Immunization Administration Training for Pharmacists

Written Self-Study Program
May 2014
Every attempt has been made to ensure the accuracy of the information contained herein at the time of writing; however, due to the nature of immunization practice, standards and recommendations change regularly. While the resources from the Centers for Disease Control and Prevention are considered authoritative and have been used in the preparation of this program, this program is not to be construed as official CDC policy.

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Program details:
Immunization Administration Training for Pharmacists

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MODULE 8 - LIVE WORKSHOP
Faculty for Module 8 will depend on where and when the Live Workshop is held. CEI has a number of qualified faculty who serve as facilitators of the Live Workshop. Each facilitator is deemed qualified through the CEI Train-the-Trainer program and is chosen based on the size of the workshop and the pharmacists being trained.

Faculty Disclosures:
Chasity Mease, Crystal Lennartz, Laurie Schenkelberg and Miranda Wilhelm do not have any actual or potential conflicts of interest in relation to this activity.

This practice-based program is worth a total of twenty contact hours, (2.0 CEUs).

Universal Activity Numbers:
Home-study UAN: 0401-9999-15-300-H01-P
(18 contact hours, 1.8 CEUs)
Live Workshop UAN: 0401-9999-15-301-L01-P
(2 contact hours, 0.2 CEUs)

Initial release date: January 1, 2015
Planned expiration date: January 1, 2018

Target Audience: Pharmacists and student pharmacists who are interested in learning the information and obtaining the skills necessary to become vaccine educators, facilitators and immunizers.

Learning Objectives:

HOME STUDY (18 contact hours, 1.8 CEUs)
Written Self-Study (10 hours)

MODULE 1: Immunology and Principles of Immunization
Upon completion of this program, the pharmacist should be able to:
1. Discuss the history of pharmacy-based immunization services.
2. Recognize the importance and public health impact of increasing access to immunizations through pharmacies.
3. Discuss basic immunology related to disease protective mechanisms of vaccines.
4. Compare and contrast active immunity and passive immunity.
5. Define antigens, immune response, antibodies, and cell-mediated immunity.
6. Describe the basic principles of vaccination.
7. Describe the classification of vaccines, including live attenuated, inactivated, polysaccharides and recombinant.
8. Outline the childhood and adult immunization schedules.
9. Discuss the precautions for vaccination.
10. Identify contraindications of vaccines.

MODULE 2: Preparing Your Pharmacy to Provide Immunization Services
Upon completion of this program, the pharmacist should be able to:

1. Develop a plan to properly and safely store vaccines.
2. Implement and accurately complete the checklist for safe vaccine handling and storage.
3. Contact the appropriate manufacturer quality control office if a question arises regarding the integrity of a vaccine.
4. Educate other pharmacy staff about safe vaccine handling and storage.
5. Establish methods to access vaccine information resources.
6. Develop a record-keeping system that complies with legal requirements.
7. Describe the benefits and use of immunization registries.
8. Develop a screening technique to identify patients needing immunization.
10. Develop an exposure plan for implementation in the pharmacy, including blood-borne pathogen directives and needle stick injury prevention.

MODULE 3: Adverse Reactions and Vaccine Safety
Upon completion of this program, the pharmacist should be able to:

1. Report an adverse event utilizing the Vaccine Adverse Event Reporting System (VAERS).
2. Describe the role of the Vaccine Injury Compensation Program.
3. Anticipate and manage common adverse events associated with vaccines and vaccination.
4. Develop an emergency plan for anaphylaxis associated with vaccine administration.
5. Discuss the safety of vaccines with patients, including how vaccines are developed and monitored to ensure their safety.

Pre-recorded Webinars (8 hours)

MODULE 4: Vaccine-Preventable Diseases Part 1
Upon completion of this program, the pharmacist should be able to:

1. Discuss the epidemiology and pathophysiology of vaccine preventable diseases, including measles, mumps, rubella, varicella, herpes zoster, rotavirus, haemophilus influ-
1. Discuss the epidemiology and pathophysiology of vaccine preventable diseases, including meningococcal disease, polio, pneumococcal disease, pertussis, diphtheria and tetanus.
2. Recommend immunizations for patients with HIV, asplenia, liver disease, coagulation disorders, diabetes and renal disease.
3. Develop an immunization strategy for pregnant patients.
4. Discuss contraindications and precautions for vaccination with an immunosuppressed patient.
5. Make appropriate recommendations for immunosuppressed patients.

MODULE 6: Establishing a Pharmacy-Based Immunization Program
Upon completion of this program, the pharmacist should be able to:
1. Describe legal requirements for immunization delivery by a pharmacist.
2. Develop a plan for implementing immunization services to adults in a pharmacy.
3. Describe methods for reimbursement for immunization services.

MODULE 7: Case Discussion and Administration Technique
Upon completion of this program, the pharmacist should be able to:
1. Recommend immunizations for patients based on their ages, concurrent illnesses or conditions and lifestyle.
2. Implement knowledge of immunization recommendations through patient cases.
3. Based on the immunization and patient, determine anatomic site and needle size.
4. Describe process to administer an immunization, including patient preparation and infection control.
5. Accurately prepare a vaccine for administration.
Program instructions:

Immunization Administration Program for Pharmacists is a 20 hour practice-based program that is conducted in two parts: 1) home study consisting of written self study and pre-recorded webinars, and 2) live immunization administration workshop. To earn continuing education credit participants must successfully complete all program components outlined in to obtain credit section above including but not limited to corresponding learning assessments and program evaluations.

Home Study (18 contact hours)

Written Self-Study (10 hours):
You are about to begin the first component of the Immunization Administration Training for Pharmacists. This written self-study contains three modules:

Module 1: Immunology and the Principles of Immunization
Module 2: Preparing your Pharmacy to Provide Immunization Services
Module 3: Vaccine Safety and Vaccine Adverse Events

Appendices: Contain a variety of tools and resources for your practice.

Each module will have case studies and assessment questions at the end of the module. It is advisable to work through these assessments as you complete each module. Upon completion of Module 3, you will go online to www.DrugStoreNewsCE.com and input your answers to all three modules in the 50 question learning assessment.

Pre-recorded Webinars (8 hours):
Upon completion of learning assessment for the written self-study, you will be eligible to complete the pre-recorded webinar series:

Module 4: Vaccine-Preventable Diseases I
Module 5: Vaccine-Preventable Diseases II
Module 6: Establishing a Pharmacy –Based Immunization Program
Module 7: Case Discussion and Administration Technique

After the 18 hours of home study are successfully completed, you will be eligible to register for the live Immunization Administration Workshop through your corporate office or College of Pharmacy.

How to obtain your CE credits:

1. Complete the case studies and assessment questions in each section of this document as you work through Modules 1-3.
2. Log into the Immunization Program at www.DrugStoreNewsCE.com with your assigned enrollee number.
3. Click on the lesson and then click on TAKE TEST box. Record the answers you completed for the written self-study assessment questions and submit. Complete the program evaluation when prompted.
4. Listen to the pre-recorded webinar series (Modules 4-7) and complete the case studies, assessment questions and program evaluation after EACH webinar.
5. Upon successful completion of Modules 1-7, including achieving a passing grade of 70% or above on the written self study and pre-recorded webinars assessments and completion of the home study evaluations, a total of 18 contact hours (1.8 CEUs) of practice-based drug-therapy CPE credit will be awarded.
6. Register with your employer or college to attend a live Immunization Administration Workshop.
7. Attend the live workshop and be certain to sign in at this event. You will be required to successfully demonstrate vaccine administration technique. After the event you will go online www.DrugStoreNewsCE.com log into the Immunization Program, attest to CPR training and complete the live program evaluation. A total of 2 contact hours (0.2 CEUs) of practice-based drug-therapy live CPE credit will be awarded.

Statements of credit can be found in your My CE/Test History folder at www.DrugStoreNewsCE.com. No partial credit will be awarded. Questions regarding statements of credit and other customer service issues should be directed to (800) 933-9666.

You will also receive a Certificate of Completion suitable for framing within 45 days after completion of the program.
Module 1:
Immunology and Principles of Immunization

Learning Objectives: At the conclusion of this module, pharmacists should be able to:

1. Discuss the history of pharmacy-based immunization services
2. Recognize the importance and public health impact of increasing access to immunizations through pharmacies
3. Discuss basic immunology related to disease protective mechanisms of vaccines
4. Compare active immunity and passive immunity
5. Define antigens, immune response, antibodies, and cell-mediated immunity
6. Describe the basic principles of vaccination
7. Describe the classification of vaccines, including live attenuated, inactivated, conjugate, polysaccharides, and recombinant
8. Outline the childhood and adult immunization schedules
9. Discuss the precautions, for vaccination
10. Identify contraindications of vaccines

The information in Module 1 that appears in a shaded box or on a shaded page is taken directly from: Centers for Disease Control and Prevention. Epidemiology and Prevention of Vaccine-Preventable Diseases. Atkinson W, Wolfe S, Hamborsky J, eds. 12th ed. - 2nd printing, Washington DC: Public Health Foundation, May, 2012. Module 1 contains: (Page numbers noted in parenthesis indicate the item's location within this document)

✓ Chapter 1: Principles of Vaccination, pages 1-7 (pg 14)
✓ Chapter 2: General Recommendations on Immunization, pages 9-30 (pg 21)
✓ Appendix A: Childhood Immunization Schedule 2013 (pg 106)
✓ Appendix A: Catch-up Immunization Schedule 2013 4mo-18yrs > 1 mo behind (pg 108)
✓ Appendix A: Adult Immunization Schedule 2013 (pg 110)
✓ Appendix A: Summary of Recommendations for Adult Immunizations (pg 112)

Also included in Module 1 in a shaded box or on a shaded page are the following:
✓ General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices. MMWR 2011; 60;(2):3-62 (pg 43)
✓ Complete List of Vaccines Licensed for Immunization and Distribution in the US; FDA, 2013; http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm (pg 9)
History and Public Health Benefits of Pharmacy-Based Immunization Services

Although pharmacists have been involved with vaccines since the mid-1800s, only since 1994 when pharmacists in the state of Washington began offering vaccines that the practice has grown into a commonly offered service in community pharmacies. The practice has grown through education of pharmacists and student pharmacists and as more pharmacies have adopted the practice. Immunizing pharmacists cite improving the public health and personal satisfaction as the factors that contribute most to their professional satisfaction. Also, pharmacists’ efforts have contributed to increasing elderly adult immunization rates.

Community pharmacies are in an excellent position to get involved in vaccination-related activities. This is because of the accessibility, convenience, and availability provided by pharmacists and community pharmacies. Many policy-makers at the federal and state levels realize the importance of pharmacy-based vaccination services, particularly pharmacist-administered vaccination services. During the past decade, many states have modified their pharmacy practice laws to authorize licensed pharmacists to administer vaccines directly to patients. Pharmacists in all states are permitted by law to administer vaccines. This new role of pharmacists and pharmacy immunization practice has been recognized and supported by the National Vaccine Advisory Committee as reflected in the official publication, Adult Immunization Programs in Nontraditional Settings: Quality Standards and Guidance for Program Evaluation.

Several studies investigating the impact of pharmacy-based vaccination-related activities were carried out. For example, pharmacy participation in vaccination promotion programs improve overall vaccination rates, and can result in reduced morbidity, mortality, and related healthcare expenses. Pharmacist-administered immunization services also have been shown to improve immunization rates. Importantly, these improved rates were found among those who had not been vaccinated in the previous year. Influenza vaccine delivered in pharmacies has lower overall societal costs. Overall immunization rates were significantly higher in states that allow pharmacists to administer vaccines compared to states that did not.

This module reviews basic immunology, mostly to reacquaint participants with the vocabulary.

Immunology Primer

“Vaccines have become modern medical miracles along with bypass surgery and the CAT scan, but with this difference—vaccines have saved more lives and prevented more deaths than any other modern medical intervention since the chlorination of water and the pasteurization of milk.” Richard M. Krause in The Jordan Report: Accelerated Development of Vaccines 1996. NIAID/NIH.

Immunization is defined as rendering a person protected from an infectious agent. Immunity to an infectious agent can be acquired by exposure to the disease, by the transfer of antibodies from mother to fetus, through the administration of immune globulin and from vaccination. Vaccination is the process of introducing an antigen into
the body to induce protection against the infectious agent without causing disease. An antigen is a substance to which an immune response is mounted. The antibody produced by the humoral arm of the immune system is usually the response that is measured as evidence of successful vaccination. However, increasing evidence exists that the cellular immune response, which is much more difficult to measure, is also a very important aspect of vaccine response.

When a vaccine is introduced to the body, the immune response that is stimulated is similar to that elicited by the natural infection. Both the cellular and humoral arms of the immune system may be activated. (Figure1) The cellular arm of the immune system consists of cytotoxic T cells, and the humoral arm consists of antibodies made by B cells.

T cells are heterogeneous and are involved in many aspects of the immune system. The helper T cell is common to both the cellular and humoral arms. As their name implies, helper T cells assist both the cellular and humoral arms of the immune system to control and magnify the immune response to an antigen. Although these arms of the immune system are described here as distinct systems, there is significant overlap and redundancy in the entire immune system.

With immunization, antigens are engulfed by antigen presenting cells (APCs) to initiate a humoral immune response. Monocytes and macrophages are examples of APCs. APCs digest the antigens into short peptides
Immunization Administration Training for Pharmacists

(REFERRED TO AS “ANTIGEN PROCESSING”), A SAMPLING OF WHICH ARE THEN TRANSPORTED TO THE SURFACES OF THE APCS. SPECIALIZED MOLECULES ON THE SURFACE OF APCS DISPLAY THE PROCESSED ANTIGENS, WHICH ARE RECOGNIZED BY HELPER T CELLS. HELPER T CELLS STIMULATE B CELLS TO PRODUCE ANTIBODIES TO THE ANTIGEN. MATURE B CELLS DEVELOP INTO PLASMA CELLS AND BECOME PROFESSIONAL ANTIBODY SECRETING CELLS.

THERE ARE FIVE CLASSES OF ANTIBODIES. (FIGURE 2) IgM IS THE FIRST ANTIBODY TO APPEAR IN RESPONSE TO AN ANTIGEN. IT IS A PENTAVALENT PROTEIN, MEANING IT IS MADE UP OF FIVE ANTIBODIES HOOKED TOGETHER. ITS MULTIVALENCY MAKES UP FOR ITS LACK OF SPECIFICITY. ALSO, SINCE IT IS SUCH A LARGE PROTEIN, ITS DISTRIBUTION IS LIMITED TO THE INTRAVASCULAR SPACE. IgE IS THE ANTIBODY THAT IS A MEDIATOR OF ALLERGY AND ANAPHYLAXIS. IgA IS FOUND PRIMARILY IN SECRETIONS OF THE GASTROINTESTINAL TRACT, GENITOURINARY TRACT, CONJUNCTIVA, AND RESPIRATORY TRACT. IgA IS ABUNDANT IN MILK. IT CONSISTS IN A DIMERIC FORM THAT IS RESistant TO DEGRADATION FROM SECRETIONS. IgG IS THE MAJOR ANTIBODY IN SERUM. IT ALSO DISTRIBUTES INTO THE EXTRAVASCULAR SPACE. IT IS THE MATURE ANTIBODY THAT PREDOMINATES UPON RE-EXPOSURE TO AN ANTIGEN.

MULTIPLE DOSES OF SOME VACCINES (BOOSTER DOSES) ARE NEEDED TO INDUCE LONG-LASTING, EFFECTIVE IMMUNITY. THE BOOSTER DOSES OF SUCH VACCINES ELICIT MEMORY RESPONSES FROM THE B CELLS THAT PRODUCE IgG. THE IMMUNE SYSTEM HAS DEVELOPED AN ARRAY OF ANTIBODIES TO THE ANTIGEN ALREADY, AND UPON RE-STIMULATION WITH A BOOSTER DOSE, THOSE B CELLS THAT PRODUCE THE MOST SPECIFIC ANTIBODIES AGAINST THE ANTIGEN ARE ACTIVATED. THIS RE-STIMULATION ALLOWS THE MOST ACTIVE ANTIBODIES AGAINST THE ANTIGEN TO BE SELECTED AND MAINTAINED IN THE “IMMUNOLOGICAL MEMORY.” Thus, THE BOOSTER DOSE RESULTS IN A RAPID, INTENSE ANTIBODY RESPONSE THAT IS LONG-LASTING.

A VACCINE MAY BE ABLE TO ELICIT A CELLULAR IMMUNE RESPONSE ALSO. A CELL-MEDIATED IMMUNE RESPONSE IS PRIMARILY DIRECTED AT VIRAL INFECTIONS. THE VIRUS INFECTS HOST CELLS. THE VIRUS USES THE HOST CELL TO REPLICATE ITSELF. IN THE REPLICATION PROCESS, VIRAL PROTEINS ARE SYNTHESIZED. THESE PROTEINS ARE PROCESSED AND PRESENTED ON THE CELL SURFACE. CYTOTOXIC T CELLS RECOGNIZE THE INFECTED CELLS AND KILL THEM BY RELEASING CYTOTOXIC CHEMICALS. ALTHOUGH THERE IS A MEMORY RESPONSE ASSOCIATED WITH CELLULAR IMMUNITY, THIS ASPECT IS NOT WELL DESCRIBED.


A PRIMARY SCIENTIFIC OBSTACLE TO EFFECTIVE VACCINE DEVELOPMENT IS AN INSUFFICIENT UNDERSTANDING OF HOST RESPONSE TO IMMUNIZATION. THIS BASIC REVIEW OF IMMUNOLOGY SHOULD PROVIDE VACCINATORS WITH AN APPRECIATION OF THE COMPLEXITY AND REDUNDANCY OF THE IMMUNE RESPONSE TO INFECTION AND VACCINATION.
Principles of Immunization

Chapter 1 from Epidemiology and Prevention of Vaccine-Preventable Diseases provides an introduction to immunology and immunization concepts, including types of products used for immunization.

General Recommendations on Immunization

Chapter 2 lays out the rules for immunization in commonly encountered clinical situations. These rules can be applied across all practices. Chapter 2 refers the reader to tables included in Appendix A. These tables are found at the end of the General Recommendations on Immunization. The tables are valuable references for practice. The General Recommendations on Immunization from the Advisory Committee on Immunization Practices is the authoritative document on immunization practice and is required reading for all immunization providers.

There are many references to Tables throughout this excerpt. Use the page reference below to quickly locate these items within this document.

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Advisory Committee on Immunization Practices  
U.S. VACCINE ABBREVIATIONS  
Abbreviations for Vaccines Included in the  
Immunization Schedules for Children, Adolescents, and Adults

Following is a table of standardized vaccine abbreviations, which was developed jointly by staff of the Centers for Disease Control and Prevention, ACIP Work Groups, the editor of the Morbidity and Mortality Weekly Report (MMWR), the editor of Epidemiology and Prevention of Vaccine-Preventable Diseases (the “Pink Book”), ACIP members, and liaison organizations to the ACIP.

These abbreviations are intended to provide a uniform approach to vaccine references used in ACIP Recommendations and Policy Notes that are published in the MMWR, the Pink Book, and the American Academy of Pediatrics Red Book; and in the U.S. immunization schedules for children, adolescents, and adults.

### Vaccine Abbreviation Table

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<tr>
<th>Vaccine</th>
<th>Abbreviation*</th>
<th>Trade Name</th>
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<tbody>
<tr>
<td><strong>Diphtheria, tetanus and pertussis-containing vaccines</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Diphtheria and tetanus toxoids adsorbed (P)</td>
<td>DT</td>
<td>several mfrs†</td>
</tr>
<tr>
<td>- Diphtheria and tetanus toxoids and acellular pertussis vaccine</td>
<td>DTaP</td>
<td>Daptacel, Infanrix</td>
</tr>
<tr>
<td>adsorbed (P)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Tetanus and diphtheria toxoids adsorbed (A)</td>
<td>Td</td>
<td>Tenivac, Decavac</td>
</tr>
<tr>
<td>- Tetanus toxoid, reduced diphtheria toxoid and acellular pertussis</td>
<td>Tdap</td>
<td>Adacel, Boostrix</td>
</tr>
<tr>
<td>vaccine, adsorbed (A)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Tetanus toxoid (P,A)</td>
<td>TT</td>
<td>generic</td>
</tr>
<tr>
<td>- Diphtheria and tetanus toxoids and acellular pertussis adsorbed,</td>
<td>DTaP-HepB-IPV</td>
<td>Pediarix</td>
</tr>
<tr>
<td>hepatitis B and inactivated poliovirus vaccine (P)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Diphtheria and tetanus toxoids and acellular pertussis adsorbed and</td>
<td>DTaP-IPV</td>
<td>Kinrix</td>
</tr>
<tr>
<td>inactivated poliovirus vaccine (P)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Diphtheria and tetanus toxoids and acellular pertussis adsorbed,</td>
<td>DTaP-IPV/Hib</td>
<td>Pentacel</td>
</tr>
<tr>
<td>inactivated poliovirus and Haemophilus influenzae type b conjugate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>vaccine (P)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Haemophilus influenzae type b-containing vaccines</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- *Haemophilus influenzae type b conjugate vaccine</td>
<td>Hib</td>
<td>PedvaxHIB</td>
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<td></td>
<td></td>
<td>Hiberix</td>
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<td></td>
<td></td>
<td>ActHIB</td>
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</tbody>
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* In descriptions of combination vaccines, dash ( - ) indicates: products in which the active components are supplied in their final (combined) form by the manufacturer; slash ( / ) indicates: products in which active components must be mixed by the user.

† several manufacturers; for complete listing, see  
[http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/us-vaccines.pdf](http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/us-vaccines.pdf) and  
[http://www.cdc.gov/vaccines/about/terms/USVaccines.html](http://www.cdc.gov/vaccines/about/terms/USVaccines.html)
<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Abbreviation*</th>
<th>Trade Name</th>
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<tbody>
<tr>
<td>&quot;Haemophilus influenzae&quot; type b conjugate and hepatitis B vaccine</td>
<td>Hib-HepB</td>
<td>Comvax</td>
</tr>
<tr>
<td>Diphtheria and tetanus toxoids and acellular pertussis adsorbed,</td>
<td>DTaP-IPV/Hib</td>
<td>Pentacel</td>
</tr>
<tr>
<td>inactivated poliovirus and &quot;Haemophilus influenzae&quot; type b conjugate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>vaccine</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bivalent meningococcal conjugate vaccine and &quot;Haemophilus influenzae&quot;</td>
<td>Hib-MenCY</td>
<td>MenHibrix</td>
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<tr>
<td>type b conjugate vaccine</td>
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**Hepatitis-containing vaccines**

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Abbreviation*</th>
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<tbody>
<tr>
<td>Hepatitis A vaccine</td>
<td>HepA</td>
<td>Havrix Vaqta</td>
</tr>
<tr>
<td>Hepatitis B vaccine</td>
<td>HepB</td>
<td>Engerix-B</td>
</tr>
<tr>
<td>Recombivax HB</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hepatitis A inactivated and hepatitis B vaccine</td>
<td>HepA-HepB</td>
<td>Twinrix</td>
</tr>
<tr>
<td>Diphtheria and tetanus toxoids and acellular pertussis adsorbed,</td>
<td>DTaP-HepB-IPV</td>
<td>Pediarix</td>
</tr>
<tr>
<td>hepatitis B and inactivated poliovirus vaccine</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&quot;Haemophilus influenzae&quot; type b conjugate and hepatitis B vaccine</td>
<td>Hib-HepB</td>
<td>Comvax</td>
</tr>
</tbody>
</table>

**Herpes zoster (shingles) vaccine**

<table>
<thead>
<tr>
<th>Vaccine</th>
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<tbody>
<tr>
<td>HZV</td>
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<td>Zostavax</td>
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**Human papillomavirus vaccines**

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<tr>
<td>Human papillomavirus vaccine (quadrivalent)</td>
<td>HPV4</td>
<td>Gardasil</td>
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<td>Human papillomavirus vaccine (bivalent)</td>
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**Influenza vaccines**

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<tr>
<td>Inactivated influenza vaccine</td>
<td>IIV</td>
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<tr>
<td>Trivalent inactivated influenza vaccine</td>
<td>IIV3</td>
<td>several mfrs</td>
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<tr>
<td>Quadrivalent inactivated influenza vaccine</td>
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<tr>
<td>Live attenuated influenza vaccine</td>
<td>LAIV</td>
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**Measles, mumps and rubella-containing vaccines**

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<td>M-M-R II</td>
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<td>Measles, mumps, rubella, and varicella vaccine</td>
<td>MMRV</td>
<td>ProQuad</td>
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**Meningococcal-containing vaccines**

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<tr>
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<tr>
<td>&quot;Haemophilus influenzae&quot; type b conjugate vaccine</td>
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<tr>
<td>Bivalent meningococcal conjugate vaccine and &quot;Haemophilus influenzae&quot;</td>
<td>Hib-MenCY</td>
<td>MenHibrix</td>
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<tr>
<td>type b conjugate vaccine</td>
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<tr>
<td>Meningococcal polysaccharide vaccine (quadrivalent)</td>
<td>MPSV4</td>
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### Pneumococcal vaccines

- Pneumococcal conjugate vaccine (7-valent)  
  - **PCV7**  
  - **Prevnar**  
- Pneumococcal conjugate vaccine (13-valent)  
  - **PCV13**  
  - **Prevnar 13**  
- Pneumococcal polysaccharide vaccine (23-valent)  
  - **PPSV23**  
  - **Pneumovax 23**

### Poliovirus-containing vaccines

- Inactivated poliovirus vaccine  
  - **IPV**  
  - **Ipol**  
- Diphtheria and tetanus toxoids and acellular pertussis adsorbed and inactivated poliovirus vaccine  
  - **DTaP-IPV**  
  - **Kinrix**  
- Diphtheria and tetanus toxoids and acellular pertussis adsorbed, hepatitis B and inactivated poliovirus vaccine  
  - **DTaP-HepB-IPV**  
  - **Pediarix**  
- Diphtheria and tetanus toxoids and acellular pertussis adsorbed and inactivated poliovirus vaccine and *Haemophilus influenzae* type b conjugate vaccine  
  - **DTaP-IPV/Hib**  
  - **Pentacel**

### Rotavirus vaccines

- Rotavirus vaccine (monovalent)  
  - **RV1**  
  - **Rotarix**  
- Rotavirus vaccine (pentavalent)  
  - **RV5**  
  - **RotaTeq**

### Varicella-containing vaccines

- Varicella vaccine  
  - **VAR**  
  - **Varivax**  
- Measles, mumps, rubella, and varicella vaccine  
  - **MMRV**  
  - **ProQuad**  
- Herpes zoster (shingles) vaccine  
  - **HZV**  
  - **Zostavax**
## Complete List of Vaccines Licensed for Immunization and Distribution in the US

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<tr>
<th>Product Name</th>
<th>Trade Name</th>
<th>Sponsor</th>
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<td>BCG Vaccine</td>
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<tr>
<td>BCG Live</td>
<td>TICE BCG</td>
<td>Organon Teknika Corp LLC</td>
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<td>Diphtheria &amp; Tetanus Toxoids Adsorbed</td>
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<td>GlaxoSmithKline Biologicals</td>
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<tr>
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<tr>
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<tr>
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<tr>
<td>Vaccine Description</td>
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<td>Toxoid Conjugate</td>
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<tr>
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<td>Influenza Virus Vaccine (Trivalent, Types A and B)</td>
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<tr>
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<td>Poliovirus Vaccine Inactivated (Monkey Kidney Cell)</td>
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<td>RabAvert</td>
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<td>Vivotif</td>
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<td>TYPHIM Vi</td>
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[http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm](http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm) (accessed 9/9/2013)
Principles of Vaccination

Immunology and Vaccine-Preventable Diseases

Immunology is a complicated subject, and a detailed discussion of it is beyond the scope of this text. However, an understanding of the basic function of the immune system is useful in order to understand both how vaccines work and the basis of recommendations for their use. The description that follows is simplified. Many excellent immunology textbooks are available to provide additional detail.

Immunity is the ability of the human body to tolerate the presence of material indigenous to the body ("self"), and to eliminate foreign ("nonself") material. This discriminatory ability provides protection from infectious disease, since most microbes are identified as foreign by the immune system. Immunity to a microbe is usually indicated by the presence of antibody to that organism. Immunity is generally specific to a single organism or group of closely related organisms. There are two basic mechanisms for acquiring immunity, active and passive.

Active immunity is protection that is produced by the person’s own immune system. This type of immunity is usually permanent.

Passive immunity is protection by products produced by an animal or human and transferred to another human, usually by injection. Passive immunity often provides effective protection, but this protection wanes (disappears) with time, usually within a few weeks or months.

The immune system is a complex system of interacting cells whose primary purpose is to identify foreign ("nonself") substances referred to as antigens. Antigens can be either live (such as viruses and bacteria) or inactivated. The immune system develops a defense against the antigen. This defense is known as the immune response and usually involves the production of protein molecules by B lymphocytes, called antibodies (or immunoglobulins), and of specific cells (also known as cell-mediated immunity) whose purpose is to facilitate the elimination of foreign substances.

The most effective immune responses are generally produced in response to a live antigen. However, an antigen does not necessarily have to be alive, as occurs with infection with a virus or bacterium, to produce an immune response. Some proteins, such as hepatitis B surface antigen, are easily recognized by the immune system. Other material, such as polysaccharide (long chains of sugar molecules that make up the cell wall of certain bacteria) are less effective antigens, and the immune response may not provide as good protection.
Passive Immunity

Passive immunity is the transfer of antibody produced by one human or other animal to another. Passive immunity provides protection against some infections, but this protection is temporary. The antibodies will degrade during a period of weeks to months, and the recipient will no longer be protected.

The most common form of passive immunity is that which an infant receives from its mother. Antibodies are transported across the placenta during the last 1–2 months of pregnancy. As a result, a full-term infant will have the same antibodies as its mother. These antibodies will protect the infant from certain diseases for up to a year. Protection is better against some diseases (e.g., measles, rubella, tetanus) than others (e.g., polio, pertussis).

Many types of blood products contain antibody. Some products (e.g., washed or reconstituted red blood cells) contain a relatively small amount of antibody, and some (e.g., intravenous immune globulin and plasma products) contain a large amount.

In addition to blood products used for transfusion (e.g., whole blood, red cells, and platelets) there are three major sources of antibody used in human medicine. These are homologous pooled human antibody, homologous human hyperimmune globulin, and heterologous hyperimmune serum.

Homologous pooled human antibody is also known as immune globulin. It is produced by combining (pooling) the IgG antibody fraction from thousands of adult donors in the United States. Because it comes from many different donors, it contains antibody to many different antigens. It is used primarily for postexposure prophylaxis for hepatitis A and measles and treatment of certain congenital immunoglobulin deficiencies.

Homologous human hyperimmune globulins are antibody products that contain high titers of specific antibody. These products are made from the donated plasma of humans with high levels of the antibody of interest. However, since hyperimmune globulins are from humans, they also contain other antibodies in lesser quantities. Hyperimmune globulins are used for postexposure prophylaxis for several diseases, including hepatitis B, rabies, tetanus, and varicella.

Heterologous hyperimmune serum is also known as antitoxin. This product is produced in animals, usually horses (equine), and contains antibodies against only one antigen. In the United States, antitoxin is available for treatment of botulism and diphtheria. A problem with this product is serum sickness, an immune reaction to the horse protein.
Immune globulin from human sources is polyclonal; it contains many different kinds of antibodies. In the 1970s, techniques were developed to isolate and “immortalize” (cause to grow indefinitely) single B cells, which led to the development of monoclonal antibody products. Monoclonal antibody is produced from a single clone of B cells, so these products contain antibody to only one antigen or closely related group of antigens. Monoclonal antibody products have many applications, including the diagnosis of certain types of cancer (colorectal, prostate, ovarian, breast), treatment of cancer (B-cell chronic lymphocytic leukemia, non-Hodgkin lymphoma), prevention of transplant rejection, and treatment of autoimmune diseases (Crohn disease, rheumatoid arthritis) and infectious diseases.

A monoclonal antibody product is available for the prevention of respiratory syncytial virus (RSV) infection. It is called palivizumab (Synagis). Palivizumab is a humanized monoclonal antibody specific for RSV. It does not contain any other antibody except RSV antibody, and so will not interfere with the response to a live virus vaccine.

**Active Immunity**

Active immunity is stimulation of the immune system to produce antigen-specific humoral (antibody) and cellular immunity. Unlike passive immunity, which is temporary, active immunity usually lasts for many years, often for a lifetime.

One way to acquire active immunity is to survive infection with the disease-causing form of the organism. In general, once persons recover from infectious diseases, they will have lifelong immunity to that disease. The persistence of protection for many years after the infection is known as immunologic memory. Following exposure of the immune system to an antigen, certain cells (memory B cells) continue to circulate in the blood (and also reside in the bone marrow) for many years. Upon reexposure to the antigen, these memory cells begin to replicate and produce antibody very rapidly to reestablish protection.

Another way to produce active immunity is by vaccination. Vaccines interact with the immune system and often produce an immune response similar to that produced by the natural infection, but they do not subject the recipient to the disease and its potential complications. Many vaccines also produce immunologic memory similar to that acquired by having the natural disease.

Many factors may influence the immune response to vaccination. These include the presence of maternal antibody, nature and dose of antigen, route of administration, and the presence of an adjuvant (e.g., aluminum-containing material.
Principles of Vaccination

Classification of Vaccines

- Live attenuated
  - viral
  - bacterial
- Inactivated

Inactivated Vaccines

Whole
- viruses
- bacteria

Fractional
- protein-based
  - toxoid
  - subunit
- polysaccharide-based
  - pure
  - conjugate

GENERAL RULE

The more similar a vaccine is to the disease-causing form of the organism, the better the immune response to the vaccine.

Live Attenuated Vaccines

- Attenuated (weakened) form of the "wild" virus or bacterium
- Must replicate to be effective
- Immune response similar to natural infection
- Usually produce immunity with one dose*  
  *except those administered orally

added to improve the immunogenicity of the vaccine). Host factors such as age, nutritional factors, genetics, and coexisting disease, may also affect the response.

Classification of Vaccines

There are two basic types of vaccines: live attenuated and inactivated. The characteristics of live and inactivated vaccines are different, and these characteristics determine how the vaccine is used.

Live attenuated vaccines are produced by modifying a disease-producing ("wild") virus or bacterium in a laboratory. The resulting vaccine organism retains the ability to replicate (grow) and produce immunity, but usually does not cause illness. The majority of live attenuated vaccines available in the United States contain live viruses. However, one live attenuated bacterial vaccine is available.

Inactivated vaccines can be composed of either whole viruses or bacteria, or fractions of either. Fractional vaccines are either protein-based or polysaccharide-based. Protein-based vaccines include toxoids (inactivated bacterial toxin) and subunit or subviruson products. Most polysaccharide-based vaccines are composed of pure cell wall polysaccharide from bacteria. Conjugate polysaccharide vaccines contain polysaccharide that is chemically linked to a protein. This linkage makes the polysaccharide a more potent vaccine.

Live Attenuated Vaccines

Live vaccines are derived from "wild," or disease-causing, viruses or bacteria. These wild viruses or bacteria are attenuated, or weakened, in a laboratory, usually by repeated culturing. For example, the measles virus used as a vaccine today was isolated from a child with measles disease in 1954. Almost 10 years of serial passage using tissue culture media was required to transform the wild virus into attenuated vaccine virus.

To produce an immune response, live attenuated vaccines must replicate (grow) in the vaccinated person. A relatively
small dose of virus or bacteria is administered, which replicates in the body and creates enough of the organism to stimulate an immune response. Anything that either damages the live organism in the vial (e.g., heat, light) or interferes with replication of the organism in the body (circulating antibody) can cause the vaccine to be ineffective.

Although live attenuated vaccines replicate, they usually do not cause disease such as may occur with the “wild” form of the organism. When a live attenuated vaccine does cause “disease,” it is usually much milder than the natural disease and is referred to as an adverse reaction.

The immune response to a live attenuated vaccine is virtually identical to that produced by a natural infection. The immune system does not differentiate between an infection with a weakened vaccine virus and an infection with a wild virus. Live attenuated vaccines produce immunity in most recipients with one dose, except those administered orally. However, a small percentage of recipients do not respond to the first dose of an injected live vaccine (such as MMR or varicella) and a second dose is recommended to provide a very high level of immunity in the population.

Live attenuated vaccines may cause severe or fatal reactions as a result of uncontrolled replication (growth) of the vaccine virus. This only occurs in persons with immunodeficiency (e.g., from leukemia, treatment with certain drugs, or human immunodeficiency virus (HIV) infection).

A live attenuated vaccine virus could theoretically revert to its original pathogenic (disease-causing) form. This is known to happen only with live (oral) polio vaccine.

Active immunity from a live attenuated vaccine may not develop because of interference from circulating antibody to the vaccine virus. Antibody from any source (e.g., transplacental, transfusion) can interfere with replication of the vaccine organism and lead to poor response or no response to the vaccine (also known as vaccine failure). Measles vaccine virus seems to be most sensitive to circulating antibody. Polio and rotavirus vaccine viruses are least affected.

Live attenuated vaccines are fragile and can be damaged or destroyed by heat and light. They must be handled and stored carefully.

Currently available live attenuated viral vaccines are measles, mumps, rubella, vaccinia, varicella, zoster (which contains the same virus as varicella vaccine but in much higher amount), yellow fever, rotavirus, and influenza (intranasal). Oral polio vaccine is a live viral vaccine but is no longer available in the United States. Live attenuated bacterial vaccines are bacille Calmette-Guérin (BCG—not currently available in the U.S.) and oral typhoid vaccine.
**Inactivated Vaccines**

Inactivated vaccines are produced by growing the bacterium or virus in culture media, then inactivating it with heat and/or chemicals (usually formalin). In the case of fractional vaccines, the organism is further treated to purify only those components to be included in the vaccine (e.g., the polysaccharide capsule of pneumococcus.)

Inactivated vaccines are not alive and cannot replicate. The entire dose of antigen is administered in the injection. These vaccines cannot cause disease from infection, even in an immunodeficient person. Inactivated antigens are less affected by circulating antibody than are live agents, so they may be given when antibody is present in the blood (e.g., in infancy or following receipt of antibody-containing blood products.)

Inactivated vaccines always require multiple doses. In general, the first dose does not produce protective immunity, but “primed” the immune system. A protective immune response develops after the second or third dose. In contrast to live vaccines, in which the immune response closely resembles natural infection, the immune response to an inactivated vaccine is mostly humoral. Little or no cellular immunity results. Antibody titers against inactivated antigens diminish with time. As a result, some inactivated vaccines may require periodic supplemental doses to increase, or “boost,” antibody titers.

Currently available whole-cell inactivated vaccines are limited to inactivated whole viral vaccines (polio, hepatitis A, and rabies). Inactivated whole virus influenza vaccine and whole inactivated bacterial vaccines (pertussis, typhoid, cholera, and plague) are no longer available in the United States. Fractional vaccines include subunits (hepatitis B, influenza, acellular pertussis, human papillomavirus, anthrax) and toxoids (diphtheria, tetanus.) A subunit vaccine for Lyme disease is no longer available in the United States.

**Polysaccharide Vaccines**

Polysaccharide vaccines are a unique type of inactivated subunit vaccine composed of long chains of sugar molecules that make up the surface capsule of certain bacteria. Pure polysaccharide vaccines are available for three diseases: pneumococcal disease, meningococcal disease, and *Salmonella* Typhi. A pure polysaccharide vaccine for *Haemophilus influenzae* type b (Hib) is no longer available in the United States.

The immune response to a pure polysaccharide vaccine is typically T-cell independent, which means that these vaccines are able to stimulate B cells without the assistance of T-helper cells. T-cell–independent antigens, including
polysaccharide vaccines, are not consistently immunogenic in children younger than 2 years of age. Young children do not respond consistently to polysaccharide antigens, probably because of immaturity of the immune system.

Repeated doses of most inactivated protein vaccines cause the antibody titer to go progressively higher, or “boost.” This does not occur with polysaccharide antigens; repeat doses of polysaccharide vaccines usually do not cause a booster response. Antibody induced with polysaccharide vaccines has less functional activity than that induced by protein antigens. This is because the predominant antibody produced in response to most polysaccharide vaccines is IgM, and little IgG is produced.

In the late 1980s, it was discovered that the problems noted above could be overcome through a process called conjugation, in which the polysaccharide is chemically combined with a protein molecule. Conjugation changes the immune response from T-cell independent to T-cell dependent, leading to increased immunogenicity in infants and antibody booster response to multiple doses of vaccine.

The first conjugated polysaccharide vaccine was for Hib. A conjugate vaccine for pneumococcal disease was licensed in 2000. A meningococcal conjugate vaccine was licensed in 2005.

**Recombinant Vaccines**

Vaccine antigens may also be produced by genetic engineering technology. These products are sometimes referred to as recombinant vaccines. Four genetically engineered vaccines are currently available in the United States. Hepatitis B and human papillomavirus (HPV) vaccines are produced by insertion of a segment of the respective viral gene into the gene of a yeast cell or virus. The modified yeast cell produces pure hepatitis B surface antigen or HPV capsid protein when it grows. Live typhoid vaccine (Ty21a) is *Salmonella* Typhi bacteria that have been genetically modified to not cause illness. Live attenuated influenza vaccine has been engineered to replicate effectively in the mucosa of the nasopharynx but not in the lungs.

