



EpiVac Pink Book Web-on-Demand Series

General Best Practices Part 2, and Vaccine Safety-2020

Immunization Services Division

National Center for Immunization and Respiratory Diseases

Centers for Disease Control and Prevention

Atlanta, GA

Learning Objectives

- 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.
- Describe an emerging immunization issue.
- 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.

Today's Agenda

**EpiVac Pink Book Web-on-Demand Series:
General Best Practices Part 2, and Vaccine Safety-2020**

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General Best Practice Guidelines for Immunization, Part 2

Vaccine Safety

July 15, 2020

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
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- 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 of a severe adverse reaction
- Action: Withhold a dose of vaccine

■ 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: Weigh the risk of withholding the dose of vaccine against the risk of giving the dose of vaccine

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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? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. Does the child have allergies to medications, food, a vaccine component, or latex? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. Has the child had a serious reaction to a vaccine in the past? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 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? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 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? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. Has the child, a sibling, or a parent had a seizure; has the child had brain or other nervous system problems? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. Does the child have cancer, leukemia, AIDS, or any other immune system problem? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 8. In the past 3 months, has the child taken cortisone, prednisone, other steroids, or anticancer drugs, or had radiation treatments? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 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? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 10. Is the child/teen pregnant or is there a chance she could become pregnant during the next month? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 11. Has the child received vaccinations in the past 4 weeks? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

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.

Technical content reviewed by the Centers for Disease Control and Prevention, October 2010

www.immunize.org/faq/faq02.pdf • Item #N642 (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? [if vaccine]

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 colds, coughs, 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? [if vaccine]

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-4-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/subunit/book/downloads/appendices/6/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? [if vaccine]

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/DTPa is a contraindication for further doses of pertussis-containing vaccine. Precautions to DTPa (not Tdap) include the following: (a) seizures 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? [if vaccine]

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? [if vaccine]

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? [if vaccine]

Children who have had a seizure 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. DTPa and Tdap are contraindicated in children who have a history of encephalopathy within 7 days following DTPa/DTPa. An unstable progressive neurologic problem is a precaution to the use of DTPa and Tdap, and a progressive neurologic disorder in a twin 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, vaccine as usual (except for 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 (IV or LAIV): If GBS has occurred within 6 weeks of a prior influenza vaccination, vaccinate with IV if at high risk for severe influenza complications.

7. Does the child have cancer, leukemia, AIDS, or any other immune system problem? [if vaccine]

Use 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. Immunocompromised 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 ACP 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? [if vaccine]

Use 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 ACP 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? [if vaccine]

Certain live virus vaccines (e.g., LAIV, MMR, MMRV, varicella) may need to be deferred, depending on several variables. Consult the most current ACP 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? [if vaccine]

Use 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, 4). 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 (5).

11. Has the child received vaccinations in the past 4 weeks? [if vaccine]

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. www.cdc.gov/vaccines/imz/faq/faq01a.html.
2. ACP. Red Book Report of the Committee on Infectious Diseases. www.aapublications.org.
3. Table of Vaccine Components. www.cdc.gov/vaccines/subunit/book/downloads/appendices/6/latex-table.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 54 \(17\):4](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5417a.htm).
5. CDC. Prevention of varicella. Recommendations of the Advisory Committee on Immunization Practices. [MMWR 54 \(7\):4](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5407a.htm).
6. CDC. Prevention and Control of Influenza—Recommendations of ACP. www.cdc.gov/flu/pandemic/resources/.
7. CDC. Example from Guidelines for preventing opportunistic infections among hematopoietic stem cell transplant recipients. [MMWR 54 \(17\):12](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5417a.htm).
8. CDC. Update to routine Perinatal ACP recommendations for avoiding pregnancy after receiving a rubella-containing vaccine. [MMWR 54 \(17\):19](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5417a.htm).
9. CDC. Prevention of pertussis, tetanus, and diphtheria among pregnant and postpartum women and their infants. Recommendations of the ACP. [MMWR 54 \(17\):16](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5417a.htm).

