General Best Practice Guidelines
Part Two

June 19, 2019

Chapter 2, Page 9

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

- A chapter in the Pink Book
  - Timing and spacing
  - Contraindications and precautions

General Recommendations

- A chapter in the Pink Book
  - Timing and spacing
  - Contraindications and precautions
    - Screening

1

Screening

Screening

- Specific questions intended to identify contraindications or precautions to vaccination
- Screening must occur at every immunization encounter (not just before the first dose)
- Use of a standardized form will facilitate effective screening
- 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, 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 health problem with asthma, lung disease, heart disease, kidney disease, metabolic disease (such as diabetes), or a blood disorder?

Screening Questions

- Does the child have cancer, leukemia, AIDS, or any other immune system problem?

- Has the child taken cortisone, 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?

Patient name: _____ Date of birth: ___/___/___ (mo.) (day) (yr.)

Screening Questionnaire for Child and Teen Immunization

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. 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 between the ages of 2 and 4 years, has a healthcare provider told you that the child had wheezing or asthma in the past 12 months?	☐	☐	☐
6. Has the child, a sibling, or a parent had a seizure; has the child had brain or other nervous system problems?	☐	☐	☐
7. Does the child have cancer, leukemia, AIDS, or any other immune system problem?	☐	☐	☐
8. In the past 3 months, has the child taken cortisone, prednisone, other steroids, or anticancer drugs, or had radiation treatments?	☐	☐	☐
9. 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?	☐	☐	☐
10. Is the child/teen pregnant or is there a chance she could become pregnant during the next month?	☐	☐	☐
11. Has the child received vaccinations in the past 4 weeks?	☐	☐	☐

Form completed by: _____ Date: _____

Form reviewed by: _____ Date: _____

Did you bring your child's 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 a personal record, ask the child's healthcare provider to give you one with all your child's vaccinations on it. Keep this record in a safe place and bring it with you every time you seek medical care for your child. Your child will need this important document for the rest of his or her life to enter day care or school, for employment, or for international travel.

Developed and reviewed by the Centers for Disease Control and Prevention, October 2010
www.immunize.org/catg.d/p4060.pdf • Item #P4060 (10/10)

Information for Health Professionals about the Screening Questionnaire for Child & Teen Immunization

Are you interested in knowing why we included a certain question on the Screening Questionnaire? If so, read the information below. If you want to find out even more, consult the references listed at the bottom of this page.

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

There is no evidence that acute illness reduces vaccine efficacy or increases vaccine adverse events (1, 2). 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]

History of anaphylactic reaction (such as hives [urticaria], wheezing or difficulty breathing, or circulatory collapse or shock [not fainting]) to a vaccine component or latex is a contraindication to some vaccines. For example, if a person experiences anaphylaxis after eating eggs, do not administer influenza vaccine, or if a person has anaphylaxis after eating gelatin, do not administer measles-mumps-rubella (MMR), MMR-Varicella (MMRV), or varicella (VAR) vaccine. A local reaction is not a contraindication. For a table of vaccines supplied in vials or syringes that contain latex, go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/latex-table.pdf. For an extensive table of vaccine components, see reference 3.

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 (1). History of encephalopathy within 7 days following DTP/DTaP is a contraindication for further doses of pertussis-containing vaccine. Precautions to DTaP (not Tdap) include the following: (a) seizure within 3 days of a dose, (b) pale or limp episode or collapse within 48 hours of a dose, (c) continuous crying for 3 or more hours within 48 hours of a dose, and (d) fever of 105°F (40°C) within 48 hours of a previous dose. 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. 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? [LAIV]

Children with any of the health conditions listed above should not be given the intranasal, live attenuated influenza vaccine (LAIV). These children should be vaccinated with the injectable influenza vaccine.

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

Children who have had a wheezing episode within the past 12 months should not be given the live attenuated influenza vaccine. Instead, these children should be given the inactivated influenza vaccine.

6. Has the child, a sibling, or a parent had a seizure; has the child had brain or other nervous system problems? [DTaP, Td, Tdap, TIV, LAIV, MMR] 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, and a progressive neurologic disorder in a teen is a precaution to the use of Td. 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 age-appropriate Tdap instead of Td if no history of prior Tdap; 2) Influenza vaccine (TIV or LAIV): if GBS has occurred within 6 weeks of a prior influenza vaccination, vaccinate with TIV if at high risk for severe influenza complications.

7. Does the child have cancer, leukemia, AIDS, or any other immune system problem? [LAIV, MMR, MMRV, TIV, VAR]

Live virus vaccines (e.g., MMR, MMRV, varicella, rotavirus, and the intranasal live, attenuated influenza vaccine [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, varicella vaccine should be considered for HIV-infected children with age-specific CD4+ T-lymphocyte percentage at 15% or greater and may be considered for children age 8 years and older with CD4+ T-lymphocyte counts of greater than or equal to 200 cells/μL. 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 rotavirus (RV) vaccine. For details, consult the ACIP recommendations (4, 5, 6).

8. In the past 3 months, has the child taken cortisone, prednisone, other steroids, or anticancer drugs, or had radiation treatments? [LAIV, MMR, MMRV, VAR]

Live virus vaccines (e.g., MMR, MMRV, varicella, LAIV) 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 (1). To find specific vaccination schedules for stem cell transplant (bone marrow transplant) patients, see reference 7. LAIV can be given only to healthy non-pregnant individuals age 2–49 years.