**Selected References**


General Recommendations on Immunization

This chapter discusses issues that are commonly encountered in vaccination practice. A more thorough discussion of issues common to more than one vaccine can be found in the General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices. These recommendations are revised every 3 to 5 years as needed; the most current edition was published in January 2011 (MMWR 2011;60 (No. RR-2):1-61. All providers who administer vaccine should have a copy of this report and be familiar with its content. It can be downloaded from the MMWR website or ordered in print version from the Centers for Disease Control and Prevention.

Timing and Spacing of Vaccines
The timing and spacing of vaccine doses are two of the most important issues in the appropriate use of vaccines. Specific circumstances that are commonly encountered in immunization practice are the timing of antibody-containing blood products and live vaccines (particularly measles and varicella-containing vaccines), simultaneous and nonsimultaneous administration of different vaccines, and the interval between subsequent doses of the same vaccine.

Antibody–Vaccine Interactions
The presence of circulating antibody to a vaccine antigen may reduce or completely eliminate the immune response to the vaccine. The amount of interference produced by circulating antibody generally depends on the type of vaccine administered and the amount of antibody.

Inactivated vaccines generally are not affected by circulating antibody to the antigen.

Live attenuated vaccines may be affected by circulating antibody to the antigen.

Live Injected Vaccines
Live vaccines must replicate in order to cause an immune response. Antibody against injected live vaccine antigen...
may interfere with replication. If a live injectable vaccine (measles-mumps-rubella [MMR], varicella, or combination measles-mumps-rubella-varicella [MMRV]) must be given around the time that antibody is given, the two must be separated by enough time so that the antibody does not interfere with viral replication. If the live vaccine is given first, it is necessary to wait at least 2 weeks (i.e., an incubation period) before giving the antibody. If the interval between the vaccine and antibody is less than 2 weeks, the recipient should be tested for immunity or the vaccine dose should be repeated.

If the antibody is given before a dose of MMR or varicella vaccine, it is necessary to wait until the antibody has waned (degraded) before giving the vaccine to reduce the chance of interference by the antibody. The necessary interval between an antibody-containing product and MMR or varicella-containing vaccine (except zoster vaccine) depends on the concentration of antibody in the product, but is always 3 months or longer. A table listing the recommended intervals between administration of antibody products and live vaccines (MMR and varicella-containing) is included in Appendix A and in the General Recommendations on Immunization (2011). The interval between administration of an antibody product and MMR or varicella vaccination can be as long as 11 months. Zoster vaccine is not known to be affected by circulating antibody so it can be administered at any time before or after receipt of an antibody-containing blood product.

Yellow fever vaccine also is not known to be affected by circulating antibody. Because few North Americans are immune to yellow fever, these products do not contain significant amounts of antibody to yellow fever virus.

Although passively acquired antibodies can interfere with the response to rubella vaccine, the low dose of anti-Rho(D) globulin administered to postpartum women has not been demonstrated to reduce the response to the rubella vaccine. Because of the importance of rubella and varicella immunity among childbearing age women, women without evidence of immunity to rubella or varicella should receive MMR or varicella vaccine (but not MMRV) in the postpartum period. Vaccination should not be delayed because of receipt of anti-Rho(D) globulin or any other blood product during the last trimester of pregnancy or at delivery. These women should be vaccinated immediately after delivery and, if possible, tested 3 months later to ensure immunity to rubella and, if necessary, to measles.

**Live Oral and Intranasal Vaccines**

Oral typhoid vaccine is not known to be affected by the administration of immune globulin or blood products. Oral
General Recommendations on Immunization

typhoid vaccine may be given simultaneously with blood products, or separated by any interval. The replication of live attenuated influenza (LAIV) and rotavirus vaccines are not believed to be affected by antibody-containing blood products. These can be given any time before or after administration of antibody-containing blood products.

Products Containing Type-Specific or Negligible Antibody

Some blood products do not contain antibodies that interfere with vaccine replication. Palivizumab (Synagis), used for the prevention of respiratory syncytial virus (RSV) infection in infants and young children, contains antibody directed only at RSV. Washed red blood cells contain a negligible amount of antibody. These products can be given anytime before or after administration of MMR or varicella-containing vaccines.

Simultaneous and Nonsimultaneous Administration

Simultaneous administration (that is, administration on the same day) of the most widely used live and inactivated vaccines does not result in decreased antibody responses or increased rates of adverse reaction. Simultaneous administration of all vaccines for which a child is eligible is very important in childhood vaccination programs because it increases the probability that a child will be fully immunized at the appropriate age. A study during a measles outbreak in the early 1990s showed that about one-third of measles cases in unvaccinated but vaccine-eligible preschool children could have been prevented if MMR had been administered at the same visit when another vaccine was given.

All indicated vaccines should be administered at the same visit. There is one exception to this rule. In children with functional or anatomic asplenia pneumococcal conjugate vaccine (PCV) and Menactra brand meningococcal conjugate vaccine should not be administered at the same visit, and should be separated by at least 4 weeks. This is because children with functional or anatomic asplenia are at very high risk of pneumococcal invasive disease and Menactra is thought to interfere with the antibody response to PCV. Individual vaccines should not be mixed in the same
General Recommendations on Immunization

Syringe unless they are licensed for mixing by the Food and Drug Administration. Only the sanofi-pasteur DTaP-IPV/Hib (Pentacel) vaccine is licensed for mixing in the same syringe. See Appendix D for additional guidelines for vaccine administration.

Combination vaccines are generally preferred over simultaneous administration of single component vaccines. Considerations should include an assessment of the number of injections, vaccine availability, likelihood of improved coverage, likelihood of patient return, and storage and costs. Considerations should also include patient choice and the potential for adverse events. For the first dose of vaccine to prevent measles, mumps, rubella and varicella, unless the parent or caregiver expresses a preference for MMRV vaccine, separate MMR and Varicella vaccines should be administered for children 12 through 47 months of age.

Nonsimultaneous Administration of Different Vaccines

In some situations, vaccines that could be given at the same visit are not. If live parenteral (injected) vaccines (MMR, MMRV, varicella, zoster, and yellow fever) and live intranasal influenza vaccine (LAIV) are not administered at the same visit, they should be separated by at least 4 weeks. This interval is intended to reduce or eliminate interference from the vaccine given first on the vaccine given later. If two live parenteral vaccines or LAIV are not administered on the same day but are separated by less than 4 weeks, the vaccine given second should be repeated in 4 weeks or confirmed to have been effective by serologic testing of the recipient (serologic testing is not recommended following LAIV, varicella, or zoster vaccines). An exception to this recommendation is yellow fever vaccine administered less than 4 weeks after single-antigen measles vaccine. A 1999 study demonstrated that yellow fever vaccine is not affected by measles vaccine given 1–27 days earlier. The effect of nonsimultaneously administered yellow fever vaccine with each of the following vaccines: mumps; varicella; zoster; LAIV; and rubella is not known.

Live vaccines administered by the oral route (oral polio vaccine [OPV] oral typhoid, and rotavirus) are not believed to interfere with each other if not given simultaneously. These vaccines may be given at any time before or after each other. Rotavirus vaccine is not approved for children older than 32 weeks, oral typhoid is not approved for children younger than 6 years of age, and OPV is no longer available in the United States, so these vaccines are not likely to be given to the same child.

Parenteral live vaccines (MMR, MMRV, varicella, zoster, and
yellow fever) and LAIV are not believed to have an effect on live vaccines given by the oral route (OPV, oral typhoid, and rotavirus). Live oral vaccines may be given at any time before or after live parenteral vaccines or LAIV.

All other combinations of two inactivated vaccines, or live and inactivated vaccines, may be given at any time before or after each other.

**Interval Between Doses of the Same Vaccine**
Immunizations are recommended for members of the youngest age group at risk for a disease for whom efficacy and safety of a vaccine have been demonstrated.

**General Rule**
- Increasing the interval between doses of a multidose vaccine does not diminish the effectiveness of the vaccine.
- Decreasing the interval between doses of a multidose vaccine may interfere with antibody response and protection.

Most vaccines in the childhood immunization schedule require two or more doses for development of an adequate and persisting antibody response. Studies have demonstrated that recommended ages and intervals between doses of the same antigen(s) provide optimal protection or have the best evidence of efficacy. Table 1 of the *General Recommendations on Immunization* (included in Appendix A) shows the recommended and minimal ages and intervals between doses of vaccines most frequently used in the United States.

Administering doses of a multidose vaccine at shorter than the recommended intervals might be necessary when an infant or child is behind schedule and needs to be brought up-to-date quickly or when international travel is pending. In these cases, an accelerated schedule using the minimum age or minimum interval criteria can be used. Accelerated schedules should not be used routinely.

Vaccine doses should not be administered at intervals less than the recommended minimal intervals or earlier than the minimal ages. Two exceptions to this may occur. The first is for measles vaccine during a measles outbreak, when the vaccine may be administered at an age younger than 12 months (this dose would not be counted, and should be repeated at 12 months of age or older). The second exception involves administering a dose a few days earlier than the minimum interval or age, which is unlikely to have a substantially negative effect on the immune response to that dose. Although vaccinations should not be scheduled at

**Minimum Intervals and Ages**
Vaccine doses should not be administered at intervals less than the minimum intervals or earlier than the minimum age.
General Recommendations on Immunization

<table>
<thead>
<tr>
<th>Violation of Minimum Intervals or Minimum Age</th>
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<tr>
<td>• ACIP recommends that vaccine doses given up to 4 days before the minimum interval or age be counted as valid</td>
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<tr>
<td>• Immunization programs and/or school entry requirements may not accept all doses given earlier than the minimum age or interval</td>
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<table>
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<tr>
<th>Extended Interval Between Doses</th>
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<tbody>
<tr>
<td>• Not all permutations of all schedules for all vaccines have been studied</td>
</tr>
<tr>
<td>• Available studies of extended intervals have shown no significant difference in final titer</td>
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<tr>
<td>• It is not necessary to restart the series or add doses because of an extended interval between doses</td>
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</table>

An interval or age less than the recommended minimums, a child may have erroneously been brought to the office early, or may have come for an appointment not specifically for vaccination. In these situations, the clinician can consider administering the vaccine earlier than the minimum interval or age. If the parent/child is known to the clinician and is reliable, it is preferable to reschedule the child for vaccination closer to the recommended interval. If the parent/child is not known to the clinician or is not reliable (e.g., habitually misses appointments), it may be preferable to administer the vaccine at that visit than to reschedule a later appointment that may not be kept.

Vaccine doses administered up to 4 days before the minimum interval or age can be counted as valid. This 4-day recommendation does not apply to rabies vaccine because of the unique schedule for this vaccine. Doses administered 5 days or earlier than the minimum interval or age should not be counted as valid doses and should be repeated as age appropriate. The repeat dose should generally be spaced after the invalid dose by an interval at least equal to the recommended minimum interval shown in Table 1 of the General Recommendations. In certain situations, local or state requirements might mandate that doses of selected vaccines be administered on or after specific ages, superseding this 4-day “grace period”.

In some cases, a scheduled dose of vaccine may not be given on time. If this occurs, the dose should be given at the next visit. Not all permutations of all schedules for all vaccines have been studied. However, available data indicate that intervals between doses longer than those routinely recommended do not affect seroconversion rate or titer when the schedule is completed. Consequently, it is not necessary to restart the series or add doses of any vaccine because of an extended interval between doses. The only exception to this rule is oral typhoid vaccine in some circumstances. Some experts recommend repeating the series of oral typhoid vaccine if the four-dose series is extended to more than 3 weeks.

**Number of Doses**

For live injected vaccines, the first dose administered at the recommended age usually provides protection. An additional dose is given to provide another opportunity for vaccine response in the small proportion of recipients who do not respond to the first dose. For instance, 95%–98% of recipients will respond to a single dose of measles vaccine. The second dose is given to ensure that nearly 100% of persons are immune (i.e., the second dose is “insurance”). Immunity following live vaccines is long-lasting, and booster doses are not necessary.
For inactivated vaccines, the first dose administered at the recommended age usually does not provide protection (hepatitis A vaccine is an exception). A protective immune response may not develop until the second or third dose. For inactivated vaccines, antibody titers may decrease (wane) below protective levels after a few years. This phenomenon is most notable for tetanus and diphtheria. For these vaccines, periodic “boosting” is required. An additional dose is given to raise antibody back to protective levels.

Not all inactivated vaccines require boosting throughout life. For example, *Haemophilus influenzae* type b (Hib) vaccine does not require boosting because Hib disease is very rare in children older than 5 years of age. Hepatitis B vaccine does not require boosting because of immunologic memory to the vaccine and the long incubation period of hepatitis B (which can produce an “autoboost”).

### Adverse Reactions Following Vaccination

Vaccines are intended to produce active immunity to specific antigens. An adverse reaction is an untoward effect caused by a vaccine that is extraneous to the vaccine’s primary purpose of producing immunity. Adverse reactions are also called vaccine side effects. A vaccine adverse event refers to any medical event that occurs following vaccination. An adverse event could be a true adverse reaction or just a coincidental event, with further research needed to distinguish between them.

Vaccine adverse reactions fall into three general categories: local, systemic, and allergic. Local reactions are generally the least severe and most frequent. Allergic reactions are the most severe and least frequent.

The most common type of adverse reactions are local reactions, such as pain, swelling, and redness at the site of injection. Local reactions may occur with up to 80% of vaccine doses, depending on the type of vaccine. Local reactions are most common with inactivated vaccines, particularly those, such as DTaP, that contain an adjuvant. Local adverse reactions generally occur within a few hours of the injection and are usually mild and self-limited. On rare occasions, local reactions may be very exaggerated or severe. Some of these reactions, referred to as Arthus reactions, are commonly seen with diphtheria and tetanus toxoids. Arthus reactions are not allergy. Arthus reactions are believed to be due to very high titers of antibody, usually caused by too many doses of toxoid.

Systemic adverse reactions are more generalized events and include fever, malaise, myalgias (muscle pain), headache, loss of appetite, and others. These symptoms are common.
and nonspecific; they may occur in vaccinated persons because of the vaccine or may be caused by something unrelated to the vaccine, like a concurrent viral infection, stress, or excessive alcohol consumption.

Systemic adverse reactions were relatively frequent with DTP vaccine, which contained a whole-cell pertussis component. However, comparison of the frequency of systemic adverse events among vaccine and placebo recipients shows they are less common with inactivated vaccines currently in use, including acellular pertussis vaccine.

Systemic adverse reactions may occur following receipt of live attenuated vaccines. Live attenuated vaccines must replicate in order to produce immunity. The adverse reactions that follow live attenuated vaccines, such as fever or rash, represent symptoms produced from viral replication and are similar to a mild form of the natural disease. Systemic adverse reactions following live vaccines are usually mild, and occur 7–21 days after the vaccine was given (i.e., after an incubation period of the vaccine virus). LAIV replicates in the mucous membranes of the nose and throat, not in the lung. As a result, LAIV may cause upper respiratory symptoms (like a cold) but not influenza-like symptoms.

A third type of vaccine adverse reaction is a severe (anaphylactic) allergic reaction. The allergic reaction may be caused by the vaccine antigen itself or some other component of the vaccine, such as cell culture material, stabilizer, preservative, or antibiotic used to inhibit bacterial growth. Severe allergic reactions may be life-threatening. Fortunately, they are rare, occurring at a rate of less than one in half a million doses. The risk of an allergic reaction can be minimized by good screening prior to vaccination. All providers who administer vaccines must have an emergency protocol and supplies to treat anaphylaxis.

**Reporting Vaccine Adverse Events**

From 1978 to 1990, CDC conducted the Monitoring System for Adverse Events Following Immunization (MSAEFI) in the public sector. In 1990, MSAEFI was replaced by the Vaccine Adverse Event Reporting System (VAERS), which includes reporting from both public and private sectors. Providers should report any clinically significant adverse event that occurs after the administration of any vaccine licensed in the United States.

Providers should report a clinically significant adverse event even if they are unsure whether a vaccine caused the event. The telephone number to call for answers to questions and to obtain VAERS forms is (800) 822-7967, or visit the VAERS website at http://vaers.hhs.gov. VAERS now accepts reports of
adverse reactions through their online system. (See Vaccine Safety chapter.)

**Contraindications and Precautions to Vaccination**

Contraindications and precautions to vaccination generally dictate circumstances when vaccines will not be given. Most contraindications and precautions are temporary, and the vaccine can be given at a later time.

A contraindication is a condition in a recipient that greatly increases the chance of a serious adverse reaction. It is a condition in the recipient of the vaccine, not with the vaccine per se. If the vaccine were given in the presence of that condition, the resulting adverse reaction could seriously harm the recipient. For instance, administering MMR vaccine to a person with a true anaphylactic allergy to gelatin could cause serious illness or death in the recipient. In general, vaccines should not be administered when a contraindication condition is present.

A precaution is similar to a contraindication. A precaution is a condition in a recipient that might increase the chance or severity of a serious adverse reaction, or that might compromise the ability of the vaccine to produce immunity (such as administering measles vaccine to a person with passive immunity to measles from a blood transfusion). Injury could result, but the chance of this happening is less than with a contraindication. In general, vaccines are deferred when a precaution condition is present. However, situations may arise when the benefit of protection from the vaccine outweighs the risk of an adverse reaction, and a provider may decide to give the vaccine.

There are very few true contraindication and precaution conditions. Only four of these conditions are generally considered to be permanent: severe (anaphylactic) allergic reaction to a vaccine component or following a prior dose of a vaccine; encephalopathy not due to another identifiable cause occurring within 7 days of pertussis vaccination; and severe combined immunodeficiency (SCID) and a history of intussusception as contraindications to rotavirus vaccine.

Conditions considered permanent precautions to further doses of pediatric pertussis-containing vaccine are temperature of 105°F or higher within 48 hours of a dose, collapse or shock-like state (hypotonic hyporesponsive episode) within 48 hours of a dose, persistent inconsolable crying lasting 3 or more hours occurring within 48 hours of a dose, or a seizure, with or without fever, occurring within 3 days of a dose. The occurrence of one of these events in a child following DTaP vaccine is not a precaution to later vaccination with the adolescent/adult formulation of pertussis vaccine (Tdap).

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**Contraindication**

- A condition in a recipient that greatly increases the chance of a serious adverse reaction

**Precaution**

- A condition in a recipient that might increase the chance or severity of an adverse reaction, or
- Might compromise the ability of the vaccine to produce immunity

---

**Permanent contraindications to vaccination:**

- Severe allergic reaction to a vaccine component or following a prior dose
- Encephalopathy not due to another identifiable cause occurring within 7 days of pertussis vaccination
- Severe combined immunodeficiency (rotavirus vaccine)
- History of intussusception (rotavirus vaccine)

**Precautions:**

- Temperature of 105°F or higher within 48 hours of a dose
- Collapse or shock-like state (hypotonic hyporesponsive episode) within 48 hours of a dose
- Persistent inconsolable crying lasting 3 or more hours occurring within 48 hours of a dose
- Seizure, with or without fever, occurring within 3 days of a dose

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**Condition**

<table>
<thead>
<tr>
<th>Condition</th>
<th>Live</th>
<th>Inactivated</th>
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<tbody>
<tr>
<td>Allergy to component</td>
<td>C</td>
<td>C</td>
</tr>
<tr>
<td>Encephalopathy</td>
<td>C</td>
<td>V*</td>
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<tr>
<td>Pregnancy</td>
<td>V</td>
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<tr>
<td>Immunosuppression</td>
<td>C</td>
<td>V</td>
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<tr>
<td>Severe illness</td>
<td>P</td>
<td>P**</td>
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<tr>
<td>Recent blood product</td>
<td>P**</td>
<td>V</td>
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*C: contraindication; P: precaution; V: vaccine; V*: vaccine if indicated except HPV and Tdap; **MMR and varicella-containing vaccines; (except rotavirus vaccine), and rotavirus vaccines only
Two conditions are temporary contraindications to vaccination with live vaccines: pregnancy and immunosuppression. Two conditions are temporary precautions to vaccination: moderate or severe acute illness (all vaccines), and recent receipt of an antibody-containing blood product. The latter precaution applies only to MMR and varicella-containing (except zoster) vaccines.

Allergy
A severe (anaphylactic) allergic reaction following a dose of vaccine will almost always contraindicate a subsequent dose of that vaccine. Anaphylactic allergies are those that are mediated by IgE, occur within minutes or hours of receiving the vaccine, and require medical attention. Examples of symptoms and signs typical of anaphylactic reactions are generalized urticaria (hives), swelling of the mouth and throat, difficulty breathing, wheezing, hypotension, or shock. With appropriate screening these reactions are very rare following vaccination.

A table listing vaccine contents is included in Appendix B. Persons may be allergic to the vaccine antigen or to a vaccine component such as animal protein, antibiotic, preservative, or stabilizer. The most common animal protein allergen is egg protein found in vaccines prepared using embryonated chicken eggs (e.g., yellow fever and influenza vaccines). Ordinarily, a person who can eat eggs or egg products can receive vaccines that contain egg; persons with histories of anaphylactic or anaphylactic-like allergy to eggs or egg proteins should be referred for further evaluation. Asking persons whether they can eat eggs without adverse effects is a reasonable way to screen for those who might be at risk from receiving yellow fever and influenza vaccines.

Several recent studies have shown that children who have a history of severe allergy to eggs rarely have reactions to MMR vaccine. This is probably because measles and mumps vaccine viruses are both grown in chick embryo fibroblasts, not actually in eggs. It appears that gelatin, not egg, might be the cause of allergic reactions to MMR. As a result, in 1998, the ACIP removed severe egg allergy as a contraindication to measles and mumps vaccines. Egg-allergic children may be vaccinated with MMR without prior skin testing.

Certain vaccines contain trace amounts of neomycin. Persons who have experienced an anaphylactic reaction to neomycin should not receive these vaccines. Most often, neomycin allergy presents as contact dermatitis, a manifestation of a delayed-type (cell-mediated) immune response, rather than anaphylaxis. A history of delayed-type reactions to neomycin is not a contraindication for administration of vaccines that contain neomycin.
Latex is sap from the commercial rubber tree. Latex contains naturally occurring impurities (e.g., plant proteins and peptides), which are believed to be responsible for allergic reactions. Latex is processed to form natural rubber latex and dry natural rubber. Dry natural rubber and natural rubber latex might contain the same plant impurities as latex but in lesser amounts. Natural rubber latex is used to produce medical gloves, catheters, and other products. Dry natural rubber is used in syringe plungers, vial stoppers, and injection ports on intravascular tubing. Synthetic rubber and synthetic latex also are used in medical gloves, syringe plungers, and vial stoppers. Synthetic rubber and synthetic latex do not contain natural rubber or natural latex, and therefore, do not contain the impurities linked to allergic reactions.

The most common type of latex sensitivity is contact-type (type 4) allergy, usually as a result of prolonged contact with latex-containing gloves. However, injection-procedure-associated latex allergies among diabetic patients have been described. Allergic reactions (including anaphylaxis) after vaccination procedures are rare. Only one report of an allergic reaction after administration of hepatitis B vaccine in a patient with known severe allergy (anaphylaxis) to latex has been published.

If a person reports a severe (anaphylactic) allergy to latex, vaccines supplied in vials or syringes that contain natural rubber should not be administered unless the benefit of vaccination clearly outweighs the risk of an allergic reaction to the vaccine. For latex allergies other than anaphylactic allergies (e.g., a history of contact allergy to latex gloves), vaccines supplied in vials or syringes that contain dry natural rubber or natural rubber latex can be administered.

**Pregnancy**

The concern with vaccination of a pregnant woman is infection of the fetus and is theoretical. Only smallpox (vaccinia) vaccine has been shown to cause fetal injury. However, since the theoretical possibility exists, live vaccines should not be administered to women known to be pregnant.

Since inactivated vaccines cannot replicate, they cannot cause fetal infection. In general, inactivated vaccines may be administered to pregnant women for whom they are indicated. An exception is human papillomavirus (HPV) vaccine, which should be deferred during pregnancy because of a lack of safety and efficacy data for this vaccine in pregnant women.

Pregnant women are at increased risk of complications of influenza. Any woman who will be pregnant during influenza season (generally December through March) should...
receive inactivated influenza vaccine. Pregnant women should not receive live attenuated influenza vaccine.

Any woman who might become pregnant is encouraged to receive a single dose of Tdap if she has not already received a dose. Women who have not received Tdap should receive a dose in the late 2nd or 3rd trimester of pregnancy or in the immediate postpartum period, before discharge from the hospital or birthing center.

Susceptible household contacts of pregnant women should receive MMR and varicella vaccines, and may receive LAIV, zoster and rotavirus vaccines if they are otherwise eligible.

**Immunosuppression**

Live vaccines can cause severe or fatal reactions in immunosuppressed persons due to uncontrolled replication of the vaccine virus. Live vaccines should not be administered to severely immunosuppressed persons for this reason. Persons with isolated B-cell deficiency may receive varicella vaccine. Inactivated vaccines cannot replicate, so they are safe to use in immunosuppressed persons. However, response to the vaccine may be decreased.

Both diseases and drugs can cause significant immunosuppression. Persons with congenital immunodeficiency, leukemia, lymphoma, or generalized malignancy should not receive live vaccines. However, MMR, varicella, rotavirus, and LAIV vaccines may be given when an immunosuppressed person lives in the same house. Household contacts of immunosuppressed persons may receive zoster vaccine if indicated. Transmission has not been documented from a person who received zoster vaccine.

Certain drugs may cause immunosuppression. For instance, persons receiving cancer treatment with alkylating agents or antimetabolites, or radiation therapy should not be given live vaccines. Live vaccines can be given after chemotherapy has been discontinued for at least 3 months. Persons receiving large doses of corticosteroids should not receive live vaccines. For example, this would include persons receiving 20 milligrams or more of prednisone daily or 2 or more milligrams of prednisone per kilogram of body weight per day for 14 days or longer. See Varicella chapter for more information about administration of zoster vaccine to immunosuppressed persons.

Aerosolized steroids, such as inhalers for asthma, are not contraindications to vaccination, nor are alternate-day, rapidly tapering, and short (less than 14 days) high-dose schedules, topical formulations, and physiologic replacement schedules.
The safety and efficacy of live attenuated vaccines administered concurrently with recombinant human immune mediators and immune modulators are not known. There is evidence that use of therapeutic monoclonal antibodies, especially the anti-tumor necrosis factor agents adalimumab, infliximab, and etanercept, may lead to reactivation of latent tuberculosis infection and tuberculosis disease and predispose to other opportunistic infections. Because the safety of live attenuated vaccines for persons receiving these drugs is not known, it is prudent to avoid administration of live attenuated vaccines for at least a month following treatment with these drugs.

Inactivated vaccines may be administered to immunosuppressed persons. Certain vaccines are recommended or encouraged specifically because immunosuppression is a risk factor for complications from vaccine-preventable diseases (i.e., influenza, invasive pneumococcal disease, invasive meningococcal disease, invasive *Haemophilus influenzae* type b disease, and hepatitis B). However, response to the vaccine may be poor depending on the degree of immunosuppression present. Because a relatively functional immune system is required to develop an immune response to a vaccine, an immunosuppressed person may not be protected even if the vaccine has been given. Additional recommendations for vaccination of immunosuppressed persons are detailed in the General Recommendations on Immunization.

**HIV Infection**

Persons infected with human immunodeficiency virus (HIV) may have no symptoms, or they may be severely immunosuppressed. In general, the same vaccination recommendations apply as with other types of immunosuppression. Live-virus vaccines are usually contraindicated, but inactivated vaccines may be administered if indicated.

Varicella and measles can be very severe illnesses in persons with HIV infection and are often associated with complications. Varicella vaccine can be considered for persons with HIV infection who are not severely immunosuppressed. Zoster vaccine should not be given to persons with AIDS or clinical manifestations of HIV infection. Measles vaccine (as combination MMR vaccine) is recommended for persons with HIV infection who are asymptomatic or mildly immunosuppressed. However, persons with severe immunosuppression due to HIV infection should not receive measles vaccine or MMR. MMRV should not be administered to persons with HIV infection. Persons with HIV infection should not receive LAIV; they should receive inactivated influenza vaccine (TIV). Yellow fever vaccine should be considered for persons who do not have AIDS or other symptomatic manifestations of HIV infection, who have established laboratory verification...
of adequate immune system function, and who cannot avoid potential exposure to yellow fever virus.

Susceptible household contacts of persons with HIV infection should receive MMR and varicella vaccines, and may receive rotavirus, zoster and LAIV vaccines if otherwise eligible.

**Vaccination of Hematopoietic Cell Transplant Recipients**

Hematopoietic cell transplant (HCT) is the infusion of hematopoietic cells from a donor into a patient who has received chemotherapy and often radiation, both of which are usually bone marrow ablative. HCT is used to treat a variety of neoplastic diseases, hematologic disorders, immunodeficiency syndromes, congenital enzyme deficiencies, and autoimmune disorders. HCT recipients can receive either their own cells (i.e., autologous HCT) or cells from a donor other than the transplant recipient (i.e., allogeneic HCT).

Antibody titers to vaccine-preventable diseases (e.g., tetanus, poliovirus, measles, mumps, rubella, and encapsulated bacteria [i.e., *Streptococcus pneumoniae* and *Haemophilus influenzae* type b]) decline during the 1–4 years after allogeneic or autologous HCT if the recipient is not revaccinated. HCT recipients are at increased risk for certain vaccine-preventable diseases. As a result, HCT recipients should be routinely revaccinated after HCT, regardless of the source of the transplanted cells. Revaccination with inactivated vaccines should begin 6 months after HCT. Influenza vaccine also should be administered at 6 months after HCT, but can be given as early as 4 months after HCT. It this circumstance an additional dose should be given. Influenza vaccine should be given annually thereafter for the life of the recipient. Three doses of PCV should be given 6 months after HCT, followed by a dose of PPSV. Revaccination to prevent pertussis should involve a primary series of DTaP followed by a Tdap booster. A dose of MCV4 should be given.

MMR and varicella vaccines should be administered 24 months after transplantation if the HCT recipient is presumed to be immunocompetent.

Household and other close contacts of HCT recipients and healthcare providers who care for HCT recipients should be appropriately vaccinated, particularly against influenza, measles, and varicella. Additional details of vaccination of HCT recipients and their contacts can be found in the ACIP statement titled *General Recommendations on Immunization*. 

**Moderate or Severe Acute Illness**

There is no evidence that a concurrent acute illness reduces vaccine efficacy or increases vaccine adverse events.
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The concern is that an adverse event (particularly fever) following vaccination could complicate the management of a severely ill person. If a person has a moderate or severe acute illness, vaccination with both live and inactivated vaccines should be delayed until the illness has improved.

Invalid Contraindications to Vaccination
Some healthcare providers inappropriately consider certain conditions or circumstances to be true contraindications or precautions to vaccinations. Such conditions or circumstances are known as invalid contraindications; these misperceptions result in missed opportunities to administer needed vaccines. Some of the most common invalid contraindications are mild illnesses, conditions related to pregnancy and breastfeeding, allergies that are not anaphylactic in nature, and certain aspects of the patient’s family history.

Mild Illness
Children with mild acute illnesses, such as low-grade fever, upper respiratory infection (URI), colds, otitis media, and mild diarrhea, should be vaccinated on schedule. Several large studies have shown that young children with URI, otitis media, diarrhea, and/or fever respond to measles vaccine as well as those without these conditions. There is no evidence that mild diarrhea reduces the success of immunization of infants in the United States.

Low-grade fever is not a contraindication to immunization. Temperature measurement is not necessary before immunization if the infant or child does not appear ill and the parent does not say the child is currently ill. ACIP has not defined a body temperature above which vaccines should not be administered. The decision to vaccinate should be based on the overall evaluation of the person rather than an arbitrary body temperature.

Antimicrobial Therapy
Antibiotics do not have an effect on the immune response to most vaccines. The manufacturer advises that Ty21a oral typhoid vaccine should not be administered to persons receiving sulfonamides or other antibiotics; Ty21a should be administered at least 72 hours after a dose of an antibacterial drug.

No commonly used antimicrobial drug will inactivate a live-virus vaccine. However, antiviral drugs may affect vaccine replication in some circumstances. Live attenuated influenza vaccine should not be administered until 48 hours after cessation of therapy using antiviral drugs active against influenza (amantadine, rimantadine, zanamivir, oseltamivir).
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Antiviral drugs active against herpesviruses (acyclovir, famciclovir) should be discontinued 24 hours before administration of a varicella-containing vaccine, if possible.

**Disease Exposure or Convalescence**

If a person is not moderately or severely ill, he or she should be vaccinated. There is no evidence that either disease exposure or convalescence will affect the response to a vaccine or increase the likelihood of an adverse event.

**Pregnant or Immunosuppressed Person in the Household**

It is critical that healthy household contacts of pregnant women and immunosuppressed persons be vaccinated. Vaccination of healthy contacts reduces the chance of exposure of pregnant women and immunosuppressed persons.

Most vaccines, including live vaccines (MMR, varicella, zoster, rotavirus, LAIV, and yellow fever) can be administered to infants or children who are household contacts of pregnant or immunosuppressed persons, as well as to breastfeeding infants (where applicable). Vaccinia (smallpox) vaccine should not be administered to household contacts of a pregnant or immunosuppressed person in a nonemergency situation. Live attenuated influenza vaccine should not be administered to persons who have contact with severely immunosuppressed persons who are hospitalized and require care in a protected environment (i.e., who are in isolation because of immunosuppression). LAIV may be administered to contacts of persons with lesser degrees of immunosuppression.

Measles and mumps vaccine viruses produce a noncommunicable infection and are not transmitted to household contacts. Rubella vaccine virus has been shown to be shed in human milk, but transmission to an infant has rarely been documented. Transmission of varicella vaccine virus is not common, and most women and older immunosuppressed persons are immune from having had chickenpox as a child. Transmission of zoster vaccine virus to household or other close contacts has not been reported.

**Breastfeeding**

Breastfeeding does not decrease the response to routine childhood vaccines and is not a contraindication for any vaccine except smallpox. Yellow fever vaccine should be avoided in breastfeeding women. However, when nursing mothers cannot avoid or postpone travel to areas endemic for yellow fever in which risk for acquisition is high, these women should be vaccinated. Breastfeeding also does not
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extend or improve the passive immunity to vaccine-preventable disease that is provided by maternal antibody except possibly for Haemophilus influenzae type b. Breastfed infants should be vaccinated according to recommended schedules. Although rubella vaccine virus might be shed in human milk, infection of an infant is rare. LAIV may be administered to a woman who is breastfeeding if she is otherwise eligible; the risk of transmission of vaccine virus is unknown but is probably low.

Preterm Birth
Vaccines should be started on schedule on the basis of the child’s chronological age. Preterm infants have been shown to respond adequately to vaccines used in infancy.

Studies demonstrate that decreased seroconversion rates might occur among preterm infants with very low birth weight (less than 2,000 grams) after administration of hepatitis B vaccine at birth. However, by 1 month chronological age, all preterm infants, regardless of initial birth weight or gestational age are as likely to respond as adequately as older and larger infants. All preterm infants born to hepatitis B surface antigen (HBsAg)-positive mothers and mothers with unknown HBsAg status must receive immunoprophylaxis with hepatitis B vaccine within 12 hours after birth. Hepatitis B immunoglobulin (HBIG) also must be given to these infants. If the maternal HBsAg status is unknown, and the infant weighs 2,000 grams or more, HBIG must be given within 7 days of birth. If the maternal HBsAg status is positive or the infant weighs less than 2,000 grams, HBIG must be given within 12 hours of birth. Note that if the infant weighs less than 2,000 grams, the initial hepatitis B vaccine dose should not be counted toward completion of the hepatitis B vaccine series, and three additional doses of hepatitis B vaccine should be administered beginning when the infant is 1 month of age.

Preterm infants with a birth weight of less than 2,000 grams who are born to women documented to be HBsAg-negative at the time of birth should receive the first dose of the hepatitis B vaccine series at 1 month of chronological age or at the time of hospital discharge.

Allergy to Products Not Present in Vaccine
Infants and children with nonspecific allergies, duck or feather allergy, or allergy to penicillin, children who have relatives with allergies, and children taking allergy shots can and should be immunized. No vaccine available in the United States contains duck antigen or penicillin.
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Allergy That is Not Anaphylactic
Anaphylactic allergy to a vaccine component (such as egg or neomycin) is a true contraindication to vaccination. If an allergy to a vaccine component is not anaphylactic or is not severe, it is not a contraindication to that vaccine.

Family History of Adverse Events
A family history of seizures is a precaution for the use of MMRV vaccine. Immunosuppression may affect the decision for varicella vaccine. A family history of adverse reactions unrelated to immunosuppression or family history of seizures or sudden infant death syndrome (SIDS) is not a contraindication to vaccination. Varicella-containing vaccine (except zoster) should not be administered to persons who have a family history of congenital or hereditary immunodeficiency in first-degree relatives (e.g., parents and siblings) unless the immunocompetence of the potential vaccine recipient has been clinically substantiated or verified by a laboratory.

Tuberculin Skin Test
Infants and children who need a tuberculin skin test (TST) can and should be immunized. All vaccines, including MMR, can be given on the same day as a TST, or any time after a TST is applied. For most vaccines, there are no TST timing restrictions.

MMR vaccine may decrease the response to a TST, potentially causing a false-negative response in someone who actually has an infection with tuberculosis. MMR can be given the same day as a TST, but if MMR has been given and 1 or more days have elapsed, in most situations a wait of at least 4 weeks is recommended before giving a routine TST. No information on the effect of varicella-containing vaccine or LAIV on a TST is available. Until such information is available, it is prudent to apply rules for spacing measles vaccine and TST to varicella vaccine and LAIV.

There is a new type of tuberculosis test known as an interferon-gamma release assay (IGRA). Even though this test improves upon the TST because it is less affected by previous doses of BCG vaccine and less affected by previous doses of tuberculosis diagnostic testing, it still may be affected by previous doses of other live vaccines so it is prudent to apply the same spacing rules as for TST.

Multiple Vaccines
As noted earlier in this chapter, administration at the same visit of all vaccines for which a person is eligible is critical.
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to reaching and maintaining high vaccination coverage. All vaccines (except vaccinia) can be administered at the same visit as all other vaccines.

Screening for Contraindications and Precautions to Vaccination

The key to preventing serious adverse reactions is screening. Every person who administers vaccines should screen every patient for contraindications and precautions before giving the vaccine dose. Effective screening is not difficult or complicated and can be accomplished with just a few questions.

Is the child (or are you) sick today?

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

Does the child have allergies to medications, food, or any vaccine?

A history of anaphylactic reaction such as hives (urticaria), wheezing or difficulty breathing, or circulatory collapse or shock (not fainting) from a previous dose of vaccine or vaccine component is a contraindication for further doses. For example, if a person experiences anaphylaxis after eating eggs, do not administer influenza vaccine. It may be more efficient to inquire about allergies in a generic way (i.e., any food or medication) rather than to inquire about specific vaccine components. Most parents will not be familiar with minor components of vaccine, but they should know if the child has had an allergic reaction to a food or medication that was severe enough to require medical attention.

Has the child had a serious reaction to a vaccine in the past?

A history of anaphylactic reaction to a previous dose of vaccine or vaccine component is a contraindication for subsequent doses. A 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 (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 hours within 48 hours of a dose, and (d) fever of 105°F (40°C) or higher 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. Usually vaccines are deferred
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when a precaution is present. However, situations may arise when the benefit outweighs the risk (e.g., during a community pertussis outbreak). A local reaction (redness or swelling at the site of injection) is not a contraindication to subsequent doses.

Has the child had a seizure, or brain or nerve problem?
DTaP and Tdap are contraindicated for 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. Children with stable neurologic disorders (including seizures) unrelated to vaccination may be vaccinated as usual.

A history of Guillain-Barré syndrome is a precaution for tetanus-containing and influenza vaccines.

Has the child had a health problem with asthma, lung disease, heart disease, kidney disease, metabolic disease such as diabetes, or a blood disorder?
Children with any of these conditions should not receive LAIV. Children with these conditions should receive inactivated influenza vaccine only.

Does the child have cancer, leukemia, AIDS, or any other immune system problem?
Live-virus vaccines (e.g., MMR, varicella, rotavirus, and the intranasal live attenuated influenza vaccine [LAIV]) are usually contraindicated in immunocompromised children. However, there are exceptions. For example, MMR and varicella vaccines are recommended for asymptomatic HIV-infected children who do not have evidence of severe immunosuppression. Persons with severe immunosuppression should not receive MMR, varicella, rotavirus, or LAIV vaccines. For details, consult the ACIP recommendations for each vaccine.

Has the child taken cortisone, prednisone, other steroids, or anticancer drugs, or had x-ray treatments in the past 3 months?
Live-virus vaccines (e.g., MMR, varicella, zoster, LAIV) should be postponed until after chemotherapy or long-term, high-dose steroid therapy has ended. Details and the length of time to postpone vaccination are described elsewhere in this chapter and in the General Recommendations on Immunization.