Invalid Contraindications and Precautions

- 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, varicella, zoster, and rotavirus vaccines
 - SHOULD receive either non-live 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 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 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



Answer

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 _____/_____/_____
YEAR MONTH DAY

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 health-care provider to explain it.

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

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 health-care 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.

 Additional copies ordered by the State for the Division of Health Care Services
Saint Paul, Minnesota • 651-547-9099 • www.immunize.org • www.mnhealth.gov
www.immunize.org/help/4p-0001.pdf • form #P4060 (P/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?
Vaccinations are given to protect children from serious diseases. However, if a child is currently sick, it is best to wait until the child is well before having a vaccine. This is because a child's immune system is busy fighting off the current illness, and it may not be able to respond as well to a vaccine. If a child is sick, it is best to wait until the child is well before having a vaccine.

2. Does the child have allergies to medications, food, a vaccine component, or latex?
Allergic reactions can occur to any substance, including vaccines. However, most children do not have allergies to vaccine components. If a child has a severe allergic reaction to a vaccine component, it is best to avoid that vaccine. However, if a child has a mild allergic reaction to a vaccine component, it is usually safe to give the vaccine. However, if a child has a severe allergic reaction to a vaccine component, it is best to avoid that vaccine.

3. Has the child had a serious reaction to a vaccine in the past?
A serious allergic reaction to a vaccine is a medical emergency. If a child has had a serious allergic reaction to a vaccine, it is best to avoid that vaccine. However, if a child has had a mild allergic reaction to a vaccine, it is usually safe to give the vaccine.

4. Has the child had a health problem with lung, heart, kidney or metabolic disease (e.g., diabetes), asthma, or a blood disorder in the past or long-term aspirin therapy?
Children with certain health conditions may have a higher risk of complications from vaccines. However, most children with these conditions can safely receive vaccines. However, if a child has a severe health problem, it is best to consult with a healthcare provider before giving a vaccine.

5. If the child to be vaccinated is 2 through 4 years of age, has a health-care provider told you that the child had wheezing or asthma in the past 12 months?
Children with asthma may have a higher risk of complications from vaccines. However, most children with asthma can safely receive vaccines. However, if a child has severe asthma, it is best to consult with a healthcare provider before giving a vaccine.

6. If your child is a baby, have you ever been told he or she has had immunosuppression?
Immunosuppression is a condition in which the immune system is weakened. Children with immunosuppression may have a higher risk of complications from vaccines. However, most children with immunosuppression can safely receive vaccines. However, if a child has severe immunosuppression, it is best to consult with a healthcare provider before giving a vaccine.

7. Has the child, a sibling, or a parent had a seizure has the child had brain or other nervous system problems?
Children with seizures may have a higher risk of complications from vaccines. However, most children with seizures can safely receive vaccines. However, if a child has severe seizures, it is best to consult with a healthcare provider before giving a vaccine.

8. Does the child or a family member have cancer, leukemia, HIV/AIDS, or any other immune system problems?
Children with certain immune system problems may have a higher risk of complications from vaccines. However, most children with these conditions can safely receive vaccines. However, if a child has severe immune system problems, it is best to consult with a healthcare provider before giving a vaccine.

9. In the past 3 months, has the child taken medications that affect the immune system such as prednisone, other steroids, or a cancer drug; drugs for the treatment of rheumatoid arthritis, Crohn's disease, or psoriasis; or had radiation treatment?
Medications that affect the immune system may increase the risk of complications from vaccines. However, most children taking these medications can safely receive vaccines. However, if a child is taking high-dose steroids, it is best to consult with a healthcare provider before giving a vaccine.

10. In the past year, has the child received a transfusion of blood or blood products, or been given immune (gamma) globulin or an antitoxin drug?
Transfusions of blood or blood products, or immune globulin, may increase the risk of complications from vaccines. However, most children receiving these treatments can safely receive vaccines. However, if a child has received a transfusion of blood or blood products, or immune globulin, within the past 3 months, it is best to consult with a healthcare provider before giving a vaccine.