9. 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? [LAIV, MMR, MMRV, VAR]

Certain live virus vaccines (e.g., LAIV, MMR, MMRV, varicella) may need to be deferred, depending on several variables. Consult the most current ACIP recommendations or the current *Red Book* for the most current information on intervals between antiviral drugs, immune globulin or blood product administration and live virus vaccines (1, 2).

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

Live virus vaccines (e.g., MMR, MMRV, varicella, LAIV) are contraindicated one month before and during pregnancy because of the theoretical risk of virus transmission to the fetus (1, 6). 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 (5, 8). On theoretical grounds, inactivated poliovirus vaccine should not be given during pregnancy; however, it may be given if risk of disease is imminent (e.g., travel to endemic areas) and immediate protection is needed. Use of Td or Tdap is not contraindicated in pregnancy. At the provider's discretion, either vaccine may be administered during the 2nd or 3rd trimester (9).

11. Has the child received vaccinations in the past 4 weeks?

[LAIV, MMR, MMRV, IIV, yellow fever]

If the child was given either live, attenuated influenza vaccine (LAIV) or an injectable live virus vaccine (e.g., MMR, MMRV, varicella, yellow fever) in the past 4 weeks, they should wait 28 days before receiving another vaccination of this type. Inactivated vaccines may be given at the same time or at any spacing interval.

References

1. CDC. General recommendations on immunization, at www.cdc.gov/mmwr/pdf/rr/rr6002.pdf
2. AAP. *Red Book: Report of the Committee on Infectious Diseases*, at www.aapredbook.org
3. Table of Vaccine Components: www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf
4. CDC. Measles, mumps, and rubella—vaccine use and strategies for elimination of measles, rubella, and congenital rubella syndrome and control of mumps. *MMWR* 1998; 47 (RR-8).
5. CDC. Prevention of varicella: Recommendations of the Advisory Committee on Immunization Practices. *MMWR* 2007; 56 (RR-4).
6. CDC. Prevention and Control of Influenza—Recommendations of ACIP, at www.cdc.gov/flu/professionals/acip.htm
7. CDC. Updated Interim Guidelines for preventing opportunistic infections among hematopoietic stem cell transplant recipients. *MMWR* 2000; 49 (RR-10), www.cdc.gov/mmwr/pdf/rr/rr4910.pdf
8. CDC. Notice to readers: Revised ACIP recommendation for avoiding pregnancy after receiving a rubella-containing vaccine. *MMWR* 2001; 50 (47).
9. CDC. Prevention of pertussis, tetanus, and diphtheria among pregnant and postpartum women and their infants: Recommendations of the ACIP. *MMWR* 2008; 57 (RR-4).

Invalid Contraindications

- Mild illness
- Antimicrobial therapy
- Disease exposure or convalescence
- Pregnant or immunosuppressed person in the household
- Breastfeeding
- Preterm birth
- Allergy to products not present in vaccine or allergy that is not severe (e.g., anaphylactic)
- Family history of adverse events
- Tuberculin skin testing
- Multiple vaccines

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 and varicella vaccines
  - SHOULD receive either nonlive influenza vaccine or LAIV
  - SHOULD receive zoster and rotavirus vaccines if eligible

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 generally NOT a contraindication

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

- Family history of a condition can also be a contraindication/precaution
  - Example: Family history of immunosuppression requires screening to assure the condition is not inherited prior to receipt of MMR and varicella vaccine

What Do You Think?

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

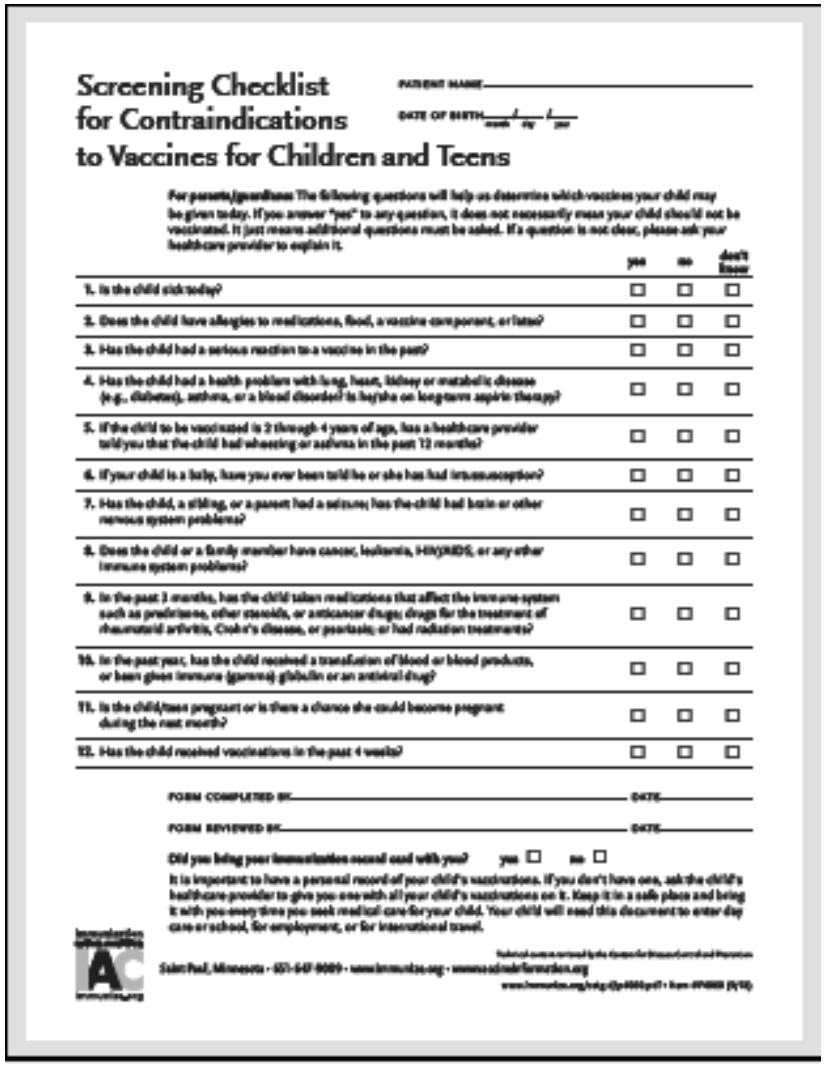
a. True

b. False

2

Resources

Screening Checklist



Screening Checklist for Contraindications to Vaccines for Children and Teens

PATIENT NAME

DATE OF BIRTH

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. 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.

