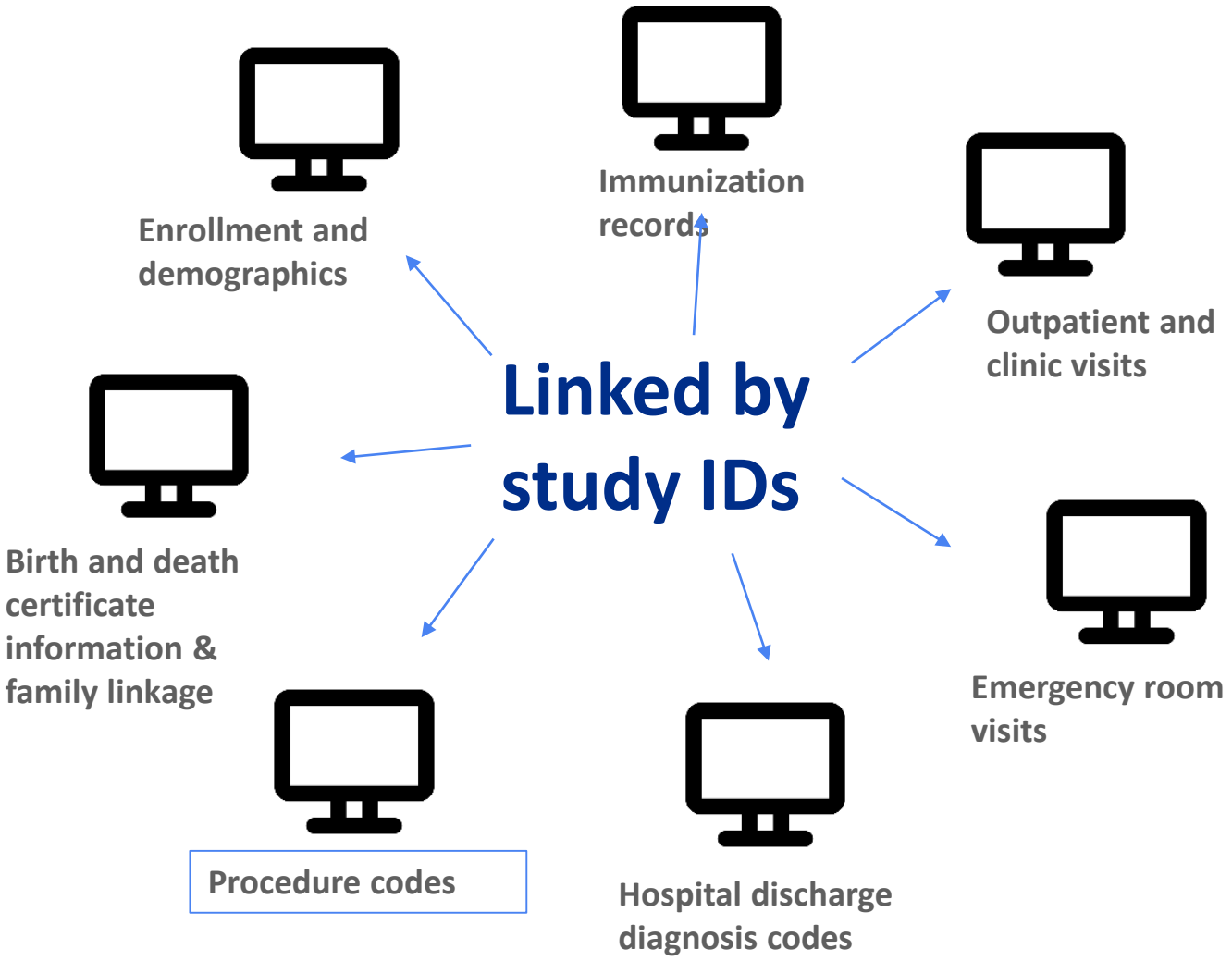
VSD

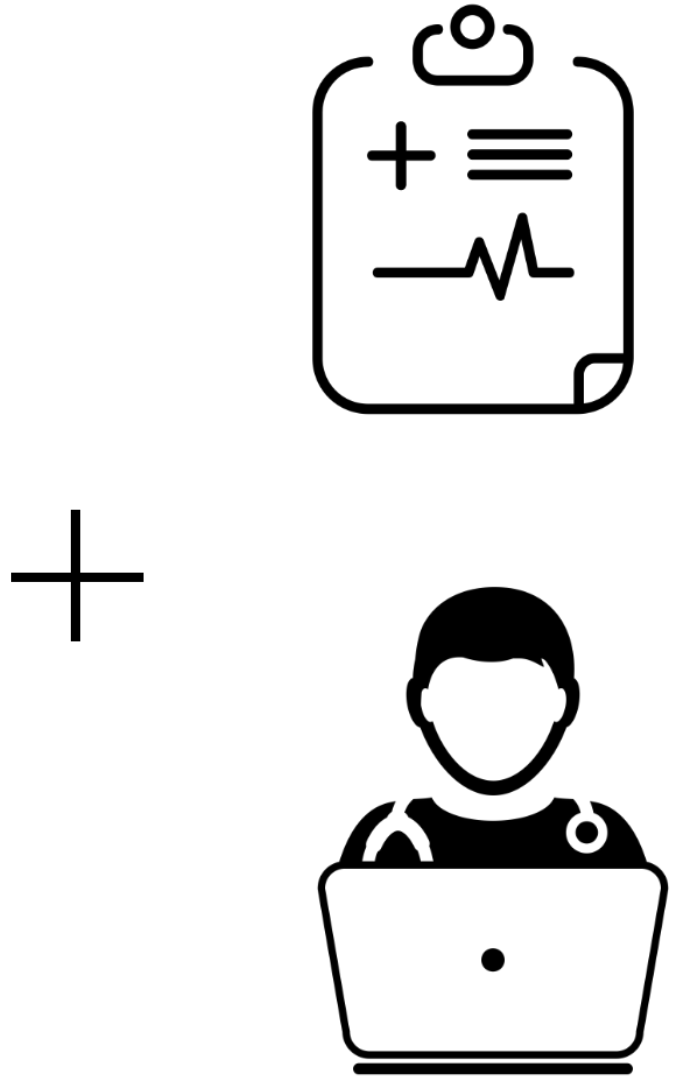
Vaccine Safety Datalink



- **9** participating integrated healthcare organizations