Has the child received a transfusion of blood or blood products, or been given a medicine called immune (gamma) globulin in the past year?
Certain live virus vaccines (e.g., MMR and varicella) may need to be deferred, depending on the type of blood
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Product and the interval since the blood product was administered. Information on recommended intervals between immune globulin or blood product administration and MMR or varicella vaccination is in Appendix A and in the General Recommendations on Immunization.

Is the child/teen pregnant or is there a chance she could become pregnant during the next month?

Live-virus vaccines (e.g., MMR, varicella, zoster, LAIV) are contraindicated during pregnancy because of the theoretical risk of virus transmission to the fetus. Sexually active young women who receive MMR or varicella vaccination should be instructed to practice careful contraception for 1 month following receipt of either vaccine. On theoretical grounds, inactivated poliovirus vaccine should not be given during pregnancy; however, it may be given if the risk of exposure is imminent (e.g., travel to endemic-disease 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 second or third trimester.

Has the child received vaccinations in the past 4 weeks?

If the child was given either live attenuated influenza vaccine or an injectable live-virus vaccine (e.g., MMR, varicella, yellow fever) in the past 4 weeks, he or she should wait 28 days before receiving another live vaccine. Inactivated vaccines may be given at the same time or at any time before or after a live vaccine.

Every person should be screened for contraindications and precautions before vaccination. Standardized screening forms for both children and adults have been developed by the Immunization Action Coalition and are available on their web site at http://www.immunize.org.

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Selected References


General Recommendations on Immunization


General Recommendations on Immunization

Recommendations of the Advisory Committee on Immunization Practices (ACIP)

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Summary

This report is a revision of the General Recommendations on Immunization and updates the 2006 statement by the Advisory Committee on Immunization Practices (ACIP) (CDC. General recommendations on immunization: recommendations of the Advisory Committee on Immunization Practices [ACIP]. MMWR 2006;55[No. RR-15]). The report also includes revised content from previous ACIP recommendations on the following topics: adult vaccination (CDC. Update on adult immunization recommendations of the immunization practices Advisory Committee [ACIP]. MMWR 1991;40[No. RR-12]); the assessment and feedback strategy to increase vaccination rates (CDC. Recommendations of the Advisory Committee on Immunization Practices: programmatic strategies to increase vaccination rates—assessment and feedback of provider-based vaccination coverage information. MMWR 1996;45:219–20); linkage of vaccination services and those of the Supplemental Nutrition Program for Women, Infants, and Children (WIC program) (CDC. Recommendations of the Advisory Committee on Immunization Practices: programmatic strategies to increase vaccination coverage by age 2 years—linkage of vaccination and WIC services. MMWR 1996;45:217–8); adolescent immunization (CDC. Immunization of adolescents: recommendations of the Advisory Committee on Immunization Practices, the American Academy of Pediatrics, the American Academy of Family Physicians, and the American Medical Association. MMWR 1996;45[No. RR-13]); and combination vaccines (CDC. Combination vaccines for childhood immunization: recommendations of the Advisory Committee on Immunization Practices [ACIP], the American Academy of Pediatrics [AAP], and the American Academy of Family Physicians [AAFP]. MMWR 1999;48[No. RR-5]).

Notable revisions to the 2006 recommendations include 1) revisions to the tables of contraindications and precautions to vaccination, as well as a separate table of conditions that are commonly misperceived as contraindications and precautions; 2) reordering of the report content, with vaccine risk-benefit screening, managing adverse reactions, reporting of adverse events, and the vaccine injury compensation program presented immediately after the discussion of contraindications and precautions; 3) stricter criteria for selecting an appropriate storage unit for vaccines; 4) additional guidance for maintaining the cold chain in the event of unavoidable temperature deviations; and 5) updated revisions for vaccination of patients who have received a hematopoietic cell transplant. The most recent ACIP recommendations for each specific vaccine should be consulted for comprehensive details. This report, ACIP recommendations for each vaccine, and additional information about vaccinations are available from CDC at http://www.cdc.gov/vaccines.

Introduction

CDC recommends routine vaccination to prevent 17 vaccine-preventable diseases that occur in infants, children, adolescents, or adults. This report provides information for clinicians and other health-care providers about concerns that commonly arise when vaccinating persons of various ages. Providers and patients encounter numerous issues, such as the timing of each dose, screening for contraindications and precautions, the number of vaccines to be administered, the educational needs of patients and parents, and interpreting and responding to adverse events. Vaccination providers help patients understand the substantial, occasionally conflicting, information about vaccination. These vaccination recommendations are intended for clinicians and other health-care providers who vaccinate patients.
The guidance in this report will help vaccination providers to assess vaccine benefits and risks, use recommended administration and storage practices, understand the most effective strategies for ensuring that vaccination coverage in the population remains high, and communicate the importance of vaccination to reduce the effects of vaccine-preventable disease. These recommendations are intended for use in the United States; vaccine availability, use, and epidemiologic circumstances might differ in other countries and might warrant different recommendations.

Methods

The Advisory Committee on Immunization Practices (ACIP) General Recommendations Work Group (GRWG) revises the General Recommendations on Immunization every 3 to 5 years. Relevant topics are those identified by ACIP as topics that relate to all vaccines, including timing and spacing of doses, vaccine administration, and vaccine storage and handling. New topics often are added when ACIP decides that previous ACIP statements on general issues such as combination vaccines, adolescent vaccination, or adult vaccination should be revised and combined with the General Recommendations on Immunization.

The recommendations in this report are based not only on available scientific evidence but also on expertise that comes directly from a diverse group of health-care providers and public health officials. GRWG includes professionals from academic medicine (pediatrics, family practice, and pharmacy); international (Canada), federal, and state public health professionals; and a member from the nongovernmental Immunization Action Coalition. GRWG, which met monthly beginning June 2007, formed subgroups on the basis of interest in topics such timing and spacing, vaccine administration, and storage and handling. These subgroups also met monthly, conducted literature reviews, and contributed expert opinion on the need for revisions to specific language. In October 2008, GRWG consulted ACIP to determine the best mechanism for approving the resulting document. ACIP concluded that the document could be approved and finalized incrementally, with a final vote on the entire document.

Revisions to the following sections were approved through consensus vote in October 2008 (i.e., were approved as a part of the entire document and not through separate votes on each section): 1) Timing and Spacing of Immunobiologics; 2) Contraindications and Precautions; 3) Preventing and Managing Adverse Reactions; 4) Reporting Vaccine Adverse Events; 5) the National Vaccine Injury Compensation Program; and 6) Vaccine Administration. In February 2009, revisions were made to Storage and Handling of Immunobiologics, and ACIP approved the section. In June 2009, ACIP voted to incorporate the contents of a 1999 ACIP statement on combination vaccines. The statement was revised by GRWG and the ACIP Combination Vaccines Work Group. ACIP also approved minor changes to the section on Special Situations and the section on Vaccination Records. In October 2009, ACIP voted to revise the entire General Recommendations on Immunization, which incorporated ACIP recommendations on adolescent vaccination (1996) and adult vaccination (1991) into the section on Vaccination Programs. Three votes were taken to approve various sections of the document, and one vote was taken to approve the entire document. At this final meeting, ACIP also discussed concerns about the lack of evidence that supports use of antipyretics before or at the time of vaccination for the prevention of fever. Consequently, CDC added information highlighting the lack of evidence for the use of antipyretics to the section on Methods for Alleviating Discomfort and Pain Associated with Vaccination. The last meeting of GRWG was held on December 2, 2009. This meeting served solely to update the work group regarding the discussions and vote of the October 2009 meeting and CDC deliberations on changes to the recommendations on the use of antipyretics.

Timing and Spacing of Immunobiologics

General Principles for Vaccine Scheduling

Optimal response to a vaccine depends on multiple factors, including the type of vaccine, age of the recipient, and immune status of the recipient. Recommendations for the age at which vaccines are administered are influenced by age-specific risks for disease, age-specific risks for complications, age-specific responses to vaccination, and potential interference with the immune response by passively transferred maternal antibodies. Vaccines are recommended for members of the youngest age group at risk for experiencing the disease for which efficacy and safety have been demonstrated.

Certain products, including inactivated vaccines, toxoids, recombinant subunit vaccines, polysaccharide conjugate vaccines, and live vaccines, require ≥2 doses to elicit an adequate antibody response. Tetanus and diphtheria toxoids require booster doses to maintain protective antibody concentrations. Unconjugated polysaccharide vaccines do not induce T-cell memory, and additional doses (although they elicit the same or a lower antibody concentration) might increase the level of protection. Conjugation with a protein carrier improves the effectiveness of polysaccharide vaccines by inducing T-lymphocyte–dependent immunologic function. Many vaccines that stimulate both cell-mediated immunity and neutralizing antibodies (e.g., live, attenuated virus
vaccines) usually can induce prolonged immunity, even if antibody titers decline over time (1). Subsequent exposure to such viruses usually results in a rapid anamnestic antibody response without viremia.

Approximately 90%–95% of recipients of a single dose of certain live vaccines administered by injection at the recommended age (i.e., measles, rubella, and yellow fever vaccines) develop protective antibodies, generally within 14 days of the dose. For varicella and mumps vaccines, 80%–85% of vaccinees are protected after a single dose. However, because a limited proportion (5%–15%) of measles, mumps, and rubella (MMR) or varicella vaccinees fail to respond to 1 dose, a second dose is recommended to provide another opportunity to develop immunity (2). Of those who do not respond to the first dose of MMR or varicella vaccine, 97%–99% respond to a second dose (3,4).

The Recommended Immunization Schedules for Persons Aged 0 Through 18 Years and the Recommended Adult Immunization Schedule are revised annually. Physicians and other health-care providers should ensure that they are following the most up-to-date schedules, which are available from CDC at http://www.cdc.gov/vaccines.

**Spacing of Multiple Doses of the Same Antigen**

Vaccination providers should adhere as closely as possible to recommended vaccination schedules (Table 1). Administration at recommended ages and in accordance with recommended intervals between doses of multidose antigens provide optimal protection.

Administration of doses of a multidose vaccine using intervals that are shorter than recommended might be necessary in certain circumstances, such as impending international travel or when a person is behind schedule on vaccinations but needs rapid protection. In these situations, an accelerated schedule can be implemented using intervals between doses that are shorter than intervals recommended for routine vaccination. The accelerated or minimum intervals and ages for scheduling catch-up vaccinations are available at http://www.cdc.gov/vaccines. Vaccine doses should not be administered at intervals less than these minimum intervals or at an age that is younger than the minimum age.*

Before administering a vaccine dose, providers might need to verify that all previous doses were administered after the minimum age and in accordance with minimum intervals (Table 1). In clinical practice, vaccine doses occasionally are administered at intervals less than the minimum interval or at ages younger than the minimum age. Doses administered too close together or at too young an age can lead to a suboptimal immune response. However, administering a dose a few days earlier the minimum interval or age is unlikely to have a substantially negative effect on the immune response to that dose. Vaccine doses administered ≤4 days before the minimum interval or age are considered valid; however, local or state mandates might supersede this 4-day guideline.† (Day 1 is the day before the day that marks the minimum age or minimum interval for a vaccine.) Because of the unique schedule for rabies vaccine, the 4-day guideline does not apply to this vaccine (5). Doses of any vaccine administered ≥5 days earlier than the minimum interval or age should not be counted as valid doses and should be repeated as age appropriate. The repeat dose should be spaced after the invalid dose by the recommended minimum interval (Table 1). For example, if the first and second doses of Haemophilus influenzae type b (Hib) were administered only 14 days apart, the second dose would be invalid and need to be repeated because the minimum interval from dose 1 to dose 2 is 4 weeks. The repeat dose should be administered ≥4 weeks after the invalid dose (in this case, the second). The repeat dose is counted as the valid second dose.

If the first dose in a series is given ≥5 days before the recommended minimum age, the dose should be repeated on or after the date when the child reaches at least the minimum age. If the vaccine is a live vaccine, ensuring that a minimum interval of 28 days has elapsed from the invalid dose is recommended. For example, if the first dose of varicella vaccine were inadvertently administered at age 10 months, the repeat dose would be administered no earlier than the child’s first birthday (the minimum age for the first dose). If the first dose of varicella vaccine were administered at age 11 months and 2 weeks, the repeat dose should be administered no earlier than 4 weeks thereafter, which would occur after the first birthday.

Certain vaccines (e.g., adult tetanus and diphtheria toxoids [Td], pediatric diphtheria and tetanus toxoids [DT]; and tetanus toxoid) produce increased rates of local or systemic reactions in certain recipients when administered more frequently than recommended (6,7). Careful record keeping, maintenance

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* During measles outbreaks, if cases are occurring among infants aged <12 months, measles vaccination of infants as young as 6 months can be used as an outbreak control measure. However, doses administered at ages <12 months should not be counted as part of the series (Sources: CDC. Measles, mumps, and rubella vaccine use and strategies for elimination of measles, rubella, and congenital rubella syndrome and control of mumps: recommendations of the Advisory Committee on Immunization Practices [ACIP]. MMWR 1998;47[No. RR-8]).

† In certain situations, local or state requirements might mandate that doses of selected vaccines be administered on or after specific ages. For example, a school entry requirement might not accept a dose of MMR or varicella vaccine administered before the child’s first birthday. ACIP recommends that physicians and other health-care providers comply with local or state vaccination requirements when scheduling and administering vaccines.
of patient histories, use of immunization information systems (IISs), and adherence to recommended schedules can decrease the incidence of such reactions without adversely affecting immunity.

**Simultaneous Administration**

Simultaneous administration of vaccines is defined as administering more than one vaccine on the same clinic day, at different anatomic sites, and not combined in the same syringe. Experimental evidence and extensive clinical experience provide the scientific basis for administering vaccines simultaneously. Simultaneously administering all vaccines for which a person is eligible at the time of a visit increases the probability that a child, adolescent, or adult will be vaccinated fully by the appropriate age (8). A study conducted during a measles outbreak demonstrated that approximately one third of measles cases among unvaccinated but vaccine-eligible preschool children might have been prevented if MMR had been administered at the same visit when another vaccine was administered (9). Simultaneous administration also is critical when preparing for foreign travel and when a health-care provider is uncertain that a patient will return for additional doses of vaccine.

With some exceptions, simultaneously administering the most widely used live and inactivated vaccines has produced seroconversion rates and rates for adverse reactions similar to those observed when the vaccines are administered separately (10–13). Routine administration of all age-appropriate doses of vaccines simultaneously is recommended for children for whom no specific contraindications exist at the time of the visit. MMR and varicella vaccine can be administered simultaneously. Live, attenuated influenza vaccine (LAIV) does not interfere with the immune response to MMR or varicella vaccines administered at the same visit. No data exist about the immunogenicity of oral Ty21a typhoid vaccine when administered concurrently or within 30 days of live virus vaccines. In the absence of such data, if typhoid vaccination is warranted, administration should not be delayed because of recent administration of live, attenuated virus vaccines (14). Simultaneous administration of pneumococcal polysaccharide vaccine (PPSV) and inactivated influenza vaccine elicits a satisfactory antibody response without increasing the incidence or severity of adverse reactions (15). Simultaneous administration of PPSV and inactivated influenza vaccine is recommended for all persons for whom both vaccines are indicated. Tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis (Tdap) and trivalent inactivated influenza vaccine (TIV) can be administered simultaneously (16). Hepatitis B vaccine administered with yellow fever vaccine is as safe and immunogenic as when these vaccines are administered separately (17). Measles and yellow fever vaccines have been administered safely at the same visit and without reduction of immunogenicity of either of the components (18,19).

Depending on which vaccines are administered during the first year of life, a child might receive up to nine injections at the 12- through 15-month visit (MMR, varicella, Hib, pneumococcal conjugate vaccine [PCV], pediatric diphtheria and tetanus toxoids and acellular pertussis [DTaP], inactivated poliovirus [IPV], hepatitis A, hepatitis B, and influenza vaccines). Although there is no exact limit on the number of injections, with a little flexibility, a provider can ensure that the primary series doses are given without administering too many injections at each visit. To reduce the number of injections at the 12- through 15-month visit, the hepatitis B series and 3 doses of IPV (20) can be administered before the child’s first birthday.

There are many other examples of ways the vaccination schedule provides flexibility. The majority of children aged 1 year who have received 2 Hib vaccine doses (polyriboosylribitol phosphate-meningococcal outer membrane protein [PRP-OMP]) or 3 Hib vaccine doses (PRP-tetanus [PRP-T]) and 3 previous doses of DTaP and PCV have protection against Hib, diphtheria, pertussis, tetanus, and pneumococcus, which lasts throughout infancy (21,22). The third (PRP-OMP) or fourth (PRP-T) dose of the Hib series and the fourth doses of DTaP and PCV are critical in boosting antibody titer and ensuring continued protection (22–25). The fourth dose of DTaP is recommended at age 15–18 months but may be administered as early as age 12 months if 6 months have elapsed since the third dose and if there is concern that the child might not return by age 18 months (23). For infants at low risk for infection with hepatitis B virus (i.e., mother tested negative for hepatitis B surface antigen [HBsAg] at the time of delivery and is not in a high risk group), the hepatitis B series can be completed at any time for children aged 6–18 months (26). The minimum age for administration of combination vaccines is the oldest minimum age for any of the individual components; the minimum interval between doses is equal to the greatest minimum interval of any of the individual components. With use of the combination Hib–hepatitis B vaccine, the minimum age of administration of the final dose is 12 months because of the minimum age requirement for the last dose of the Hib series (26). Recommended spacing of doses should be maintained (Table 1).

**Combination Vaccines**

Combination vaccines merge equivalent component vaccines into single products to prevent more than one disease
or to protect against multiple strains of infectious agents causing the same disease. Licensed combination vaccines can be used whenever any components of the combination are indicated and its other components are not contraindicated and if licensed by the Food and Drug Administration (FDA) for that dose in the series. Use of combination vaccines can reduce the number of injections patients receive and alleviate concern associated with the number of injections (20,27,28). Studies have demonstrated that parents and providers might be uncomfortable with multiple injections during single visits (29–31). Potential advantages of combination vaccines include 1) improved vaccine coverage rates (32), 2) timely vaccination coverage for children who are behind the schedule (33,34), 3) reduced shipping and stocking costs, 4) reduced costs for extra health-care visits necessitated by deferral of vaccination, and 5) facilitation of additional new vaccines into vaccination programs.

Potential disadvantages of combination vaccines include the following: 1) adverse events that might occur more frequently after administration of a combination vaccine compared with administration of separate antigens at the same visit, such as those that occur with the combination measles, mumps, rubella, and varicella (MMRV) vaccine and combination DTaP-hepatitis B-IPV vaccine (35,36); 2) confusion and uncertainty about selection of vaccine combinations and schedules for subsequent doses, especially when vaccinations are given by multiple providers who might be using different products; 3) reduced immunogenicity of one or more components (37); 4) extra doses of certain antigens in the fixed product (e.g., a provider who uses DTaP-hepatitis B-IPV vaccine will give an extra dose of hepatitis B component); and 5) a shorter shelf-life than the individual component vaccines. The economic impact of the use of combination vaccines is unclear because combination products have the potential for either increased or decreased costs compared with single-antigen component vaccines. The price of a combination vaccine might exceed the total price of separate vaccines containing the same antigens. However, combination vaccines might represent a better overall economic value if the direct and indirect costs of extra injections, delayed or missed vaccinations, and additional handling and storage are taken into consideration (38).

Licensed Combination Vaccines

In this report, a combination vaccine is defined as a product containing components that can be divided equally into independently available routine vaccines. A dash (−) between vaccine products indicates that products are supplied in their final form by the manufacturer and do not require mixing or reconstitution by the user. A slash (/) indicates that the products must be mixed or reconstituted by the user. Seven combination vaccines for which separate antigens or antigen combinations exist have been licensed by FDA since 1996 in the United States (Table 2) (39–45). In the future, combination vaccines might include increasing numbers of components in different arrays to protect against these and other diseases. (The status of licensure and recommendations for new vaccines is available at http://aapredbook.aappublications.org/news/vaccstatus.shtml.) The use of a combination vaccine generally is preferred over separate injections of the equivalent component vaccines. Considerations should include provider assessment, patient preference, and the potential for adverse events. An exception is the first dose of MMRV. Unless the parent or caregiver expresses a preference for MMRV vaccine, MMR and varicella vaccine should be administered for the first dose for children aged 12–47 months (35).

Situations might arise in which one component of a combination vaccine is specifically preferred to another component in that same vaccine. Future research considerations for newly licensed combination vaccines should focus on safety of doses that are not needed because a patient is already vaccinated against the agents, whether the combination vaccine will improve the timeliness of vaccination, and potential reduced costs from disease prevention resulting from timely vaccination.

Combination Vaccines and FDA Licensure

Only combination vaccines licensed by FDA should be used. Vaccination providers should not combine separate vaccines into the same syringe to administer together unless mixing is indicated for the patient’s age and is explicitly specified on the FDA-approved product label inserts. Only two combination vaccines (DTaP-IPV/Hib vaccine, marketed as Pentacel, and DTaP/Hib, marketed as TriHibit) contain separate antigen components for which FDA approves mixing by the user. The safety, immunogenicity, and effectiveness of unlicensed combinations are unknown.

Interchangeability of Formulations

FDA generally licenses a combination vaccine based on studies demonstrating that the product’s immunogenicity (or efficacy) and safety are comparable or equivalent to monovalent or combination products licensed previously (46). FDA licensure also generally indicates that a combination vaccine may be used interchangeably with monovalent formulations and other combination products with similar component antigens produced by the same manufacturer to continue the vaccination series. For example, DTaP, DTaP/Hib, and future

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5Provider assessment should include number of injections, vaccine availability, likelihood of improved coverage, likelihood of patient return, and storage and cost considerations.
DTaP vaccines that contain similar acellular pertussis antigens from the same manufacturer may be used interchangeably if licensed and indicated for the patient’s age (45).

**Interchangeability of Combination Vaccines from Different Manufacturers**

Licensure of a vaccine by FDA does not necessarily indicate that the vaccine is interchangeable with products from other manufacturers. Such data are ascertained and interpreted more readily for diseases with known correlates of protective immunity (e.g., specific serologic markers). For diseases without such surrogate laboratory markers, prelicensure field vaccine efficacy (phase III) trials or postlicensure surveillance generally are required to determine protection (47). ACIP prefers that doses of vaccine in a series come from the same manufacturer; however, if this is not possible or if the manufacturer of doses given previously is unknown, providers should administer the vaccine that they have available.

**Vaccine Supply**

Although vaccination providers should stock sufficient quantities of combination and monovalent vaccines needed to vaccinate children, adolescents, and adults against all diseases for which vaccines are recommended (20,28), all available types or brand-name products need not be stocked. Potential advantages of stocking a limited number of vaccines include 1) reducing confusion and potential errors when staff members must handle redundant products and formulations, 2) minimizing waste when less commonly used products expire, 3) decreasing cold storage capacity requirements, and 4) minimizing administrative costs related to accounting, purchasing, and handling.

**Extra Doses of Vaccine Antigens**

Administering extra antigens contained in a combination vaccine should be avoided in most situations. Using combination vaccines containing certain antigens not indicated at the time of administration to a patient might be justified when 1) the extra antigen is not contraindicated, 2) products that contain only the needed antigens are not readily available, and 3) potential benefits to the patient outweigh the potential risk for adverse events associated with the extra antigens. An extra dose of many live-virus vaccines and Hib or hepatitis B vaccine has not been found to be harmful (48). However, the risk for an adverse event might increase when extra doses are administered at an earlier time than the recommended interval for certain vaccines (e.g., tetanus toxoid vaccines and PPSV) (16,24,49).

A vaccination provider might not have vaccines available that contain only the antigens needed as indicated by a child’s vaccination history. Alternatively, although the indicated vaccines might be available, the provider might prefer to use a combination vaccine to reduce the required number of injections. In such cases, the benefits and risks of administering the combination vaccine with an unneeded antigen should be carefully considered and discussed with the patient or parent. When inactivated (i.e., killed), or particularly subunit vaccines (which are often adsorbed to aluminum-salt adjuvants), are administered, the reactogenicity of the vaccine must be considered in balancing the benefits and risks of extra doses. Because clinical experience suggests low reactogenicity, an extra dose of Hib or hepatitis B vaccine may be administered as part of a combination vaccine to complete a vaccination series for another component of the combination. Administration of extra doses of tetanus toxoid vaccines earlier than the recommended intervals can increase the risk for hypersensitivity reactions (16,24,50). Examples of such vaccines include DTaP, DTap/Hib, DT (for children), Td (for adolescents and adults), and Tdap. Extra doses of tetanus-toxoid–containing vaccines might be appropriate for certain patients, including for children who previously received DT or Td vaccine and need protection from pertussis (in DTap or Tdap) or for immigrants with uncertain vaccination histories.

**Conjugate Vaccine Carrier Proteins**

Certain carrier proteins in existing conjugated Hib vaccines also are used as components of other vaccines (e.g., pneumococcal and meningococcal vaccines) (51). Protein conjugates used in Hib conjugate vaccines produced in the United States include an outer membrane protein complex from *Neisseria meningitidis* (in PRP-OMP), and tetanus toxoid (in PRP-T). Simultaneous administration of quadrivalent meningococcal conjugate vaccine (MCV4), PCV, and Tdap, all of which contain diphtheria toxoid, is not associated with reduced immunogenicity or an increase in local adverse events (24,51).

**Nonsimultaneous Administration**

There is no evidence that inactivated vaccines interfere with the immune response to other inactivated vaccines or to live vaccines. Any inactivated vaccine can be administered either simultaneously or at any time before or after a different inactivated vaccine or live vaccine (Table 3). Limited data are available regarding interference between live vaccines used in the United States. The immune response to one live-virus vaccine might be impaired if administered within 28 days (i.e., 4 weeks) of another live-virus vaccine (52,53). In a study conducted in two U.S. health maintenance organizations, the risk for varicella vaccine failure (i.e., varicella disease in a vaccinated person) among persons who received varicella
Recommendations and Reports

Spacing of Vaccines and Antibody-Containing Products

Live Vaccines

Ty21a typhoid, yellow fever, LAIV, zoster, and rotavirus vaccines may be administered at any time before, concurrent with, or after administration of any immune globulin, hyperimmune globulin, or intravenous immune globulin (IGIV) (55). Blood (e.g., whole blood, packed red blood cells, and plasma) and other antibody-containing blood products (e.g., immune globulin, hyperimmune globulin, and IGIV) can inhibit the immune response to measles and rubella vaccines for ≥3 months. The effect of blood and immune globulin preparations on the response to mumps and varicella vaccines is unknown; however, commercial immune globulin preparations contain antibodies to these viruses. Blood products available in the United States are unlikely to contain a substantial amount of antibody to yellow fever vaccine virus. The length of time that interference with injectable live-virus vaccine (other than yellow fever) can persist after the antibody-containing product is a function of the amount of antigen-specific antibody contained in the product (56–58). Therefore, after an antibody-containing product is received, live vaccines (other than yellow fever, oral Ty21a typhoid, LAIV, zoster, and rotavirus) should be delayed until the passive antibody has degraded (Table 4). If a dose of injectable live-virus vaccine (other than yellow fever and zoster) is administered after an antibody-containing product but at an interval shorter than recommended in this report, the vaccine dose should be repeated unless serologic testing is feasible and indicates a response to the vaccine. The repeat dose or serologic testing should be performed after the interval indicated for the antibody-containing product (Table 5).

Although passively acquired antibodies can interfere with the response to rubella vaccine, the low dose of anti-Rho(D) globulin administered to postpartum women has not been demonstrated to reduce the response to the RA27/3 strain rubella vaccine (59). Because of the importance of rubella and varicella immunity among women of child-bearing age (4,60), the postpartum vaccination of women without evidence of immunity to rubella or varicella with MMR, varicella, or MMRV vaccines should not be delayed because of receipt of anti-Rho(D) globulin or any other blood product during the last trimester of pregnancy or at delivery. These women should be vaccinated immediately after giving birth and, if possible, tested ≥3 months later to ensure immunity to rubella and, if appropriate, to measles (2).

Interference might occur if administration of an antibody-containing product becomes necessary after administration of MMR or varicella vaccines. Usually, vaccine virus replication and stimulation of immunity occurs 1–2 weeks after vaccination. If the interval between administration of any of these vaccines and subsequent administration of an antibody-containing product is <14 days, vaccination should be repeated after the recommended interval (Tables 4 and 5) unless serologic testing indicates a protective antibody response.

A humanized mouse monoclonal antibody product (palivizumab) is available as prophylaxis for serious lower respiratory tract disease from respiratory syncytial virus among infants and young children. This product contains only antibody to respiratory syncytial virus and does not interfere with the immune response to licensed live or inactivated vaccines.

Inactivated Vaccines

Antibody-containing products interact less with inactivated vaccines, toxoids, recombinant subunit, and polysaccharide vaccines than with live vaccines (61). Therefore, administering inactivated vaccines and toxoids either simultaneously with or at any interval before or after receipt of an antibody-containing product should not substantially impair development of a protective antibody response (Table 4). The vaccine or toxoid and antibody preparation should be administered at different sites using the standard recommended dose. Increasing the vaccine dose volume or number of vaccinations is not indicated or recommended.

Interchangeability of Single-Component Vaccines from Different Manufacturers

Certain vaccines that provide protection from the same diseases are available from different manufacturers, and these
vaccines usually are not identical in antigen content or in amount or method of formulation. Manufacturers use different production processes, and their products might contain different concentrations of antigen per dose or a different stabilizer or preservative.

Available data indicate that infants who receive sequential doses of different Hib conjugate, hepatitis B, and hepatitis A vaccines produce a satisfactory antibody response after a complete primary series (62–65). All brands of Hib conjugate, hepatitis B, hepatitis A, rotavirus, and quadrivalent meningococcal conjugate vaccines are interchangeable within their respective series. If different brands of a particular vaccine require a different number of doses for series completion (e.g., Hib and rotavirus vaccines) and a provider mixes brands, the higher number of doses is recommended for series completion (e.g., 3 doses of either rotavirus or Hib vaccines).

Limited data are available about the safety, immunogenicity, and efficacy of using acellular pertussis (e.g., DTaP) vaccines from different manufacturers for successive doses of the pertussis series. Data from one study indicate that for the first 3 doses of the DTaP series, 1–2 doses of Tripedia (Sanofi Pasteur) followed by Engerix-B (GlaxoSmithKline) for the remaining dose (or doses) is comparable to 3 doses of Tripedia with regard to immunogenicity, as measured by antibodies to diphtheria, tetanus, and pertussis toxoids, and filamentous hemagglutinin (66). However, in the absence of a clear serologic correlate of protection for pertussis, the relevance of these immunogenicity data for protection against pertussis is unknown. When feasible, the same brand of DTaP vaccine should be used for all doses of the vaccination series. If vaccination providers do not know or have available the type of DTaP vaccine previously administered to a child, any DtaP vaccine may be used to continue or complete the series. For a child who needs 2 doses of influenza vaccine (TIV or LAIV), it is preferable to use the same type of vaccine for both doses. However, if the child is eligible for either TIV or LAIV, and the type of vaccine used for the first dose is not available, either vaccine can be used for the second dose. For vaccines in general, vaccination should not be deferred because the brand used for previous doses is not available or is unknown (23,67).

Lapsed Vaccination Schedule

Vaccination providers should administer vaccines as close to the recommended intervals as possible. However, intervals between doses that are longer than recommended typically do not reduce final antibody concentrations, although protection might not be attained until the recommended number of doses has been administered. With exception of oral typhoid vaccine, an interruption in the vaccination schedule does not require restarting the entire series of a vaccine or toxoid or addition of extra doses.

Unknown or Uncertain Vaccination Status

Vaccination providers frequently encounter persons who do not have adequate documentation of vaccinations. With the exception of influenza vaccine and PPSV, providers should only accept written, dated records as evidence of vaccination; self-reported doses of influenza vaccine and PPSV are acceptable (49,68). Although vaccinations should not be postponed if records cannot be found, an attempt to locate missing records should be made by contacting previous health-care providers, reviewing state or local IISs, and searching for a personally held record. If records cannot be located within a reasonable time, these persons should be considered susceptible and started on the age-appropriate vaccination schedule. Serologic testing for immunity is an alternative to vaccination for certain antigens (e.g., measles, rubella, hepatitis A, and tetanus). However, commercial serologic testing might not always be sufficiently sensitive or standardized for detection of vaccine-induced immunity (with the exception of hepatitis B vaccination at 1–2 months after the final dose), and research laboratory testing might not be readily available.

Contraindications and Precautions

Contraindications and precautions to vaccination are conditions under which vaccines should not or likely should not be administered. Because the majority of contraindications and precautions are temporary, vaccinations often can be administered later if one or more exist. A contraindication is a condition in a recipient that increases the risk for a serious adverse reaction. A vaccine should not be administered when a contraindication is present; for example, MMR vaccine should not be administered to severely immunocompromised persons. In contrast, certain conditions are commonly misperceived as contraindications (i.e., are not valid reasons to defer vaccination).

National standards for pediatric vaccination practices have been established and include descriptions of valid contraindications and precautions to vaccination. Persons who administer vaccines should screen patients for contraindications and precautions to the vaccine before each dose of vaccine is administered (Table 6). Screening is facilitated by consistent use of screening questionnaires, which are available from certain

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4 The exception is the 2-dose hepatitis B vaccination series for adolescents aged 11–15 years. Only Recombivax HB (Merck Vaccine Division) should be used in this schedule. Engerix-B (GlaxoSmithKline) is not approved by FDA for this schedule.

** Based on expert opinion.
The only contraindication applicable to all vaccines is a history of a severe allergic reaction (i.e., anaphylaxis) after a previous dose of vaccine or to a vaccine component (unless the recipient has been desensitized; see Special Situations section). In addition, severely immunocompromised persons generally should not receive live vaccines. Children who experienced encephalopathy within 7 days after administration of a previous dose of diphtheria and tetanus toxoids and whole-cell pertussis vaccine (DTP), DTaP, or Tdap not attributable to another identifiable cause should not receive additional doses of a vaccine that contains pertussis. Because of the theoretical risk to the fetus, women known to be pregnant generally should not receive live, attenuated virus vaccines (see Special Situations section).

A precaution is a condition in a recipient that might increase the risk for a serious adverse reaction or that might compromise the ability of the vaccine to produce immunity (e.g., administering measles vaccine to a person with passive immunity to measles from a blood transfusion or administering influenza vaccine to someone with a history of Guillain-Barré syndrome within 6 weeks of a previous influenza vaccination). A person might experience a more severe reaction to the vaccine than would have otherwise been expected; however, the risk for this happening is less than the risk expected with a contraindication. In general, vaccinations should be deferred when a precaution is present. However, a vaccination might be indicated in the presence of a precaution if the benefit of protection from the vaccine outweighs the risk for an adverse reaction. For example, a dose of DTaP should be considered for a person in a community with a pertussis outbreak even if that person previously developed Guillain-Barré syndrome after a dose.

The presence of a moderate or severe acute illness with or without fever is a precaution to administration of all vaccines (Table 6). A personal or family history of seizures is a precaution for MMRV vaccination. A recent study found an increased risk for febrile seizures in children who receive MMRV compared with MMR and varicella vaccine (35).

Clinicians or other health-care providers might misperceive certain conditions or circumstances as valid contraindications or precautions to vaccination when they actually do not preclude vaccination (Table 7). These misperceptions result in missed opportunities to administer recommended vaccines (69). Among the most common conditions mistakenly considered to be contraindications are diarrhea, minor upper respiratory tract illnesses (including otitis media) with or without fever, mild to moderate local reactions to a previous dose of vaccine, current antimicrobial therapy, and being in the convalescent phase of an acute illness.

The decision to administer or delay vaccination because of a current or recent acute illness depends on the severity of symptoms and etiology of the condition. The safety and efficacy of vaccinating persons who have mild illnesses have been documented (70–73). Vaccination should not be delayed because of the presence of mild respiratory tract illness or other acute illness with or without fever. Vaccination should be deferred for persons with a moderate or severe acute illness. This precaution avoids causing diagnostic confusion between manifestations of the underlying illness and possible adverse effects of vaccination or superimposing adverse effects of the vaccine on the underlying illness. After screening them for contraindications, persons with moderate or severe acute illness should be vaccinated as soon as the acute illness has improved. Studies indicate that failure to vaccinate children with minor illnesses can impede vaccination efforts (74–76). Among persons whose compliance with medical care cannot be ensured, use of every opportunity to administer appropriate vaccines is critical.

Routine physical examinations and procedures (e.g., measuring temperatures) are not prerequisites for vaccinating persons who appear to be healthy. The provider should ask the parent or guardian if the child is ill. If the child has a moderate or severe illness, the vaccination should be postponed.

### Preventing and Managing Adverse Reactions

#### Benefit and Risk Communication

Parents, guardians, legal representatives, and adolescent and adult patients should be informed about the benefits of and risks from vaccines in language that is culturally sensitive and at an appropriate educational level. Opportunity for questions should be provided before each vaccination. Discussion of the benefits of and risks from vaccination is sound medical practice and is required by law.

The National Childhood Vaccine Injury Act of 1986†† requires that vaccine information materials be developed for each vaccine covered by the act. These materials, known as vaccine information statements (VISs), must be provided by all public and private vaccination providers each time a vaccine is administered. Copies of VISs are available from state health authorities responsible for vaccination and from CDC (http://www.cdc.gov/vaccines). Translations of VISs into languages other than English are available from certain state vaccination programs and from the Immunization Action Coalition website.

(http://www.immunize.org). The act does not require that a signature be obtained; however, documentation of consent might be recommended or required by certain state or local health authorities or school authorities.

Certain parents or patients question the need for or safety of vaccinations and want to discuss the risks from and benefits of certain vaccines. Some refuse certain vaccines or reject all vaccinations for personal or religious reasons. Having a basic understanding of how patients and parents of patients view vaccine risk and developing effective approaches to address vaccine safety concerns are imperative for vaccination providers.

Each person understands and reacts to vaccine information on the basis of different factors, including previous experience, education, personal values, method of data presentation, perceptions of the risk for disease and perceived ability to control these risks, and risk preference. Increasingly, decisions about vaccination are based on inaccurate information about risk provided by the media and certain websites. Websites and other sources of vaccine information might be inaccurate or incomplete. Health-care providers can be a pivotal source of science-based credible information by discussing with parents and patients the risks from and benefits of vaccines, which helps patients make informed decisions.

When a parent or patient initiates a discussion about a perceived vaccine adverse reaction, the health-care provider should discuss the specific concerns and provide factual information, using appropriate language. Effective, empathetic vaccine risk communication is essential in responding to misinformation and concerns, with health-care providers recognizing that risk assessment and decision-making can be difficult and confusing. Certain vaccines might be acceptable to a parent who is resistant to other vaccines. This partial acceptance can be used to facilitate additional communication. Their concerns can be addressed using the VIS and offering other resource materials (e.g., vaccination information from CDC: http://www.cdc.gov/vaccines). The American Academy of Pediatrics (AAP) does not recommend that providers exclude from their practice patients whose parents or guardians question or refuse vaccination. A limited number of providers might exclude patients on this basis; however, an effective public health strategy is to identify common ground and discuss measures that need to be followed if the decision is to defer vaccination. Health-care providers should reinforce key points about each vaccine, including safety, and emphasize risks for disease among unvaccinated children. Parents should be advised of state laws regarding entry to schools or child-care facilities, which might require that unvaccinated children be excluded from the facility during outbreaks. These discussions should be documented in the patient’s medical record, including the refusal to receive certain vaccines (i.e., informed refusal).

Preventing Adverse Reactions

Vaccines are intended to produce active immunity to specific antigens. An adverse reaction is an undesirable side effect that occurs after a vaccination. Vaccine adverse reactions are classified as 1) local, 2) systemic, or 3) allergic (additional information available at http://www.fda.gov). Local reactions (e.g., redness) are usually the least severe and most frequent. Systemic reactions (e.g., fever) occur less frequently than local reactions, and severe allergic reactions (e.g., anaphylaxis) are the least frequent reactions. Severe adverse reactions are rare.

Syncope (vasovagal or vasodepressor reaction) can occur after vaccination and is most common among adolescents and young adults. In 2005, the Vaccine Adverse Event Reporting System (VAERS) began detecting a trend of increasing syncope reports that coincided with the licensure of three vaccines for adolescents: human papillomavirus (HPV), MCV4, and Tdap (77). Of particular concern among adolescents has been the risk for serious secondary injuries, including skull fracture and cerebral hemorrhage. Of 463 VAERS reports of syncope during January 1, 2005, to July 31, 2007, a total of 41 listed syncope with secondary injury with information on the timing after vaccination, and the majority of these syncope reports (76%) occurred among adolescents. Among all age groups, 80% of reported syncope episodes occur within 15 minutes of vaccine administration (additional information available at http://www.cdc.gov/vaccinesafety/concern/syncope.htm). Providers should take appropriate measures to prevent injuries if a patient becomes weak or dizzy or loses consciousness. Adolescents and adults should be seated or lying down during vaccination. Vaccine providers, particularly when vaccinating adolescents, should consider observing patients (with patients seated or lying down) for 15 minutes after vaccination to decrease the risk for injury should they faint (77). If syncope develops, patients should be observed until the symptoms resolve.