Immunization Action Coalition

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

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.

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)

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

Appendix A24: Interval Between Antibody-Containing Products and Measles- and Varicella-Containing Vaccines

Recommended intervals between administration of **immune globulin preparations** and **measles-** or **varicella-containing vaccine**

Product / Indication	Dose, including mg immunoglobulin G (IgG)/kg body weight	Recommended interval before measles or varicella-containing[1] vaccine administration
Blood transfusion		
- Red blood cells (RBCs), washed	10 mL/kg (negligible IgG/kg) IV	None
- RBCs, adenine-saline added	10 mL/kg (10 mg IgG/kg) IV	3 months
- Packed RBCs (hematocrit 65%)[2]	10 mL/kg (60 mg IgG/kg) IV	6 months
- Whole blood (hematocrit 35%-50%)[2]	10 mL/kg (60-100 mg IgG/kg) IV	6 months
- Plasma/platelet products	10 mL/kg (160 mg IgG/kg) IV	7 months
Botulinum Immune Globulin Intravenous (Human)	1.5 mL/kg (75 mg IgG/kg) IV	6 months
Cytomegalovirus IGIV	150 mg/kg maximum	6 months
Hepatitis A IG		
- Contact prophylaxis	0.02 mL/kg (3.3 mg IgG/kg) IM	3 months
- International travel	0.06 mL/kg (10 mg IgG/kg) IM	3 months
Hepatitis B IG (HBIG)	0.06 mL/kg (10 mg IgG/kg) IM	3 months
IGIV		
- Replacement therapy for immune deficiencies[3]	300-400 mg/kg IV	8 months
- Immune thrombocytopenic purpura treatment	400 mg/kg IV	8 months
- Measles IG, contact prophylaxis (immunocompromised contact)	400 mg/kg IV	8 months
- Postexposure varicella prophylaxis	400 mg/kg IV	8 months
- Immune thrombocytopenic purpura treatment	1,000 mg/kg IV	10 months
Measles IG, contact prophylaxis - Standard (i.e., nonimmunocompromised) contact	0.5 mL/kg (80 mg IgG/kg) IM	6 months
Monoclonal antibody to respiratory syncytial virus F protein (Synagis™)[4]	15 mg/kg (IM)	None
Rabies IG (RIG)	20 IU/kg (22 mg IgG/kg) IM	4 months
Tetanus IG (TIG)	250 units (10 mg IgG/kg) IM	3 months
Varicella IG[5]	125 units/10 kg (60-200 mg IgG/kg) IM, maximum 625 units	5 months

This table is not intended for determining the correct indications and dosages for using antibody-containing products. Unvaccinated persons might not be fully protected against measles during the entire recommended interval, and additional doses of IG or measles vaccine might be indicated after measles exposure. Concentrations of measles antibody in an IG preparation can vary by manufacturer's lot. Rates of antibody clearance after receipt of an IG preparation also might vary. Recommended intervals are extrapolated from an estimated half-life of 30 days for passively acquired antibody and an observed interference with the immune response to measles vaccine for 5 months after a dose of 80 mg IgG/kg.