11. Is the child/teen pregnant or is there a chance she could become pregnant during the next month?
Vaccines are generally safe for pregnant women. However, some vaccines are not recommended for pregnant women. If a woman is pregnant or planning to become pregnant, it is best to consult with a healthcare provider before giving a vaccine.

12. Has the child received vaccinations in the past 4 weeks?
Children who have recently received a vaccine may not need another vaccine. However, if a child has not received a vaccine in the past 4 weeks, it is best to give the vaccine.

REFERENCES

1. CDC. General information guidelines for...
2. CDC. Live virus vaccines...
3. CDC. Live virus vaccines...
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5. CDC. Live virus vaccines...
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11. CDC. Live virus vaccines...
12. CDC. Live virus vaccines...

Minnesota Immunization Action Plan • Saint Paul, Minnesota • 651-547-9099 • www.immunize.org • www.mnhealth.gov
www.immunize.org/help/4p-0001.pdf • form #P4060 - page 2 (P/12)



Vaccine Safety

3

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% |
| <i>Haemophilus influenzae</i> | 20,000 | 22* | > 99% |

[†] JAMA. 2007;298(18):2155-2163

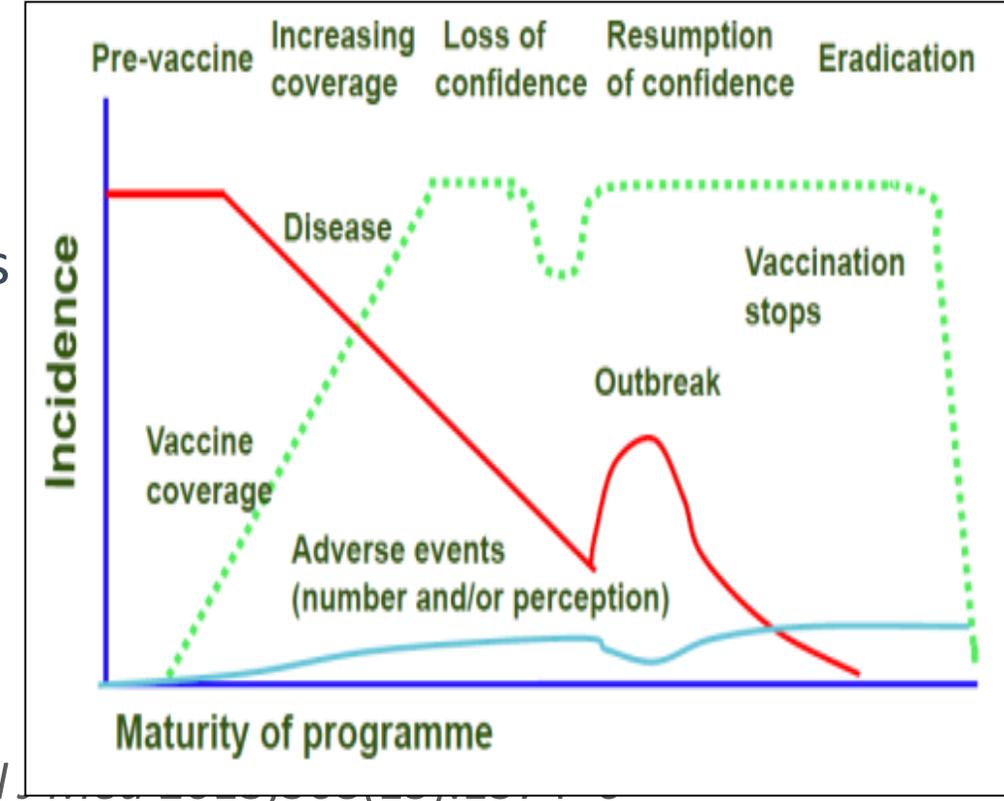
^{††} CDC. National Notifiable Diseases Surveillance System, Week 52, 2017 Weekly Tables of Infectious Disease Data. Atlanta, GA. CDC Division of Health Informatics and Surveillance, 2018. Available at: www.cdc.gov/nndss/infectious-tables.html. Accessed on January 4, 2018.