- Data on over **12 million** persons per year

VSD electronic files + chart review



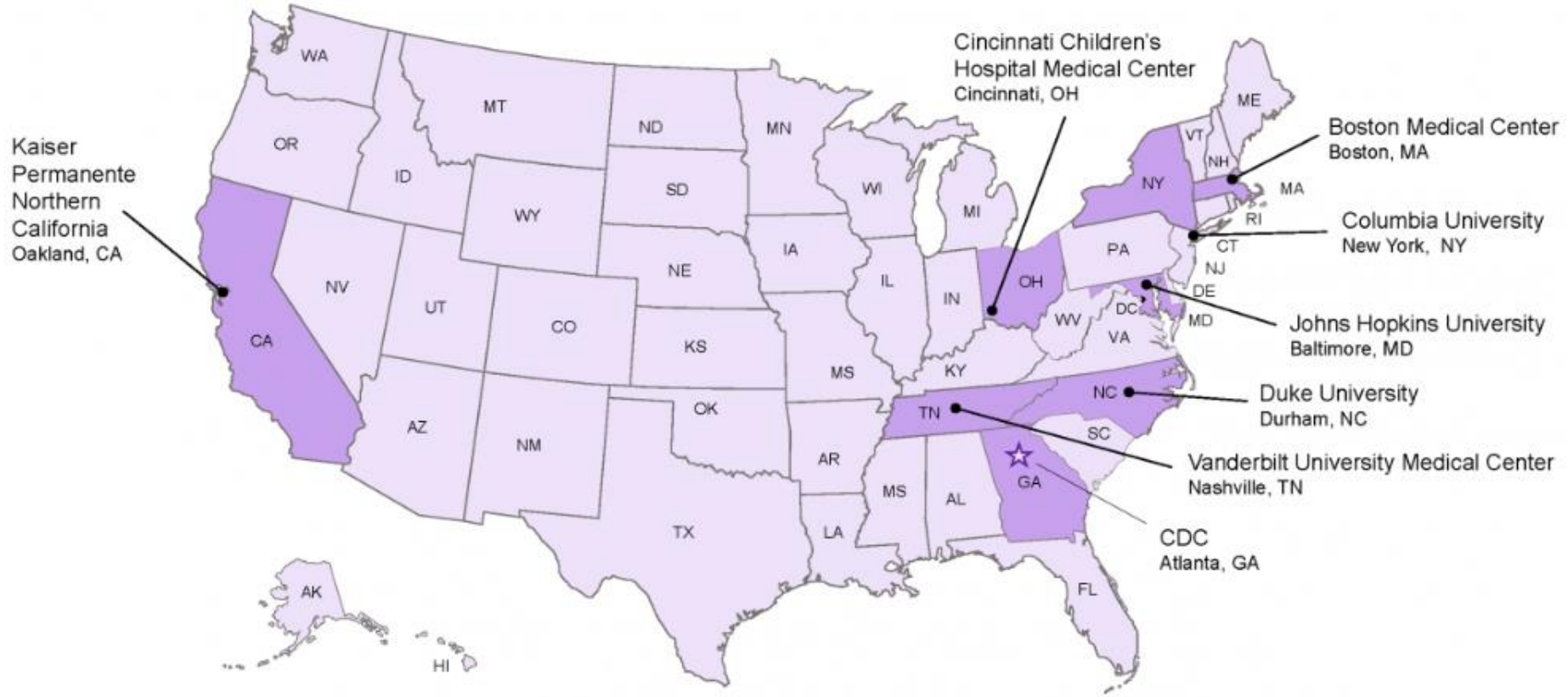


Images created by Wilson Joseph, Megan Mitchell, Ananth, and Iga from the noun project