1 Does not include zoster vaccine. Zoster vaccine may be given with antibody-containing blood products.

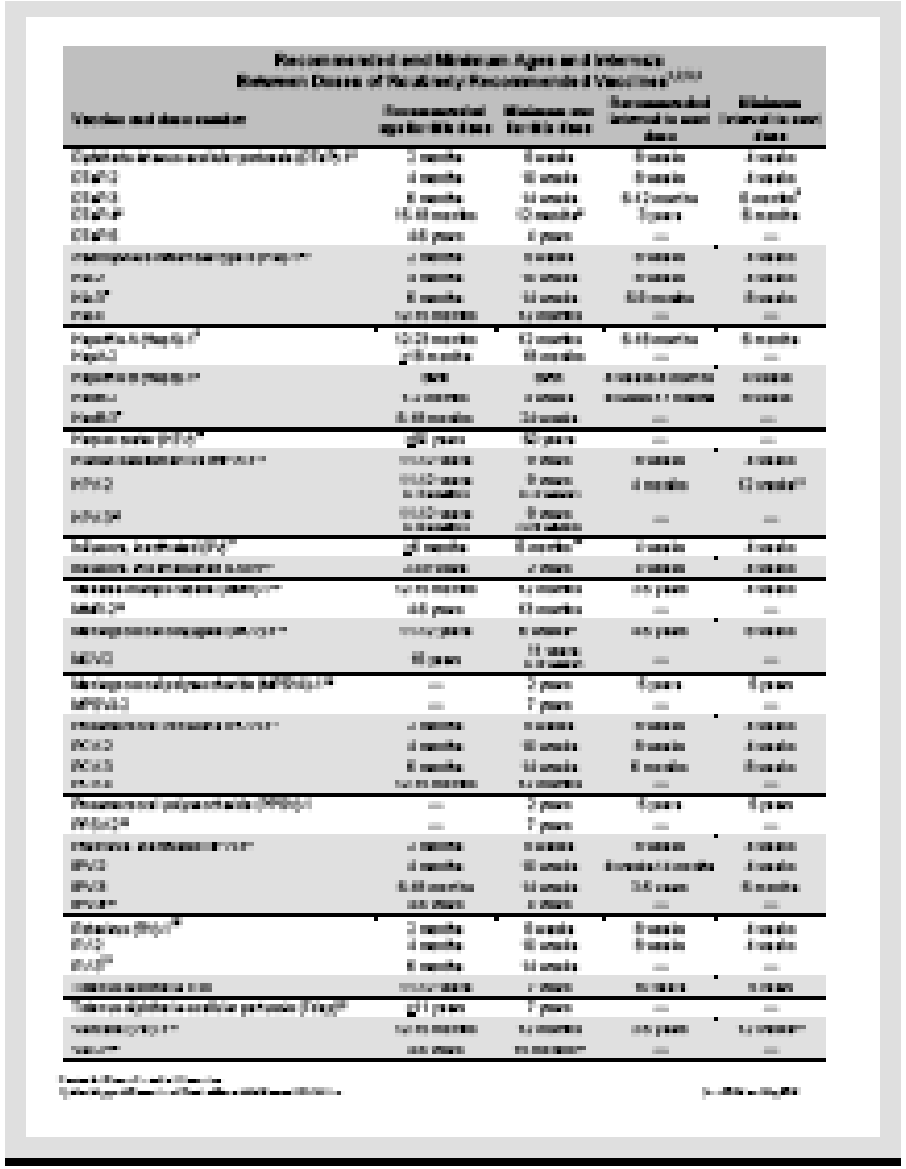
2 Assumes a serum IgG concentration of 16 mg/mL.

3 Measles vaccination is recommended for children with mild or moderate immunosuppression from human immunodeficiency virus (HIV) infection, and varicella vaccination may be considered for children with mild or moderate immunosuppression from HIV, but both are contraindicated for persons with severe immunosuppression from HIV or any other immunosuppressive disorder.

4 Contains antibody only to respiratory syncytial virus.

5 Licensed VariZIG is a purified human IG preparation made from plasma containing high levels of anti-varicella antibodies (IgG).

Adapted from Table 5, ACIP General Recommendations on Immunization — June 2014



Included in Pink Book Appendix A-13

https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/a/age-interval-table.pdf

Recommended and Minimum Ages and Intervals Between Doses of Routinely Recommended Vaccines[1,2,3,4]				
Vaccine and dose number	**Recommended age for this dose**	**Minimum age for this dose**	**Recommended interval to next dose**	**Minimum interval to next dose**
Diphtheria-tetanus-acellular pertussis (DTaP)-1[5]	2 months	6 weeks	8 weeks	4 weeks
DTaP-2	4 months	10 weeks	8 weeks	4 weeks
DTaP-3	6 months	14 weeks	6-12 months	6 months[6]
DTaP-4[6]	15-18 months	12 months[6]	3 years	6 months
DTaP-5	4-6 years	4 years	—	—
Haemophilus influenzae type b (Hib)-1[5,7]	2 months	6 weeks	8 weeks	4 weeks
Hib-2	4 months	10 weeks	8 weeks	4 weeks
Hib-3[8]	6 months	14 weeks	6-9 months	8 weeks
Hib-4	12-15 months	12 months	—	—
Hepatitis A (HepA)-1[5]	12-23 months	12 months	6-18 months	6 months
HepA-2	≥18 months	18 months	—	—
Hepatitis B (HepB)-1[5]	Birth	Birth	4 weeks-4 months	4 weeks
HepB-2	1-2 months	4 weeks	8 weeks-17 months	8 weeks
HepB-3[9]	6-18 months	24 weeks	—	—

Included in Pink Book Appendix A-13

https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/a/age-interval-table.pdf

Vaccine Safety

Chapter 4

June 19, 2019

1

Background

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

Disease	20th Century Annual Morbidity†	2017 Reported Cases ††	Percent Decrease
Smallpox	29,005	0	100%
Diphtheria	21,053	0	100%
Measles	530,217	122	> 99%
Mumps	162,344	5,629	97%
Pertussis	200,752	15,808	92%
Polio (paralytic)	16,316	0	100%
Rubella	47,745	9	> 99%
Congenital Rubella Syndrome	152	2	99%
Tetanus	580	31	95%
Haemophilus influenzae	20,000	22*	> 99%