* *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*

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.

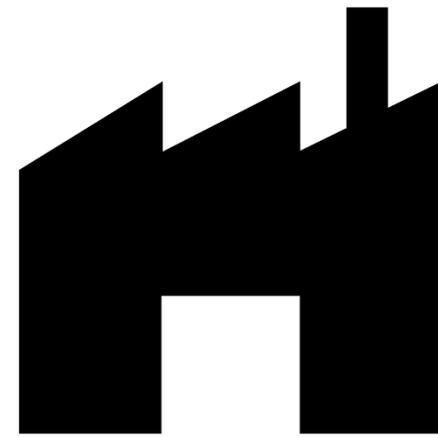
Prelicensure Vaccine Safety Studies

- 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.

4

**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

The screenshot shows the VAERS website homepage. At the top, there is a navigation bar with the VAERS logo and the text "Vaccine Adverse Event Reporting System". Below the navigation bar, there are several menu items: "Report an Adverse Event", "About VAERS", "VAERS Data", "Vaccine Resources", "Information for Healthcare Professionals", "Information for U.S. States and Territories", and "Information for Vaccine Manufacturers". A search bar is located in the top right corner.

The main content area is divided into several sections. On the left, there is a text block describing the VAERS program, its purpose, and how it works. Below this, there is a note about browser compatibility: "This Web site is best viewed on Internet Explorer version 11.0. IE browsers 10 and below may not be supported. Download the latest IE browser [here](#)."

In the center, there is a purple box with the heading "Have you or your child had a reaction following vaccination?". It contains a list of steps: 1. Contact your health care provider, 2. Report the reaction, 3. Submit Follow-Up Information, and 4. Visit the National Vaccine Injury Compensation (if appropriate). Below this list, there is an "Important note" and a link to "Report the reaction".

On the right, there is a green box with the heading "¿Ha tenido usted o su hijo una reacción adversa después de recibir una vacuna?". It contains a list of steps: 1. Contacte a su proveedor de salud, 2. Reporte una reacción adversa, and 3. Visite el Programa Nacional de Compensación por Daños Derivados de Vacunas (si es necesario). Below this list, there is a "Search VAERS Data" button.

At the bottom, there are two video thumbnails: "VIDEO: An Overview of VAERS" and "VIDEO: Searching the VAERS Database".

On the far right, there is a "Featured Resources" section with a list of links: "Seasonal Flu Update", "Summary of 2016-2017 Influenza Vaccine Information", "Government Agencies" (including Immunization Safety Office, National Center for Immunization and Respiratory Diseases, National Vaccine Injury Compensation Program, National Vaccine Program Office, and Center for Biologics Evaluation and Research), and "Health Topics" (including Vaccine Safety, Immunization Schedules, Preventing Flu with Vaccination, Traveler's Health: Vaccinations, Vaccine-Preventable Diseases, and CDC en Español: Inmunización).

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
[https://vaers.hhs.gov/docs/VAERS Table of Reportable Events Following Vaccination.pdf](https://vaers.hhs.gov/docs/VAERS%20Table%20of%20Reportable%20Events%20Following%20Vaccination.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 | 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 | 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: American Indian or Alaska Native Asian Black or African American Native Hawaiian or Other Pacific Islander
(Check all that apply). 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 (8/17) 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) 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



Answer

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



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

| | <u>Disease</u> | <u>No disease</u> |
|-------------------|----------------|-------------------|
| <u>Vaccine</u> | a | b |
| <u>No vaccine</u> | 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

| | <u>ASD</u> | <u>No ASD</u> |
|--|------------|-----------------------------------|
| <u>Vaccine</u> | 345 | 440,310 |
| <u>No vaccine</u> | 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 | | |

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
<https://www.hrsa.gov/sites/default/files/hrsa/vaccine-compensation/vaccine-injury-table.pdf>

Vaccine Injury Compensation Program website: www.hrsa.gov/vaccinecompensation/index.html



National Vaccine Injury Compensation Program

Vaccines save lives by preventing disease.