CISA

Clinical Immunization Safety Assessment (CISA) Project

7 participating medical research centers with vaccine safety experts



- clinical consult services*

  CISAeval@cdc.gov

- clinical research

*More information about clinical consults available at http://www.cdc.gov/vaccinesafety/Activities/CISA.html

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/vaccine-compensation/vaccine-injury-table.pdf

www.hrsa.gov/vaccinecompensation/index.html

The Provider's Role

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

Benefit and Risk Communication

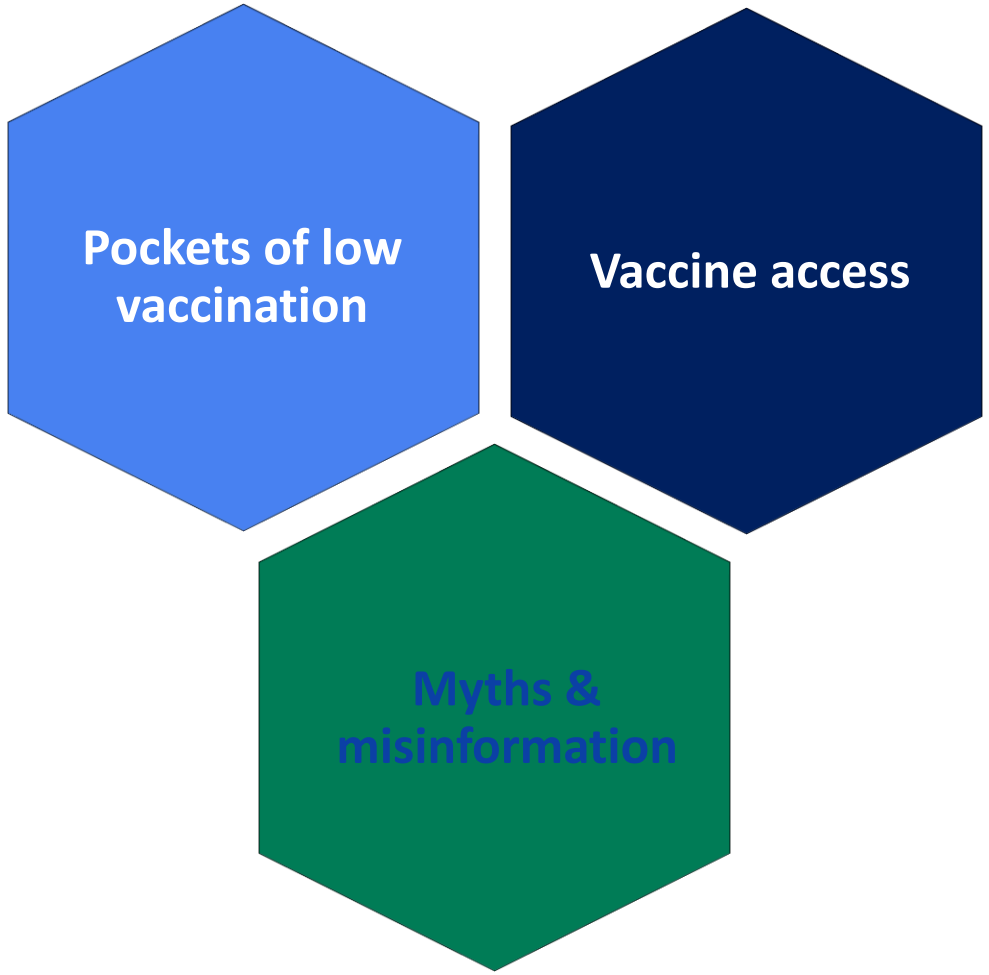
- **Opportunities for questions should be provided before each vaccination**

- **Vaccine information statements (VISs)**
  - Must be provided before each dose of vaccine
  - Public and private providers
  - CDC provides English versions at Vaccine Information Statement | Current VISs | CDC
  - Available in multiple languages at Vaccine Information Statements - VISs - CDC information sheets for patients (immunize.org)

4

Vaccinate with Confidence

Vaccinate with Confidence: Responding to dynamics shared by recent outbreaks



Vaccinate with Confidence

Protect communities. Empower families. Stop myths.

Vaccinate with Confidence is CDC's strategic framework for strengthening vaccine confidence and preventing outbreaks of vaccine-preventable diseases in the United States

Vaccinate with **Confidence**

Protect communities. Empower families. Stop myths.

- ***Protect communities***
  - Use every tool available to find and protect communities at risk using tailored, targeted approaches.
- ***Empower families***
  - Ensure parents are confident in decision to vaccinate by strengthening provider-parent vaccine conversations.
- ***Stop myths***
  - Use local partners and trusted messengers, establish new partnerships to contain the spread of misinformation, and educate critical stakeholders about vaccines.

Continuing Education Information

- **CE credit, go to**: https://tceols.cdc.gov/
- **Search course number: WD4564-071922**
- **CE credit expires: July 1, 2024**
- **CE instructions are available on the Pink Book Web-on-Demand Series web page**
- **Questions and additional help with the online CE system, e-mail** CE@cdc.gov

E-mail Your Immunization Questions to Us

- NIPINFO@cdc.gov

Thank You From Atlanta!