† JAMA. 2007;298(18):2155-2163

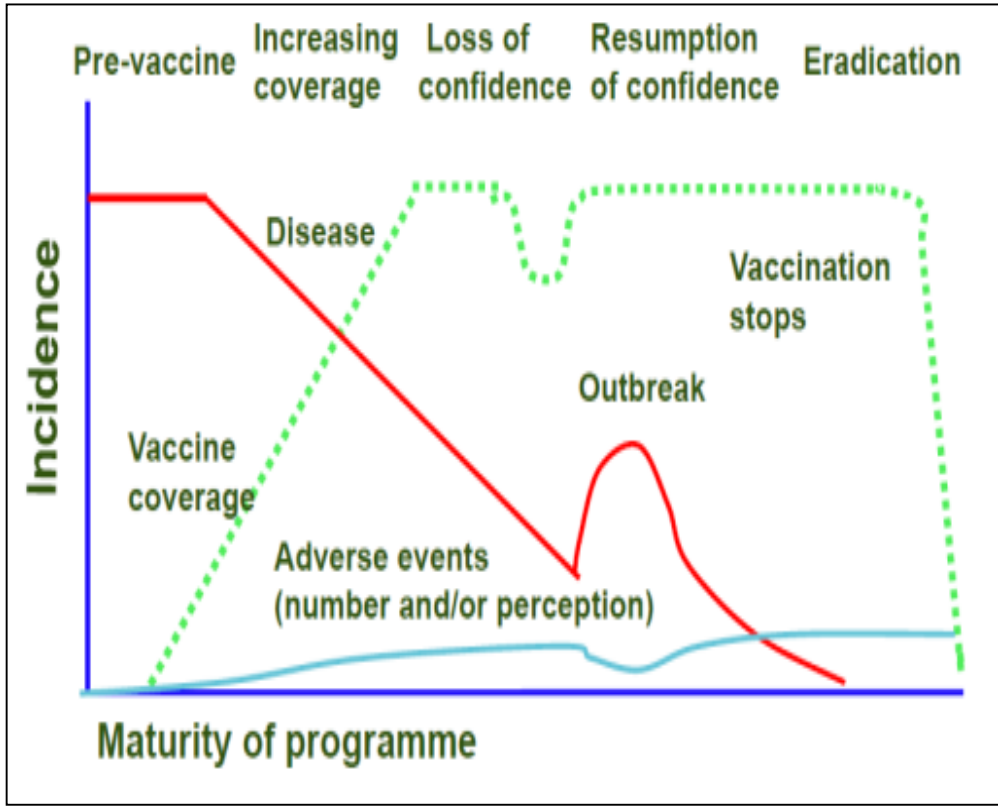
†† CDC. *National Notifiable Diseases Surveillance System, Week 52, 2017 Weekly Tables of Infectious Disease Data*. Atlanta, GA. CDC Division of Health Informatics and Surveillance, 2018. Available at: www.cdc.gov/nndss/infectious-tables.html. Accessed on January 4, 2018.

* *Haemophilus influenzae* type b (Hib) < 5 years of age. An additional 11 cases of Hib are estimated to have occurred among the 237 notifications of Hi (< 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
  - Vaccinees 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?

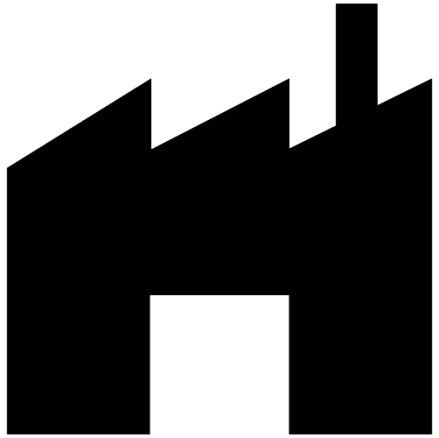
  No vaccine is 100% effective

- Remind parents that to do nothing is to take a risk

Prelicensure Vaccine Safety Studies

- Laboratory
- Animals
- Humans

Prelicensure Human Studies



- Phase I, II, III trials
- Phase III trials usually include a control group that receives a placebo
- Common 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

Postlicensure Surveillance

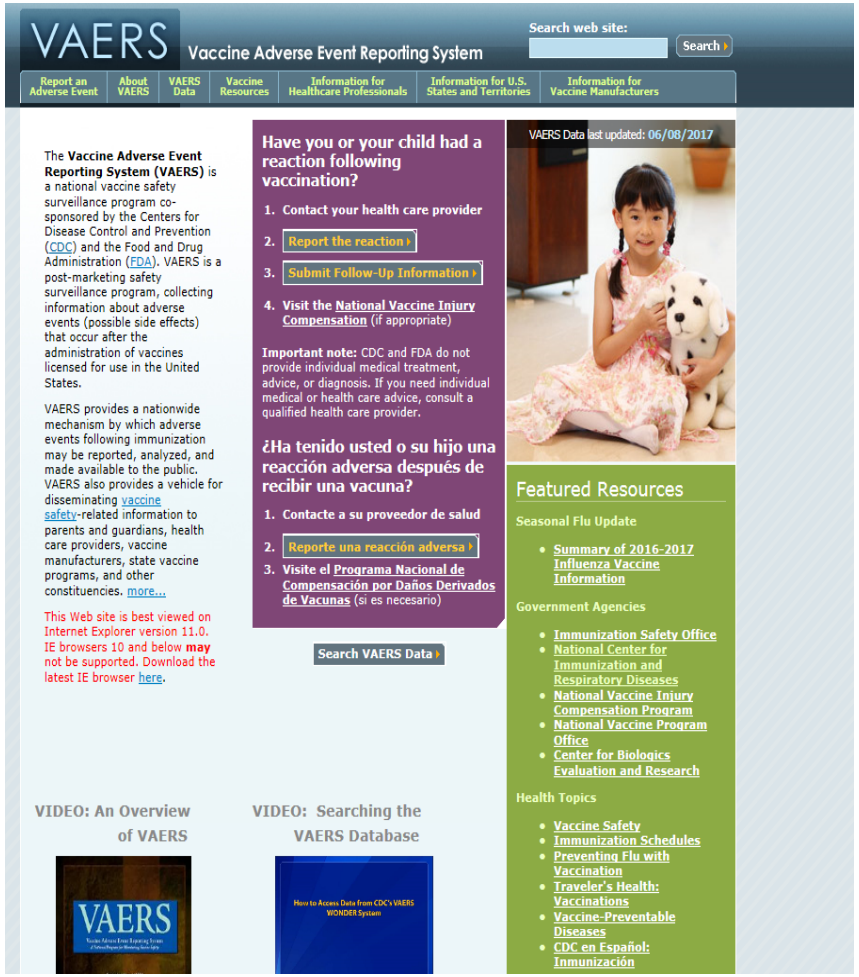
- Identify rare reactions
- Monitor increases in known reactions - identify risk factors for reactions
- Identify vaccine lots with increased rates of reactions
- Identify “signals”–reports of adverse events more numerous than would be expected