Managing Acute Vaccine Reactions

Although anaphylactic reactions are rare after vaccination, their immediate onset and life-threatening nature require that all personnel and facilities providing vaccinations have procedures in place for anaphylaxis management. All vaccination providers should be familiar with the office emergency plan and be currently certified in cardiopulmonary resuscitation. Epinephrine and equipment for maintaining an airway should be available for immediate use.

Anaphylaxis usually begins within minutes of vaccine administration (78–80). Rapid recognition and initiation of treatment are required to prevent possible progression to cardiovascular collapse. If flushing, facial edema, urticaria, itching, swelling of the mouth or throat, wheezing, dyspnea, or other
signs or symptoms of anaphylaxis occur, the patient should be placed in a recumbent position with the legs elevated if possible (81,82). Administration of epinephrine is the management of choice. Additional drugs also might be indicated (Table 8) (83). Maintenance of the airway and oxygen administration might be necessary. After the patient is stabilized, arrangements should be made for immediate transfer to an emergency facility for additional evaluation and treatment.

**Reporting Adverse Events After Vaccination**

Modern vaccines are safe and effective; however, adverse events have been reported after administration of all vaccines (84). More complete information about adverse reactions to a specific vaccine is available in the package insert for each vaccine and from CDC at http://www.cdc.gov/vaccines/vac-gen/side-effects.htm. An adverse event is an untoward event that occurs after a vaccination that might be caused by the vaccine product or vaccination process. These events range from common, minor, local reactions to rare, severe, allergic reactions (e.g., anaphylaxis). Establishing evidence for cause and effect on the basis of case reports and case series alone is usually not possible because health problems that have a temporal association with vaccination do not necessarily indicate causality.

Many adverse events require more detailed epidemiologic studies to compare the incidence of the event among vaccinees to the incidence among unvaccinated persons. Reporting adverse events, including serious events, to VAERS is a key mechanism for identifying potential vaccine safety concerns. Potential causal associations between reported adverse events after vaccination can be assessed through epidemiologic or clinical studies.

The National Childhood Vaccine Injury Act requires health-care providers and vaccine manufacturers to report to VAERS specific adverse events that occur after vaccination. The reporting requirements are different for manufacturers and health-care providers. Manufacturers are required to report all adverse events that occur after vaccination to VAERS, whereas health-care providers are required to report events that appear in the reportable events table on the VAERS website at http://vaers.hhs.gov/reportable.htm.

In addition to the mandated reporting of events listed on the reportable events table, health-care providers should report to VAERS all events listed in product inserts as contraindications, as well as all clinically significant adverse events, even if they are uncertain that the adverse event is related causally to vaccination. Persons other than health-care providers also can report adverse events to VAERS.

There are three ways to report to VAERS:
1. Submit the report online via a secure website at https://vaers.hhs.gov/esub/step1,
2. Fax a completed VAERS form to 877-721-0366, or
3. Mail a completed VAERS form: VAERS, P.O. Box 1100, Rockville, MD 20849-1100.

A VAERS form can be downloaded from the VAERS website at http://vaers.hhs.gov/resources/vaers_form.pdf. VAERS forms also can be requested by e-mail (info@vaers.org), telephone (800-822-7967), or fax (877-721-0366).

**National Vaccine Injury Compensation Program**

The National Vaccine Injury Compensation Program, established by the National Childhood Vaccine Injury Act of 1986, is a no-fault system in which persons thought to have experienced an injury or to have died as a result of administration of a covered vaccine can seek compensation. The program became operational on October 1, 1988, and is intended as an alternative to civil litigation under the traditional tort system in that negligence need not be proven. Claims arising from covered vaccines must first be adjudicated through the program before civil litigation can be pursued.

The program relies on the Vaccine Injury Table, which lists the vaccines covered by the program and the injuries (including death), disabilities, illnesses, and conditions for which compensation might be awarded. The table defines the time during which the first symptom or substantial aggravation of an injury must appear after vaccination to be eligible. Successful claimants receive a legal presumption of causation if a condition listed in the table is proven, thus avoiding the need to prove actual causation in an individual case. Claimants also can prevail for conditions not listed in the reportable events table if they prove causation for covered vaccines. Additional information is available from the Health Resources and Services Administration (HRSA) (http://www.hrsa.gov/vaccinecompensation, telephone: 800-338-2382). Persons who would like to file a claim for vaccine injury should contact the U.S. Court of Federal Claims (717 Madison Place, N.W., Washington, DC 20005; telephone: 202-357-6400).

**Vaccine Administration**

**Infection Control and Sterile Technique**

**General Precautions**

Persons administering vaccinations should follow appropriate precautions to minimize risk for spread of disease. Hands
Needles and Syringes

Needles and syringes used for vaccine injections must be sterile and disposable. A separate needle and syringe should be used for each injection. Changing needles between drawing vaccine from a vial and injecting it into a recipient is not necessary unless the needle has been damaged or contaminated. Different vaccines should never be mixed in the same syringe unless specifically licensed for such use, and no attempt should be made to transfer between syringes. Single-dose vials and manufacturer-filled syringes are designed for single-dose administration and should be discarded if vaccine has been withdrawn or reconstituted and subsequently not used within the time frame specified by the manufacturer. This typically is no longer than the same clinic day (typically recommended as a maximum for inactivated vaccines).

Sometimes providers prefll syringes themselves. ACIP discourages the routine practice of preflling syringes because of the potential for administration errors and vaccine wastage. Because the majority of vaccines have a similar appearance after being drawn into a syringe, preflling might result in administration errors. In certain circumstances in which a single vaccine type is being used (e.g., in preparation for a community influenza vaccination campaign), filling a small number of syringes may be considered. Vaccine doses should not be drawn into a syringe until immediately before administration. When syringes are filled, the type of vaccine, lot number, and date of filling must be labeled on each syringe, and the doses should be administered as soon as possible after filling. Unused syringes filled by the end user (i.e., not filled by the manufacturer) should be discarded at the end of the vaccination session. In addition to administration errors, preflling of syringes is a concern because FDA does not license administration syringes for vaccine storage. Unused syringes that are preflled by the manufacturer and activated (i.e., syringe cap removed or needle attached) should be discarded at the end of the clinic day. When in doubt about the appropriate handling of a vaccine, vaccination providers should contact the manufacturer.

Bloodborne diseases (e.g., hepatitis B, hepatitis C, and human immunodeficiency virus [HIV]) are occupational hazards for clinicians and other health-care providers. The Needlestick Safety and Prevention Act was enacted in 2000 to reduce the incidence of needle-stick injury and the consequent risk for bloodborne diseases acquired from patients. The act directed OSHA to strengthen its existing bloodborne pathogen standards. The revised standards became effective in 2001. These federal regulations require that safety-engineered injection devices (e.g., needle-shielding syringes or needle-free injectors) be used for injectable vaccination in all clinical settings. The regulations also require maintenance of records documenting injuries caused by needles and other medical sharp objects and that nonmanagerial employees be involved in the evaluation and selection of safety-engineered devices before they are procured.

Safety-engineered needles and syringes or needle-free injection devices are preferred and should be encouraged to reduce risk for injury. To prevent inadvertent needle-stick injury or reuse, safety mechanisms should be deployed after use and needles and syringes should be discarded immediately in labeled, puncture-proof containers located in the same room where the vaccine is administered. Used needles should never be recapped.

Needle-shielding or needle-free devices that might satisfy the occupational safety regulations for administering injectable vaccines are available in the United States. Additional information about implementation and enforcement of these regulations is available from OSHA (http://www.osha.gov).

Route of Administration

Oral Route

Rotavirus and oral typhoid vaccines are the only vaccines administered orally in the United States. Oral typhoid capsules should be administered as directed by the manufacturer. The capsules should not be opened or mixed with any other substance. Rotavirus vaccines are licensed for infants. There are two brands of rotavirus vaccine, and they have different types of applicators. Providers should consult the package insert for details. A dose of rotavirus vaccine need not be repeated if the vaccine is spit up or vomited. The infant should receive the remaining recommended doses of rotavirus vaccine following the routine schedule.

Intranasal Route

LAIV is licensed for healthy nonpregnant persons aged 2–49 years and is the only vaccine administered by the intranasal route. The administration device is a nasal sprayer with a dose-divider clip that allows introduction of one 0.1-mL spray into each naris. The tip should be inserted slightly into the naris before administration. Even if the person coughs or sneezes immediately after administration or the dose is expelled any other way, the vaccine...
Intramuscular Injections

Needle Length

Injectable immunobiologics should be administered where local, neural, vascular, or tissue injury is unlikely. Use of longer needles has been associated with less redness or swelling than occurs with shorter needles because of injection into deeper muscle mass (92). Appropriate needle length depends on age and body mass. Injection technique is the most important parameter to ensure efficient intramuscular vaccine delivery.

For all intramuscular injections, the needle should be long enough to reach the muscle mass and prevent vaccine from seeping into subcutaneous tissue, but not so long as to involve underlying nerves, blood vessels, or bone (91,95–97). Vaccinators should be familiar with the anatomy of the area into which they are injecting vaccine. Intramuscular injections are administered at a 90-degree angle to the skin, preferably into the anterolateral aspect of the thigh or the deltoid muscle of the upper arm, depending on the age of the patient (Table 10).

A decision on needle size and site of injection must be made for each person on the basis of the size of the muscle, the thickness of adipose tissue at the injection site, the volume of the material to be administered, injection technique, and the depth below the muscle surface into which the material is to be injected (Figure 1). Aspiration before injection of vaccines or toxoids (i.e., pulling back on the syringe plunger after needle insertion but before injection) is not necessary because no large blood vessels are present at the recommended injection sites, and a process that includes aspiration might be more painful for infants (98).

Infants (Aged <12 Months)

For the majority of infants, the anterolateral aspect of the thigh is the recommended site for injection because it provides a large muscle mass (Figure 2). In certain circumstances (e.g., physical obstruction to other sites and no reasonable indication to defer doses), the gluteal muscle can be used. If the gluteal muscle must be used, care should be taken to define the anatomic landmarks. Injection technique is the most important parameter to ensure efficient intramuscular vaccine delivery. If the subcutaneous and muscle tissue are bunched to minimize the chance of striking bone (95), a 1-inch needle is required to ensure intramuscular administration in infants aged ≥1 month. For the majority of infants, a 1-inch, 22- to 25-gauge needle is sufficient to penetrate the thigh muscle. For neonates (first 28 days of life) and preterm infants, a ¼-inch needle usually is adequate if the skin is stretched flat between the thumb and forefinger and the needle is inserted at a 90-degree angle to the skin (97).

Toddlers (Aged 12 Months–2 Years)

For toddlers, the anterolateral thigh muscle is preferred, and if used, the needle should be at least 1 inch long. The deltoid muscle can be used if the muscle mass is adequate. A ¼-inch needle is adequate only for the deltoid muscle and only if the skin is stretched flat between thumb and forefinger and the needle is inserted at a 90-degree angle to the skin.

Children (Aged 3–18 Years)

The deltoid muscle is preferred for children aged 3–18 years (Figure 3); the needle size for deltoid site injections can range from 22 to 25 gauge and from ¼ to 1 inch on the basis of technique. Knowledge of body mass can be useful for estimating

If the gluteal muscle is chosen, injection should be administered lateral and superior to a line between the posterior superior iliac spine and the greater trochanter or in the ventrogluteal site, the center of a triangle bounded by the anterior superior iliac spine, the tubercle of the iliac crest, and the upper border of the greater trochanter.
the appropriate needle length (99); however, neither a physical examination nor measurement of body mass is necessary to administer vaccines. Most children in this age range require a ½- or 1-inch needle (or intermediate size, if available).

Adults (Aged ≥19 Years)

For adults, the deltoid muscle is recommended for routine intramuscular vaccinations. The anterolateral thigh also can be used. For men and women who weigh <130 lbs (<60 kg), a ⅝-inch needle is sufficient to ensure intramuscular injection in the deltoid muscle if the injection is made at a 90-degree angle and the tissue is not bunched. For men and women who weigh 130–152 lbs (60–70 kg), a 1-inch needle is sufficient. For women who weigh 152–200 lbs (70–90 kg) and men who weigh 152–260 lbs (70–118 kg), a 1- to 1½-inch needle is recommended. For women who weigh >200 lbs (>90 kg) or men who weigh >260 lbs (>118 kg), a 1½-inch needle is recommended (Table 10) (96).

Subcutaneous Injections

Subcutaneous injections are administered at a 45-degree angle, usually into the thigh for infants aged <12 months and in the upper-outer triceps area of persons aged ≥12 months. Subcutaneous injections may be administered into the upper-outer triceps area of an infant if necessary. A ¾-inch, 23- to 25-gauge needle should be inserted into the subcutaneous tissue (Figures 4 and 5).

Multiple Injections

If multiple vaccines are administered at a single visit, administer each preparation at a different anatomic site. For infants and younger children, if more than two vaccines are injected in a single limb, the thigh is the preferred site because of the greater muscle mass; the injections should be sufficiently separated (i.e., ≥1 inch if possible) so that any local reactions can be differentiated (92,100). For older children and adults, the deltoid muscle can be used for more than one intramuscular injection. If a vaccine and an immune globulin preparation are administered simultaneously (e.g., Td/Tdap and tetanus immune globulin [TIG], hepatitis B and hepatitis B immunoglobulin [HBIG]), separate anatomic sites (i.e., different limbs) should be used for each injection. The location of all injection sites should be documented in the patient’s medical record. Health-care practices should consider using a vaccination site map so that all persons administering vaccines routinely use a particular anatomic site for each different vaccine.

Jet Injections

Jet injectors are needle-free devices that pressurize liquid medication, forcing it through a nozzle orifice into a narrow stream capable of penetrating skin to deliver a drug or vaccine into intradermal, subcutaneous, or intramuscular tissues (101,102). Jet injectors prevent needle-stick injuries to health-care providers (86) and can overcome improper, unsterile reuse and other drawbacks of needles and syringes in developing countries (87,103–104). Immune responses generated by jet injectors against both attenuated and inactivated viral and bacterial antigens are usually equivalent to, and occasionally greater than, immune responses induced by needle injection. However, local reactions or injuries are sometimes more frequent on delivery of vaccine by jet injectors compared with needle injection, depending on the inherent irritability of the vaccine and operator technique (102). Jet injectors that use the same nozzle for consecutive injections without intervening sterilization were used in mass vaccination campaigns from the 1950s through the 1990s (102); however, these were found to be unsafe because of the possibility of bloodborne pathogen transmission (105–108) and should not be used. A new generation of jet injectors with disposable cartridges and syringes has been developed since the 1990s. With a new, sterile dose chamber and nozzle for each patient and correct use, these devices do not have the same safety concerns as multiple-use nozzle jet injectors. Several of the newer devices have been approved by FDA for sale in the United States (102).

Methods for Alleviating Discomfort and Pain Associated with Vaccination

Comfort measures, such as distraction (e.g., playing music or pretending to blow away the pain), ingestion of sweet liquids, breastfeeding, cooling of the injection site, and topical analgesia, can help infants or children cope with the discomfort associated with vaccination (109,110). Pretreatment (30–60 minutes before injection) with a 5% topical lidocaine-prilocaine emulsion might decrease the pain of vaccination by causing superficial anesthesia (111,112). Evidence indicates that this cream does not interfere with the immune response to MMR (113). Topical lidocaine-prilocaine emulsion should not be used on infants aged <12 months who are receiving treatment with methemoglobin-inducing agents because of the possible development of methemoglobinemia (114). Use of a topical refrigerant (vapocoolant) spray immediately before vaccination can reduce the short-term pain associated with injections and can be as effective as lidocaine-prilocaine cream (115). Evidence does not support use of antipyretics before or at the time of vaccination; however, they can be used for the treatment of fever and local discomfort that might occur following vaccination. Studies of children with previous febrile seizures have not demonstrated antipyretics to be effective in the prevention of febrile seizures (116).
Nonstandard Vaccination Practices

Recommendations for route, site, and dosage of immunobiologics are derived from data from clinical trials, practical experience, normal periodicity of health-care visits, and theoretical considerations. ACIP discourages variations from the recommended route, site, volume, or number of doses of any vaccine.

Variation from the recommended route and site can result in inadequate protection. In adults (but not in infants) (117), the immunogenicity of hepatitis B is substantially lower when the gluteal rather than the deltoid site is used for administration (90). Hepatitis B administered intradermally might result in a lower seroconversion rate and final titer of hepatitis B surface antibody than when administered by the deltoid intramuscular route (118,119). Hepatitis B administered by any route other than intramuscular, or in adults at any site other than the deltoid or anterolateral thigh, should not be counted as valid and should be repeated. Similarly, doses of rabies vaccine administered in the gluteal site should not be counted as valid doses and should be repeated (120). MCV4 should be administered intramuscularly; however, revaccination is not necessary if a vaccine dose is administered subcutaneously (121). Inactivated influenza vaccine is immunogenic when administered in a lower than standard dose by the intradermal route to healthy adult volunteers (122). However, the immunogenicity for persons aged ≥60 years is inadequate, and varying the recommended route and dose is not recommended.

Live, attenuated injectable vaccines (e.g., MMR, varicella, and yellow fever) and certain inactivated vaccines (e.g., meningococcal polysaccharide) are recommended by the manufacturers to be administered by subcutaneous injection. PPSV and IPV are recommended by the manufacturer to be administered by the subcutaneous or intramuscular route. Response to vaccines recommended by the subcutaneous route are unlikely to be affected if the vaccines are administered by the intramuscular rather than subcutaneous route. Repeating doses of vaccine administered by the intramuscular route when recommended to be by the subcutaneous route is not necessary.

Administering volumes smaller than recommended (e.g., inappropriately divided doses) might result in inadequate protection. Using reduced doses administered at multiple vaccination visits that equal a full dose or using smaller divided doses is not recommended. Any vaccination using less than the standard dose should not be counted, and the person should be revaccinated according to age unless serologic testing indicates that an adequate response has developed. If less than a full recommended dose of a parenteral vaccine is administered because of syringe or needle leakage, the dose should be repeated. Using larger than recommended dosages can be hazardous because of excessive local or systemic concentrations of antigens or other vaccine constituents.

Storage and Handling of Immunobiologics

Failure to adhere to recommended specifications for storage and handling of immunobiologics can reduce or destroy their potency, resulting in inadequate or no immune response in the recipient. Recommendations in the product package inserts, including methods for reconstitution of the vaccine, should be followed carefully. Maintenance of vaccine quality is the shared responsibility of all handlers of vaccines from the time a vaccine is manufactured until administration. All vaccines should be inspected on delivery and monitored during storage to ensure that the recommended storage temperatures are maintained. Vaccines should continue to be stored at recommended temperatures immediately on receipt until use. Inadequate vaccine storage also can result in the loss of thousands of dollars worth of vaccine inventory and the cost of inventory replacement.

Storage Temperature

Vaccines licensed for refrigerator storage should be stored at 35°F–46°F (2°C–8°C). Liquid vaccines containing an aluminum adjuvant permanently lose potency when exposed to freezing temperatures. Live, attenuated virus vaccines that should be frozen lose potency when exposed to higher temperatures because the viruses degrade more quickly at storage temperatures that are warmer than recommended (Table 11).

Storage Units

Refrigerators and freezers used for vaccine storage must maintain the required temperature range year-round, be large enough to hold the year’s largest inventory, and be dedicated to storage of vaccines. Vaccine storage units must be carefully selected, used properly, and consistently monitored to ensure that recommended temperatures are maintained. Refrigerators without freezers and stand-alone freezers (either manual defrost or automatic defrost) are usually the most effective at maintaining the precise temperatures required for vaccine storage. Such single-purpose units sold for home use are less expensive alternatives to medical specialty equipment (123) and are preferable to combination units. A combination refrigerator-freezer unit sold for home use might be adequate for storing limited quantities of vaccines if the refrigerator and freezer compartments have separate external doors. Before using the refrigerator for vaccine storage, the temperature should be allowed to stabilize and then be measured in various locations within the refrigerator compartment to document that a consistent temperature can be maintained within the compartment (Table 11) (124). New units might need ≥2 days of operation to establish a stable operating temperature; vaccine should not be stored in the unit.
until the unit maintains an appropriate and stable storage temperature. Refrigerator temperatures are most reflective of the actual compartment temperature after the door has remained closed and undisturbed for several hours (e.g., overnight). The refrigerator temperature should be set at the midpoint of the recommended range (i.e., 40°F [5°C]) (125,126). A storage unit should be sufficiently sized so that vaccines can be placed away from the walls in the part of the unit best able to maintain the constant, required temperature. Combination units, with separate compartments of smaller size, can only be used to store limited quantities of vaccines. Frequent opening and closing of doors can cause fluctuations in compartment temperature; food, beverages, and clinical specimens should not be stored in vaccine storage units. If it becomes necessary to store clinical specimens in the same unit as vaccines, the clinical specimens should be on a shelf below the vaccine to prevent contamination should the specimen leak.

**Temperature Monitoring**

Temperature monitoring is a critical component of temperature management. All office and clinical staff members should be aware of vaccine vulnerabilities and storage requirements. Assigning one person in the office the primary responsibility for maintaining and reviewing temperature logs (Figure 6) generally is most effective, with a second person assigned as backup. Temperatures for both the refrigerator and freezer may be documented twice a day and recorded. The backup person should review the log at least once each week. Temperature logs should be maintained for 3 years unless state or local authorities require a longer time. An automated monitoring system that alerts staff when a temperature deviation occurs is optimal. However, even if an automated monitoring system is used, temperatures still should be manually checked and recorded twice each day.

Thermometers should be placed in each compartment near the vaccines. Different types of thermometers can be used, including standard fluid-filled, minimum-maximum, and continuous chart recorder thermometers (Table 12). Standard fluid-filled thermometers are the simplest and least expensive products. Product temperature thermometers are encased in biosafe liquids and generally reflect refrigerator temperature more accurately than standard fluid-filled thermometers. Minimum-maximum thermometers monitor the temperature range. Continuous chart recorder thermometers monitor temperature range and duration. All thermometers used for monitoring vaccine storage temperatures should be calibrated and certified by an appropriate agency (e.g., National Institute of Standards and Technology or the American Society for Testing and Materials). Because all thermometers are calibrated as part of the manufacturing process, this recommendation refers to a second calibration process that occurs after manufacturing but before marketing and is documented with a certificate that comes with the product. Some products (e.g., continuous chart recorder thermometers) usually include a manufacturer-defined schedule for additional recalibration. For many types of thermometers, replacement might be less expensive than recalibration. Thermometers that require batteries need to have the batteries changed; review the documentation that comes with the product for guidance.

**Response to Out-of-Range Temperature Reading**

An out-of-range temperature reading should prompt immediate action. A plan should be developed ahead of time to address various types of emergencies that might require removal of vaccine from the original storage unit. Transfer of vaccines to a predesignated alternative emergency storage site might be necessary if a temperature problem cannot be resolved immediately (e.g., plugging in an unplugged unit or closing a door that has been left open). Vaccine should be marked “do not use” and moved to the alternate site after verifying that the alternate unit is at the proper temperature. After the vaccine has been moved, determine whether the vaccine is still useable by contacting the state or local health department or manufacturer. Damage to the immunogenicity of a vaccine exposed to temperatures outside of the recommended range might not be apparent visually. As a general rule, vaccines that have been stored at inappropriate temperatures should not be administered. If such vaccines already have been administered, guidance is available from the state health department or CDC. Vaccine exposed to inappropriate temperatures that is inadvertently administered should generally be repeated. Clinicians should consult with state or local health departments in these situations.

**Expiration Dates and Windows**

All vaccines have an expiration date determined by the manufacturer that must be observed. Providers should record the vaccine expiration dates and lot numbers on a stock or inventory record for each vaccine vial when a shipment is received. When vaccines are removed from storage, clinicians and other health-care providers should note whether an expiration window exists for vaccine stored at room temperature or at an intermediate temperature. For example, single-component varicella vaccine that is stored frozen must be discarded after 72 hours of storage at refrigerator temperature. Vaccine transport between the storage site and the administration clinic is
discouraged unless the cold chain is maintained, and vaccine transport by the patient (e.g., transporting zoster vaccine from a pharmacy to a clinic) is particularly discouraged. An expiration window also applies to vaccines that have been reconstituted. For example, after reconstitution, MMR vaccine should be kept at refrigerator temperature and must be administered within 8 hours. Doses of expired vaccines that are administered inadvertently generally should not be counted as valid and should be repeated. Inactivated vaccines should be repeated as soon as possible. Live vaccines should be repeated after a 28-day interval from the invalid dose to reduce the risk for interference from interferon on the subsequent doses. Additional information about expiration dates is available at http://www.cdc.gov/vaccines/recs/storage.

**Multidose Vials**

Certain vaccines (i.e., quadrivalent meningococcal polysaccharide vaccine [MPSV4], PPSV, TIV, IPV, and yellow fever) are available in multidose vials. Because several doses are withdrawn from the same vial, proper technique must be followed to prevent contamination. For multidose vials that do not require reconstitution, doses that remain after withdrawal of a dose can be administered until the expiration date printed on the vial or vaccine packaging if the vial has been stored correctly and the vaccine is not visibly contaminated, unless otherwise specified by the manufacturer. Multidose vials that require reconstitution must be used within the interval specified by the manufacturer. After reconstitution, the new expiration date should be written on the vial.

**Altered Immunocompetence**

**General Principles**

Altered immunocompetence, a term often used synonymously with immunosuppression and immunocompromise, can be classified as primary or secondary. Primary immunodeficiencies generally are inherited and include conditions defined by an absence or quantitative deficiency of cellular or humoral components or both that provide immunity. Examples include congenital immunodeficiency diseases such as X-linked agammaglobulinemia, severe combined immunodeficiency disease, and chronic granulomatous disease. Secondary immunodeficiency generally is acquired and is defined by loss or qualitative deficiency in cellular or humoral immune components that occurs as a result of a disease process or its therapy. Examples of secondary immunodeficiency include HIV infection, hematopoietic malignancies, treatment with radiation, and treatment with immunosuppressive drugs including alkylating agents and antimetabolites. The degree to which immunosuppressive drugs cause clinically significant immunodeficiency generally is dose related and varies by drug. Primary and secondary immunodeficiencies might include a combination of deficits in both cellular and humoral immunity. In this report, the general term altered immunocompetence also is used to include conditions such as asplenia and chronic renal disease, and treatments with therapeutic monoclonal antibodies (specifically, the tumor necrosis factor inhibitors) (127–132) and prolonged administration of high-dose corticosteroids.

Determination of altered immunocompetence is important to the vaccine provider because incidence or severity of some vaccine-preventable diseases is higher in persons with altered immunocompetence; therefore, certain vaccines (e.g., inactivated influenza vaccine and pneumococcal vaccines) are recommended specifically for persons with these diseases (28,68). Vaccines might be less effective during the period of altered immunocompetence. Live vaccines might need to be deferred until immune function has improved. Inactivated vaccines administered during the period of altered immunocompetence might need to be repeated after immune function has improved. In addition, persons with altered immunocompetence might be at increased risk for an adverse reaction after administration of live, attenuated vaccines because of uninhibited replication.

The degree of altered immunocompetence in a patient should be determined by a physician. The challenge for clinicians and other health-care providers is assessing the safety and effectiveness of vaccines for conditions associated with primary or secondary immunodeficiency, especially when new therapeutic modalities are being used and information about the safety and effectiveness of vaccines has not been characterized fully in persons receiving these drugs (Table 13). Laboratory studies can be useful for assessing the effects of a disease or drug on the immune system. Tests useful to assess humoral immunity include immunoglobulin (and immunoglobulin subset) levels and specific antibody levels (e.g., tetanus and diphtheria). Tests that demonstrate the status of cellular immunity include lymphocyte numbers (i.e., a complete blood count with differential), a test that delineates concentrations and proportions of lymphocyte subsets (i.e., B and T lymphocytes, CD4+ T versus CD8+ T lymphocytes), and tests that measure T-cell proliferation in response to specific or nonspecific stimuli (e.g., lymphocyte proliferation assays) (133,134). The ability to characterize a drug or disease condition as affecting cellular or humoral immunity is only the first step; using this information to draw inferences about whether particular vaccines are indicated or whether caution is advised with use of live or inactivated vaccines is more complicated and might require consultation with an infectious disease or immunology specialist.
Altered Immunocompetence as an Indication to Receive a Vaccine

Persons with altered immunocompetence generally are advised to receive TIV and age-appropriate polysaccharide-based vaccines (PCV, PPSV, MCV4, MPSV4, and Hib) on the basis of demonstrated effectiveness or an increased risk for disease if the vaccine is withheld.

Pneumococcal Vaccines

Two types of vaccine against invasive pneumococcal disease are available in the United States: PCV and PPSV. PCV is recommended routinely for all children beginning at age 2 months. PCV is recommended routinely up to age 59 months for healthy children and up to 71 months for children with conditions that place them at high risk for invasive disease from *Streptococcus pneumoniae*. PPSV is licensed for persons aged ≥2 years and recommended for persons with certain underlying medical conditions (including altered immunocompetence) and for all persons aged ≥65 years. Complete recommendations on use of PCV and PPSV are available in the *Recommended Immunization Schedules for Persons Aged 0 Through 18 Years* and the *Recommended Adult Immunization Schedule* (25,49).

Influenza Vaccines

Two types of influenza vaccine are used in the United States: TIV and LAIV. Vaccination with TIV is recommended specifically for persons with altered immunocompetence, including HIV infection. LAIV usually is contraindicated for persons with altered immunocompetence, although healthy persons with anatomic or functional asplenia and household and other close contacts of persons with altered immunocompetence can receive this vaccine (68).

Meningococcal Vaccines

Two types of meningococcal vaccine are licensed in the United States: MCV4 and MPSV4. Persons with asplenia, C3 complement deficiency (51), or persistent complement component deficiency are at increased risk for meningococcal disease and should receive MCV4 or MPSV4. Quadrivalent MCV4 is licensed for persons aged 2–55 years; persons aged ≥56 years should receive MPSV4.

Hib Vaccines

Hib conjugate vaccines are available in single or combined antigen preparations. Hib vaccine is recommended routinely for all children through age 59 months. However, a single dose of Hib vaccine also may be considered for asplenic older children, adolescents, and adults who did not receive the vaccine series in childhood. Clinicians and other health-care providers might consider use of Hib vaccine for persons with HIV infection who did not receive the vaccine during infancy or childhood.

Vaccination of Contacts of Persons with Altered Immunocompetence

Household contacts and other close contacts of persons with altered immunocompetence may receive all age-appropriate vaccines, with the exception of smallpox vaccine. MMR, varicella, and rotavirus vaccines should be administered to susceptible household contacts and other close contacts of immunocompromised patients when indicated. MMR vaccine viruses are not transmitted to contacts, and transmission of varicella vaccine is rare (2,4,135). No specific precautions are needed unless the varicella vaccine recipient has a rash after vaccination, in which case direct contact with susceptible household contacts should be avoided until the rash resolves (4,135). All members of the household should wash their hands after changing the diaper of an infant. This minimizes rotavirus transmission, for an undetermined number of weeks after vaccination, from an infant who received rotavirus vaccine (136). Household and other close contacts of persons with altered immunocompetence should receive annual influenza vaccination. LAIV may be administered to healthy household and other close contacts of persons with altered immunocompetence (68).

Vaccination with Inactivated Vaccines

All inactivated vaccines can be administered safely to persons with altered immunocompetence whether the vaccine is a killed whole-organism or a recombinant, subunit, toxoid, polysaccharide, or polysaccharide protein-conjugate vaccine. If inactivated vaccines are indicated for persons with altered immunocompetence, the usual doses and schedules are recommended. However, the effectiveness of such vaccinations might be suboptimal.

Except for inactivated influenza vaccine, vaccination during chemotherapy or radiation therapy should be avoided if possible because antibody response might be suboptimal. Patients vaccinated within 14 days before starting immunosuppressive therapy or while receiving immunosuppressive therapy should be considered unimmunized and should be revaccinated at least 3 months after therapy is discontinued if immune competence has been restored.
**Vaccination with Live, Attenuated Viral and Bacterial Vaccines**

Severe complications have followed vaccination with live, attenuated viral and live, attenuated bacterial vaccines among persons with altered immunocompetence (137–145). Persons with most forms of altered immunocompetence should not receive live vaccines (MMR, varicella, MMRV, LAIV, zoster, yellow fever, Ty21a oral typhoid, BCG, and rotavirus).

Children with defects in phagocyte function (e.g., chronic granulomatous disease or myeloperoxidase deficiency) can receive live, attenuated viral vaccines in addition to inactivated vaccines but should not receive live, attenuated bacterial vaccines (e.g., BCG or Ty21a oral typhoid vaccines). Children with deficiencies in complement or with asplenia can receive live, attenuated viral and live, attenuated bacterial vaccines.

Persons with severe cell-mediated immunodeficiency should not receive live, attenuated viral or bacterial vaccines. However, two factors support vaccination of HIV-exposed or HIV-infected infants: 1) the HIV diagnosis might not be established in infants born to HIV-infected mothers before the age of the first rotavirus vaccine dose (only 1.5% to 3% of HIV-exposed infants in the United States will be determined to be HIV-infected), and 2) vaccine strains of rotavirus are considerably attenuated (136,146).

Children with HIV infection are at increased risk for complications from varicella and herpes zoster compared with immunoassertive children (145,147). Limited data among HIV-infected children (specifically CDC class N, A, or B with age-specific CD4+ T-lymphocyte percentages of ≥15%) indicate that varicella vaccine is immunogenic, effective, and safe (4,147). Varicella vaccine should be considered for children who meet these criteria. Eligible children should receive 2 doses of varicella vaccine with a 3-month interval between doses (4,147). Doses separated by <3 months are invalid for persons with altered immunocompetence.

Persons with HIV infection are at increased risk for severe complications if infected with measles. No severe or unusual adverse events have been reported after measles vaccination among HIV-infected persons who did not have evidence of severe immunosuppression (148–151). Therefore, MMR vaccination is recommended for all asymptomatic HIV-infected persons who do not have evidence of severe immunosuppression (age-specific CD4+ T-lymphocyte percentages of ≥15%) and for whom measles vaccination would otherwise be indicated. Similarly, MMR vaccination should be considered for mildly symptomatic HIV-infected persons (pediatric category A1 or A2 or adolescent/adult category A) who do not have evidence of severe immunosuppression (age-specific CD4+ T-lymphocyte percentages ≥15%) for whom measles vaccination would otherwise be indicated (2,146). MMRV (licensed only through age 12 years) should not be administered to children or adolescents with HIV infection (35).

HIV-infected persons who are receiving regular doses of IGIV might not respond to varicella vaccine or MMR vaccine because of the continued presence of passively acquired antibody. However, because of the potential benefit, MMR and varicella vaccines should be considered approximately 14 days before the next scheduled dose of IGIV (if not otherwise contraindicated), although an optimal immune response might not occur depending on the dose and interval since the previous dose of IGIV. Unless serologic testing indicates that specific antibodies have been produced, vaccination should be repeated (if not otherwise contraindicated) after the recommended interval (Table 5). In most cases, this is after the therapy has been discontinued. An additional dose of IGIV should be considered for persons receiving maintenance IGIV therapy who are exposed to measles or varicella ≥3 weeks after administering a standard dose (100–400 mg/kg body weight) of IGIV. Patients with leukemia, lymphoma, or other malignancies whose disease is in remission, who have restored immunocompetence, and whose chemotherapy has been discontinued for at least 3 months can receive live-virus vaccines. Persons with impaired humoral immunity (e.g., hypogammaglobulinemia or dysgammaglobulinemia) may be vaccinated with varicella vaccine (4). However, most persons with these disorders also receive periodic doses of IGIV. Appropriate spacing should be maintained between administration of IGIV and varicella vaccine to prevent an inadequate response to vaccination caused by the presence of neutralizing antibodies from the IGIV. Household members should not receive smallpox vaccine.

Zoster incidence is higher in persons with altered immunocompetence (55). Adults with most types of altered immunocompetence are expected to maintain residual immunity to varicella-zoster virus because of previous infection that protects against primary varicella but provides incomplete protection against zoster. Zoster vaccine is contraindicated in persons with primary or acquired immunodeficiency (e.g., lymphoma, leukemia, tumors involving bone marrow, and patients receiving chemotherapy) and some patients with AIDS (55). ACIP has no recommendation for or against vaccination of persons with HIV infection with CD4+ T-lymphocyte counts >200 cells/μL. Zoster vaccine may be administered to certain persons with altered immunocompetence, such as persons with HIV infection who have CD4+ T-lymphocyte counts >200 cells/μL.
**Recipients of Hematopoietic Cell Transplants**

A hematopoietic cell transplant (HCT) results in immunosuppression because of the hematopoietic ablative therapy administered before the transplant, drugs used to prevent or treat graft-versus-host disease, and, in some cases, from the underlying disease process necessitating transplantation (152–154). HCT involves ablation of the bone marrow followed by reimplantation of the person’s own stem cells or stem cells from a donor. Antibody titers to vaccine-preventable diseases (e.g., tetanus, poliovirus, measles, mumps, rubella, and encapsulated bacteria) decrease 1–4 years after autologous or allogeneic HCT if the recipient is not revaccinated. HCT recipients of all ages are at increased risk for certain vaccine-preventable diseases, including diseases caused by encapsulated bacteria (i.e., pneumococcal, meningococcal, and Hib infections). As a result, HCT recipients should be revaccinated routinely after HCT, regardless of the source of the transplanted stem cells (152–154). Most inactivated vaccines should be initiated 6 months after the HCT (154). Inactivated influenza vaccine should be administered beginning at least 6 months after HCT and annually thereafter for the life of the patient. A dose of inactivated influenza vaccine can be given as early as 4 months after HCT, but a second dose should be considered in this situation (154). A second dose is recommended routinely for all children receiving influenza vaccine for the first time. Sequential administration of 3 doses of pneumococcal conjugate vaccine is recommended, beginning 3–6 months after the transplant, followed by a dose of PPSV (152). A 3-dose regimen of Hib vaccine should be administered beginning 6 months after transplant; at least 1 month should separate the doses (154). MMR vaccine should be administered 24 months after transplant if the HCT recipient is immunocompetent. Because of insufficient experience using varicella vaccine among HCT recipients, physicians should assess the immune status of each recipient on a case-by-case basis and determine the risk for infection before using the vaccine. If a decision is made to vaccinate with varicella vaccine, the vaccine should be administered a minimum of 24 months after transplantation if the HCT recipient is presumed to be immunocompetent (152,153).

**Conditions or Drugs that Might Cause Immunodeficiencies**

Asplenia and use of corticosteroids or certain drugs have the potential to be immunosuppressive and are presumed to cause some degree of altered immunocompetence.

**Anatomic or Functional Asplenia**

Persons with anatomic asplenia (e.g., surgical removal or congenital absence of the spleen) or functional asplenia (as occurs in persons with sickle cell disease) are at increased risk for infection by encapsulated bacteria, especially by *S. pneumoniae* (pneumococcus), *N. meningitidis* (meningococcus), and Hib (22,49,31). Children aged <5 years with anatomic or functional asplenia should receive an age-appropriate series of PCV. Persons aged ≥2 years should receive 2 doses of PPSV separated by 5 years (20,25,28,49).

Meningococcal vaccine is recommended for persons with anatomic or functional asplenia. A specific MCV4 (Menactra), is approved for persons aged 2–55 years and is the recommended vaccine for this age group unless a contraindication exists. Another MCV4 (Menveo) is approved only for ages 11–55 years. Persons aged ≥56 years should receive MPSV4. The duration of immunity after meningococcal vaccination is not certain; however, on the basis of serologic testing with recently licensed assays, revaccination is recommended for persons at continued high risk. A 3-year interval to the next dose is recommended for children at high risk who receive their first dose at ages 2–6 years. A 5-year interval is recommended for persons at high risk who receive their first dose at age ≥7 years.

No efficacy data are available on which to base a recommendation for use of Hib vaccine for older children and adults with the chronic conditions that are associated with an increased risk for Hib disease. Administering 1 dose of Hib vaccine to these patients who have not previously received Hib vaccine is not contraindicated.

Pneumococcal, meningococcal, and Hib vaccinations should be administered at least 14 days before elective splenectomy, if possible. If the vaccinations are not administered before surgery, they should be administered after the procedure as soon as the patient’s condition is stable.

**Corticosteroids**

The amount of systemically absorbed corticosteroids and the duration of administration needed to suppress the immune system of an otherwise immunocompetent person are not well defined. Corticosteroid therapy usually is not a contraindication to administering live-virus vaccine when administration is 1) short term (i.e., <14 days); 2) a low to moderate dose (<20 mg of prednisone or equivalent per day); 3) long-term, alternate-day treatment with short-acting preparations; 4) maintenance physiologic doses (replacement therapy); or 5) topical (skin or eyes), inhaled, or by intraarticular, bursal, or tendon injection (154). No evidence of more severe reactions to live, attenuated viral vaccines has been reported among persons receiving corticosteroid therapy by aerosol, and such
therapy is not a reason to delay vaccination. Although the immunosuppressive effects of steroid treatment vary, the majority of clinicians consider a dose equivalent to either ≥2 mg/kg of body weight or ≥20 mg/day of prednisone or equivalent for persons who weigh >10 kg when administered for ≥14 days as sufficiently immunosuppressive to raise concern about the safety of vaccination with live-virus vaccines (154). Corticosteroids used in greater than physiologic doses also can reduce the immune response to vaccines. Vaccination providers should defer live-virus vaccination for at least 1 month after discontinuation of high-dose systemically absorbed corticosteroid therapy administered for >14 days.