Most people who get vaccines have no serious problems. Vaccines, like any medicines, can cause side effects, but most are very rare and very mild. Some health problems that follow vaccinations are not caused by vaccines.

In very rare cases, a vaccine can cause a serious problem, such as a severe allergic reaction.

In these instances, the National Vaccine Injury Compensation Program (VICP) may provide financial compensation to individuals who file a petition and are found to have been injured by a VICP-covered vaccine. Even in cases in which such a finding is not made, petitioners may receive compensation through a settlement.

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

Your Source for VISs

www.immunize.org

Vaccine Information Statements

By Federal Law, You Must Provide Current VISs

VACCINE INDEX

- English
- Amharic
- Arabic
- Armenian
- Bengali
- Bosnian
- Burmese
- Cambodian (Khmer)
- Chinese
- Chuukese
- Croatian
- Farsi
- French
- German
- Haitian Creole

LANGUAGE INDEX

- Hindi
- Hmong
- Ilokano
- Indonesian
- Italian
- Japanese
- Karen
- Khmer (Cambodian)
- Korean
- Laotian
- Marshallese
- Nepali
- Polish
- Portuguese
- Punjabi

A-Z

- Romanian
- Russian
- Samoan
- Serbian
- Somali
- Spanish
- Swahili
- Tagalog
- Thai
- Tigrigna
- Turkish
- Urdu
- Vietnamese
- Yiddish

NEW New and Revised VISs
Check here for weekly updates

Current VIS Dates

Check your stock of VISs against this list. If you have outdated VISs, get current versions.

| | | | |
|-------------|---------|---------------|---------|
| Adenovirus | 6/11/14 | MMRV | 5/21/10 |
| Anthrax | 3/10/10 | Multi-vaccine | 11/5/15 |
| Chickenpox | 3/13/08 | PCV13 | 11/5/15 |
| DTaP | 5/17/07 | PPSV | 4/24/15 |
| Hib | 4/2/15 | Polio | 7/20/16 |
| Hepatitis A | 7/20/16 | Rabies | 10/6/09 |
| Hepatitis B | 7/20/16 | Rotavirus | 4/15/15 |
| HPV | 12/2/16 | Shingles | 10/6/09 |
| Influenza | 8/7/15 | Td | 4/11/17 |
| J. enceph. | 1/24/14 | Tdap | 2/24/15 |
| MCV4/MPSV4 | 3/31/16 | Typhoid | 5/29/12 |
| MenB | 8/9/16 | Y. fever | 3/30/11 |
| MMR | 4/20/12 | | |