2

Federal Vaccine Safety Monitoring

Vaccine Adverse Event Reporting System (VAERS)

- Jointly administered by CDC and FDA
- National reporting system
- Receives ~30,000 reports per year
- Passive–depends on health care providers and others to report



https://vaers.hhs.gov/index

Vaccine Adverse Event Reporting System (VAERS)

- Detects:
  - New or rare events
  - Increases in rates of known events
  - Patient risk factors

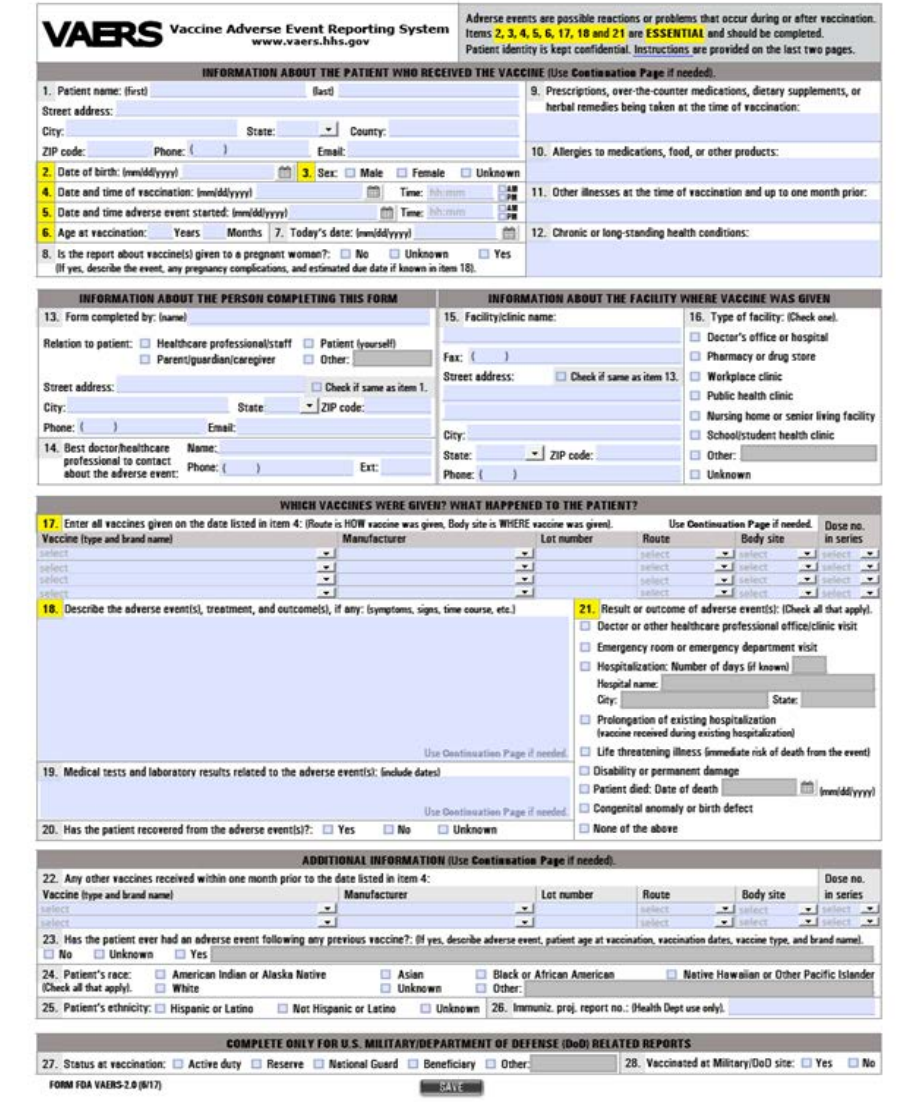
- VAERS cannot establish causality
  - Additional studies required to confirm VAERS signals and causality

- Not all reports of adverse events are causally related to vaccine

- Reportable Events Table (Pink Book Appendix D-2)

Vaccine Adverse Event Reporting System (VAERS) and VAERS reporting form

- VAERS
  - National spontaneous reporting system for monitoring the safety of U.S.-licensed vaccines
  - Co-managed by CDC and FDA
  - Accepts reports from anyone (providers, patients, etc.)
- 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

Post hoc ergo propter hoc

“After this therefore because of this”

- Temporal association does not prove causation

- Just because one event follows another does not mean that the first caused the second
- Causation requires knowledge of
  - Correct diagnosis of event
  - Clinical and/or laboratory evidence
  - Known causal association between event and vaccine
  - Any evidence against a causal association?
  - Specific laboratory test supporting vaccine role

Elements Needed To Assess Correlation of Vaccine Adverse Events

	Disease	No disease
Vaccine	a	b
No vaccine	c	d

$$\frac{\text{Rate in “vaccine” group}}{\text{Rate in “no vaccine” group}} = \frac{a\ /a + b}{c/\ c + d}$$

If the rate in “vaccine” group is higher than the rate in the “no vaccine” group, then vaccines may be the cause