Other Immunosuppressive Drugs

When feasible, clinicians should administer all indicated vaccines to all persons before initiation of chemotherapy, before treatment with other immunosuppressive drugs, and before radiation or splenectomy. Persons receiving chemotherapy or radiation for leukemia and other hematopoietic malignancies, for solid tumors, or after solid organ transplant should be assumed to have altered immunocompetence. Live, attenuated vaccines should not be administered for at least 3 months after such immunosuppressive therapy. Inactivated vaccines administered during chemotherapy should be readministered after immune competence is regained. Children receiving chemotherapy for leukemia, lymphoma, other malignancies, or radiation generally are thought to retain immune memory after treatment, although revaccination with the common childhood vaccines after chemotherapy for acute lymphoblastic leukemia might be indicated (155). In general, revaccination of a person after chemotherapy or radiation therapy is considered unnecessary if the previous vaccination occurred before therapy and not during therapy, with the exception of recipients of HCT, who should be revaccinated as recommended previously. Determination of the level of immune memory and the need for revaccination should be made by the treating physician.

Inactivated vaccines may be administered during low-dose intermittent or maintenance therapy with immunosuppressive drugs. The safety and efficacy of live, attenuated vaccines during such therapy is unknown. Physicians should carefully weigh the risks for and benefits of providing injectable live vaccines to adult patients receiving low-dose therapies for chronic autoimmune disease. The safety and efficacy of live, attenuated vaccines administered concurrently with recombinant human immune mediators and immune modulators are unknown. Evidence that use of therapeutic monoclonal antibody preparations, especially the antitumor necrosis factor agents adalimumab, infliximab, and etanercept, causes reactivation of latent tuberculosis infection and tuberculosis disease and predisposes persons to other opportunistic infections suggests caution in the use of live vaccines in patients receiving these drugs (127–132). Until additional information becomes available, avoidance of live, attenuated vaccines during intermittent or low-dose chemotherapy or other immunosuppressive therapy is prudent, unless the benefit of vaccination outweighs the hypothetical increased risk for an adverse reaction after vaccination.

Special Situations

Concurrent Administration of Antimicrobial Agents and Vaccines

With a few exceptions, use of an antimicrobial agent is not a contraindication to vaccination. Antibacterial agents have no effect on the response to live, attenuated vaccines, except live oral Ty21a typhoid vaccine, and have no effect on inactivated, recombinant subunit, or polysaccharide vaccines or toxoids. Ty21a typhoid vaccine should not be administered to persons receiving antimicrobial agents until 24 hours after the last dose of antimicrobial (14). If feasible, to avoid a possible reduction in vaccine effectiveness, antibacterial drugs should not be started or resumed until 1 week after the last dose of Ty21a.

Antiviral drugs used for treatment or prophylaxis of influenza virus infections have no effect on the response to inactivated influenza vaccine (68). However, live, attenuated influenza vaccine should not be administered until 48 hours after cessation of therapy with antiviral influenza drugs. If feasible, to avoid possible reduction in vaccine effectiveness, antiviral medication should not be administered for 14 days after LAIV administration (68). Antiviral drugs active against herpesviruses (e.g., acyclovir or valacyclovir) might reduce the efficacy of live, attenuated varicella and zoster vaccines (4,55). These drugs should be discontinued at least 24 hours before administration of vaccines containing varicella zoster virus, including zoster vaccine, if possible. Delay use or resumption of antiviral therapy for 14 days after vaccination. No data exist to suggest that commonly used antiviral drugs have an effect on rotavirus vaccine or MMR.

Tuberculosis Screening and Skin Test Reactivity

Measles illness, severe acute or chronic infections, HIV infection, and malnutrition can create a relatively anergic state during which the tuberculin skin test (TST) might have a false-negative reaction (156–158). Although any live, attenuated measles vaccine theoretically can suppress TST reactivity, the degree of suppression is likely less than that occurring from acute infection from wild-type measles virus. Although routine
TST screening of all children is no longer recommended, TST screening is sometimes needed (e.g., for well child care, school entrance, or employee health reasons) at the same time as administration of a measles-containing vaccine.

The TST and measles-containing vaccine can be administered at the same visit (preferred option). Simultaneously administering the TST and measles-containing vaccine does not interfere with reading the TST result at 48–72 hours and ensures that the person has received measles vaccine.

If the measles-containing vaccine has been administered recently, TST screening should be delayed for at least 4 weeks after vaccination. A delay in performing the TST removes the concern of any theoretical but transient suppression of TST reactivity from the vaccine.

TST screening can be performed and read before administration of the measles-containing vaccine. This option is the least favored because it delays receipt of the measles-containing vaccine. If a person is suspected to have tuberculosis, not only should the MMR vaccine be withheld before the TST, it should be withheld until after treatment has been initiated because a person with active tuberculosis who is moderately or severely ill should not receive MMR vaccine. In a general screening situation in which tuberculosis is not suspected, a TST may be administered simultaneously with live vaccines or should be deferred for 28 days after vaccination.

No data exist regarding the potential degree of TST suppression that might be associated with other live, attenuated virus vaccines (e.g., varicella or yellow fever). However, in the absence of data, following guidelines for measles-containing vaccine when scheduling TST screening and administering other live, attenuated virus vaccines is prudent. If the opportunity to vaccinate might be missed, vaccination should not be delayed only because of these theoretical considerations. Because of similar concerns about smallpox vaccine and TST suppression, a TST should not be performed until 4 weeks after smallpox vaccination (159).

A more specific test for diagnosis of tuberculosis or latent tuberculosis infection was licensed in 2005. The interferon-gamma release assay (IGRA) requires only one visit to complete and is less sensitive to the effects of previous BCG vaccination (160). The same timing guidelines that apply to the interval between a live vaccine and TST apply to IGRA (i.e., 28 days between live vaccine and IGRA if they do not occur on the same day), because IGRA (like TST) might be suppressed through immunologic mechanisms.

The potential for TST to cause boosting of results should be considered in adults who might have latent tuberculosis and have a negative initial TST (160). The two-step tuberculin test is recommended for certain situations (160). Because this test consists of two TSTs (or a TST followed by IGRA) separated by an interval of 1–3 weeks, there is a greater window of time during which live vaccine replication could suppress reactivity. If a live vaccine is administered, the first dose of a two-step TST should be delayed for 4 weeks, and if additional doses of live vaccines are indicated thereafter, they should be delayed until the second TST (or the IGRA after an initial TST).

TST or IGRA reactivity in the absence of tuberculosis disease is not a contraindication to administration of any vaccine, including live, attenuated virus vaccines. Tuberculosis disease is not a contraindication to vaccination, unless the person is moderately or severely ill. Although no studies have reported on the effects of MMR vaccine on persons with untreated tuberculosis, a theoretical basis exists for concern that measles vaccine might exacerbate tuberculosis disease (2). As a result, before administering MMR to persons with untreated active tuberculosis, initiating antituberculosis therapy is advisable (2). Considering whether concurrent immunosuppression (e.g., immunosuppression caused by HIV infection) is a concern before administering live, attenuated vaccines also is prudent.

Severe Allergy to Vaccine Components

Vaccine components can cause allergic reactions among certain recipients. These reactions can be local or systemic and can include anaphylaxis or anaphylactoid-like responses (e.g., generalized urticaria or hives, wheezing, swelling of the mouth and throat, dyspnea, hypotension, and shock). Allergic reactions might be caused by the vaccine antigen, residual protein, antimicrobial agents, preservatives, stabilizers, or other vaccine components (161). Children who have had an apparent severe allergic reaction to a vaccine should be evaluated by an allergist to determine the responsible allergen and to make recommendations regarding future vaccination. Components of each vaccine are listed in the respective package insert. An extensive list of vaccine components and their use, as well as the vaccines that contain each component, has been published (162) and is also available from CDC (http://www.cdc.gov/vaccines).

The most common animal protein allergen is egg protein, which is found in influenza and yellow fever vaccines because they are prepared using embryonated chicken eggs. Ordinarily, persons who are able to eat eggs or egg products safely can receive these vaccines; persons who have had an anaphylactic or anaphylactoid-like allergy to eggs or egg proteins generally should not receive these vaccines. Asking persons if they can eat eggs without adverse effects is a reasonable way to determine which persons might be at risk for allergic reactions from yellow fever and influenza vaccines. A regimen for administering influenza vaccine to children with egg hypersensitivity and severe asthma has been developed (163,164).
Measles and mumps vaccine viruses are grown in chick embryo fibroblast tissue culture. However, persons with a severe egg allergy can receive measles- or mumps-containing vaccines without skin testing or desensitization to egg protein (2). Rubella and varicella vaccines are grown in human diploid cell cultures and can safely be administered to persons with a severe allergy to eggs or egg proteins. The rare severe allergic reactions after measles or mumps vaccination or MMR are not thought to be caused by egg antigens but to other components of the vaccine (e.g., gelatin) (165–168). MMR, MMRV, and other vaccines contain hydrolyzed gelatin as a stabilizer. Extreme caution should be used when administering vaccines that contain gelatin to persons who have had an anaphylactic reaction to gelatin or gelatin-containing products.

Certain vaccines contain trace amounts of antimicrobial agents or other preservatives (e.g., neomycin or thimerosal) to which patients might be allergic, although such allergies are rare. The information provided in vaccine package inserts should be reviewed carefully before deciding whether a patient with such allergies should receive the vaccine. No licensed vaccine contains penicillin or penicillin derivatives.

Persons who have had anaphylactic reactions to neomycin should not receive vaccines containing neomycin. Most often, a neomycin allergy is a contact dermatitis, a manifestation of a delayed-type (cell-mediated) immune response rather than anaphylaxis (169,170). A history of delayed-type reactions to neomycin is not a contraindication for administration of these vaccines.

Thimerosal, an organic mercurial compound in use since the 1930s, is added to certain immunobiologics as a preservative. Since mid-2001, vaccines routinely recommended for young infants have been manufactured without thimerosal as a preservative. Live, attenuated vaccines have never contained thimerosal. Thimerosal-free formulations of inactivated influenza vaccine are available. Inactivated influenza vaccine also is available in formulations with trace thimerosal, in which thimerosal remains as a manufacturing residual but does not function as a preservative, and in formulations that contain thimerosal as a preservative. Thimerosal at a preservative concentration is present in certain other vaccines that can be administered to children (e.g., Td and DT). Information about the thimerosal content of vaccines is available from FDA (http://www.fda.gov/cber/vaccine/thimerosal.htm).

On the basis of limited scientific data, some investigators have asserted that receiving thimerosal-containing vaccines might induce an allergy. Allergies to thimerosal usually have been described as local delayed-type hypersensitivity reactions (171–173). Thimerosal elicits positive delayed-type hypersensitivity patch tests in 1%–18% of persons tested; however, these tests have limited or no clinical relevance (174,175). The majority of persons do not experience reactions to thimerosal administered as a component of vaccines even when patch or intradermal tests for thimerosal indicate hypersensitivity (175). A local or delayed-type hypersensitivity reaction to thimerosal is not a contraindication to receipt of a vaccine that contains thimerosal.

**Latex Allergy**

Latex is sap from the commercial rubber tree. Latex contains naturally occurring impurities (e.g., plant proteins and peptides) that might be responsible for allergic reactions. Latex is processed to form natural rubber latex and dry, natural rubber. Natural rubber latex and dry, natural rubber might contain the same plant impurities as latex but in lesser amounts. Natural rubber latex is used to produce medical gloves, catheters, and other products. Dry, natural rubber is used in the tip of syringe plungers, the tip on prefilled syringes, vial stoppers, and injection ports on intravascular tubing. Synthetic rubber and synthetic latex also are used in medical gloves, syringe plungers, and vial stoppers. Synthetic rubber and synthetic latex do not contain natural rubber or natural latex and do not contain impurities linked to allergic reactions. Latex or dry, natural rubber used in vaccine packaging generally is noted in the manufacturers’ package inserts.

The most common type of latex sensitivity is a contact-type (type 4) allergy, usually as a result of prolonged contact with latex-containing gloves (176). However, latex allergies associated with injection procedures have been described among patients with diabetes mellitus (177–179). Allergic reactions (including anaphylaxis) after vaccinations are rare. A review of reports to VAERS identified only 28 cases of possible immediate-type anaphylactic reactions among more than 160,000 vaccine adverse event reports (180).

If a person reports a severe (anaphylactic) allergy to latex, vaccines supplied in vials or syringes that contain natural rubber latex should not be administered unless the benefit of vaccination clearly outweighs the risk for a potential allergic reaction. In these cases, providers should be prepared to treat patients who are having an allergic reaction. For latex allergies other than anaphylactic allergies (e.g., a history of contact allergy to latex gloves), vaccines supplied in vials or syringes that contain dry, natural rubber or natural rubber latex may be administered.

**Vaccination of Preterm Infants**

In the majority of cases, preterm infants (infants born before 37 weeks’ gestation), regardless of birth weight, should be vaccinated at the same chronological age and according to the same schedule and using the same precautions as for full-term
infants and children. Birth weight and size are not factors in deciding whether to vaccinate a clinically stable preterm infant (181–185), except for hepatitis B vaccination. The full recommended dose of each vaccine should be used. Divided or reduced doses are not recommended.

Decreased seroconversion rates might occur among certain preterm infants (i.e., with low birth weights [<2,000 g]) after administration of hepatitis B vaccine at birth (186). However, by the chronological age of 1 month, all preterm infants, regardless of initial birth weight, are likely to respond as adequately as larger infants (187–189). Preterm infants born to HBsAg-positive mothers and mothers with unknown HBsAg status must receive immunoprophylaxis with hepatitis B vaccine within 12 hours after birth. The initial vaccine dose should not be counted toward completion of the hepatitis B series, and 3 additional doses of hepatitis B vaccine should be administered, beginning when the infant is aged 1 month. For mothers with unknown HBsAg status, attempts should be made to determine HBsAg status. The infant must be given HBIG within 12 hours of birth unless the mother is found to be HBsAg negative (26). Infants weighing <2,000 g born to HBsAg-negative mothers should receive the first dose of the hepatitis B series at chronological age 1 month or at hospital discharge.

If a child aged at least 6 weeks has been in the hospital since birth, deferral of rotavirus vaccine is recommended until the time of discharge (136). The rotavirus vaccine series should not be initiated for infants aged ≥15 weeks, 0 days.

**Breastfeeding and Vaccination**

Neither inactivated nor live-virus vaccines administered to a lactating woman affect the safety of breastfeeding for women or their infants. Although live viruses in vaccines can replicate in vaccine recipients (i.e., the mother), the majority of live viruses in vaccines have been demonstrated not to be excreted in human milk. Varicella vaccine virus has not been found in human milk (190). Although rubella vaccine virus might be excreted in human milk, the virus usually does not infect the infant. If infection does occur, it is well tolerated because the virus is attenuated (191). Inactivated, recombinant, subunit, polysaccharide, and conjugate vaccines, as well as toxoids, pose no risk for mothers who are breastfeeding or for their infants.

Breastfeeding is a contraindication for smallpox vaccination of the mother because of the theoretical risk for contact transmission from mother to infant. Yellow fever vaccine should be avoided in breastfeeding women (19). However, when nursing mothers cannot avoid or postpone travel to areas endemic for yellow fever in which risk for acquisition is high, these women should be vaccinated.

Limited data indicate that breastfeeding can enhance the response to certain vaccine antigens (192). There are no data to suggest that passive transfer of antibodies in human milk can affect the efficacy of live-virus vaccines. Breastfed infants should be vaccinated according to the recommended schedule (193–195).

**Vaccination During Pregnancy**

Risk to a developing fetus from vaccination of the mother during pregnancy is theoretical. No evidence exists of risk to the fetus from vaccinating pregnant women with inactivated virus or bacterial vaccines or toxoids (196,197). Live vaccines administered to a pregnant woman pose a theoretical risk to the fetus; therefore, live, attenuated virus and live bacterial vaccines generally are contraindicated during pregnancy. Benefits of vaccinating pregnant women usually outweigh potential risks when the likelihood of disease exposure is high, when infection would pose a risk to the mother or fetus, and when the vaccine is unlikely to cause harm. Recommendations for vaccination during pregnancy are developed using ACIP’s Guiding Principles for Development of ACIP Recommendations for Vaccination During Pregnancy and Breastfeeding (198).

Pregnant women who received the last dose of tetanus-toxoid–containing vaccine >10 years previously should generally receive Td rather than Tdap while they are pregnant (16), although Tdap is not contraindicated during pregnancy. A dose of Td during pregnancy ensures adequate tetanus immunity in the mother and prevents disease in both mother and infant. In specific situations, the dose of Td can be withheld if the provider is confident the pregnant woman is immune to tetanus (199). Regardless of a recent Td vaccination, pregnant women who have not already received Tdap should receive a dose of Tdap as soon as possible after delivery to ensure pertussis immunity and reduce the risk for transmission to the newborn. Pregnant women who are not vaccinated or are only partially vaccinated against tetanus should complete the primary series (16). Women for whom Td is indicated but who did not complete the recommended 3-dose series during pregnancy should receive follow-up after delivery to ensure the series is completed. Because Tdap is recommended as a one-time dose, pregnant women who previously have received Tdap should receive Td if indicated.

Women in the second and third trimesters of pregnancy are at increased risk for hospitalization from influenza (68,200). Because vaccinating against influenza before the season begins is critical, and because predicting exactly when the season will begin is impossible, routine influenza vaccination is recommended for all women who are or will be pregnant (in any
IPV can be administered to pregnant women who are at risk for exposure to wild-type poliovirus infection (201). Hepatitis A, pneumococcal polysaccharide, meningococcal conjugate, and meningococcal polysaccharide vaccines should be considered for women at increased risk for those infections (49,51,202). Pregnant women who must travel to areas where the risk for yellow fever is high should receive yellow fever vaccine because the limited theoretical risk from vaccination is outweighed substantially by the risk for yellow fever infection (19,203). Hepatitis B vaccine is not contraindicated in pregnancy and should be given to a pregnant woman who has an indication for hepatitis B vaccine (26,204).

Pregnancy is a contraindication for smallpox (vaccinia) vaccine and measles-, mumps-, rubella-, and varicella-containing vaccines. Smallpox vaccine is the only vaccine known to harm a fetus when administered to a pregnant woman. In addition, smallpox vaccine should not be administered to a household contact of a pregnant woman (159). Data from studies of children born to mothers vaccinated with rubella vaccine during pregnancy demonstrate rubella antibody levels in unvaccinated infants. This could represent passive transfer of maternal antibody or a fetal antibody response to vaccine virus infection in the fetus. No cases of congenital rubella or abnormalities attributable to fetal infection have been observed among infants born to susceptible women who received rubella or varicella vaccines during pregnancy (205–207). Because of the importance of protecting women of childbearing age against rubella and varicella, reasonable practices in any vaccination program include asking women if they are pregnant or might become pregnant in the next 4 weeks; not vaccinating women who state that they are or plan to become pregnant; explaining the theoretical risk for the fetus if MMR, varicella, or MMRV vaccine were administered to a woman who is pregnant; and counseling women who are vaccinated not to become pregnant during the 4 weeks after MMR, varicella, or MMRV vaccination (2,59,205–207). MMRV is an unlikely option for a pregnant woman because the vaccine is only licensed through 12 years of age. Routine pregnancy testing of women of childbearing age before administering a live-virus vaccine is not recommended (2,4). If a pregnant woman is inadvertently vaccinated or becomes pregnant within 4 weeks after MMR or varicella vaccination, she should be counseled about the theoretical basis of concern for the fetus; however, MMR or varicella vaccination during pregnancy should not be considered a reason to terminate pregnancy (2,4,207).

Persons who receive MMR vaccine do not transmit the vaccine viruses to contacts (2). Transmission of varicella vaccine virus to contacts is rare (4). MMR and varicella vaccines should be administered when indicated to children and other household contacts of pregnant women (2,4). Infants living in households with pregnant women should be vaccinated with rotavirus vaccine according to the same schedule as infants in households without pregnant women.

Pregnant women should be evaluated for immunity to rubella and varicella and be tested for the presence of HBsAg during every pregnancy (2,26,60). Women susceptible to rubella and varicella should be vaccinated immediately after delivery. A woman found to be HBsAg positive should be monitored carefully to ensure that the infant receives HIBG and begins the hepatitis B vaccine series no later than 12 hours after birth and that the infant completes the recommended hepatitis B vaccine series on schedule (26). No known risk exists for the fetus from passive immunization of pregnant women with immune globulin preparations.

**Persons Vaccinated Outside the United States**

Clinicians have a limited ability to determine whether persons are protected on the basis of their country of origin and their records alone. Vaccines administered outside the United States generally can be accepted as valid if the schedule (i.e., minimum ages and intervals) is similar to that recommended in the United States. With the exception of the influenza vaccine and PPSV, only written documentation should be accepted as evidence of previous vaccination. Written records are more likely to predict protection if the vaccines, dates of administration, intervals between doses, and age at the time of vaccination are comparable to U.S. recommendations. Although vaccines with inadequate potency have been produced in other countries (208,209), the majority of vaccines used worldwide are produced with adequate quality control standards and are potent.

The number of U.S. families adopting children from outside the United States has increased substantially in the last decade (209). Adopted children’s birth countries often have vaccination schedules that differ from the recommended childhood vaccination schedule in the United States. Differences in the U.S. schedule and those used in other countries include the vaccines administered, the recommended ages of administration, and the number and timing of doses.

Data are inconclusive regarding the extent to which an internationally adopted child’s vaccination record reflects the child’s protection. A child’s record might indicate administration of MMR vaccine when only single-antigen measles vaccine was administered. A study of children adopted from orphanages in the People’s Republic of China, Russia, and countries in Eastern Asia found that the number of children who received MMR vaccine at 1 year of age was higher in the People’s Republic of China than in Russia or Eastern Asia (208). The differences were not statistically significant, but the numbers were small.

**Recommendations and Reports**
Europe determined that 67% of children with documentation of ≥3 doses of DTP before adoption had nonprotective titers to these antigens (209). In contrast, children adopted from these countries who received vaccination in the community (not only from orphanages) and had documentation of ≥1 doses of DTP exhibited protective titers 67% of the time (209). However, antibody testing was performed by using a hemagglutination assay, which tends to underestimate protection and cannot directly be compared with antibody concentration (210). Data are likely to remain limited for areas other than the People’s Republic of China, Russia, and Eastern Europe. Health-care providers should ensure that household contacts of international adoptees are vaccinated adequately, particularly for measles, hepatitis A, and hepatitis B (211).

Health-care providers may use one of multiple approaches if the immunogenicity of vaccines administered to persons outside the United States is in question. Repeating the vaccinations is an acceptable option that usually is safe and prevents the need to obtain and interpret serologic tests. If avoiding unnecessary injections is desired, judicious use of serologic testing might help determine which vaccinations are needed. For some vaccines, the most readily available serologic tests cannot document protection against infection. These recommendations provide guidance on possible approaches to evaluation and revaccination for each vaccine recommended in the United States (Table 14).

**DTaP Vaccine**

Vaccination providers can revaccine children with DTaP vaccine without regard to recorded doses; however, data indicate increased rates of local adverse reactions after the fourth and fifth doses of DTaP (67). If a revaccination approach is adopted and a severe local reaction occurs, serologic testing for specific IgG antibody to tetanus and diphtheria toxins can be measured before administering additional doses. Protective concentration indicates that additional doses are unnecessary and subsequent vaccination should occur as age-appropriate. No established serologic correlates exist for protection against pertussis.

For a child whose record indicates receipt of ≥3 doses of DTP or DTaP, serologic testing for specific IgG antibody to both diphtheria and tetanus toxin before additional doses is a reasonable approach. If a protective concentration is present, recorded doses are considered valid, and the vaccination series should be completed as age appropriate. An indeterminate antibody concentration might indicate immunologic memory but waning antibody; serologic testing can be repeated after a booster dose if the vaccination provider wants to avoid revaccination with a complete series.

Alternately, for a child whose records indicate receipt of ≥3 doses, a single booster dose can be administered followed by serologic testing after 1 month for specific IgG antibody to both diphtheria and tetanus toxins. If the child has a protective concentration, the recorded doses are considered valid, and the vaccination series should be completed as age appropriate. Children with an indeterminate concentration after a booster dose should be revaccinated with a complete series.

**Hepatitis A Vaccine**

Children aged 12–23 months without documentation of hepatitis A vaccination or serologic evidence of immunity should be vaccinated on arrival in the United States (202). Persons who have received 1 dose should receive the second dose if 6–18 months have passed since the first dose was administered.

**Hepatitis B Vaccine**

Persons not known to be vaccinated for hepatitis B should receive an age-appropriate series of hepatitis B vaccine. A person whose records indicate receipt of ≥3 doses of vaccine are considered protected, and additional doses are not needed if ≥1 dose was administered at age ≥24 weeks. Persons who received their last hepatitis B vaccine dose at an age <24 weeks should receive an additional dose at age ≥24 weeks. People who have received <3 doses of vaccine should complete the series at the recommended intervals and ages.

All foreign-born persons and immigrants, refugees, and internationally adopted children born in Asia, the Pacific Islands, Africa, and other regions of high or intermediate endemicity should be tested for HBsAg, regardless of vaccination status (212). Those determined to be HBsAg-positive should be monitored for development of liver disease. Household members of HBsAg-positive children or adults should be vaccinated if they are not already immune.

**Hib Vaccine**

Interpretation of a serologic test to verify whether children who were vaccinated >2 months previously are protected against Hib bacteria can be difficult. Because the number of vaccinations needed for protection decreases with age and because adverse events are rare (22), age-appropriate vaccination should be provided. Hib vaccination is not recommended routinely for persons aged ≥5 years (20).
MMR Vaccine

The simplest approach to resolving concerns about MMR vaccination is to revaccinate with 1 or 2 doses of MMR vaccine, depending on age. Serious adverse events after MMR vaccinations are rare (2). No evidence indicates that administering MMR vaccine increases the risk for adverse reactions among persons who are already immune to measles, mumps, or rubella as a result of previous vaccination or natural disease. Doses of measles-containing vaccine administered before the first birthday should not be counted as part of the series (2). Alternatively, serologic testing for IgG antibody to vaccine viruses indicated on the vaccination record can be considered. Serologic testing is widely available for measles and rubella IgG antibody. A person whose record indicates receipt of monovalent measles or measles-rubella vaccine on or after the first birthday and who has protective antibody against measles and rubella should receive 1 or 2 doses of MMR or MMRV as age appropriate to ensure protection against mumps and varicella (and rubella if measles vaccine alone had been administered). If a person whose record indicates receipt of MMR at age ≥12 months has a protective concentration of antibody to measles, no additional vaccination is needed unless a second dose is required for school entry.

Pneumococcal Vaccines

Many industrialized countries are now routinely using pneumococcal vaccines. Although recommendations for pneumococcal polysaccharide vaccine also exist in many countries, the vaccine might not be routinely administered. PCV and PPSV should be administered according to age-appropriate vaccination schedules or as indicated by the presence of underlying medical conditions (25,49).

Poliovirus Vaccine

The simplest approach to vaccinating with poliovirus vaccine is to revaccinate persons aged <18 years with IPV according to the U.S. schedule. Adverse events after IPV are rare (201). Children appropriately vaccinated with 3 doses of OPV in economically developing countries might have suboptimal seroconversion, including to type 3 poliovirus (201). Serologic testing for neutralizing antibody to poliovirus types 1, 2, and 3 can be obtained commercially and at certain state health department laboratories. Persons with protective titers against all three types do not need to repeat doses but should complete the schedule as age appropriate.

Rotavirus Vaccine

Rotavirus vaccination should not be initiated for infants aged ≥15 weeks, 0 days. Infants who began the rotavirus vaccine series outside the United States but who did not complete the series and who are still aged ≤8 months, 0 days, should follow the routine schedule and receive doses to complete the series. If the brand of a previously administered dose is RV5 or unknown, a total of 3 doses of rotavirus vaccine should be documented for series completion. All doses should be administered by age 8 months, 0 days.

Td and Tdap Vaccines

Children aged ≥7 years who need the primary series doses of tetanus-toxoid–containing vaccine should receive Td or Tdap as age appropriate.

Varicella Vaccine

Varicella vaccine is not available in the majority of countries. A person who lacks reliable evidence of varicella immunity should be vaccinated as age appropriate (4,20).

Zoster Vaccine

Zoster vaccination is recommended for all persons aged ≥60 years who have no contraindications, including persons who report a previous episode of zoster or who have chronic medical conditions. The vaccine should be offered at the patient’s first clinical encounter with the health-care provider. The vaccine is administered as a single 0.65-mL subcutaneous dose. Zoster vaccination is not indicated to treat acute zoster, to prevent persons with acute zoster from developing postherpetic neuralgia, or to treat ongoing postherpetic neuralgia. Before administration of zoster vaccine, patients do not need to be asked about their history of varicella or to have serologic testing conducted to determine zoster immunity.

Vaccinating Persons with Bleeding Disorders

Because of the risk for hematoma formation after injections, intramuscular injections are often avoided among persons with bleeding disorders by using the subcutaneous or intradermal routes for vaccines that normally are administered intramuscularly. In one study, hepatitis B vaccine was administered intramuscularly to 153 persons with hemophilia. The vaccination was administered with a 23-gauge or smaller caliber needle, followed by application of steady pressure to the site for 1–2 minutes. The vaccinations resulted in a low (4%) bruising rate, and no patients required factor supplementation (213). Whether antigens that produce more local reactions (e.g., pertussis) would produce an equally low rate of bruising is unknown.

When hepatitis B or any other intramuscularly administered vaccine is indicated for a patient with a bleeding disorder, the vaccine should be administered intramuscularly if a physician
familiar with the patient’s bleeding risk determines that the vaccine can be administered by this route with reasonable safety. If the patient receives antihemophilia or similar therapy, intramuscularly administered vaccinations can be scheduled shortly after such therapy is administered. A fine-gauge needle (23 gauge or smaller caliber) should be used for the vaccination, followed by firm pressure on the site, without rubbing, for at least 2 minutes. The patient or family should be given information on the risk for hematoma from the injection. Patients receiving anticoagulation therapy presumably have the same bleeding risk as patients with clotting factor disorders and should follow the same guidelines for intramuscular administration.

Vaccination Records

Records of Health-Care Providers

Appropriate and timely vaccination documentation helps ensure not only that persons in need of recommended vaccine doses receive them but also that adequately vaccinated patients do not receive excess doses. Curtailing the number of excess doses administered to patients controls costs incurred by patients, providers, insurers, vaccination programs, and other stakeholders. In addition, excess doses of inactivated vaccines might increase the risk for an adverse reaction. Health-care providers who administer vaccines covered by the National Childhood Vaccine Injury Act are required to ensure that the permanent medical record of the recipient (or a permanent office log or file) indicates the date the vaccine was administered, the vaccine manufacturer, the vaccine lot number, and the name, address, and title of the person administering the vaccine. In addition, the provider is required to record the edition date of the VIS distributed and the date those materials were provided. The act considers a health-care provider to be any licensed health-care professional, organization, or institution, whether private or public (including federal, state, and local departments and agencies), under whose authority a specified vaccine is administered. This information should be kept for all vaccines, not just for those required by the act. Providers and staff members also should systematically update patient’s permanent medical records to reflect any documented episodes of adverse events after vaccination and any serologic test results related to vaccine-preventable diseases (e.g., those for rubella screening and antibody to HBsAg).

Personal Records of Patients

Official childhood vaccination records have been adopted by every state and territory and the District of Columbia to encourage uniformity of records and to facilitate assessment of vaccination status by schools and child-care centers. The records also are key tools in vaccination education programs aimed at increasing parental and patient awareness of the need for vaccines. A permanent vaccination record card should be established for each newborn infant and maintained by the parent or guardian. The parent or guardian should be educated about the importance of keeping the record up to date and instructed to keep the record indefinitely as part of the child’s permanent medical record. These cards should be distributed to new mothers before discharge from the hospital. Using vaccination record cards for adolescents and adults also is encouraged. Standardized adult vaccination records are available at http://www.immunize.org.

Immunization Information Systems

IISs (formerly referred to as immunization registries) are confidential, population-based, computerized information systems that collect and consolidate vaccination data from multiple health-care providers within a geographic area. IISs are a critical tool that can increase and sustain vaccination coverage by consolidating vaccination records from multiple providers, generating reminder and recall vaccination notices for each person, and providing official vaccination forms and vaccination coverage assessments (214). Changing vaccination providers during the course of an individual’s vaccination series is common in the United States. The 2007 National Health Interview Survey Summary Health Statistics for U.S. Children documented that 95% of children have a usual place of health care; 6% go to more than one health venue most of the time. Individual eligibility for Medicaid and resulting enrollment in Medicaid managed-care health plans tends to be sporadic, with an average duration of 9 months and a median of <12 months in 2000 (215). In addition to changes in providers, the vaccination records of persons who have changed vaccination providers often are unavailable or incomplete or might not have been entered into an IIS (214). Missing or inaccurate information regarding vaccines received previously might preclude accurate determination of which vaccines are indicated at the time of a visit, resulting in administration of extra doses.

A fully operational IIS also can prevent duplicate vaccinations, limit missed appointments, reduce vaccine waste, and reduce staff time required to produce or locate vaccination records or certificates. Most IISs have additional capabilities, such as vaccine management, maintenance of lifetime vaccination histories, and interoperability with other health information systems. The National Vaccine Advisory Committee strongly encourages development of community- or state-based IISs
and recommends that vaccination providers participate in these systems when possible. One of the national health objectives for 2010 was 95% participation of children aged <6 years in a fully operational population-based IIS (objective 20.1) (216). Participating in an IIS means having two or more vaccinations recorded in the IIS. 2008 IIS data indicate that approximately 75% of children aged <6 years with two or more vaccinations were participating in IISs (217). Inclusion of adults into IISs also would be worthwhile. A new national health objective for 2020 is 80% of adolescents (aged 11–18 years) with two or more age-appropriate vaccinations recorded in IISs (http://www.healthypeople.gov/hp2020/objectives/topicarea.aspx?id=30&topicarea=immunization+and+infectious+diseases).

**Vaccination Programs**

In the United States, vaccination programs have eliminated many vaccine-preventable diseases and reduced the incidence of several others (218). Because infants and young children were the principle recipients of most vaccines developed during the twentieth century (e.g., poliovirus vaccine), many persons in the United States might believe that vaccinations are solely for the young; however, vaccinations are recommended for persons of all ages (20,28). Improved vaccination coverage can result in additional reductions in the incidence of vaccine-preventable diseases and decrease associated morbidity and mortality. Universal vaccination is a critical part of quality health care and should be accomplished through routine and catch-up vaccination provided in physicians’ offices, public health clinics, and other appropriate complementary settings. Every patient encounter represents an opportunity to review and, when needed, improve a patient’s vaccination status through administration of recommended vaccines.

**Vaccination of Children and Adolescents**

Physicians and other pediatric vaccination providers should adhere to the standards for child and adolescent vaccination practices (8). These standards were published by the National Vaccine Advisory Committee and define appropriate vaccination practices for both public and private sectors. The standards provide guidance on practices that eliminate barriers to vaccination, including eliminating unnecessary prerequisites for receiving vaccinations, eliminating missed opportunities to vaccinate, improving procedures to assess vaccination needs, enhancing knowledge about vaccinations among parents and providers, and improving management and reporting of adverse events. In addition, the standards address the importance of recall and reminder systems and using assessments to monitor clinic or office vaccination coverage levels. Health-care providers should simultaneously administer as many vaccine doses as possible as indicated on the Recommended Immunization Schedules for Persons Aged 0 Through 18 Years (20).

Community health-care providers, as well as staff members at both state and local vaccination programs, should coordinate with partners to maximize outreach to populations at risk for undervaccination and vaccine-preventable diseases. For example, the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) is a categorical federal grant program administered by the U.S. Department of Agriculture through state health departments. The program provides supplemental foods, health-care referrals, and nutrition education to low-income pregnant, breastfeeding, or postpartum women, as well as to infants and children aged <5 years. More than 8.7 million people participated in this program in 2008 (http://www.fns.usda.gov/pd/wicmain.htm). In collaboration, WIC and state vaccination programs should assess regularly the vaccination coverage levels of WIC participants and develop new strategies and aggressive outreach procedures in sites with coverage levels <90%. Vaccination programs and private providers are encouraged to refer eligible children to obtain WIC nutritional services (219).

**Adolescents**

Vaccinations are recommended throughout life, including during adolescence. The age range for adolescence is defined as 11–21 years by many professional associations, including the American Academy of Pediatrics and the American Medical Association (220,221). Definitions of these age cutoffs differ depending on the source of the definition and the source’s purpose for creating a definition. Vaccination of adolescents is critical for preventing diseases for which adolescents are at particularly high or increasing risk, such as meningococcal disease and human papillomavirus infection. Three vaccines recommended for adolescents have been licensed since 2005: MCV4, HPV, and the Tdap vaccine. A second dose of varicella vaccine is recommended for persons who received 1 dose of varicella vaccine after age 12 months, and this group includes many adolescents. In addition, annual seasonal influenza vaccination is recommended for persons aged >6 months who have no contraindications. To ensure vaccine coverage, clinicians and other health-care providers who treat adolescents must screen for a complete vaccination history on every occasion that an adolescent has an office visit.

National goals for vaccination coverage for adolescents aged 13–15 years were included in Healthy People 2010 (216). Targets for 90% coverage were specified for established vaccine recommendations including those for 3 doses of hepatitis B vaccine, 1 dose of MMR vaccine, 1 dose of varicella vaccine (excluding persons with a history of varicella), and 1 dose of...
Td vaccine. Results of the published 2008 National Immunization Survey—Teen indicate that, for the first time, coverage targets for hepatitis B and MMR vaccines were met. For ≥1 dose of varicella, coverage increased to 86%. However, coverage for ≥1 dose of either Td or Tdap was unchanged at 71%, remaining below the coverage target of 90%. Coverage for MCV4 is 42%. New objectives from Healthy People 2020 include 1 dose of Tdap and ≥2 doses of varicella vaccine (excluding persons who have had varicella disease) (http://www.healthypeople.gov/hp2020/objectives/topicarea.aspx?id=30&topicarea=immunization+and+infectious+diseases).

Ensuring adolescents receive routine and catch-up vaccination and increasing vaccination coverage in this age group present challenges. In general, adolescents do not visit health-care providers frequently. Health-care providers should promote annual preventive visits (217), including one specifically for adolescents aged 11 and 12 years. The annual visits should be used as opportunities to provide routinely recommended vaccine doses, additional catch-up doses needed for lapsed vaccine series, vaccines recommended for high-risk groups, additional doses that might have been recently recommended, and other recommended health-care services.

All vaccine doses should be administered according to ACIP vaccine-specific statements and with the most recent schedules for both routine and catch-up vaccination. Before leaving any visit for medical care, adolescents should be encouraged to schedule return visits for any additional vaccine doses needed. During visits that occur outside of influenza season, providers should discuss and recommend seasonal influenza vaccination and make explicit plans for vaccination, including timing and anticipated setting (e.g., health-care provider’s office, school, or pharmacy). Catch-up vaccination with multidose adolescent vaccines generally can occur according to the routine dosing schedule for these vaccines, although in some circumstances the clinician or health-care provider might use minimum intervals for vaccine doses. These circumstances include an outbreak that increases risk for disease or the likelihood that doses will be missed in the future (e.g., because of an impending loss of health-care coverage or transportation challenges). Because of lack of efficacy data for HPV vaccine administration using minimum intervals, providers are encouraged, when possible, to use routine dosing intervals for females aged 11–26 years who have not yet received 3 HPV vaccine doses as recommended (20,28).

One of the challenges of adolescent vaccination is ensuring that current, complete vaccination histories are available. Insurers, covered services, or reimbursement levels can change, and these changes might affect reimbursement for vaccine doses and vaccination services directly while also causing disruptions in an adolescent’s access to vaccination providers or venues. In circumstances in which a vaccination record is unavailable, vaccination providers should attempt to obtain this information from various sources (e.g., parent, previous providers, or school records). More detail about how to obtain these records is available at from CDC at http://www.cdc.gov/vaccines/recs/immuniz-records.htm. With the exception of influenza and pneumococcal polysaccharide vaccines, if documentation of a vaccine dose is not available, the adolescent should be considered unvaccinated for that dose. Regardless of the venue in which an adolescent receives a dose of vaccine, that vaccine dose should be documented in the patient’s chart or in an office log, and the information should be entered into an IIS. The adolescent also should be provided with a record card that documents the vaccination history.