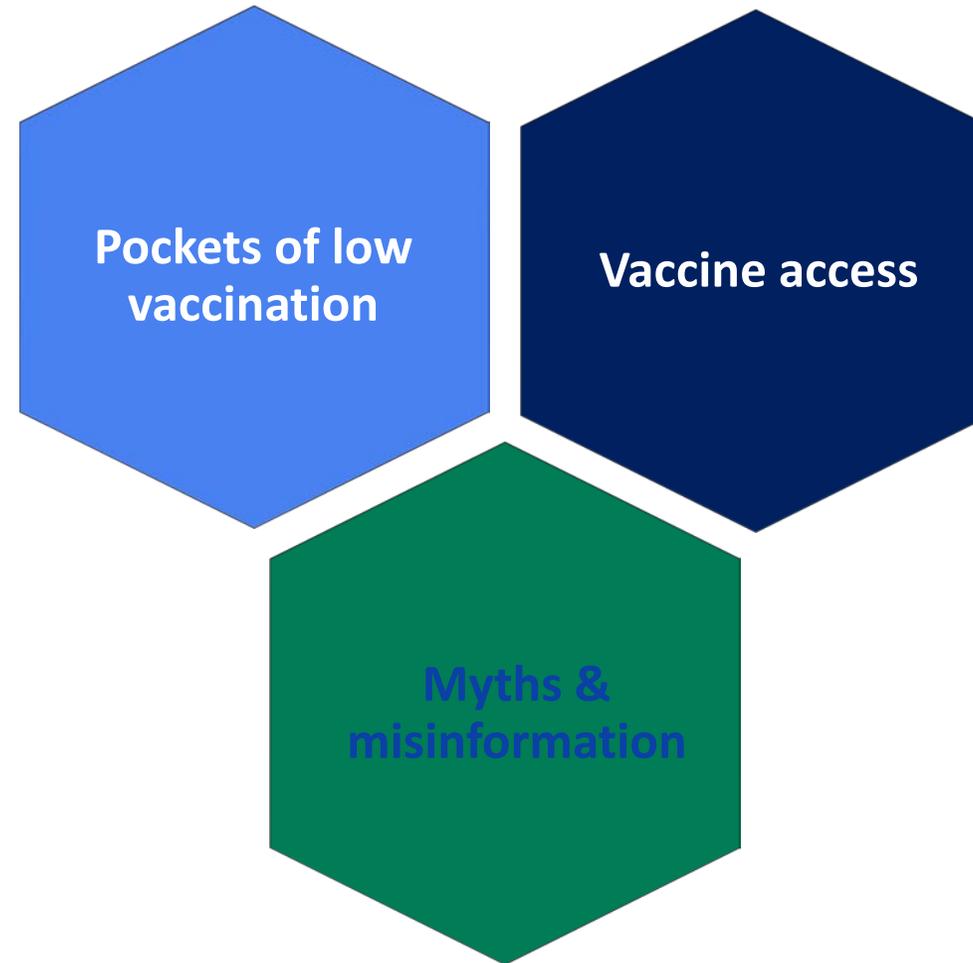
PRINT VERSION 

 Feedback: VIS Translations
Let us know what you think

5

**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.

Questions



Frequently Asked Questions

Continuing Education Information

- CE credit, go to: www.cdc.gov/GetCE
- Search course number: WD4344-071520
- CE credit expires: July 1, 2022
- CE instructions are available on the EpiVac Pink Book Web-on-Demand Series web page
- Questions and additional help with the online CE system, e-mail CE@cdc.gov

Training and Continuing Education Online (TCEO)



TRAINING AND CONTINUING EDUCATION ONLINE

- TCEO Home
- Search Courses
- Create Account
- 9 Simple Steps to Earn CE
- Frequently Asked Questions
- Contact TCEO

New to TCEO?
Visit [Create Account](#). Once your account has been created, you will be able to search for courses and complete requirements to receive CE.

Already have a TCEO account from the previous system?
To move your account to the new system please sign in above using your existing TCEO username and password. Once signed in, follow the prompts to verify and update your account. After your account is updated forward you will use this email address and password to sign in.

Not sure how to get started?
Follow these [9 Simple Steps](#) to earn continuing education for the courses you have taken or conferences you have attended!



Welcome to TCEO

Training and Continuing Education Online (TCEO) is a system that provides access to CDC educational activities for continuing education (CE). Use TCEO to search for CE opportunities, complete course

E-mail Your Immunization Questions to Us

NIPINFO@cdc.gov

Write “Web-on-Demand–GBP2”
in the subject line



EpiVac Pink Book Web-on-Demand Resources

- Comprehensive list of resources for ALL sessions
- Located on the web page for this web-on-demand session at www.cdc.gov/vaccines/ed/webinar-epv/index.html
- Additional materials located on this webpage include:
 - Principles of Vaccination slide set
 - Web-on-demand questions and answers
 - Transcript of this session
 - Continuing education instructions