Risk of Autism Spectrum Disorder (ASD) Among Children in Denmark, 1991-1998

	ASD	No ASD
Vaccine	345	440,310
No vaccine	77	96,571

$$\frac{\text{Risk in “vaccine” group}}{\text{Risk in “no vaccine” group}} = \frac{7.83/10{,}000}{7.96/10{,}000}$$

Relative Risk = 0.98

Madsen et al. *N Eng J Med* 2002;347:1477-82

Postlicensure Vaccine Safety Activities

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

Vaccine Safety Datalink

- Vaccine Safety Datalink:
  - Large linked databases
  - Connects vaccination and health records
  - Partnership with large health plans: population under “active surveillance”
    - 9 HMOs
    - >3% (~12 million) of U.S. population
- Plans, executes immunization safety studies
- Investigates hypotheses from medical literature, VAERS reports, changes in schedules, introduction of new vaccines

- Improve understanding of vaccine safety issues at individual level
- Evaluate individual cases with adverse health events
- Develop strategies to assess individuals
- Conduct studies to identify risk factors

Vaccine Injury Compensation Program

- Established by National Childhood Vaccine Injury Act (1986)
- “No fault” program
- Covers all routinely recommended childhood vaccines
- Vaccine Injury Table (Appendix D-5, D-6)

Vaccine Injury Compensation Program website: 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

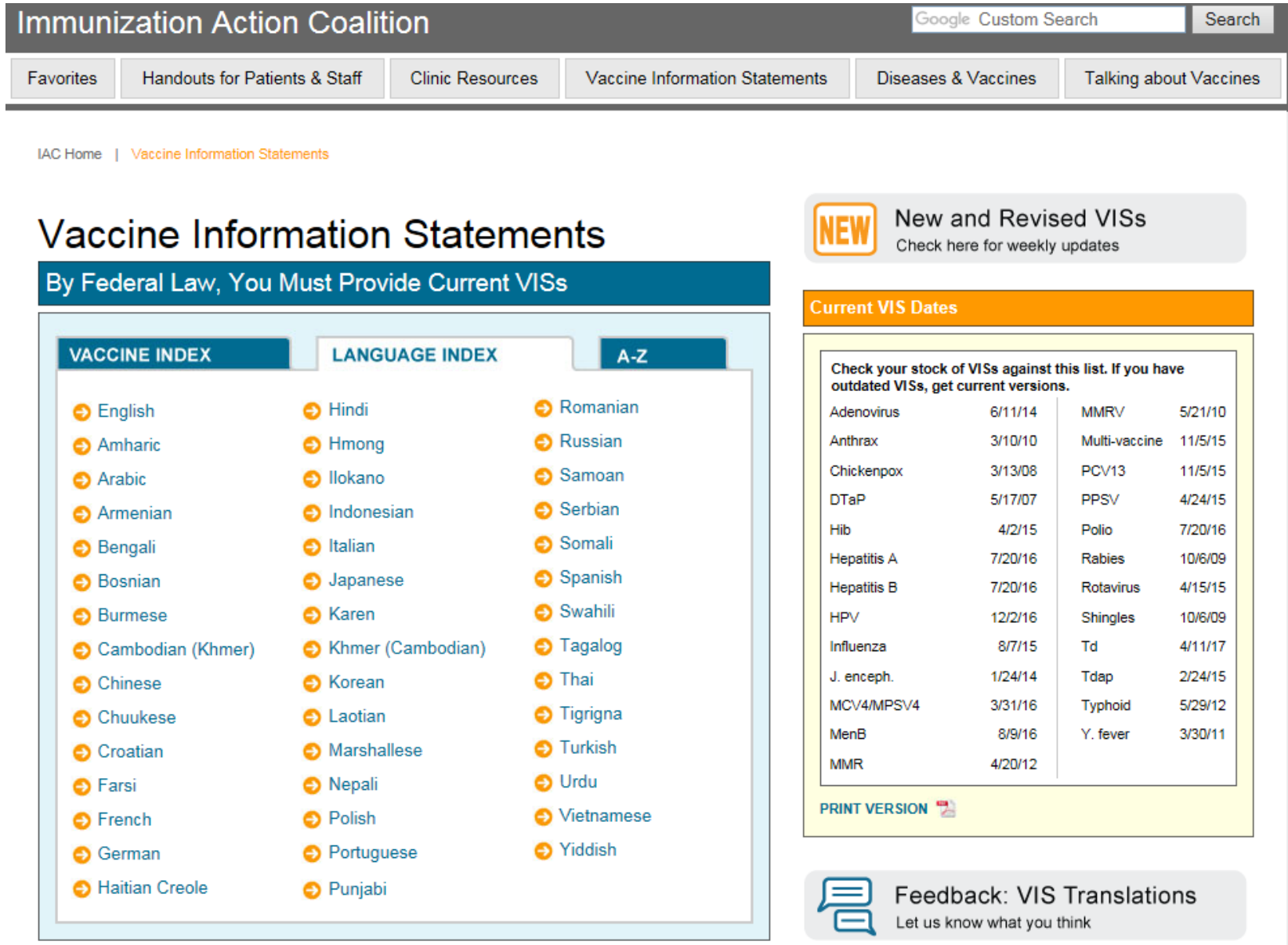
- Opportunities for questions should be provided before each vaccination

- Vaccine Information Statements (VISs)
  - Must be provided before each dose of vaccine
  - Public and private providers
  - Available in multiple languages

Communicating with Parents

- For providers:
  - If provider recommends it, parents more likely to follow
  - Ask, acknowledge, and advise
  - Start at prenatal visit, develop trust
  - Offer reliable resources
  - Know the science
  - Do not get defensive