**Adult Vaccination**

The incidence of vaccine-preventable diseases in adults in the United States is high. Approximately 45,000 adults die each year from vaccine-preventable diseases, the majority from influenza (222). In 2008, an estimated 44,000 cases of invasive pneumococcal disease were reported with approximately 4,500 deaths, the majority occurring among persons aged >35 years (http://www.cdc.gov/abcs/survreports/spneu08.htm). Because of recent licensure of new vaccines approved for adults and new ACIP recommendations for the use of many vaccines in adults, providers of adult health care now share a greater responsibility for putting these recommendations into practice. In 2009, an estimated 4,070 deaths were caused by infection with the HPV strains causing the majority of cervical cancers in this country that are preventable with HPV vaccine and routine Papanicolaou smear testing (http://www.cancer.org/docroot/home/index.asp). Herpes zoster causes considerable morbidity in adults aged >50 years (55). A painful complication of herpes zoster infection is postherpetic neuralgia, which is characterized by severe pain that can persist for up to a year after the herpes zoster rash has subsided. A vaccine to prevent herpes zoster was licensed in 2006.

In 2003, the National Vaccine Advisory Committee published standards for adult vaccination (222). These standards include ensuring vaccine availability, review of records, communicating the risks and benefits of vaccination, use of standing orders, and recommending simultaneous administration of all indicated doses according to the *Recommended Adult Immunization Schedule* (28).

Vaccination with vaccines recommended for all adults or for those in specific age groups is generally cost-effective, if not cost-saving, for society. The National Commission on Prevention Priorities (NCPP) ranked clinical preventive services based on
clinically preventable disease effects and cost-effectiveness (223). In the NCPP report, influenza vaccination for adults aged ≥50 years and pneumococcal vaccination for adults aged ≥65 years ranked high, with 8 of 10 possible points in the scoring system used. Most other studies have found influenza vaccination reduces or minimizes health care, societal, and individual costs or the productivity losses and absenteeism associated with influenza illness (224–226). Economic analyses among adults aged ≥65 years have found influenza vaccination to be cost-effective (225–227).

A 2008 study of the cost-effectiveness of PPSV demonstrated that vaccination resulted in a gain of $3,341 per quality-adjusted life year; the result is sensitive to vaccine uptake assumptions (228). PPSV administered at ages 50–65 years might be clinically favorable and, depending on cost-effectiveness criteria used, economically favorable (228).

Hepatitis B vaccine is not recommended routinely for all adults. However, multiple studies have established the cost-effectiveness of providing hepatitis B vaccinations at counseling and testing sites for HIV and other sexually transmitted diseases, correctional institutions, drug-abuse treatment centers, and other settings serving adults at risk for hepatitis B virus infection (229–230).

Four studies have estimated the cost-effectiveness of a routine herpes zoster vaccination program of immunocompetent persons aged ≥60 years (231–234). At a vaccine cost of $150 per dose, the societal costs of routinely vaccinating immunocompetent persons aged ≥60 years range from $27,000 to $112,000 per quality-adjusted life year gained (231–234). The estimated cost per quality-adjusted life year for zoster vaccination covers a wide range that appears acceptable compared with either standard thresholds or other established interventions but is at the intermediate to high end of that range.

Vaccination rates in adults are considered suboptimal (235–238). Healthy People 2010 goals for adult vaccination coverage with influenza and pneumococcal polysaccharide vaccines are 90% for each vaccine. For the 2007–2008 season, influenza vaccination coverage among adults aged 50–64 years was 34%, and coverage among adults aged ≥65 years was 66% (67). In 2008, 60% of adults aged ≥65 years received a dose of PPSV (http://www.cdc.gov/nchs/data/hestat/vaccine_coverage.htm). New Healthy People 2020 goals for influenza and pneumococcal polysaccharide vaccines include specific subsets of adults, including institutionalized adults aged ≥18 years (for both influenza and pneumococcal polysaccharide vaccines) and noninstitutionalized adults at high risk aged >18 years (for pneumococcal polysaccharide vaccine) (http://www.healthypeople.gov/hp2020/objectives/topicarea.aspx?id=30&topicarea=immunization+and+infectious+diseases).

The most substantial barrier to vaccination coverage is lack of knowledge about these vaccines among adult patients and adult providers. Other barriers are cost (lack of additional insurance to Medicare) (239) and the lack of financing mechanisms for newly licensed and recommended vaccines.

A common challenge for health-care providers is vaccinating adults with unknown vaccination records. In general (except for influenza and pneumococcal polysaccharide vaccines), adults should receive a vaccine dose if the dose is recommended and no record of previous administration exists. If an adult has a record of military service and does not have records available, providers can assume that the person has received all vaccines recommended by the military at the time of service entry. Serologic testing might be helpful in clarifying immune status if questions remain because at different times and depending on military assignments, there might be interservice and individual differences.

**Evidence-Based Interventions to Increase Vaccination Coverage**

The independent, nonfederal Task Force on Community Preventive Services, whose membership is appointed by CDC, provides public health decision-makers with recommendations on population-based interventions to promote health and prevent disease, injury, disability, and premature death. The recommendations are based on systematic reviews of the scientific literature about effectiveness and cost-effectiveness of these interventions. In addition, the task force identifies critical information about the other effects of these interventions, the applicability to specific populations and settings, and the potential barriers to implementation. Additional information, including updates of published reviews, is available from The Community Guide at http://www.thecommunityguide.org.

Beginning in 1996, the task force systematically reviewed published evidence on the effectiveness and cost-effectiveness of population-based interventions to increase coverage of vaccines recommended for routine use among children, adolescents, and adults. A total of 197 articles were identified that evaluated a relevant intervention, met inclusion criteria, and were published during 1980–1997. Reviews of 17 specific interventions were published in 1999 (235–238). Using the results of their review, the task force made recommendations about the use of these interventions (238). Several interventions were identified and recommended on the basis of published evidence. Follow-up reviews were published in 2000, and a review of interventions to improve the coverage of adults at high risk was conducted in 2005 (238,239). The interventions and the recommendations are summarized in this report (Table 15).

In 1997, the task force categorized as a recommended strategy vaccination requirements for child care, school, and college (236). When appropriate, health agencies should take necessary steps to develop and enforce these requirements.
A 2008 update of the original task force systematic review of the evidence on the effectiveness of provider assessment and feedback for increasing coverage rates found that this strategy remains an effective intervention. A later update reviewed 19 new studies published during 1997–2007. The updated review supports the original task force recommendation for use of assessment and feedback based on strong evidence of effectiveness. The task force reviewed studies of assessment and feedback as a strategy that were conducted in a range of settings, including private practice, managed care, public health, community health settings, and academic centers. Studies have assessed the effectiveness of this intervention to improve coverage with MMR, DTP, DTaP, Hib, influenza, pneumococcal, and Td vaccines (237). The most updated information on this review is available at http://www.thecommunityguide.org/vaccines/universally/providerassessment.html. As recognized by the task force, routine assessment and feedback of vaccination rates obtained at the provider site is one of the most effective strategies for achieving high, sustainable vaccine coverage. Since 1995, all states receiving federal funds for vaccination programs have been required to conduct annual assessments of vaccination rates both in public health clinics and in private provider offices. Primarily to aid local and state health departments in their efforts to conduct assessments and assist providers, CDC has developed numerous software applications to measure vaccination rates in provider practices.

Other General Programmatic Issues

Programmatic challenges, evolving issues, and effective interventions related to adult and adolescent vaccination programs have been described by other advisory groups and expert groups. Additional evidence-based approaches are being developed for certain issues (e.g., settings for adolescent vaccination delivery) through ongoing research and evaluation. Among current programmatic challenges, vaccine financing is especially difficult because certain problems and solutions differ markedly from one state to another. Practitioners interested in beginning or continuing to provide vaccinations to patients are encouraged to consult with local and state public health vaccination programs to learn about publicly funded programs that might be available in their areas for patients who need vaccination but have insufficient health insurance coverage and no financial resources. If not already participating, providers who care for adolescents and children aged <19 years should enroll in the Vaccines for Children Program (http://www.cdc.gov/vaccines/programs/vfc/default.htm). Through this program’s provision of ACIP-recommended, federally purchased vaccines, participating providers are able to fully vaccinate eligible children whose parents might not otherwise be able to afford the vaccinations. Interested providers are encouraged to work with insurers, state and specialty-specific medical organizations, vaccine manufacturers, and other stakeholders to address financial barriers to achieving high vaccination coverage. With availability of safe and effective vaccines for 17 vaccine-preventable diseases, the capacity for realizing the potential benefits of these products in the United States depends on reaching children, adolescents, and adults through dedicated, knowledgeable vaccination providers and efficient, strong vaccination programs at local, state, and federal levels.

Vaccine Information Sources

In addition to these general recommendations, the following sources contain specific and updated vaccine information.

CDC-INFO Contact Center

The CDC-INFO contact center is supported by CDC and provides public health-related information, including vaccination information, for health-care providers and the public, 24 hours a day, 7 days a week (telephone [English and Spanish]: 800-232-4636; telephone [TTY]: 800-232-6348).

CDC’s National Center for Immunization and Respiratory Diseases

CDC’s National Center for Immunization and Respiratory Diseases website provides direct access to vaccination recommendations of ACIP, vaccination schedules, automated child schedulers, an adult immunization scheduler, vaccine safety information, publications, provider education and training, and links to other vaccination-related websites (http://www.cdc.gov/vaccines).

MMWR

ACIP recommendations regarding vaccine use, statements of vaccine policy as they are developed, and reports of specific disease activity are published by CDC in the MMWR series and can be found at http://www.cdc.gov/vaccines/pubs/ACIP-list.htm. Electronic subscriptions are free (http://www.cdc.gov/mmwr/mmwrsubscribe.html). Subscriptions to print versions also are available from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402-9235 (telephone: 202-512-1800).

American Academy of Pediatrics (AAP)

Every 3 years, AAP issues the Red Book: Report of the Committee on Infectious Diseases, which contains a composite summary of AAP and ACIP recommendations concerning infectious diseases and vaccinations for infants, children, and

**American Academy of Family Physicians (AAFP)**

Information from the professional organization of family physicians is available at http://www.aafp.org.

**Immunization Action Coalition**

The Immunization Action Coalition provides extensive free provider and patient information, including translations of VISs into multiple languages. Printed materials are reviewed by CDC for technical accuracy (http://www.immunize.org and http://www.vaccineinformation.org).

**National Network for Immunization Information**

This National Network for Immunization Information is an affiliation of the Infectious Diseases Society of America, the Pediatric Infectious Diseases Society, AAP, the American Nurses Association, AAFP, the National Association of Pediatric Nurse Practitioners, the American College of Obstetricians and Gynecologists, the University of Texas Medical Branch, the Society for Adolescent Medicine, and the American Medical Association. This source provides the public, health professionals, policy makers, and the media with up-to-date, scientifically valid information (http://www.immunizationinfo.org).

**Vaccine Education Center**

Located at the Children’s Hospital of Philadelphia, the Vaccine Education Center provides patient and provider vaccine information (http://www.vaccine.chop.edu).

**Institute for Vaccine Safety**

Located at Johns Hopkins University School of Public Health, the Institute for Vaccine Safety provides information about vaccine safety concerns and objective and timely information to physicians and health-care providers and parents (http://www.vaccinesafety.edu).

**Group on Immunization Education of the Society of Teachers of Family Medicine**

The Group on Immunization Education of the Society of Teachers of Family Medicine provides information for clinicians, including the free program Shots. Shots includes the childhood, adolescent, and adult schedules for iPhone, Palm, and Windows devices, as well as online versions (http://www.immunizationed.org).

**State and Local Health Departments**

State and local health departments provide technical advice through hotlines, e-mail, and websites, including printed information regarding vaccines and immunization schedules, posters, and other educational materials.

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TABLE 1. Recommended and minimum ages and intervals between vaccine doses*†

<table>
<thead>
<tr>
<th>Vaccine and dose number</th>
<th>Recommended age for this dose</th>
<th>Minimum age for this dose</th>
<th>Recommended interval to next dose</th>
<th>Minimum interval to next dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>HepB-1§</td>
<td>Birth</td>
<td>Birth</td>
<td>1–4 months</td>
<td>4 weeks</td>
</tr>
<tr>
<td>HepB-2</td>
<td>1–2 months</td>
<td>4 weeks</td>
<td>2–17 months</td>
<td>8 weeks</td>
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<td>6–18 months</td>
<td>24 weeks</td>
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<td>4 weeks</td>
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<tr>
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<td>6 weeks</td>
<td>2 months</td>
<td>4 weeks</td>
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<tr>
<td>DTaP-5</td>
<td>4–6 years</td>
<td>4 years</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Hib-1§§</td>
<td>2 months</td>
<td>6 weeks</td>
<td>2 months</td>
<td>4 weeks</td>
</tr>
<tr>
<td>Hib-2</td>
<td>4 months</td>
<td>10 weeks</td>
<td>2 months</td>
<td>4 weeks</td>
</tr>
<tr>
<td>Hib-3¶¶</td>
<td>6 months</td>
<td>14 weeks</td>
<td>6–9 months</td>
<td>8 weeks</td>
</tr>
<tr>
<td>Hib-4</td>
<td>12–15 months</td>
<td>12 months</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>IPV-1§§</td>
<td>2 months</td>
<td>6 weeks</td>
<td>2 months</td>
<td>4 weeks</td>
</tr>
<tr>
<td>IPV-2</td>
<td>4 months</td>
<td>10 weeks</td>
<td>2–14 months</td>
<td>4 weeks</td>
</tr>
<tr>
<td>IPV-3</td>
<td>6–18 months</td>
<td>14 weeks</td>
<td>3–5 years</td>
<td>6 months</td>
</tr>
<tr>
<td>IPV-4***</td>
<td>4–6 years</td>
<td>4 years</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>PCV-1§§§</td>
<td>2 months</td>
<td>6 weeks</td>
<td>8 weeks</td>
<td>4 weeks</td>
</tr>
<tr>
<td>PCV-2</td>
<td>4 months</td>
<td>10 weeks</td>
<td>8 weeks</td>
<td>4 weeks</td>
</tr>
<tr>
<td>PCV-3</td>
<td>6 months</td>
<td>14 weeks</td>
<td>6 months</td>
<td>8 weeks</td>
</tr>
<tr>
<td>PCV-4</td>
<td>12–15 months</td>
<td>12 months</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>MMR-1†††</td>
<td>12–15 months</td>
<td>12 months</td>
<td>3–5 years</td>
<td>4 weeks</td>
</tr>
<tr>
<td>MMR-2†††</td>
<td>4–6 years</td>
<td>13 months</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Varicella-1†††</td>
<td>12–15 months</td>
<td>12 months</td>
<td>3–5 years</td>
<td>12 weeks§§§</td>
</tr>
<tr>
<td>Varicella-2†††</td>
<td>4–6 years</td>
<td>15 months</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>HepA-1</td>
<td>12–23 months</td>
<td>12 months</td>
<td>6–18 months**</td>
<td>6 months**</td>
</tr>
<tr>
<td>HepA-2</td>
<td>≥18 months</td>
<td>18 months</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Influenza, inactivated¶¶¶</td>
<td>≥6 months</td>
<td>6 months****</td>
<td>1 month</td>
<td>4 weeks</td>
</tr>
<tr>
<td>LAIV (intranasal)¶¶¶¶</td>
<td>2–49 years</td>
<td>2 years</td>
<td>1 month</td>
<td>4 weeks</td>
</tr>
<tr>
<td>MCV4-1††††</td>
<td>11–12 years</td>
<td>2 years</td>
<td>5 years</td>
<td>8 weeks</td>
</tr>
<tr>
<td>MCV4-2</td>
<td>16 years</td>
<td>11 years (+8 weeks)</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>MPSV4-1††††</td>
<td>—</td>
<td>2 years</td>
<td>5 years</td>
<td>5 years</td>
</tr>
<tr>
<td>MPSV4-2</td>
<td>—</td>
<td>7 years</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Td</td>
<td>11–12 years</td>
<td>7 years</td>
<td>10 years</td>
<td>5 years</td>
</tr>
<tr>
<td>Tdap§§§§</td>
<td>≥11 years</td>
<td>7 years</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>PPSV-1</td>
<td>—</td>
<td>2 years</td>
<td>5 years</td>
<td>5 years</td>
</tr>
<tr>
<td>PPSV-2§§§§</td>
<td>—</td>
<td>7 years</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>HPV-1*****</td>
<td>11–12 years</td>
<td>9 years</td>
<td>2 months</td>
<td>4 weeks</td>
</tr>
<tr>
<td>HPV-2</td>
<td>11–12 years (+2 months)</td>
<td>9 years (+4 weeks)</td>
<td>4 months</td>
<td>12 weeks†††††</td>
</tr>
<tr>
<td>HPV-3†††††</td>
<td>11–12 years (+6 months)</td>
<td>9 years (+24 weeks)</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Rotavirus-1§§§§</td>
<td>2 months</td>
<td>6 weeks</td>
<td>2 months</td>
<td>4 weeks</td>
</tr>
<tr>
<td>Rotavirus-2</td>
<td>4 months</td>
<td>10 weeks</td>
<td>2 months</td>
<td>4 weeks</td>
</tr>
<tr>
<td>Rotavirus-3†††††</td>
<td>6 months</td>
<td>14 weeks</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Herpes zoster*****</td>
<td>≥60 years</td>
<td>60 years</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

See table footnotes on page 37
TABLE 1. (Continued) Recommended and minimum ages and intervals between vaccine doses*,†

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Trade name (year licensed)</th>
<th>Age range</th>
<th>Routinely recommended ages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hib-HepB</td>
<td>Comvax (1996)</td>
<td>6 weeks–71 months</td>
<td>Three-dose schedule at 2, 4, and 12–15 months of age</td>
</tr>
<tr>
<td>DTaP-Hib</td>
<td>TriHib (1996)</td>
<td>15–18 months</td>
<td>Fourth dose of Hib and DTaP series</td>
</tr>
<tr>
<td>HepA-HepB</td>
<td>Twinrix (2001)</td>
<td>≥18 years</td>
<td>Three-dose series at 2, 4, and 6 months of age</td>
</tr>
<tr>
<td>DTaP-HepB-IPV</td>
<td>Pediarix (2002)</td>
<td>6 weeks–6 years</td>
<td>Two doses, the first at 12–15 months, the second at 4–6 years</td>
</tr>
<tr>
<td>MMRV</td>
<td>ProQuad (2005)</td>
<td>12 months–12 years</td>
<td>Fifth dose of DTaP and fourth dose of IPV</td>
</tr>
<tr>
<td>DTaP-IPV</td>
<td>Kinrix (2008)</td>
<td>4–6 years</td>
<td>Four-dose schedule at 2, 4, 6, and 15–18 months of age</td>
</tr>
<tr>
<td>DTaP-IPV/Hib</td>
<td>Pentacel (2008)</td>
<td>6 weeks–4 years</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: DTaP = diphtheria and tetanus toxoids and acellular pertussis; HepA = hepatitis A; HepB = hepatitis B; Hib = Haemophilus influenzae type b; HPV = human papillomavirus; IPV = inactivated poliovirus; LAIV = live, attenuated influenza vaccine; MCV4 = quadrivalent meningococcal conjugate vaccine; MMR = measles, mumps, and rubella; MMRV = measles, mumps, rubella, and varicella; PCV = pneumococcal conjugate vaccine; PPSV = pneumococcal polysaccharide vaccine; PRP-OMP = polyribosylribitol phosphate-meningococcal outer membrane protein conjugate; Td = tetanus and diphtheria toxoids; TIV = trivalent inactivated influenza vaccine; Tdap = tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis; Var = varicella vaccine.

* Combination vaccines are available. Use of licensed combination vaccines is generally preferred to separate injections of their equivalent component vaccines. When administering combination vaccines, the minimum age for administration is the oldest age for any of the individual components; the minimum interval between doses is equal to the greatest interval of any of the individual components.

† Information on travel vaccines, including typhoid, Japanese encephalitis, and yellow fever, is available at http://www.cdc.gov/travel. Information on other vaccines that are licensed in the United States but not distributed, including anthrax and smallpox, is available at http://www.bt.cdc.gov.

‡ Combination vaccines containing the hepatitis B component are available (see Table 2). These vaccines should not be administered to infants aged <6 weeks because of the other components (i.e., Hib, DTaP, HepA, and IPV).

§ HepB-3 should be administered at least 8 weeks after HepB-2 and at least 16 weeks after HepB-1 and should not be administered before age 24 weeks.

** The recommended minimum interval for the first dose of Hib-containing vaccine is 6 months.

†† The minimum interval for Hib-containing vaccine is 5 years.

§§ The minimum interval from Varicella-1 to Varicella-2 for persons beginning the series at age ≥13 years is 4 weeks.

††† A dash ( - ) between vaccine products indicates that products are supplied in their final form by the manufacturer and do not require mixing or reconstitution by the user. A slash ( / ) indicates that the products must be mixed or reconstituted by the user.

†††† Revaccination with meningococcal vaccine is recommended for previously vaccinated persons who remain at high risk for meningococcal disease. (Source: CDC. Updated recommendations from the Advisory Committee on Immunization Practices (ACIP) for revaccination of persons at prolonged increased risk for meningococcal disease. MMWR 2006;55[1042–31].)

§§§§§ The first dose of rotavirus must be administered at age 6 weeks through 14 weeks and 6 days. The vaccine series should not be started for infants aged ≥15 weeks, 0 days. Rotavirus should not be administered to children older than 8 months, 0 days of age regardless of the number of doses received between 6 weeks and 8 months, 0 days of age.

¶¶¶¶¶ If 2 doses of Rotarix (GlaxoSmithKline) are administered as age appropriate, a third dose is not necessary.

***** Herpes zoster vaccine is recommended as a single dose for persons aged ≥60 years.

††† Combination MMRV vaccine can be used for children aged 12 months–12 years. See text for details.

TABLE 2. FDA-licensed combination vaccines*

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Trade name (year licensed)</th>
<th>Age range</th>
<th>Routinely recommended ages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hib-HepB</td>
<td>Comvax (1996)</td>
<td>6 weeks–71 months</td>
<td>Three-dose schedule at 2, 4, and 12–15 months of age</td>
</tr>
<tr>
<td>DTaP-Hib</td>
<td>TriHib (1996)</td>
<td>15–18 months</td>
<td>Fourth dose of Hib and DTaP series</td>
</tr>
<tr>
<td>HepA-HepB</td>
<td>Twinrix (2001)</td>
<td>≥18 years</td>
<td>Three-dose series on a schedule of 0, 1, and 6 months</td>
</tr>
<tr>
<td>DTaP-IPV</td>
<td>Pediarix (2002)</td>
<td>6 weeks–6 years</td>
<td>Two doses, the first at 12–15 months, the second at 4–6 years</td>
</tr>
<tr>
<td>MMRV</td>
<td>ProQuad (2005)</td>
<td>12 months–12 years</td>
<td>Fifth dose of DTaP and fourth dose of IPV</td>
</tr>
<tr>
<td>DTaP-IPV</td>
<td>Kinrix (2008)</td>
<td>4–6 years</td>
<td>Four-dose schedule at 2, 4, 6, and 15–18 months of age</td>
</tr>
<tr>
<td>DTaP-IPV/Hib</td>
<td>Pentacel (2008)</td>
<td>6 weeks–4 years</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: DT = diphtheria and tetanus toxoids; DTaP = diphtheria and tetanus toxoids and acellular pertussis; FDA = Food and Drug Administration; HepA = hepatitis A; HepB = hepatitis B; Hib = Haemophilus influenzae type b; IPV = inactivated poliovirus; MMR = measles, mumps, and rubella; MMRV = measles, mumps, rubella, and varicella; Td = tetanus and diphtheria toxoids; TIV = trivalent inactivated influenza vaccine; Tdap = tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis; Var = varicella vaccine.

* Although MMR, DTaP, DT, and Tdap are combination vaccines, they are not included on this list because they are not available in the United States as single-antigen products.

A slash ( / ) between vaccine products indicates that products are supplied in their final form by the manufacturer and do not require mixing or reconstitution by the user. A slash ( / ) indicates that the products must be mixed or reconstituted by the user. A slash ( / ) indicates that the products must be mixed or reconstituted by the user.
### TABLE 3. Guidelines for spacing of live and inactivated antigens

<table>
<thead>
<tr>
<th>Antigen combination</th>
<th>Recommended minimum interval between doses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Two or more inactivated*</td>
<td>May be administered simultaneously or at any interval between doses</td>
</tr>
<tr>
<td>Inactivated and live</td>
<td>May be administered simultaneously or at any interval between doses</td>
</tr>
<tr>
<td>Two or more live injectable†</td>
<td>28 days minimum interval, if not administered simultaneously</td>
</tr>
</tbody>
</table>

* Certain experts suggest a 28-day interval between tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis (Tdap) vaccine and tetravalent meningococcal conjugate vaccine if they are not administered simultaneously.

† Live oral vaccines (e.g., Ty21a typhoid vaccine and rotavirus vaccine) may be administered simultaneously or at any interval before or after inactivated or live injectable vaccines.

### TABLE 4. Guidelines for administering antibody-containing products* and vaccines

<table>
<thead>
<tr>
<th>Type of administration</th>
<th>Products administered</th>
<th>Recommended minimum interval between doses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Simultaneous (during the same office visit)</td>
<td>Antibody-containing products and inactivated antigen</td>
<td>Can be administered simultaneously at different anatomic sites or at any time interval between doses</td>
</tr>
<tr>
<td></td>
<td>Antibody-containing products and live antigen</td>
<td>Should not be administered simultaneously.† If simultaneous administration of measles-containing vaccine or varicella vaccine is unavoidable, administer at different sites and revaccinate or test for seroconversion after the recommended interval (see Table 5)</td>
</tr>
<tr>
<td>Nonsimultaneous</td>
<td>Administered first</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Antibody-containing products</td>
<td>No interval necessary</td>
</tr>
<tr>
<td></td>
<td>Inactivated antigen</td>
<td>No interval necessary</td>
</tr>
<tr>
<td></td>
<td>Antibody-containing products</td>
<td>Dose related†§</td>
</tr>
<tr>
<td></td>
<td>Live antigen</td>
<td>2 weeks†</td>
</tr>
<tr>
<td></td>
<td>Antibody-containing products</td>
<td></td>
</tr>
</tbody>
</table>

* Blood products containing substantial amounts of immune globulin include intramuscular and intravenous immune globulin, specific hyperimmune globulin (e.g., hepatitis B immune globulin, tetanus immune globulin, varicella zoster immune globulin, and rabies immune globulin), whole blood, packed red blood cells, plasma, and platelet products.

† Yellow fever vaccine; rotavirus vaccine; oral Ty21a typhoid vaccine; live, attenuated influenza vaccine; and zoster vaccine are exceptions to these recommendations. These live, attenuated vaccines can be administered at any time before or after or simultaneously with an antibody-containing product.

§ The duration of interference of antibody-containing products with the immune response to the measles component of measles-containing vaccine, and possibly varicella vaccine, is dose related (see Table 5).
TABLE 5. Recommended intervals between administration of antibody-containing products and measles- or varicella-containing vaccine, by product and indication for vaccination

<table>
<thead>
<tr>
<th>Product/Indication</th>
<th>Dose (mg IgG/kg) and route*</th>
<th>Recommended interval before measles- or varicella-containing vaccine† administration (months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tetanus IG</td>
<td>250 units (10 mg IgG/kg) IM</td>
<td>3</td>
</tr>
<tr>
<td><strong>Hepatitis A IG</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contact prophylaxis</td>
<td>0.02 mL/kg (3.3 mg IgG/kg) IM</td>
<td>3</td>
</tr>
<tr>
<td>International travel</td>
<td>0.06 mL/kg (10 mg IgG/kg) IM</td>
<td>3</td>
</tr>
<tr>
<td><strong>Hepatitis B IG</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contact prophylaxis</td>
<td>0.06 mL/kg (10 mg IgG/kg) IM</td>
<td>3</td>
</tr>
<tr>
<td><strong>Rabies IG</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20 IU/kg (22 mg IgG/kg) IM</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td><strong>Varicella IG</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contact prophylaxis</td>
<td>125 units/10 kg (60–200 mg IgG/kg) IM, maximum 625 units</td>
<td>5</td>
</tr>
<tr>
<td><strong>Measles prophylaxis IG</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Standard (i.e., nonimmunocompromised) contact</td>
<td>0.25 mL/kg (40 mg IgG/kg) IM</td>
<td>5</td>
</tr>
<tr>
<td>Immunocompromised contact</td>
<td>0.50 mL/kg (80 mg IgG/kg) IM</td>
<td>6</td>
</tr>
<tr>
<td><strong>Blood transfusion</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RBCs, washed</td>
<td>10 mL/kg, negligible IgG/kg IV</td>
<td>None</td>
</tr>
<tr>
<td>RBCs, adenine-saline added</td>
<td>10 mL/kg (10 mg IgG/kg) IV</td>
<td>3</td>
</tr>
<tr>
<td>Packed RBCs (hematocrit 65%)§</td>
<td>10 mL/kg (60 mg IgG/kg) IV</td>
<td>6</td>
</tr>
<tr>
<td>Whole blood (hematocrit 35%–50%)§</td>
<td>10 mL/kg (80–100 mg IgG/kg) IV</td>
<td>6</td>
</tr>
<tr>
<td>Plasma/platelet products</td>
<td>10 mL/kg (160 mg IgG/kg) IV</td>
<td>7</td>
</tr>
<tr>
<td><strong>Cytomegalovirus IGIV</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Replacement therapy for immune deficiencies¶</td>
<td>300–400 mg/kg IV¶</td>
<td>8</td>
</tr>
<tr>
<td>Immune thrombocytopenic purpura treatment</td>
<td>400 mg/kg IV</td>
<td>8</td>
</tr>
<tr>
<td>Postexposure varicella prophylaxis**</td>
<td>400 mg/kg IV</td>
<td>8</td>
</tr>
<tr>
<td>Immune thrombocytopenic purpura treatment</td>
<td>1000 mg/kg IV</td>
<td>10</td>
</tr>
<tr>
<td>Kawasaki disease</td>
<td>2 g/kg IV</td>
<td>11</td>
</tr>
<tr>
<td><strong>Monoclonal antibody to respiratory syncytial virus</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F protein (Synagis [MedImmune])††</td>
<td>15 mg/kg IM</td>
<td>None</td>
</tr>
</tbody>
</table>

**Abbreviations:** HIV = human immunodeficiency virus; IG = immune globulin; IgG = immune globulin G; IGIV = intravenous immune globulin; mg IgG/kg = milligrams of immune globulin G per kilogram of body weight; IM = intramuscular; IV = intravenous; RBCs = red blood cells.

* This table is not intended for determining the correct indications and dosages for using antibody-containing products. Unvaccinated persons might not be protected fully 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.

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

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

¶ Measles and varicella vaccinations are recommended for children with asymptomatic or mildly symptomatic HIV infection but are contraindicated for persons with severe immunosuppression from HIV or any other immunosuppressive disorder.

** The investigational VarizIG, similar to licensed varicella-zoster IG (VZIG), is a purified human IG preparation made from plasma containing high levels of antivaricella antibodies (IgG). The interval between VarizIG and varicella vaccine (Var or MMRV) is 5 months.

†† Contains antibody only to respiratory syncytial virus
### TABLE 6. Contraindications and precautions* to commonly used vaccines

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Contraindications</th>
<th>Precautions</th>
</tr>
</thead>
<tbody>
<tr>
<td>DTaP</td>
<td>Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component</td>
<td>Progressive neurologic disorder, including infantile spasms, uncontrolled epilepsy, progressive encephalopathy; defer DTaP until neurologic status clarified and stabilized</td>
</tr>
<tr>
<td></td>
<td>Encephalopathy (e.g., coma, decreased level of consciousness, or prolonged seizures), not attributable to another identifiable cause, within 7 days of administration of previous dose of DTP or DTaP</td>
<td>Temperature of ≥105°F (≥40.5°C) within 48 hours after vaccination with a previous dose of DTP or DTaP</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Collapse or shock-like state (i.e., hypotonic hyporesponsive episode) within 48 hours after receiving a previous dose of DTP/DTaP</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Seizure ≤3 days after receiving a previous dose of DTP/DTaP</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Persistent, inconsolable crying lasting ≥3 hours within 48 hours after receiving a previous dose of DTP/DTaP</td>
</tr>
<tr>
<td></td>
<td></td>
<td>GBS &lt;6 weeks after previous dose of tetanus toxoid–containing vaccine</td>
</tr>
<tr>
<td></td>
<td></td>
<td>History of arthus-type hypersensitivity reactions after a previous dose of tetanus toxoid–containing vaccine; defer vaccination until at least 10 years have elapsed since the last tetanus toxoid–containing vaccine</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Moderate or severe acute illness with or without fever</td>
</tr>
<tr>
<td>DT, Td</td>
<td>Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component</td>
<td>GBS &lt;6 weeks after previous dose of tetanus toxoid–containing vaccine</td>
</tr>
<tr>
<td></td>
<td></td>
<td>History of arthus-type hypersensitivity reactions after a previous dose of tetanus toxoid–containing vaccine; defer vaccination until at least 10 years have elapsed since the last tetanus toxoid–containing vaccine</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Moderate or severe acute illness with or without fever</td>
</tr>
<tr>
<td>Tdap</td>
<td>Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component</td>
<td>GBS &lt;6 weeks after a previous dose of tetanus toxoid–containing vaccine</td>
</tr>
<tr>
<td></td>
<td>Encephalopathy (e.g., coma, decreased level of consciousness, or prolonged seizures), not attributable to another identifiable cause, within 7 days of administration of previous dose of DTP, DTaP, or Tdap</td>
<td>History of arthus-type hypersensitivity reactions after a previous dose of tetanus toxoid–containing vaccine; defer vaccination until at least 10 years have elapsed since the last tetanus toxoid–containing vaccine</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Moderate or severe acute illness with or without fever</td>
</tr>
<tr>
<td>IPV</td>
<td>Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component</td>
<td>Pregnancy</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Moderate or severe acute illness with or without fever</td>
</tr>
<tr>
<td>MMR†,§</td>
<td>Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component</td>
<td>Recent (≤11 months) receipt of antibody-containing blood product (specific interval depends on product)**</td>
</tr>
<tr>
<td></td>
<td>Pregnancy</td>
<td>History of thrombocytopenia or thrombocytopenic purpura</td>
</tr>
<tr>
<td></td>
<td>Known severe immunodeficiency (e.g., from hematologic and solid tumors, receipt of chemotherapy, congenital immunodeficiency, or long-term immunosuppressive therapy§ or patients with HIV infection who are severely immunocompromised)§</td>
<td>Need for tuberculin skin testing††</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Moderate or severe acute illness with or without fever</td>
</tr>
<tr>
<td>Hib</td>
<td>Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component</td>
<td>Moderate or severe acute illness with or without fever</td>
</tr>
<tr>
<td></td>
<td>Age &lt;6 weeks</td>
<td></td>
</tr>
<tr>
<td>Hepatitis B</td>
<td>Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component</td>
<td>Infant weight &lt;2,000 gm§§</td>
</tr>
<tr>
<td>Hepatitis A</td>
<td>Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component</td>
<td>Pregnancy</td>
</tr>
<tr>
<td>Varicella</td>
<td>Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component</td>
<td>Recent (≤11 months) receipt of antibody-containing blood product (specific interval depends on product)**</td>
</tr>
<tr>
<td></td>
<td>Known severe immunodeficiency (e.g., from hematologic and solid tumors, receipt of chemotherapy, congenital immunodeficiency, or long-term immunosuppressive therapy§ or patients with HIV infection who are severely immunocompromised)§</td>
<td>Moderate or severe acute illness with or without fever</td>
</tr>
<tr>
<td></td>
<td>Pregnancy</td>
<td></td>
</tr>
</tbody>
</table>

See table footnotes on page 41
### TABLE 6. (Continued) Contraindications and precautions* to commonly used vaccines

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Contraindications</th>
<th>Precautions</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCV</td>
<td>Severe allergic reaction (e.g., anaphylaxis) after a previous dose (of PCV7, PCV13, or any diphtheria toxoid–containing vaccine) or to a component of a vaccine (PCV7, PCV13, or any diphtheria toxoid–containing vaccine)</td>
<td>Moderate or severe acute illness with or without fever</td>
</tr>
<tr>
<td>TIV</td>
<td>Severe allergic reaction (e.g., anaphylaxis) after previous dose or to vaccine component, including egg protein</td>
<td>GBS &lt;6 weeks after a previous dose of influenza vaccine</td>
</tr>
<tr>
<td>LAIV</td>
<td>Severe allergic reaction (e.g., anaphylaxis) after previous dose or to vaccine component, including egg protein Pregnancy Imunosuppression Certain chronic medical conditions***</td>
<td>GBS &lt;6 weeks after a previous dose of influenza vaccine</td>
</tr>
<tr>
<td>PPSV</td>
<td>Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component</td>
<td>Moderate or severe acute illness with or without fever</td>
</tr>
<tr>
<td>MCV4</td>
<td>Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component</td>
<td>Moderate or severe acute illness with or without fever</td>
</tr>
<tr>
<td>MPSV4</td>
<td>Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component</td>
<td>Moderate or severe acute illness with or without fever</td>
</tr>
<tr>
<td>HPV</td>
<td>Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component</td>
<td>Pregnancy</td>
</tr>
<tr>
<td>Rotavirus</td>
<td>Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component SCID</td>
<td>Altered immunocompetence other than SCID History of intussusception Chronic gastrointestinal disease††† Spina bifida or bladder extrophy††††</td>
</tr>
<tr>
<td>Zoster</td>
<td>Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component Substantial suppression of cellular immunity Pregnancy</td>
<td>Moderate or severe acute illness with or without fever</td>
</tr>
</tbody>
</table>

**Abbreviations:** DT = diphtheria and tetanus toxoids; DTP = diphtheria and tetanus toxoids and acellular pertussis; GBS = Guillain-Barré syndrome; HBsAg = hepatitis B surface antigen; Hib = Haemophilus influenzae type b; HIV = human immunodeficiency virus; HPV = human papillomavirus; IPV = inactivated poliovirus; LAIV = live, attenuated influenza vaccine; MCV4 = quadrivalent meningococcal conjugate vaccine; MMRV = measles, mumps, rubella, and varicella; MPSV4 = quadrivalent meningococcal polysaccharide vaccine; PCV = pneumococcal polysaccharide vaccine; PPSV = pneumococcal polysaccharide vaccine; SCID = severe combined immunodeficiency; Td = tetanus and diphtheria toxoids; Tdap = tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis; TIV = trivalent inactivated influenza vaccine.

* Events or conditions listed as precautions should be reviewed carefully. Benefits of and risks for administering a specific vaccine to a person under these circumstances should be considered. If the risk from the vaccine is believed to outweigh the benefit, the vaccine should not be administered. If the benefit of vaccination is believed to outweigh the risk, the vaccine should be administered. Whether and when to administer DTaP to children with proven or suspected underlying neurologic disorders should be decided on a case-by-case basis.

†‡‡‡ Measles vaccination might suppress tuberculin reactivity temporarily. Measles-containing vaccine can be administered on the same day as tuberculin skin testing. If testing cannot be performed until after the day of MMR vaccination, the test should be postponed for ≥4 weeks after the vaccination. If an urgent need exists to skin test, do so with the understanding that reactivity might be reduced by the vaccine.

‡‡‡‡‡ Hepatitis B vaccination should be deferred for infants weighing <2,000 g if the mother is documented to be HBsAg-negative at the time of the infant’s birth. Vaccination can commence at chronological age 1 month or at hospital discharge. For infants born to HBsAg-positive women, hepatitis B immune globulin and hepatitis B vaccine should be administered within 12 hours after birth, regardless of weight.

†¶†††† For details, see CDC. Prevention of rotavirus gastroenteritis among infants and children: recommendations of the Advisory Committee on Immunization Practices. MMWR 2009;58(RR-2).

* Events or conditions listed as precautions should be reviewed carefully. Benefits of and risks for administering a specific vaccine to a person under these circumstances should be considered. If the risk from the vaccine is believed to outweigh the benefit, the vaccine should not be administered. If the benefit of vaccination is believed to outweigh the risk, the vaccine should be administered. Whether and when to administer DTaP to children with proven or suspected underlying neurologic disorders should be decided on a case-by-case basis.

†‡‡‡‡‡ Measles vaccination might suppress tuberculin reactivity temporarily. Measles-containing vaccine can be administered on the same day as tuberculin skin testing. If testing cannot be performed until after the day of MMR vaccination, the test should be postponed for ≥4 weeks after the vaccination. If an urgent need exists to skin test, do so with the understanding that reactivity might be reduced by the vaccine.

‡‡‡‡‡‡‡ Hepatitis B vaccination should be deferred for infants weighing <2,000 g if the mother is documented to be HBsAg-negative at the time of the infant’s birth. Vaccination can commence at chronological age 1 month or at hospital discharge. For infants born to HBsAg-positive women, hepatitis B immune globulin and hepatitis B vaccine should be administered within 12 hours after birth, regardless of weight.