COURSE RESOURCES

Epidemiology and Prevention of Vaccine-Preventable Diseases

- ▶ Epidemiology and Prevention of Vaccine-Preventable Diseases (Pink Book) Supplement: www.cdc.gov/vaccines/pubs/pinkbook/supplement.html

Overall Resources

- ▶ Current childhood and adult immunization schedules: www.cdc.gov/vaccines/schedules/index.html
- ▶ CDC Vaccine Schedules App for Health Care Providers: www.cdc.gov/vaccines/schedules/hcp/schedule-app.html
- ▶ Advisory Committee on Immunization Practices (ACIP) recommendations: www.cdc.gov/vaccines/hcp/acip-recs/index.html
- ▶ CDC General Best Practice Guidelines for Immunization: www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html
- ▶ CDC Continuing Education Information: www.cdc.gov/vaccines/ed/ce-credit-how-to.html
- ▶ Health Care Personnel Vaccination Recommendations: www.immunize.org/catg.d/p2017.pdf
- ▶ Pink Book Webinar Series: www.cdc.gov/vaccines/ed/webinar-epv/index.html
- ▶ Vaccines Licensed for Use in the United States Package Inserts: www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm
- ▶ You Call the Shots: www.cdc.gov/vaccines/ed/youcalltheshots.html

Course Intro and Objectives

- ▶ What is the Advisory Committee on Immunization Practices (ACIP)?: www.cdc.gov/vaccines/hcp/conversations/downloads/vacsafe-acip-color-office.pdf
- ▶ CDC Immunization Resources for You and Your Patients: www.cdc.gov/vaccines/hcp/admin/downloads/Resource-Booklet.pdf
- ▶ Parents' Guide to Childhood Immunizations: www.cdc.gov/vaccines/parents/tools/parents-guide/index.html
- ▶ Order Information for Free CDC Immunization Materials for Providers and Patients: www.cdc.gov/pubs/CDCInfoOnDemand.aspx

Principles of Vaccination

- ▶ Immune System Research: www.niaid.nih.gov/research/immune-system-research
- ▶ What is the Immune System?: www.vaccines.gov/basics/work/prevention
- ▶ Understanding How Vaccines Work: www.cdc.gov/vaccines/hcp/conversations/downloads/vacsafe-understand-color-office.pdf
- ▶ Vaccines Work: www.vaccines.gov/basics/work/index.html
- ▶ Vaccine Basics: How Vaccines Work: www.vaccineinformation.org/how-vaccines-work/
- ▶ The History of Vaccines: How Vaccines Work: www.historyofvaccines.org/content/how-vaccines-work

General Best Practice Guidelines

- ▶ Ask the Experts-Scheduling Vaccines FAQs: www.immunize.org/askexperts/scheduling-vaccines.asp
- ▶ Ask the Experts-Combination Vaccines FAQs: www.immunize.org/askexperts/experts_combo.asp
- ▶ Ask the Experts-Precautions and Contraindications FAQs: www.immunize.org/askexperts/precautions-contraindications.asp
- ▶ Foreign Language Vaccine-Preventable Disease Terms: www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/foreign-products-tables.pdf
- ▶ Guide to Contraindications and Precautions to Commonly Used Vaccines: www.immunize.org/catg.d/p3072a.pdf
- ▶ Guidelines for Vaccinating Pregnant Women: www.cdc.gov/vaccines/pregnancy/hcp/guidelines.html
- ▶ IDSA 2013 Clinical Practice Guideline for Vaccination of the Immunocompromised Host: www.idsociety.org/Guidelines/Patient_Care/IDSA_Practice_Guidelines/Vaccination_of_the_Immunocompromised_Host/
- ▶ Interval Between Antibody-Containing Products and Measles- and Varicella-Containing Vaccines: www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/a/mmr_ig.pdf



Thank You From Atlanta!