Your Source for VISs
www.immunize.org



3

Common Concerns

Childhood Immunization Schedule and Safety - 2013

- National Academy of Medicine–Mission
  - Review scientific findings and stakeholder concerns related to the safety of the recommended childhood immunization schedule
  - Identify potential research approaches, methodologies, and study designs that could inform this question
  - Issue a summary report

- Findings
  - committee finds no evidence that the schedule is unsafe
  - Following the complete childhood immunization schedule is strongly associated with reducing vaccine-preventable diseases
  - Committee calls for continued study of the immunization schedule using existing data systems

www.iom.edu/childimmunizationschedule

National Academy of Medicine, August 2011

- Committee findings:
  - CAUSAL RELATIONSHIP between some vaccines and adverse events
    - MMR, VZV, Influenza, etc., and anaphylaxis
  - REJECTION OF 5 RELATIONSHIPS
    - Including MMR and autism, TIV and asthma

- Overall, the committee concluded that few health problems are caused by or clearly associated with vaccines

http://nationalacademies.org/HMD/Reports/2011/Adverse-Effects-of-Vaccines-Evidence-and-Causality.aspx

Multiple Vaccines

- Early vaccination is important to prevent diseases

- Vaccines are given at a young age because infants and children are at highest risk of getting sick or dying if they get these diseases

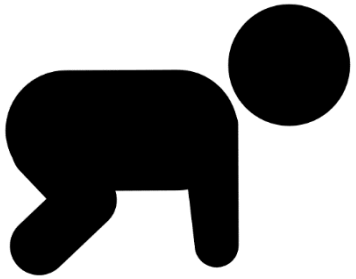
- Newborn babies have antibodies to some diseases from their mothers. BUT
  - Maternal antibodies lasts a few months–passive immunity
  - Most babies do not get protective antibodies against diphtheria, pertussis polio, tetanus, hepatitis B, or Hib from their mothers.
  - Therefor should vaccinate a child before she or he is exposed to a disease.

Antigens in Vaccines for Children, 1960-2019

Vaccine	1960	1980	2000	2019
Smallpox	~200	Not recommended		
Diphtheria	1	1	1	1
Tetanus	1	1	1	1
W cell pertussis	~3,000	~3,000	Acellular pertussis 2-5	2-5
Polio	15	15	15	15
Measles		10	10	10
Mumps		9	9	9
Rubella		5	5	5
Hib			2	2
Varicella			69	69
Pneumococcal			8	8
Hep B			1	1
Hep A				4
Rotavirus				11-16
Influenza			11	11
Total	~3,217	~3,041	134-137	149-157

Adapted from
https://www.chop.edu/centers-programs/vaccine-education-center/vaccine-safety/immune-system-and-health

Multiple Vaccines



- Babies are exposed to thousands of germs and other antigens in the environment from the time they are born
  - When a baby is born, his or her immune system is ready to respond to the many antigens in the environment and the selected antigens in vaccines
  - Vaccines contain weakened or killed versions of the germs that cause a disease
- Getting multiple vaccines at the same time has been shown to be safe
  - The recommended vaccines have been shown to be as effective in combination as they are individually
- ACIP childhood vaccination schedule ensures children get the best protection

Autism and Vaccines

- Multiple population-based studies have examined the rate of autism among vaccinated and unvaccinated children

- Available evidence does not indicate that autism is more common among children who receive MMR or thimerosal-containing vaccines than among children who do not receive vaccines

http://www.cdc.gov/vaccinesafety/Concerns/Autism/Index.html

Studies of Autism and Vaccines*

- Kaye JA, et al. Measles, mumps, and rubella vaccine and incidence of autism recorded by general practitioners: a time-trend analysis. Brit Med J 322:460-463, 2001.

- Madsen KM, et al. A population-based study of measles, mumps, and rubella vaccination and autism. N Engl J Med. 2002;347:1477-1482.

- Frambonne E, et al. Pervasive developmental disorders in Montreal, Quebec, Canada: prevalence and links with immunizations. Pediatrics 118:e139-50, 2006.

- Thompson WW, et al. Early thimerosal exposure and neuro-psychological outcomes at 7 to 10 years. N Engl J Med 2007; 357(13):1281-92.

- Schechter R, Grether JK. Continuing increases in autism reported to California's developmental services system: mercury in retrograde. Arch Gen Psychiatry 2008;65(1):19-24.

- Taylor LE, Swerdfeger AL, Eslick GD. Vaccines are not associated with autism: An evidence-based meta-analysis of case-control and cohort studies. Vaccine. 2014 June;32(29):3623–3629

*Partial listing of representative studies

Autism Speaks™ | Be Informed | Get Involved | Walk Events | Community | Science

AUTISM SPEAKS

Autism Speaks™

Science News | News Archive | CAN News Archive

SEARCH

- Overview
- Science News
- Research & Grants

An Interview with Dr. Geri Dawson, Chief Science Officer, Autism Speaks, about the Organization's Research Funding and Position on Vaccines and Autism

Donate

Store

Resources

"... given what the scientific literature tells us today, there is no evidence that thimerosal or the MMR vaccine cause autism. Evidence does not support the theory that vaccines are causing an autism epidemic."

- Dr. Geri Dawson, July 30, 2009

Geri Dawson
Chief Science Officer
Autism Speaks

What Do You Think?

The Vaccine Adverse Event Reporting System (VAERS) detects new or rare events, increases in rates of known events, and patient risk factors associated with vaccination. VAERS cannot establish causality.

a. True

b. False