†¶††††† For details, see CDC. Prevention of rotavirus gastroenteritis among infants and children: recommendations of the Advisory Committee on Immunization Practices. MMWR 2009;58(RR-2).
<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Conditions commonly misperceived as contraindications to vaccination (i.e., vaccination may be administered under these conditions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>General for all vaccines, including DTaP, pediatric DT, adult Td, adolescent-adult Tdap, IPV, MMR, Hib, hepatitis A, hepatitis B, varicella, rotavirus, PCV, TIV, LAIV, PPSV, MCV4, MPSV4, HPV, and herpes zoster</td>
<td>Mild acute illness with or without fever&lt;br&gt;Mild-to-moderate local reaction (i.e., swelling, redness, soreness); low-grade or moderate fever after previous dose&lt;br&gt;Lack of previous physical examination in well-appearing person&lt;br&gt;Current antimicrobial therapy*&lt;br&gt;Convalescent phase of illness&lt;br&gt;Preterm birth (hepatitis B vaccine is an exception in certain circumstances)†&lt;br&gt;Recent exposure to an infectious disease&lt;br&gt;History of penicillin allergy, other nonvaccine allergies, relatives with allergies, or receiving allergen extract immunotherapy</td>
</tr>
<tr>
<td>DTaP</td>
<td>Fever of &lt;105°F (&lt;40.5°C), fussiness or mild drowsiness after a previous dose of DTP/DTaP&lt;br&gt;Family history of seizures&lt;br&gt;Family history of sudden infant death syndrome&lt;br&gt;Family history of an adverse event after DTP or DTaP administration&lt;br&gt;Stable neurologic conditions (e.g., cerebral palsy, well-controlled seizures, or developmental delay)</td>
</tr>
<tr>
<td>Tdap</td>
<td>Fever of ≥105°F (≥40.5°C) for &lt;48 hours after vaccination with a previous dose of DTP or DTaP&lt;br&gt;Collapse or shock-like state (i.e., hypotonic hyporesponsive episode) within 48 hours after receiving a previous dose of DTP/DTaP&lt;br&gt;Seizure ≤3 days after receiving a previous dose of DTP/DTaP&lt;br&gt;Persistent, intractable crying lasting ≥3 hours within 48 hours after receiving a previous dose of DTP/DTaP&lt;br&gt;History of extensive limb swelling after DTP/DTaP/Td that is not an atopy-induced reaction&lt;br&gt;Stable neurologic disorder&lt;br&gt;History of brachial neuritis&lt;br&gt;Latex allergy that is not anaphylactic&lt;br&gt;Breastfeeding&lt;br&gt;Immunosuppression</td>
</tr>
<tr>
<td>IPV</td>
<td>Previous receipt of ≥1 dose of oral polio vaccine</td>
</tr>
<tr>
<td>MMR§,¶</td>
<td>Positive tuberculin skin test&lt;br&gt;Simultaneous tuberculin skin testing**&lt;br&gt;Breastfeeding&lt;br&gt;Pregnancy of recipient’s mother or other close or household contact&lt;br&gt;Recipient is female of child-bearing age&lt;br&gt;Immunodeficient family member or household contact&lt;br&gt;Asymptomatic or mildly symptomatic HIV infection&lt;br&gt;Allergy to eggs</td>
</tr>
<tr>
<td>Hepatitis B</td>
<td>Pregnancy&lt;br&gt;Autoimmune disease (e.g., systemic lupus erythematosus or rheumatoid arthritis)</td>
</tr>
<tr>
<td>Varicella</td>
<td>Pregnancy of recipient’s mother or other close or household contact&lt;br&gt;Immunodeficient family member or household contact†&lt;br&gt;Asymptomatic or mildly symptomatic HIV infection&lt;br&gt;Humoral immunodeficiency (e.g., agammaglobulinemia)</td>
</tr>
<tr>
<td>TIV</td>
<td>Nonsevere (e.g., contact) allergy to latex, thimerosal, or egg&lt;br&gt;Concurrent administration of coumadin or aminophylline</td>
</tr>
<tr>
<td>LAIV</td>
<td>Health-care providers that see patients with chronic diseases or altered immunocompetence (an exception is providers for severely immunocompromised patients requiring care in a protected environment)&lt;br&gt;Breastfeeding&lt;br&gt;Contacts of persons with chronic disease or altered immunocompetence (an exception is contacts of severely immunocompromised patients requiring care in a protected environment)</td>
</tr>
<tr>
<td>PPSV</td>
<td>History of invasive pneumococcal disease or pneumonia</td>
</tr>
<tr>
<td>HPV</td>
<td>Immunosuppression&lt;br&gt;Previous equivocal or abnormal Papanicolaou test&lt;br&gt;Known HPV infection&lt;br&gt;Breastfeeding&lt;br&gt;History of genital warts</td>
</tr>
</tbody>
</table>

See table footnotes on page 43.
TABLE 7. (Continued) Conditions commonly misperceived as contraindications to vaccination

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Conditions commonly misperceived as contraindications (i.e., vaccination may be administered under these conditions)</th>
</tr>
</thead>
</table>
| Rotavirus | Prematurity  
Immunosuppressed household contacts  
Pregnant household contacts |
| Zoster | Therapy with low-dose methotrexate (≤0.4 mg/kg/week), azathioprine (≤3.0 mg/kg/day), or 6-mercaptopurine (≤1.5 mg/kg/day) for treatment of rheumatoid arthritis, psoriasis, polymyositis, sarcoidosis, inflammatory bowel disease, or other conditions  
Health-care providers of patients with chronic diseases or altered immunocompetence  
Contacts of patients with chronic diseases or altered immunocompetence  
Unknown or uncertain history of varicella in a U.S.-born person |

Abbreviations: DT = diphtheria and tetanus toxoids; DTP = diphtheria toxoid, tetanus toxoid, and pertussis; DTaP = diphtheria and tetanus toxoids and acellular pertussis; HBsAg = hepatitis B surface antigen; Hib = *Haemophilus influenzae* type b; HPV = human papillomavirus; IPV = inactivated poliovirus; LAIV = live, attenuated influenza vaccine; MCV4 = quadrivalent meningococcal conjugate vaccine; MMR = measles, mumps, and rubella; MPSV4 = quadrivalent meningococcal polysaccharide vaccine; PCV = pneumococcal conjugate vaccine; PPSV = pneumococcal polysaccharide vaccine; Td = tetanus and diphtheria toxoids; Tdap = tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis; TIV = trivalent inactivated influenza vaccine.

* Antibacterial drugs might interfere with Ty21a oral typhoid vaccine, and certain antiviral drugs might interfere with varicella-containing vaccines and LAIV.
† Hepatitis B vaccination should be deferred for infants weighing <2,000 g if the mother is documented to be HBsAg-negative at the time of the infant’s birth. Vaccination can commence at chronological age 1 month or at hospital discharge. For infants born to HBsAg-positive women, hepatitis B immune globulin and hepatitis B vaccine should be administered within 12 hours after birth, regardless of weight.
§ MMR and varicella vaccines can be administered on the same day. If not administered on the same day, these vaccines should be separated by at least 28 days.
** Measles vaccination might suppress tuberculin reactivity temporarily. Measles-containing vaccine can be administered on the same day as tuberculin skin testing. If testing cannot be performed until after the day of MMR vaccination, the test should be postponed for at least 4 weeks after the vaccination. If an urgent need exists to skin test, do so with the understanding that reactivity might be reduced by the vaccine.
†† If a vaccinee experiences a presumed vaccine-related rash 7–25 days after vaccination, the person should avoid direct contact with immunocompromised persons for the duration of the rash.

TABLE 8. Treatment of anaphylaxis in children and adults with drugs administered intramuscularly or orally

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Children</strong></td>
<td></td>
</tr>
<tr>
<td>Primary regimen</td>
<td>Epinephrine 1:1000 (aqueous) (1 mg/mL)* 0.01 mg/kg up to 0.5 mg (administer 0.01 mL/kg/dose up to 0.5 mL) IM repeated every 10–20 minutes up to 3 doses</td>
</tr>
</tbody>
</table>
| Secondary regimen | Diphenhydramine 1–2 mg/kg oral, IM, or IV, every 4–6 hours (100 mg, maximum single dose)  
Hydroxyzine 0.5–1 mg/kg oral, IM, every 4–6 hours (100 mg, maximum single dose)  
Prednisone 1.5–2 mg/kg oral (60 mg, maximum single dose); use corticosteroids as long as needed |
| **Adults** | |
| Primary regimen | Epinephrine 1:1000 (aqueous)* 0.01 mg/kg up to 0.5 mg (administer 0.01 mL/kg/dose up to 0.5 mL) IM repeated every 10–20 minutes up to 3 doses |
| Secondary regimen | Diphenhydramine 1–2 mg/kg up to 100 mg IM or oral, every 4–6 hours |

Abbreviations: IM = intramuscular; IV = intravenous.
* If the agent causing the anaphylactic reaction was administered by injection, epinephrine may be injected into the same site to slow absorption.
TABLE 9. Dose and route of administration for selected vaccines

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Dose</th>
<th>Route</th>
</tr>
</thead>
<tbody>
<tr>
<td>DTaP, DT, Td, Tdap</td>
<td>0.5 mL</td>
<td>IM</td>
</tr>
<tr>
<td>DTaP-HepB-IPV</td>
<td>0.5 mL</td>
<td>IM</td>
</tr>
<tr>
<td>DTaP/Hib</td>
<td>0.5 mL</td>
<td>IM</td>
</tr>
<tr>
<td>DTaP-IPV/Hib</td>
<td>0.5 mL</td>
<td>IM</td>
</tr>
<tr>
<td>DTaP-IPV</td>
<td>0.5 mL</td>
<td>IM</td>
</tr>
<tr>
<td>Hib</td>
<td>0.5 mL</td>
<td>IM</td>
</tr>
<tr>
<td>Combination Hib/HepB</td>
<td>0.5 mL</td>
<td>IM</td>
</tr>
<tr>
<td>HepA</td>
<td>≤18 years: 0.5 mL</td>
<td>IM</td>
</tr>
<tr>
<td></td>
<td>≥19 years: 1.0 mL</td>
<td></td>
</tr>
<tr>
<td>HepB</td>
<td>≤19 years: 0.5 mL*</td>
<td>IM</td>
</tr>
<tr>
<td></td>
<td>≥20 years: 1.0 mL</td>
<td></td>
</tr>
<tr>
<td>HepA-HepB</td>
<td>≥18 years: 1.0 mL</td>
<td>IM</td>
</tr>
<tr>
<td>LAIV</td>
<td>0.2 mL divided dose between nares</td>
<td>Intranasal spray</td>
</tr>
<tr>
<td>TIV</td>
<td>6–35 months: 0.25 mL</td>
<td>IM</td>
</tr>
<tr>
<td></td>
<td>≥3 years: 0.5 mL</td>
<td></td>
</tr>
<tr>
<td>MMR</td>
<td>0.5 mL</td>
<td>SC</td>
</tr>
<tr>
<td>MMRV</td>
<td>0.5 mL</td>
<td>SC</td>
</tr>
<tr>
<td>MCV4</td>
<td>0.5 mL</td>
<td>IM</td>
</tr>
<tr>
<td>MPSV4</td>
<td>0.5 mL</td>
<td>SC</td>
</tr>
<tr>
<td>PCV</td>
<td>0.5 mL</td>
<td>IM</td>
</tr>
<tr>
<td>PPSV</td>
<td>0.5 mL</td>
<td>IM or SC</td>
</tr>
<tr>
<td>HPV (HPV2 or HPV4)</td>
<td>0.5 mL</td>
<td>IM</td>
</tr>
<tr>
<td>IPV</td>
<td>0.5 mL</td>
<td>IM or SC</td>
</tr>
<tr>
<td>Rotavirus (RV1 or RVS)</td>
<td>(1.0 mL or 2.0 mL)</td>
<td>Oral</td>
</tr>
<tr>
<td>Varicella</td>
<td>0.5 mL</td>
<td>SC</td>
</tr>
<tr>
<td>Herpes zoster</td>
<td>0.65 mL</td>
<td>SC</td>
</tr>
</tbody>
</table>

**Abbreviations:** DT = diphtheria and tetanus toxoids; DTP = diphtheria toxoid, tetanus toxoid, and pertussis; DTaP = diphtheria and tetanus toxoids and acellular pertussis; HepA = hepatitis A; HepB = hepatitis B; Hib = *Haemophilus influenzae* type b; HPV = human papillomavirus; HPV2 = bivalent HPV vaccine; HPV4 = quadrivalent HPV vaccine; IM = intramuscular; IPV = inactivated poliovirus; LAIV = live, attenuated influenza vaccine; MCV4 = quadrivalent meningococcal conjugate vaccine; MMR = measles, mumps, and rubella; MMRV = measles, mumps, rubella, and varicella; MPSV4 = quadrivalent meningococcal polysaccharide vaccine; PCV = pneumococcal conjugate vaccine; PPSV = pneumococcal polysaccharide vaccine; SC = subcutaneous; Td = tetanus and diphtheria toxoids; Tdap = tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis; TIV = trivalent inactivated influenza vaccine.

**Source:** Adapted from Immunization Action Coalition: http://www.immunize.org.

* Persons aged 11–15 years may be administered Recombivax HB (Merck), 1.0 mL (adult formulation) on a 2-dose schedule.
### TABLE 10. Needle length and injection site of IM injections for children aged ≤18 years (by age) and adults aged ≥19 years (by sex and weight)

<table>
<thead>
<tr>
<th>Age group</th>
<th>Needle length</th>
<th>Injection site</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Children (birth–18 yrs)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neonates*</td>
<td>⅝ inch (16 mm)†</td>
<td>Anterolateral thigh</td>
</tr>
<tr>
<td>Infants, 1–12 mos</td>
<td>1 inch (25 mm)</td>
<td>Anterolateral thigh</td>
</tr>
<tr>
<td>Toddlers, 1–2 yrs</td>
<td>1–1½ inch (25–32 mm)</td>
<td>Anterolateral thigh§</td>
</tr>
<tr>
<td>Children, 1–2 yrs</td>
<td>⅝–1 inch (16–25 mm)</td>
<td>Deltoid muscle of arm</td>
</tr>
<tr>
<td><strong>Adults (≥19 yrs)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Men and women, &lt;60 kg (130 lbs)</td>
<td>1 inch (25 mm)¶</td>
<td>Anterolateral thigh</td>
</tr>
<tr>
<td>Men and women, 60–70 kg (130–152 lbs)</td>
<td>1 inch (25 mm)</td>
<td>Deltoid muscle of arm</td>
</tr>
<tr>
<td>Women, 70–90 kg (152–200 lbs)</td>
<td>1–1½ inches (25–38 mm)</td>
<td>Anterolateral thigh</td>
</tr>
<tr>
<td>Men, &gt;118 kg (260 lbs)</td>
<td>1½ inches (38 mm)</td>
<td></td>
</tr>
<tr>
<td>Women, &gt;90 kg (200 lbs)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Abbreviation:** IM = intramuscular.

**Source:** Adapted from Poland GA, Borrud A, Jacobsen RM, et al. Determination of deltoid fat pad thickness: implications for needle length in adult immunization. JAMA 1997;277:1709–11.

* First 28 days of life.
† If skin is stretched tightly and subcutaneous tissues are not bunched.
§ Preferred site.
¶ Some experts recommend a ⅝-inch needle for men and women who weigh <60 kg.
### TABLE 11. Vaccine storage temperature recommendations

<table>
<thead>
<tr>
<th>Vaccines</th>
<th>Vaccine storage temperature</th>
<th>Diluent storage temperature</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Nonlyophilized, aluminum-adjuvanted vaccines</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diphtheria-tetanus–containing vaccines (DT, Td) or pertussis-containing vaccines (DTaP, Tdap)</td>
<td>35°F–46°F (2°C–8°C)</td>
<td>No diluent*</td>
<td>Irreversible loss of potency occurs with exposure to freezing temperatures.</td>
</tr>
<tr>
<td>HepA and HepB</td>
<td>35°F–46°F (2°C–8°C)</td>
<td>No diluent</td>
<td>Irreversible loss of potency occurs with exposure to freezing temperatures.</td>
</tr>
<tr>
<td>PCV</td>
<td>35°F–46°F (2°C–8°C)</td>
<td>No diluent</td>
<td>Irreversible loss of potency occurs with exposure to freezing temperatures.</td>
</tr>
<tr>
<td>HPV†</td>
<td>35°F–46°F (2°C–8°C)</td>
<td>No diluent</td>
<td>Irreversible loss of potency occurs with exposure to freezing temperatures.</td>
</tr>
<tr>
<td><strong>Nonlyophilized, non–aluminum-adjuvanted vaccines</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PRP-OMP Hib</td>
<td>35°F–46°F (2°C–8°C)</td>
<td>No diluent</td>
<td>—</td>
</tr>
<tr>
<td>IPV</td>
<td>35°F–46°F (2°C–8°C)</td>
<td>No diluent</td>
<td>Data on thermostability properties of these vaccines are lacking.</td>
</tr>
<tr>
<td>MCV4†,§</td>
<td>35°F–46°F (2°C–8°C)</td>
<td>No diluent</td>
<td>Data on thermostability properties of these vaccines are lacking.</td>
</tr>
<tr>
<td>PPSV</td>
<td>35°F–46°F (2°C–8°C)</td>
<td>No diluent</td>
<td>Data on thermostability properties of these vaccines are lacking.</td>
</tr>
<tr>
<td>TIV†</td>
<td>35°F–46°F (2°C–8°C)</td>
<td>No diluent</td>
<td>Data on thermostability properties of these vaccines are lacking.</td>
</tr>
<tr>
<td><strong>Lyophilized (nonvaricella) vaccines</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PRP-T Hib†</td>
<td>35°F–46°F (2°C–8°C)¶</td>
<td>35°F–46°F (2°C–8°C)</td>
<td>—</td>
</tr>
<tr>
<td>MMR†</td>
<td>35°F–46°F (2°C–8°C)¶</td>
<td>35°F–77°F (2°C–25°C)</td>
<td>Do not expose to light or temperatures above the recommended range.</td>
</tr>
<tr>
<td>MPSV4</td>
<td>35°F–46°F (2°C–8°C)¶</td>
<td>Data are lacking on ideal pre-reconstitution storage requirements. After reconstitution, vaccine should be stored at 35°F–46°F (2°C–8°C).</td>
<td>Freeze dried (lyophilized) vaccine. Data on the effect of freezing temperatures on potency are lacking.</td>
</tr>
<tr>
<td><strong>Varicella-containing vaccines</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MMRV†</td>
<td>-58°F–5°F (-50°C to -15°C)</td>
<td>35°F–77°F (2°C–25°C)</td>
<td>—</td>
</tr>
<tr>
<td>Varicella†</td>
<td>≤5°F (≤–15°C)</td>
<td>35°F–77°F (2°C–25°C)</td>
<td>—</td>
</tr>
<tr>
<td>Herpes zoster†</td>
<td>≤5°F (≤–15°C)</td>
<td>35°F–77°F (2°C–25°C)</td>
<td>—</td>
</tr>
<tr>
<td><strong>Noninjectable vaccines</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RV5 vaccine†</td>
<td>35°F–46°F (2°C–8°C)</td>
<td>No diluent</td>
<td>—</td>
</tr>
<tr>
<td>RV1 vaccine†</td>
<td>35°F–46°F (2°C–8°C)</td>
<td>Do not freeze.</td>
<td>—</td>
</tr>
<tr>
<td>LAIV</td>
<td>35°F–46°F (2°C–8°C)</td>
<td>No diluent</td>
<td>Do not expose to temperatures above the recommended range.</td>
</tr>
</tbody>
</table>

Abbreviations: DT = diphtheria and tetanus toxoids; DTaP = diphtheria and tetanus toxoids and acellular pertussis; HepA = hepatitis A; HepB = hepatitis B; Hib = Haemophilus influenzae type b; HPV = human papillomavirus; IPV = inactivated poliovirus; LAIV = live, attenuated influenza vaccine; MCV4 = quadrivalent meningococcal conjugate vaccine; MMR = measles, mumps, and rubella; MMRV = measles, mumps, rubella, and varicella; MPSV4 = quadrivalent meningococcal polysaccharide vaccine; PCV = pneumococcal conjugate vaccine; PPSV = pneumococcal polysaccharide vaccine; PRP-OMP = polyribosylribitol phosphate–meningococcal outer membrane protein conjugate; PRP-T = polyribosylribitol phosphate polysaccharide conjugated to a tetanus toxoid; RV = rotavirus; RV1 = live, attenuated monovalent rotavirus vaccine; RV5 = live, reassortment pentavalent rotavirus vaccine; Td = tetanus and diphtheria toxoids; Tdap = tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis; TIV = trivalent inactivated influenza vaccine.

* DTaP–Tripedia is sometimes used as a diluent for ActHib.
† Protect from light.
§ There are two meningococcal conjugate vaccines; Menactra is nonlyophilized, and Menevo is lyophilized. Both powder and diluent should be stored at 35°F–46°F.
‡ The lyophilized pellet may be stored at freezer temperature; the reconstituted vaccine should be stored at refrigerator temperature.
TABLE 12. Comparison of thermometers used to monitor vaccine temperatures

<table>
<thead>
<tr>
<th>Thermometer type</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Continuous chart recorder</td>
<td>Most accurate Continuous 24-hour readings of temperature range and duration Can be recalibrated at regular intervals</td>
<td>Most expensive Requires most training and maintenance</td>
</tr>
<tr>
<td>Minimum-maximum</td>
<td>Inexpensive Monitors temperature range</td>
<td>Accurate within a range of +/- 1°C. No information about the duration of out-of-range temperature Cannot be recalibrated at routine intervals</td>
</tr>
<tr>
<td>Standard fluid filled</td>
<td>Inexpensive and simple to use Because thermometers encased in biosafe liquids, can reflect vaccine temperatures more accurately than those directly exposed to the air</td>
<td>Accurate within a range of +/- 1°C No information about duration of out-of-temperature exposure No information on minimum/maximum temperatures Cannot be recalibrated at routine intervals Might experience poor performance from inexpensive models</td>
</tr>
</tbody>
</table>

Source: Adapted from CDC. Guidelines for maintaining and managing the vaccine cold chain. MMWR 2003;52:1023–5; and Langley A, Grant S, eds. Proceedings of the National Vaccine Storage Workshop; June 28–30; Brisbane, Australia. Maroochydore: Queensland Health; 2004.
### TABLE 13. Vaccination of persons with primary and secondary immunodeficiencies

<table>
<thead>
<tr>
<th>Primary Immunodeficiency</th>
<th>Contraindicated Vaccines*</th>
<th>Risk-specific Recommended Vaccines*</th>
<th>Effectiveness and Comments</th>
</tr>
</thead>
</table>
| B-lymphocyte (humoral)   | OPV†                     | Pneumococcal Consider measles and varicella vaccination | Effectiveness of any vaccine is uncertain if it depends only on the humoral response (e.g., PPSV or MPSV4).
| Severe antibody deficiencies (e.g., X-linked agammaglobulinemia and common variable immunodeficiency) | Smallpox LAIV BCG Ty21a (live typhoid) Yellow fever | | IGIV interferes with the immune response to measles vaccine and possibly varicella vaccine. |
| Less severe antibody deficiencies (e.g., selective IgA deficiency and IgG subclass deficiency) | OPV† BCG Yellow fever | Pneumococcal | All vaccines likely effective; immune response might be attenuated. |
| Other live vaccines appear to be safe. | | | |
| T-lymphocyte (cell-mediated and humoral) | All live vaccines§,¶,** | Pneumococcal | Vaccines might be ineffective. |
| Complete defects (e.g., severe combined immunodeficiency [SCID] disease, complete DiGeorge syndrome) | All live vaccines§,¶,** | Pneumococcal Meningococcal | Effectiveness of any vaccine depends on degree of immune suppression. |
| Partial defects (e.g., most patients with DiGeorge syndrome, Wiskott-Aldrich syndrome, ataxia-telangiectasia) | Live bacterial vaccines§ | Pneumococcal†† | All inactivated vaccines safe and likely effective. |
| Complement | Persistent complement, properdin, or factor B deficiency | None | Pneumococcal Meningococcal | All routine vaccines likely effective. |
| Phagocytic function | Chronic granulomatous disease, leukocyte adhesion defect, and myeloperoxidase deficiency. | Live bacterial vaccines§ | Pneumococcal†† | All inactivated vaccines safe and likely effective. |
| Secondary HIV/AIDS | OPV† Smallpox BCG LAIV Withhold MMR and varicella in severely immunocompromised persons. Yellow fever vaccine might have a contraindication or a precaution depending on clinical parameters of immune function*** | Pneumococcal Consider Hib (if not administered in infancy) and meningococcal vaccination. | Effectiveness of any vaccine depends on degree of immune suppression. MMR, varicella, rotavirus, and all inactivated vaccines, including inactivated influenza, might be effective.§§ |
| Malignant neoplasm, transplantation, immunosuppressive or radiation therapy | Live viral and bacterial, depending on immune status§,¶ | Pneumococcal | Effectiveness of any vaccine depends on degree of immune suppression. |
| Asplenia | None | Pneumococcal Meningococcal | All routine vaccines likely effective. |
| Chronic renal disease | LAIV | Pneumococcal Hepatitis B†† | All routine vaccines likely effective. |

**Abbreviations:** AIDS = acquired immunodeficiency syndrome; BCG = bacille Calmette-Guérin; Hib = *Haemophilus influenzae* type b; HIV = human immunodeficiency virus; IG = immunoglobulin; IGIV = immune globulin intravenous; LAIV = live, attenuated influenza vaccine; MMR = measles, mumps, and rubella; MPSV4 = quadrivalent meningococcal polysaccharide vaccine; OPV = oral poliovirus vaccine (live); PPSV = pneumococcal polysaccharide vaccine; TIV = trivalent inactivated influenza vaccine.

* Other vaccines that are universally or routinely recommended should be given if not contraindicated.
†† Pneumococcal polysaccharide vaccine is not indicated for children with chronic granulomatous disease beyond age-based universal recommendations for PCV. Children with chronic granulomatous disease are not at increased risk for pneumococcal disease.
¶¶ Indicated based on the risk from dialysis-based bloodborne transmission.
** Regarding T-lymphocyte immunodeficiency as a contraindication for rotavirus vaccine, data exist only for severe combined immunodeficiency.
††† Pneumococcal polysaccharide vaccine is not indicated for children with chronic granulomatous disease beyond age-based universal recommendations for PCV. Children with chronic granulomatous disease are not at increased risk for pneumococcal disease.
§§ HIV-infected children should receive IG after exposure to measles and may receive varicella and measles vaccine if CD4+ T-lymphocyte count is ≥15%.
††††† Indicated based on the risk from dialysis-based bloodborne transmission.
*** Symptomatic HI virus infection or CD4+ T-lymphocyte count of <200/mm³ or <15% of total lymphocytes for children aged <6 years is a contraindication to yellow fever vaccine administration. Asymptomatic HIV infection with CD4+ T-lymphocyte count of 200–499/mm³ for persons aged ≥6 years or 15%–24% of total lymphocytes for children aged <6 years is a precaution for yellow fever vaccine administration. Details of yellow fever vaccine recommendations are available from CDC. (CDC. Yellow fever vaccine: recommendations of the Advisory Committee on Immunization Practices [ACIP]. MMWR 2010;59[No. RR-7].)
### TABLE 14. Approaches to evaluation and vaccination of persons vaccinated outside the United States who have no (or questionable) vaccination records

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Recommended approach</th>
<th>Alternative approach*</th>
</tr>
</thead>
<tbody>
<tr>
<td>MMR</td>
<td>Revaccination with MMR</td>
<td>Serologic testing for IgG antibodies to measles, mumps, and rubella</td>
</tr>
<tr>
<td>Hib</td>
<td>Age-appropriate revaccination</td>
<td>—</td>
</tr>
<tr>
<td>Hepatitis A</td>
<td>Age-appropriate revaccination</td>
<td>—</td>
</tr>
<tr>
<td>Hepatitis B</td>
<td>Age-appropriate revaccination and serologic testing for HBsAg†</td>
<td>—</td>
</tr>
<tr>
<td>Poliovirus</td>
<td>Revaccination with inactivated poliovirus vaccine</td>
<td>Serologic testing for neutralizing antibody to poliovirus types 1, 2, and 3 (limited availability)</td>
</tr>
<tr>
<td>DTaP</td>
<td>Revaccination with DTaP, with serologic testing for specific IgG antibody to tetanus and diphtheria toxins in the event of a severe local reaction</td>
<td>Persons whose records indicate receipt of ≥3 doses: serologic testing for specific IgG antibody to diphtheria and tetanus toxins before administering additional doses (see text), or administer a single booster dose of DTaP, followed by serologic testing after 1 month for specific IgG antibody to diphtheria and tetanus toxins with revaccination as appropriate (see text)</td>
</tr>
<tr>
<td>Tdap</td>
<td>Age-appropriate vaccination of persons who are candidates for Tdap vaccine on the basis of time since last diphtheria and tetanus-toxoid–containing vaccines.</td>
<td>—</td>
</tr>
<tr>
<td>Varicella</td>
<td>Age-appropriate vaccination of persons who lack evidence of varicella immunity</td>
<td>—</td>
</tr>
<tr>
<td>Pneumococcal conjugate</td>
<td>Age-appropriate vaccination</td>
<td>—</td>
</tr>
<tr>
<td>Rotavirus</td>
<td>Age-appropriate vaccination</td>
<td>—</td>
</tr>
<tr>
<td>HPV</td>
<td>Age-appropriate vaccination</td>
<td>—</td>
</tr>
<tr>
<td>Zoster</td>
<td>Age-appropriate vaccination</td>
<td>—</td>
</tr>
</tbody>
</table>

**Abbreviations:** DTaP = diphtheria and tetanus toxoids and acellular pertussis; HBsAg = hepatitis B surface antigen; Hib = Haemophilus influenzae type b; HPV = human papillomavirus; IgG = immune globulin G; MMR = measles, mumps, and rubella; Tdap = tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis.

* There is a recommended approach for all vaccines and an alternative approach for some vaccines.

† In rare instances, hepatitis B vaccine can give a false-positive HBsAg result up to 18 days after vaccination; therefore, blood should be drawn to test for HBsAg before vaccinating (Source: CDC. A comprehensive immunization strategy to eliminate transmission of hepatitis B virus infection in the United States: recommendations of the Advisory Committee on Immunization Practices [ACIP]; Part I: Immunization in Infants, Children, and Adolescents. MMWR 2005;54(No. RR-16).)
<table>
<thead>
<tr>
<th>Intervention</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Increase community demand for vaccination</strong></td>
<td></td>
</tr>
<tr>
<td>Client reminder or recall systems</td>
<td>Strongly recommended</td>
</tr>
<tr>
<td>Multicomponent interventions, including education</td>
<td>Strongly recommended</td>
</tr>
<tr>
<td>Requirements for entry to schools, child-care facilities, and colleges</td>
<td>Recommended</td>
</tr>
<tr>
<td>Community education alone</td>
<td>Insufficient evidence</td>
</tr>
<tr>
<td>Clinic-based education</td>
<td>Insufficient evidence</td>
</tr>
<tr>
<td>Patient or family incentives or sanctions</td>
<td>Insufficient evidence</td>
</tr>
<tr>
<td>Client-held medical records</td>
<td>Insufficient evidence</td>
</tr>
<tr>
<td><strong>Enhance access to vaccination services</strong></td>
<td></td>
</tr>
<tr>
<td>Reducing out-of-pocket costs</td>
<td>Strongly recommended</td>
</tr>
<tr>
<td>Enhancing access through the U.S. Department of Agriculture's Women, Infants, and Children program</td>
<td>Recommended</td>
</tr>
<tr>
<td>Home visits, outreach, and case management</td>
<td>Recommended</td>
</tr>
<tr>
<td>Enhancing access at schools</td>
<td>Recommended</td>
</tr>
<tr>
<td>Expanding access in health care settings</td>
<td>Recommended as part of multicomponent interventions only</td>
</tr>
<tr>
<td>Enhancing access at child care centers</td>
<td>Insufficient evidence</td>
</tr>
<tr>
<td><strong>Focus on providers</strong></td>
<td></td>
</tr>
<tr>
<td>Reminder or recall systems</td>
<td>Strongly recommended</td>
</tr>
<tr>
<td>Assessment and feedback</td>
<td>Strongly recommended</td>
</tr>
<tr>
<td>Standing orders</td>
<td>Strongly recommended</td>
</tr>
<tr>
<td>Provider education alone</td>
<td>Insufficient evidence</td>
</tr>
</tbody>
</table>

FIGURE 1. Intramuscular needle insertion

Source: Adapted from California Immunization Branch.

FIGURE 2. Intramuscular/subcutaneous site of administration: anterolateral thigh

Source: Adapted from Minnesota Department of Health.

FIGURE 3. Intramuscular site of administration: deltoid

Source: Adapted from Minnesota Department of Health.

FIGURE 4. Subcutaneous site of administration: triceps

Source: Adapted from Minnesota Department of Health.

FIGURE 5. Subcutaneous needle insertion

Source: Adapted from California Immunization Branch.
### References


### FIGURE 6. Sample temperature log

<table>
<thead>
<tr>
<th>Temperature Log for Vaccines (Fahrenheit)</th>
<th>Month/Year: _______________</th>
<th>Days 1–15</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day of Month</td>
<td>Staff Initials</td>
<td>Room Temp.</td>
</tr>
<tr>
<td></td>
<td>Exact Time</td>
<td>*F Temp</td>
</tr>
<tr>
<td></td>
<td></td>
<td>am pm</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td>49°</td>
</tr>
<tr>
<td>2</td>
<td></td>
<td>48°</td>
</tr>
<tr>
<td>3</td>
<td></td>
<td>47°</td>
</tr>
<tr>
<td>4</td>
<td></td>
<td>46°</td>
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<tr>
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<td>45°</td>
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<td></td>
<td>41°</td>
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<td>23</td>
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<td>4°</td>
</tr>
<tr>
<td>24</td>
<td></td>
<td>3°</td>
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</tbody>
</table>


16. CDC. Preventing tetanus, diphtheria, and pertussis among adults: use of tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine. MMWR 2006;55(No. RR-17).


20. CDC. Recommended immunization schedules for persons aged 0 through 18 years—United States, 2011. MMWR 2011;60(5).


22. CDC. Haemophilus b conjugate vaccines for prevention of Haemophilus influenzae type b disease among infants and children two months of age and older: recommendations of the ACIP. MMWR 1991;40 (No. RR-1).


26. CDC. A comprehensive immunization strategy to eliminate transmission of hepatitis B virus infection in the United States: recommendations of the Advisory Committee on Immunization Practices (ACIP); part 1: immunization of infants, children, and adolescents. MMWR 2005;54(No. RR-16).


28. CDC. Recommended adult immunization schedule—United States, 2011. MMWR 2011;60(4).


35. CDC. Recommendations from the Advisory Committee on Immunization Practices (ACIP) regarding administration of combination MMRV vaccine. MMWR 2010;59(No. RR-3).


40. CDC. FDA approval of a Haemophilus b conjugate vaccine combined with reconstitution with an acellular pertussis vaccine. MMWR 1996;45:993–5.

41. CDC. Notice to readers: FDA approval for a combined hepatitis A and B vaccine. MMWR 2001;50:806–7.

42. CDC. Notice to readers. FDA licensure of diphtheria and tetanus toxoids and acellular pertussis adsorbed, hepatitis B (recombiant), and poliovirus vaccine combined, (PEDIARIX) for use in infants. MMWR 2003;52:203–4.


44. CDC. Licensure of a diphtheria and tetanus toxoids and acellular pertussis adsorbed and inactivated poliovirus vaccine and guidance for use as a booster dose. MMWR 2008;57:1078–9.


55. CDC. Prevention of herpes zoster: Recommendations of the Advisory Committee on Immunization Practices. MMWR 2008;57 (No. RR-5).


57. Mason W, Takahashi M, Schneider T. Persisting passively acquired measles antibody following gamma globulin therapy for Kawasaki disease and response to live virus vaccination [Abstract 311]. Presented at the 32nd meeting of the Interscience Conference on Antimicrobial Agents and Chemotherapy; Los Angeles, California; October 1992.


60. CDC. Control and prevention of rubella: evaluation and management of suspected outbreaks, rubella in pregnant women, and surveillance for congenital rubella syndrome. MMWR 2001;50 (No. RR-12).


84. CDC. Update: vaccine side effects, adverse reactions, contraindications, and precautions: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 1996;45 (No. RR-12).


123. CDC. Guidelines for maintaining and managing the vaccine cold chain. MMWR 2003;52:1023–5.


175. Wantke F, Demmer CM, Götz M, Jarisch R. Contact dermatitis from thimerosal: 2 years experience with ethylmercuric chloride in patch testing thimerosal-sensitive patients. Contact Dermatitis 1994;30:115–8.
198. CDC. Guiding principles for development of ACIP recommendations for vaccinating during pregnancy and breastfeeding. MMWR 2008;57:580.
202. CDC. Prevention of hepatitis A through active or passive immunization of pregnant women and postpartum women and their infants: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2008;57(No. RR-4).
205. CDC. A comprehensive immunization strategy to eliminate transmission of hepatitis B virus infection in the United States: Recommendations of the Advisory Committee on Immunization Practices (ACIP) part II: immunization of adults. MMWR 2006; 55(No. RR-16)[1-33].

206. CDC. Revised ACIP recommendation for avoiding pregnancy after receiving a rubella-containing vaccine. MMWR 2001;50:1117.


211. CDC. Updated recommendations from the Advisory Committee on Immunization Practices (ACIP) for use of hepatitis A vaccine in close contacts of newly arriving international adoptees. MMWR 2009;58.

212. CDC. Recommendations for identification and public health management of persons with chronic hepatitis B virus infection. MMWR 2008;57(No. RR-8).


219. CDC. Recommendations of the Advisory Committee on Immunization Practices (ACIP). Notice to readers: Programmatic strategies to increase vaccination coverage by age 2 years—linkage of vaccination and WIC services. MMWR 1996;45:217–8.


221. CDC. Immunization of adolescents: recommendations of the Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP), the American Academy of Family Physicians (AAFP), and the American Medical Association (AMA). MMWR 1996;45(No. RR-13).


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Abbreviations

AAFP American Academy of Family Physicians
AAP American Academy of Pediatrics
ACIP Advisory Committee on Immunization Practices
DT pediatric diphtheria-tetanus toxoid
DTaP pediatric diphtheria and tetanus toxoids and acellular pertussis
FDA Food and Drug Administration
GBS Guillain-Barré syndrome
HBIG hepatitis B immune globulin
HBsAg hepatitis B surface antigen
Hib *Haemophilus influenzae* type b
HIV human immunodeficiency virus
HPV human papillomavirus
HCT hematopoietic cell transplant
IgG immunoglobulin G
IGIV intravenous immune globulin
IPV inactivated poliovirus
LAIV live, attenuated influenza vaccine
MCV4 quadrivalent meningococcal conjugate vaccine
MMR measles, mumps, and rubella
MMRV measles, mumps, rubella, and varicella
MPSV4 quadrivalent meningococcal polysaccharide vaccine
OPV oral poliovirus
OSHA Occupational Safety and Health Administration
PCV pneumococcal conjugate vaccine
PRP-OMP *Haemophilus influenzae* type b-polyribosylribitol phosphate-meningococcal outer membrane protein conjugate
PPSV pneumococcal polysaccharide vaccine
RV1 live, attenuated monovalent rotavirus vaccine
RV5 live, reassortant pentavalent rotavirus vaccine
Td adult tetanus and diphtheria toxoids
Tdap tetanus and reduced diphtheria toxoids and acellular pertussis (for adolescents and adults)
TIV trivalent inactivated influenza vaccine
TST tuberculin skin test
VAERS Vaccine Adverse Event Reporting System
VIS vaccine information statement
ZOS herpes zoster vaccine
**Adverse event.** An untoward event that occurs after a vaccination that might be caused by the vaccine product or vaccination process. Adverse events include those that have the following characteristics: 1) vaccine induced (caused by the intrinsic characteristic of the vaccine preparation and the individual response of the vaccinee); these events would not have occurred without vaccination (e.g., vaccine-associated paralytic poliomyelitis); 2) vaccine potentiated: the events would have occurred anyway but were precipitated by the vaccination (e.g., first febrile seizure in a predisposed child); 3) programmatic error: the event was caused by technical errors in vaccine preparation, handling, or administration; and 4) incidental: the event was associated temporarily with vaccination by chance or caused by underlying illness. Special studies are needed to determine whether an adverse event is a reaction to the vaccine or the result of another cause (Sources: Chen RT. Special methodological issues in pharmacoepidemiology studies of vaccine safety. In: Strom BL, ed. Pharmacoepidemiology. 3rd ed. Sussex, England: John Wiley & Sons; 2000:707–32; and Fenichel GM, Lane DA, Livengood JR, Horwitz SJ, Menkes JH, Schwartz JF. Adverse events following immunization: assessing probability of causation. Pediatr Neurol 1989;5:287–90).

**Adverse reaction.** An undesirable medical condition that has been demonstrated to be caused by a vaccine. Evidence for the causal relation is usually obtained through randomized clinical trials, controlled epidemiologic studies, isolation of the vaccine strain from the pathogenic site, or recurrence of the condition with repeated vaccination (i.e., rechallenge); synonyms include side effect and adverse effect.

**Adjuvant.** A vaccine component distinct from the antigen that enhances the immune response to the antigen.

**Antitoxin.** A solution of antibodies against a toxin. Antitoxin can be derived from either human (e.g., tetanus immune globulin) or animal (usually equine) sources (e.g., diphtheria and botulism antitoxin). Antitoxins are used to confer passive immunity and for treatment.

**Hyperimmune globulin (specific).** Special preparations obtained from blood plasma from donor pools preselected for a high antibody content against a specific antigen (e.g., hepatitis B immune globulin, varicella-zoster immune globulin, rabies immune globulin, tetanus immune globulin, vaccinia immune globulin, cytomegalovirus immune globulin, botulism immune globulin). Immune globulin. A sterile solution containing antibodies, which are usually obtained from human blood. It is obtained by cold ethanol fractionation of large pools of blood plasma and contains 15%–18% protein. Intended for intramuscular administration, immune globulin is primarily indicated for routine maintenance of immunity among certain immunodeficient persons and for passive protection against measles and hepatitis A.

**Vaccine.** A suspension of live (usually attenuated) or inactivated microorganisms (e.g., bacteria or viruses) or fractions thereof administered to induce immunity and prevent infectious disease or its sequelae. Some vaccines contain highly defined antigens (e.g., the polysaccharide of _Haemophilus influenzae_ type b or the surface antigen of hepatitis B); others have antigens that are complex or incompletely defined (e.g., _Bordetella pertussis_ antigens or live, attenuated viruses).

**Monoclonal antibody.** An antibody product prepared from a single lymphocyte clone, which contains only antibody against a single antigen.

**Simultaneous.** In the context of vaccine timing and spacing, occurring on the same clinic day, at different anatomic sites, and not combined in the same syringe.

**Toxoid.** A modified bacterial toxin that has been made nontoxic, but retains the ability to stimulate the formation of antibodies to the toxin.

**Vaccination and immunization.** The terms vaccine and vaccination are derived from _sacca_, the Latin term for cow. Vaccine was the term used by Edward Jenner to describe material used (i.e., cowpox virus) to produce immunity to smallpox. The term vaccination was used by Louis Pasteur in the 19th century to include the physical act of administering any vaccine or toxoid. Immunization is a more inclusive term, denoting the process of inducing or providing immunity by administering an immunobiologic. Immunization can be active or passive. Active immunization is the production of antibody or other immune responses through administration of a vaccine or toxoid. Passive immunization means the provision of temporary immunity by the administration of preformed antibodies. Although persons often use the terms vaccination and immunization interchangeably in reference to active immunization, the terms are not synonymous because the administration of an immunobiologic cannot be equated automatically with development of adequate immunity.
Advisory Committee on Immunization Practices
Membership List, October 2009

Chair: Carol Baker, MD, Baylor College of Medicine, Houston, Texas.

Executive Secretary: Larry Pickering, MD, National Center for Immunization and Respiratory Diseases, CDC, Atlanta, Georgia.

Members: Lance Chilton, MD, University of New Mexico, Albuquerque, New Mexico; Paul Cieslak, MD, Oregon Public Health Division, Portland, Oregon; Kristen Ehresmann, MPH, Minnesota Department of Health, St. Paul, Minnesota; Janet Englund, MD, University of Washington and Children’s Hospital and Regional Medical Center, Seattle, Washington; Franklynudson, MD, University of Colorado Health Sciences Center, Denver, Colorado; Wendy Keitel, MD, Baylor College of Medicine, Houston, Texas; Susan Lett, MD, Massachusetts Department of Public Health, Boston, Massachusetts; Michael Marcy, MD, UCLA Center for Vaccine Research, Torrance, California; Cody Meissner, MD, Tufts Medical Center, Boston, Massachusetts; Kathleen Neuzil, MD, University of Washington; Seattle, Washington; Mark Sawyer, MD, University of California - San Diego, California; Ciro Valent Sumaya, MD, Texas A&M Health Science Center, College Station, Texas; Jonathan Tette, MD, University of Wisconsin School of Medicine and Public Health, Madison, Wisconsin.

Ex Officio Members: James E. Cheek, MD, Indian Health Service, Albuquerque, New Mexico; Wayne Hachey, DO, Department of Defense, Falls Church, Virginia; Geoffrey S. Evans, MD, Health Resources and Services Administration, Rockville, Maryland; Bruce Gellin, MD, National Vaccine Program Office, Washington, District of Columbia; Linda Murphy, Centers for Medicare and Medicaid Services, Baltimore, Maryland; George T. Curlin, MD, National Institutes of Health, Bethesda, Maryland; Norman Baylor, PhD, Food and Drug Administration, Bethesda, Maryland; Linda Kinsinger, MD, Department of Veterans Affairs, Durham, North Carolina.

Liaison Representatives: American Academy of Family Physicians, Doug Campos-Outcalt, MD, Phoenix, Arizona; American Academy of Pediatrics, Joseph Bocchini, MD, Shreveport, Louisiana, David Kimberlin, MD, Birmingham, Alabama; American College Health Association, James C. Turner, MD, Charlotte, Virginia; American College of Obstetricians and Gynecologists, Stanley Gall, MD, Louisville, Kentucky; American College of Physicians, Gregory Polond, MD, Rochester, Minnesota; American Geriatrics Society, Kenneth Schmader, MD, Durham, North Carolina; America’s Health Insurance Plans, Mark Netoskie, MD, MBA, Houston, Texas; American Medical Association, Litjen Tan, PhD, Chicago, Illinois; American Osteopathic Association, Stanley Grogg, DO, Tulsa, Oklahoma; American Pharmacists Association, Stephen L. Foster, PharmD, Memphis, Tennessee; Association for Prevention Teaching and Research, W. Paul McKinney, MD, Louisville, Kentucky; Biotechnology Industry Organization, Clement Lewin, PhD, Cambridge, Massachusetts; Canadian National Advisory Committee on Immunization, Joanne Langley, MD, Halifax, Nova Scotia, Canada; Department of Health, United Kingdom David M. Salisbury, MD, London, United Kingdom; Healthcare Infection Control Practices Advisory Committee, Alexis Elward, MD, St. Louis, Missouri; Infectious Diseases Society of America, Samuel L. Katz, MD, Durham, North Carolina; National Association of County and City Health Officials, Jeff Duchin, MD, Seattle, Washington; National Association of Pediatric Nurse Practitioners, Patricia Stinchfield, MPH, St. Paul, Minnesota; National Foundation for Infectious Diseases, William Schaffner, MD, Nashville, Tennessee; National Immunization Council and Child Health Program, Mexico, Vesta Richardson, MD, Mexico City, Mexico; National Medical Association, Patricia Whiteley-Williams, MD, New Brunswick, New Jersey; National Vaccine Advisory Committee; Guthrie Birkhead, MD, Albany, New York; Pharmaceutical Research and Manufacturers of America, Damian A. Braga, Swiftwater, Pennsylvania, Peter Paradiso, PhD, Collegeville, Pennsylvania; Society for Adolescent Medicine, Amy Middleman, MD, Houston, Texas; Society for Healthcare Epidemiology of America, Harry Keyserling, MD, Atlanta, Georgia.

Members of the General Recommendations on Immunization Working Group

Advisory Committee on Immunization Practices (ACIP), Ciro V. Sumaya, MD; Lance Chilton, MD; Susan Lett, MD; Mark H. Sawyer, MD; ACIP Liaison and Ex-Officio Members, Doug Campos-Outcalt, MD, American Academy of Family Physicians; Geoffrey S. Evans, MD, Health Resources and Services Administration; Stephen L. Foster, PharmD, American Pharmacists Association; Stanley Grogg, DO, American Osteopathic Association; Harry Keyserling, MD, Society for Healthcare Epidemiology of America; CDC staff members, William L. Atkinson, MD, Angela Calugar, MD, Ted Cieslak, MD, Amanda Cohn, MD, Christine Robinette Curtis, MD, Carol Friedman, DO,* Sophie Greer, Andrew Kroger, MD, Nancy Levine, PhD, Elaine Miller, Gina Mootrey, DO, Larry Pickering, MD, Jean Smith, MD, Greg Wallace, MD; other members and consultants, Richard Clover, MD, University of Louisville School of Public Health; Sandra Jo Hammer, RN, California Department of Public Health; Kelly L. Moore, MD, Tennessee Department of Health; Lorry Rubin, MD, Schneider Children’s Hospital; Shainoor Ismail, MD, Public Health Agency of Canada; Deborah Wexler, MD, Immunization Action Coalition; Richard Zimmerman, MD, University of Pittsburgh School of Medicine.

* Deceased.
Immunization Schedules

Both the childhood and adult immunization schedules are updated frequently and published annually in January. The schedules are widely available in several journals and on the Centers for Disease Control and Prevention (CDC) website. If not posted in the pharmacy, these documents should be readily available for pharmacy staff. Immunization schedules are the starting point to determine immunization indications for almost all patient populations.

References:
FIGURE 2. Recommendations regarding influenza vaccination of persons who report allergy to eggs: Advisory Committee on Immunization Practices, United States, 2013-14 Influenza season.

Can the person eat lightly cooked egg (e.g., scrambled egg) without reaction?**†

Yes
- Administer vaccine per usual protocol

No

After eating eggs or egg-containing foods, does the person experience only hives?

Yes
- Administer RIV3, if patient aged 18 through 49 yrs.
  OR
  Administer IIV
  Observe for reaction for at least 30 minutes following vaccination

No

After eating eggs or egg-containing foods, does the individual experience other symptoms such as:
- Cardiovascular changes (e.g., hypotension)
- Respiratory distress (e.g., wheezing)
- Gastrointestinal (e.g., nausea/vomiting)
- Reaction requiring epinephrine
- Reaction requiring emergency medical attention

Yes
- Administer RIV3, if patient aged 18 through 49 yrs.
  OR
  Refer to a physician with expertise in management of allergic conditions for further evaluation

No

IIV=Inactivated Influenza Vaccine; RIV3=Recombinant Influenza Vaccine, Trivalent

*Individuals with egg allergy may tolerate egg in baked products (e.g. bread, cake). Tolerance to egg-containing foods does not exclude the possibility of egg allergy (2).

† For individuals who have no known history of exposure to egg, but who are suspected of being egg-allergic on the basis of previously performed allergy testing, consultation with a physician with expertise in the management of allergic conditions should be obtained prior to vaccination. Alternatively, RIV3 may be administered if the recipient is aged 18 through 49 years.

http://www.cdc.gov/flu/professionals/acip/2013-summary-recommendations.htm#figure2
Influenza Vaccination of Persons with a History of Egg Allergy

1. Persons with a history of egg allergy who have experienced only hives after exposure to egg should receive influenza vaccine. Because relatively little data are available for use of LAIV in this setting, IIV or RIV should be used. RIV is egg-free and may be used for persons aged 18-49 years who have no other contraindications. However, IIV (egg- or cell-culture based) may also be used, with the following additional safety measures (Figure 2):
   1. Vaccine should be administered by a healthcare provider who is familiar with the potential manifestations of egg allergy; and
   2. Vaccine recipients should be observed for at least 30 minutes for signs of a reaction after administration of each vaccine dose (1).
2. Persons who report having had reactions to egg involving such symptoms as angioedema, respiratory distress, lightheadedness, or recurrent emesis; or who required epinephrine or another emergency medical intervention may receive RIV3, if aged 18 through 49 years and there are no other contraindications. If RIV3 is not available or the the recipient is not within the indicated age range, such persons should be referred to a physician with expertise in the management of allergic conditions for further risk assessment before receipt of vaccine (Figure 2).
3. All vaccines should be administered in settings in which personnel and equipment for rapid recognition and treatment of anaphylaxis are available.
4. Some persons who report allergy to egg might not be egg-allergic. Those who are able to eat lightly cooked egg (e.g., scrambled egg) without reaction are unlikely to be allergic. Egg-allergic persons might tolerate egg in baked products (e.g., bread or cake). Tolerance to egg-containing foods does not exclude the possibility of egg allergy (2). Egg allergy can be confirmed by a consistent medical history of adverse reactions to eggs and egg-containing foods, plus skin and/or blood testing for immunoglobulin E antibodies to egg proteins.
5. For individuals who have no known history of exposure to egg, but who are suspected of being egg-allergic on the basis of previously performed allergy testing, consultation with a physician with expertise in the management of allergic conditions should be obtained prior to vaccination (Figure 2). Alternatively, RIV3 may be administered if the recipient is aged 18 through 49 years.
6. A previous severe allergic reaction to influenza vaccine, regardless of the component suspected to be responsible for the reaction, is a contraindication to future receipt of the vaccine.

http://www.cdc.gov/flu/professionals/acip/2013-summary-recommendations.htm#egg-allergy
Figure 1. Recommended immunization schedule for persons aged 0 through 18 years – 2013. (For those who fall behind or start late, see the catch-up schedule [Figure 2].)

These recommendations must be read with the footnotes that follow. For those who fall behind or start late, provide catch-up vaccination at the earliest opportunity as indicated by the green bars in Figure 1. To determine minimum intervals between doses, see the catch-up schedule (Figure 2). School entry and adolescent vaccine age groups are in bold.

### Vaccines

<table>
<thead>
<tr>
<th>Vaccines</th>
<th>Birth</th>
<th>1 mo</th>
<th>2 mos</th>
<th>4 mos</th>
<th>6 mos</th>
<th>9 mos</th>
<th>12 mos</th>
<th>15 mos</th>
<th>18 mos</th>
<th>19–23 mos</th>
<th>2-3 yrs</th>
<th>4-6 yrs</th>
<th>7-10 yrs</th>
<th>11-12 yrs</th>
<th>13–15 yrs</th>
<th>16-18 yrs</th>
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<tr>
<td>Hepatitis B (HepB)</td>
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<td>Rotavirus (RV)</td>
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<td>Diphtheria, tetanus, &amp; acellular pertussis*</td>
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<td>Tetanus, diphtheria, &amp; acellular pertussis*</td>
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<td>Pneumococcal conjugate** (PCV13)</td>
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<td>Inactivated Poliovirus (IPV)</td>
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<td>Merck/Novartis conjugate</td>
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<td>Varicella** (VAR)</td>
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<tr>
<td>Human papillomavirus** (HPV2, females only; HPV4: males and females)</td>
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**Range of recommended ages for all children**

**Range of recommended ages for catch-up immunization**

**Range of recommended ages for certain high-risk groups**

**Range of recommended ages during which catch-up is encouraged and for certain high-risk groups**

This schedule includes recommendations in effect as of January 1, 2013. Any dose not administered at the recommended age should be administered at a subsequent visit, when indicated and feasible. The use of a combination vaccine generally is preferred over separate injections of its equivalent component vaccines. Vaccination providers should consult the relevant Advisory Committee on Immunization Practices (ACIP) statement for detailed recommendations, available online at http://www.cdc.gov/vaccines/pubs/acip-list.htm. Clinically significant adverse events that follow vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS) online (http://vaers.hhs.gov) or by telephone (800-822-7967). Suspected cases of vaccine-preventable diseases should be reported to the state or local health department. Additional information, including precautions and contraindications for vaccination, is available from CDC online (http://www.cdc.gov/vaccines) or by telephone (800-CDC-INFO (800-232-4636)).

This schedule is approved by the Advisory Committee on Immunization Practices (http://www.cdc.gov/vaccines/acip/index.html), the American Academy of Pediatrics (http://www.aap.org), the American Academy of Family Physicians (http://www.aafp.org), and the American College of Obstetricians and Gynecologists (http://www.acog.org).

**NOTE:** The above recommendations must be read along with the footnotes of this schedule.

### Footnotes

**Recommended immunization schedule for persons aged 0 through 18 years—United States, 2013**

For further guidance on the use of the vaccines mentioned below, see: [http://www.cdc.gov/vaccines/pubs/acip-list.htm](http://www.cdc.gov/vaccines/pubs/acip-list.htm)

1. **Hepatitis B (HepB) vaccine. (Minimum age: birth)**
   - **Routine vaccination:**
     - At birth
       - Administer monovalent HepB vaccine to all newborns before hospital discharge.
       - For infants born to hepatitis B surface antigen (HBsAg)-positive mothers, administer HepB vaccine and 0.5 mL of hepatitis B immune globulin (HBIG) within 12 hours of birth. These infants should be tested for HBsAg and antibody to HBsAg (anti-HBs) 1 to 2 months after completion of the HepB series, at age 9 through 18 months (preferably at the next well-child visit).
       - If mother’s HBsAg status is unknown, within 12 hours of birth administer HepB vaccine to all infants regardless of birth weight. For infants weighing <2,000 grams, administer HBIG in addition to HepB within 12 hours of birth. Determine mother’s HBsAg status as soon as possible and, if she is HBsAg-positive, also administer HBIG for infants weighing ≥2,000 grams (no later than age 1 week).
   - **Doses following the birth dose**
     - The second dose should be administered at age 1 or 2 months. Monovalent HepB vaccine should be used for doses administered before age 6 weeks.
     - Infants who receive a birth dose should receive 3 doses of a HepB-containing vaccine on a schedule of 0, 1 to 2 months, and 6 months starting as soon as feasible. See Figure 2.
     - The minimum interval between dose 1 and dose 2 is 4 weeks and between dose 2 and 3 is 8 weeks. The final (third or fourth) dose in the HepB vaccine series should be administered no earlier than age 24 weeks, and at least 16 weeks after the first dose.
     - Administration of a total of 4 doses of HepB vaccine is recommended when a combination vaccine containing HepB is administered after the birth dose.
   - **Catch-up vaccination:**
     - Unvaccinated persons should complete a 3-dose series.
     - A 2-dose series (doses separated by at least 4 months) of adult formulation Recombivax HB is licensed for use in children aged 11 through 15 years.
     - For other catch-up issues, see Figure 2.
   - **2. Rotavirus (RV) vaccines. (Minimum age: 6 weeks for both RV-1 [Rotarix] and RV-5 [Rotarix]).**
     - **Routine vaccination:**
       - Administer a series of RV vaccine to all infants as follows: 1. If RV-1 is used, administer a 2-dose series at 2 and 4 months of age.
       - If RV-5 is used, administer a 3-dose series at ages 2, 4, and 6 months.
       - If any dose in series was RV-5 or vaccine product is unknown for any dose in the series, a total of 3 doses of RV vaccine should be administered.
     - **Catch-up vaccination:**
       - The maximum age for the first dose in the series is 14 weeks, 6 days.
       - Vaccination should not be initiated for infants aged 15 weeks 0 days or older.
       - The maximum age for the final dose in the series is 8 months, 0 days.
       - If RV-1/Rotarix is administered for the first and second doses, a third dose is not indicated.
       - For other catch-up issues, see Figure 2.
   - **3. Diphtheria and tetanus toxoids and acellular pertussis (DTaP) vaccine. (Minimum age: 6 weeks)**
     - **Routine vaccination:**
       - Administer a 5-dose series of DTaP vaccine at ages 2, 4, 6, 15–18 months, and 4 through 6 years. The fourth dose may be administered as early as age 12 months, provided at least 6 months have elapsed since the third dose.
       - **Catch-up vaccination:**
       - The fifth (booster) dose of DTaP vaccine is not necessary if the fourth dose was administered at age 4 years or older.
       - For other catch-up issues, see Figure 2.
   - **4. Tetanus and diphtheria toxoids and acellular pertussis (Tdap) vaccine. (Minimum age: 10 years for boostrix, 11 years for Adacel).**
     - **Routine vaccination:**
       - Administer 1 dose of Tdap vaccine to all adolescents aged 11 through 12 years.
       - Tdap vaccine can be administered regardless of the interval since the last tetanus and diphtheria toxoid-containing vaccine.
       - Administer one dose of Tdap vaccine to pregnant adolescents during each pregnancy (preferred during 27 through 36 weeks gestation) regardless of number of years from prior Td or Tdap vaccination.
     - **Catch-up vaccination:**
       - Persons aged 7 through 10 years who are not fully immunized with the childhood DTaP vaccine series, should receive Tdap vaccine as the first dose in the catch-up series; if additional doses are needed, use Td vaccine. For these children, an adolescent Tdap vaccine should not be given.
       - Persons aged 11 through 18 years who have not received Tdap vaccine should receive a dose followed by tetanus and diphtheria toxoids (Td) booster doses every 10 years thereafter.
       - An inadvertent dose of DTaP vaccine administered to children aged 7 through 10 years can count as part of the catch-up series. This dose can count as the adolescent Tdap dose, or the child can later receive a Tdap booster dose at age 11–12 years.
       - For other catch-up issues, see Figure 2.
   - **5. Haemophilus influenzae type b (Hib) conjugate vaccine. (Minimum age: 6 weeks)**
     - **Routine vaccination:**
       - Administer a Hib vaccine primary series and a booster dose to all infants. The primary series doses should be administered at 2, 4, and 6 months of age; however, if PRP-OMP (PedvaxHib or Comvax) is administered at 2 and 4 months of age, a dose at age 6 months is not indicated. One booster dose should be administered at age 12 through 15 months.
       - Hibexis (PRP-T) should only be used for the booster (final) dose in children aged 12 months through 4 years, who have received at least 1 dose of Hib.
     - **Catch-up vaccination:**
       - If dose 1 was administered at ages 12–14 months, administer booster (as final dose) at least 8 weeks after dose 1.
       - If the first 2 doses were PRP-OMP (PedvaxHib or Comvax), and were administered at age 11 months or younger, the third (and final) dose should be administered at age 12 through 15 months and at least 8 weeks after the second dose.
       - If the first dose was administered at age 7 through 11 months, administer the second dose at least 4 weeks later and a final dose at age 12 through 15 months, regardless of Hib vaccine (PRP-T or PRP-OMP) used for first dose.
       - For unvaccinated children aged 15 months or older, administer only 1 dose.
9. For further guidance on the use of the vaccines mentioned below, see: http://www.cdc.gov/vaccines/pubs/acip-list.htm.

8a. Pneumococcal conjugate vaccine (PCV). (Minimum age: 6 weeks)

Route vaccination:
- Administer a series of PCV13 vaccine at ages 2, 4, 6–18 months, with a booster at age 4–6 years. The final dose in the series should be administered on or after the fourth birthday and at least 6 months after the previous dose.

Catch-up vaccination:
- For children aged 24 through 71 months with certain underlying medical conditions (see footnote 6c), administer 1 dose of PCV13 if 3 doses of PCV were received previously, or administer 2 doses of PCV13 at least 8 weeks apart if fewer than 3 doses of PCV were received previously.
- A single dose of PCV13 may be administering to previously unvaccinated children aged 6 through 18 years who have been vaccinated or functional (including sickle cell disease), HIV or immunocompromising condition, cochlear implant or cerebral palsy fluid leak. See MMWR2010;59(No. RR-9), available at http://www.cdc.gov/mmwr/pdf/rr/rr5909.pdf.

- Administer PPSV23 at least 8 weeks after the last dose of PCV to children aged 2 years or older with certain underlying medical conditions (see footnotes 6b and 6c).

b. Hemophilus influenzae type b (Hib) conjugate vaccine (PRP-OMP). (Minimum age: 2 years) Vaccination of persons with high-risk conditions:

- Administer PPSV23 at least 8 weeks after the last dose of PCV to children aged 2 years or older with certain underlying medical conditions (see footnote 6c). A single revaccination with PPSV should be administered after 5 years to children with anatomic or functional (including sickle cell disease) or an immunocompromised condition.

9c. Medical conditions for which PPSV23 is indicated in children aged 2 years and older for which use of PCV13 is not recommended:

- Immunocompetent children with chronic heart disease (particular coexisting congenital heart disease and cardiac failure); chronic lung disease (including asthma treated with high-dose oral corticosteroid therapy), diabetes mellitus, chronic renal failure, or chronic liver disease.
- Children with anatomic or functional asplenia (including sickle cell disease and other hemoglobinopathies, congenital or acquired asplenia, or splenic dysfunction).
- Children with immunocompromising conditions: HIV infection, chronic renal failure and nephrotic syndrome, diabetes mellitus, diabetes associated with treatment with immunosuppressive drugs or radiation therapy, including malignancies, leukemias, lymphomas and Hodgkin disease; or solid organ transplantation, congenital immunodeficiency.

7. Inactivated poliovirus vaccine (IPV). (Minimum age: 6 weeks)

Routine vaccination:
- Administer a series of IPV at ages 2, 4–6, 18 months, with a booster at age 4–6 years. The final dose in the series should be administered on or after the fourth birthday and at least 6 months after the previous dose.

Catch-up vaccination:
- In the first 6 months of life, minimum age and minimum intervals are only recommended if the person is at risk for imminent exposure to circulating poliovirus (i.e., travel to a polio-endemic region or during an outbreak).
- If 4 or more doses are administered before age 4 years, an additional dose should be administered at age 4 through 6 years.
- A fourth dose is not necessary if the third dose was administered at age 4 years or older and at least 6 months after the previous dose.
- If both OPV and IPV are administered as part of a series, a total of 4 doses should be administered, regardless of the child’s current age.
- IPV is not routinely recommended for U.S. residents aged 18 years or older.

For other catch-up issues, see Figure 2.

8. Influenza vaccines. (Minimum age: 6 months for inactivated influenza vaccine [IV]; 2 years for live, attenuated influenza vaccine [LAV]).

Routine vaccination:
- Administer influenza vaccine annually to all children beginning at age 6 months. For most healthy, nonpregnant persons aged 2 through 49 years, either LAV or IV may be used. However, LAV should NOT be administered to some persons, including 1) those with asthma, 2) children 2 through 4 years who had wheezing in the past 12 months, or 3) those who have any other underlying medical conditions that predispose them to influenza complications. For all other contraindications to use of LAV see MMWR2010;59(No. RR-8), available at http://www.cdc.gov/mmwr/pdf/rr/rr5908.pdf.

- Administer 1 dose to persons aged 9 years and older.

For children aged 6 months through age 8 years:

- For the 2013–14 season, follow dosing guidelines in the 2013 AICP influenza vaccine recommendations.

9. Measles, mumps, and rubella (MMR) vaccine. (Minimum age: 12 months for routine vaccination; Minimum age: 6 months for catch-up vaccination)

Route vaccination:
- Administer the first dose of MMR vaccine at age 12 through 15 months, and the second dose at age 4 through 6 years. The second dose may be administered before age 4 years, provided at least 4 weeks have elapsed since the first dose.

- Administer 1 dose of MMR vaccine to infants aged 6 through 11 months before departure from the United States for international travel. These children should be revaccinated with 2 doses of MMR vaccine, the first at age 12 through 15 months (if the child remains in an area where disease risk is high), and the second dose at least 4 weeks later.

- Administer MMR vaccines to children aged 12 months and older, before departure from the United States for international travel. The first dose should be administered on or after age 12 months and the second dose at least 4 weeks later.

- For children aged 7 through 12 years the recommended minimum interval between 2 doses is 4 weeks (if the second dose was administered at least 4 weeks after the first dose, it can be accepted as valid).

- For children aged 6 through 11 years the recommended minimum interval between doses is 3 months (if the second dose was administered at least 4 weeks after the first dose, it can be accepted as valid); for persons aged 13 years and older, the minimum interval between doses is 4 weeks.

10. Varicella (VAR) vaccine. (Minimum age: 12 months)

Routine vaccination:
- Administer the first dose of VAR vaccine at age 12 through 15 months, and the second dose at age 4 through 6 years. The second dose may be administered before age 4 years, provided at least 3 months have elapsed since the first dose. If the second dose was administered at least 4 weeks after the first dose, it can be accepted as valid.

- For children aged 7 through 18 years without evidence of immunity (see MMWR2007;56[No. RR-4], available at http://www.cdc.gov/mmwr/pdf/rr/rr5604.pdf) have 2 doses of varicella vaccine. For children aged 7 through 12 years the recommended minimum interval between doses is 3 months (if the second dose was administered at least 4 weeks after the first dose, it can be accepted as valid); for persons aged 13 years and older, the minimum interval between doses is 4 weeks.

11. Hepatitis A vaccine (HepA). (Minimum age: 12 months)

Routine vaccination:
- Initial catch-up: HepA vaccine series for children aged 12 through 23 months; separate the 2 doses by 6 to 18 months.

- For children who have received 1 dose of HepA vaccine before age 24 months, should receive a second dose at least 4 months after the first dose.

- For children who have received 2 doses of HepA vaccine separated by 6 to 18 months may be administered if immunity against hepatitis A virus infection is desired.

Catch-up vaccination:
- The minimum interval between the two doses is 6 months.

Special populations:
- Administer an additional dose of Hep A vaccine to individuals aged 6 months to 6 years who live in areas where vaccination programs target older children, or who are at increased risk for infection.

12. Human papillomavirus (HPV) vaccines. (HPV4 [Gardasil] and HPV2 [Cervarix]). (Minimum age: 9 years)

Routine vaccination:
- Administer a 3-dose series of HPV vaccine on a schedule of 0, 1-2, and 6 months to all adolescents aged 9-18 years. Either HPV4 or HPV2 may be used for females, and only HPV4 may be used for males.

- The vaccine series can be started beginning at age 9 years.

- Administer the second dose 1 to 2 months after the first dose and the third dose 6 months after the first dose (at least 24 weeks after the first dose).

Catch-up vaccination:
- Administer HPV vaccine to persons aged 13 through 18 years if not previously vaccinated.

- Use recommended routine catch-up intervals (see above) for vaccine series catch-up.

13. Meningococcal conjugate vaccines (MCV). (Minimum age: 6 weeks for Hib-MCV, 9 months for Menactra [MCV4-D], 2 years for Menveo [MCV4-CRM]).

Routine vaccination:
- Administer MCV4 vaccine at age 11–12 years, with a booster dose at age 16 years.

- Adolescents aged 11 through 18 years with human immunodeficiency virus (HIV) infection should receive a 2-dose primary series of MCV4, with at least 8 weeks between doses. See MMWR2011;60:1018–1019 available at http://www.cdc.gov/mmwr/pdf/ww/mm6013.pdf.

- For children aged 2 months through 10 years with high-risk conditions, see below.

Catch-up vaccination:
- Administer MCV4 vaccine at age 13 through 18 years if not previously vaccinated.

- If the first dose is administered at age 13 through 15 years, a booster dose should be administered at age 16 through 18 years with a minimum interval of at least 8 weeks between doses.

- If the first dose is administered at age 16 years or older, a booster dose is not needed.

For other catch-up issues, see Figure 2.

Vaccination of persons with high-risk conditions:
- For children younger than 19 months of age with anatomic or functional asplenia (including sickle cell disease), they should receive an influenza vaccine to protect against serogroups A and W-135. Prior receipt of Hib-MenCY is not sufficient for children traveling to the meningitis belt or to the Hajj, see MMWR2011;60:1391–2 available at http://www.cdc.gov/mmwr/pdf/ww/mm6013.pdf.

- For children aged 9 months and older who are residents of or travelers to countries in the African meningitis belt or to the Hajj, administer an appropriate formulation and series of MCV4 for protection against serogroups A and W-135. Prior receipt of Hib-MenCY is not sufficient for children traveling to the meningitis belt or the Hajj. See MMWR2011;60:1391–2 available at http://www.cdc.gov/mmwr/pdf/ww/mm6013.pdf.

- For children who are present during outbreaks caused by a vaccine serogroup, administer or complete an age and formulation-appropriate series of Hib-MenCY or MCV4.

For booster doses among persons with high-risk conditions refer to http://www.cdc.gov/vaccines/pubs/acip-list.html.
FIGURE 2. Catch-up immunization schedule for persons aged 4 months through 18 years who start late or who are more than 1 month behind—United States • 2013

The figure below provides catch-up schedules and minimum intervals between doses for children whose vaccinations have been delayed. A vaccine series does not need to be restarted, regardless of the time that has elapsed between doses. Use the section appropriate for the child's age. Always use this table in conjunction with Figure 1 and the footnotes that follow.

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Minimum Age for Dose 1</th>
<th>Minimum Interval Between Doses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hepatitis B*</td>
<td>Birth</td>
<td>Dose 1 to dose 2</td>
</tr>
<tr>
<td>Rotavirus</td>
<td>6 weeks</td>
<td>4 weeks</td>
</tr>
<tr>
<td>Diphtheria, tetanus, pertussis*</td>
<td>6 weeks</td>
<td>4 weeks</td>
</tr>
<tr>
<td>Haemophilus influenzae type b</td>
<td>6 weeks</td>
<td>4 weeks if first dose administered at younger than age 12 months</td>
</tr>
<tr>
<td>Pneumococcal*</td>
<td>6 weeks</td>
<td></td>
</tr>
<tr>
<td>Inactivated poliovirus*</td>
<td>6 weeks</td>
<td></td>
</tr>
<tr>
<td>Meningococcal</td>
<td>6 weeks</td>
<td>8 weeks</td>
</tr>
<tr>
<td>Measles, mumps, rubella*</td>
<td>12 months</td>
<td>4 weeks</td>
</tr>
<tr>
<td>Varicella*</td>
<td>12 months</td>
<td>3 months</td>
</tr>
<tr>
<td>Hepatitis A*</td>
<td>12 months</td>
<td>6 months</td>
</tr>
</tbody>
</table>

Persons aged 4 months through 6 years

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Minimum Age for Dose 1</th>
<th>Minimum Interval Between Doses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hepatitis B</td>
<td>Birth</td>
<td>4 weeks</td>
</tr>
<tr>
<td>Rotavirus*</td>
<td>6 weeks</td>
<td>4 weeks</td>
</tr>
<tr>
<td>Diphtheria, tetanus, pertussis*</td>
<td>6 weeks</td>
<td>4 weeks</td>
</tr>
<tr>
<td>Haemophilus influenzae type b</td>
<td>6 weeks</td>
<td>4 weeks if first dose administered at younger than age 12 months</td>
</tr>
<tr>
<td>Pneumococcal*</td>
<td>6 weeks</td>
<td></td>
</tr>
<tr>
<td>Inactivated poliovirus*</td>
<td>6 weeks</td>
<td></td>
</tr>
<tr>
<td>Meningococcal*</td>
<td>6 weeks</td>
<td>8 weeks</td>
</tr>
<tr>
<td>Measles, mumps, rubella*</td>
<td>12 months</td>
<td>4 weeks</td>
</tr>
<tr>
<td>Varicella*</td>
<td>12 months</td>
<td>4 weeks</td>
</tr>
</tbody>
</table>

Persons aged 7 through 18 years

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Minimum Age for Dose 1</th>
<th>Minimum Interval Between Doses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tetanus, diphtheria; tetanus, diphtheria, pertussis*</td>
<td>7 years*</td>
<td>4 weeks</td>
</tr>
<tr>
<td>Human papillomavirus*</td>
<td>9 years*</td>
<td>Routine dosing intervals are recommended*</td>
</tr>
<tr>
<td>Hepatitis A*</td>
<td>12 months</td>
<td>6 months</td>
</tr>
<tr>
<td>Hepatitis B*</td>
<td>Birth</td>
<td>4 weeks</td>
</tr>
<tr>
<td>Inactivated poliovirus*</td>
<td>6 weeks</td>
<td>4 weeks</td>
</tr>
<tr>
<td>Meningococcal*</td>
<td>6 weeks</td>
<td>8 weeks*</td>
</tr>
<tr>
<td>Measles, mumps, rubella*</td>
<td>12 months</td>
<td>4 weeks</td>
</tr>
<tr>
<td>Varicella*</td>
<td>12 months</td>
<td>4 weeks</td>
</tr>
</tbody>
</table>

NOTE: The above recommendations must be read along with the footnotes of this schedule.

Footnotes — Recommended immunization schedule for persons aged 0 through 18 years—United States, 2013

For further guidance on the use of the vaccines mentioned below, see: http://www.cdc.gov/vaccines/pubs/acip-list.htm.

1. Hepatitis B (HepB) vaccine. (Minimum age: birth)
   Routine vaccination:
   - At birth:
     - Administer monovalent HepB vaccine to all newborns before hospital discharge.
     - For infants born to hepatitis B surface antigen (HBsAg)-positive mothers, administer HepB vaccine and 0.5 ML of hepatitis B immune globulin (HBIG) within 12 hours of birth. These infants should be tested for HBsAg and antibody to HBsAg (anti-HBs) 1 to 2 months after completion of the HepB series, at age 9 through 18 months (preferably at the next well-child visit).
   - If mother's HBsAg status is unknown, within 12 hours of birth administer HepB vaccine to all infants regardless of birth weight. For infants weighing <2,000 grams, administer HBIG in addition to HepB within 12 hours of birth. Determine mother's HBsAg status as soon as possible and, if she is HBsAg-positive, also administer HBIG for infants weighing ≥2,000 grams (no later than age 1 week).
   - Doses following the birth dose:
     - The second dose should be administered at age 1 or 2 months. Monovalent HepB vaccine should be used for doses administered before age 6 weeks.
     - Infants who did not receive a birth dose should receive 3 doses of a HepB-containing vaccine on a schedule of 0, 1 to 2 months, and 6 months, starting as soon as feasible. See Figure 2.
     - The minimum interval between dose 1 and dose 2 is 4 weeks and between dose 2 and 3 is 8 weeks. The final (third or fourth) dose in the HepB vaccine series should be administered no earlier than age 24 weeks, and at least 16 weeks after the first dose.
     - Administration of a total of 4 doses of HepB vaccine is recommended when a combination vaccine containing HepB is administered after the birth dose.
   - Catch-up vaccination:
     - Unvaccinated persons should complete a 3-dose series.
     - A 2-dose series (doses separated by at least 4 months) of adult formulation Recombivax HB is licensed for use in children aged 11 through 15 years.
     - For other catch-up issues, see Figure 2.

2. Rotavirus (RV) vaccines. (Minimum age: 6 weeks for both RV1 [Rotarix] and RV5 [RotaTeq]).
   Routine vaccination:
   - Administer a series of RV vaccine to all infants as follows:
     1. If RV1 is used, administer a 2-dose series at 2 and 4 months of age.
     2. If RV5 is used, administer a 3-dose series at ages 2, 4, and 6 months.
     3. If any dose in series was RV5 or vaccine product is unknown for any dose in the series, a total of 3 doses of RV vaccine should be administered.
   - Catch-up vaccination:
     - The maximum age for the first dose in the series is 14 weeks, 6 days.
     - Vaccination should not be initiated for infants aged 15 weeks to 0 days of age.
     - The maximum age for the final dose in the series is 8 months, 0 days.
     - If RV1 (Rotarix) is administered for the first and second doses, a third dose is not indicated.
     - For other catch-up issues, see Figure 2.

3. Diphtheria and tetanus toxoids and acellular pertussis (DTaP) vaccine. (Minimum age: 6 weeks)
   Routine vaccination:
   - Administer a 5-dose series of DTaP vaccine at ages 2, 4, 6, 15–18 months, and 4 through 6 years. The fourth dose may be administered as early as age 12 months, provided at least 6 months have elapsed since the third dose.
   - Catch-up vaccination:
     - The fifth (booster) dose of DTaP vaccine is not necessary if the fourth dose was administered at age 4 years or older.
     - For other catch-up issues, see Figure 2.

4. Tetanus and diphtheria toxoids and acellular pertussis (Tdap) vaccine. (Minimum age: 10 years for Boostrix, 11 years for Adacel).
   Routine vaccination:
   - Administer 1 dose of Tdap vaccine to all adolescents aged 11 through 12 years.
   - Tdap can be administered regardless of the interval since the last tetanus and diphtheria toxoid-containing vaccine.
• Administer one dose of Tdap vaccine to pregnant adolescents during each pregnancy (preferred during 27 through 36 weeks gestation) regardless of number of years from prior Td or Tdap vaccination.

Catch-up vaccination:
• Persons aged 7 through 10 years who are not fully immunized with the childhood DTaP vaccine series, should receive Tdap vaccine as the first dose in the catch-up series; if additional doses are needed, use Td vaccine. For these children, an adolescent Td vaccine should not be given.
• Persons aged 11 through 18 years who have not received Tdap vaccine should receive a dose followed by tetanus and diptheria toxoids (Td) booster doses every 10 years thereafter.
• An initial dose of Tdap vaccine administered to children aged 7 through 10 years can count as part of the catch-up series. This dose can count as the adolescent Tdap dose, or the child can later receive a Tdap booster dose at age 11–12 years.
• For former catch-up see, Figure 2.

5. Haemophilus influenzae type b (HiB) conjugate vaccine. (Minimum age: 6 weeks)
Routine vaccination:
• Administer a HiB vaccine primary series and a booster dose to all infants. The primary series doses should be administered at 2, 4, and 6 months of age; however, if PRP-OMP (Pedirrix HiB or Conrixis) is administered at 2 and 4 months of age, an additional dose at 6 months is not indicated. One booster dose should be administered at age 12 through 15 months.
• Hib (PRP-T) should only be used for the booster (final) dose in children aged 12 months through 4 years, who have not received at least 1 dose of Hib.
Catch-up vaccination:
• If dose 1 was administered at ages 12-14 months, administer booster (as final dose) at least 8 weeks after dose 1. If the first 2 doses were PCV13 (No. 1) or PCV7 (PedvaxHib or Comrixis), and were administered at age 11 months or younger, the third (and final) dose should be administered at age 12 through 15 months and at least 8 weeks after the second dose.
• If dose 1 was administered at age 7 through 11 months, administer the second dose at least 4 weeks later and a final dose at age 12 through 15 months, regardless of Hib vaccine (PRP-T or PRP-OMP) used for first dose.
• For unvaccinated children aged 15 years or older, only administer one dose.
• For catch-up issues, see Figure 2.

Vaccination of persons with high-risk conditions:
• Hib vaccine is not routinely recommended for patients older than 5 years of age. However one dose of Hib vaccine should be administered to unvaccinated children aged 5 years or older who have leukemia, malignant lymphomas, neoplastic or functional asplenia (including sickle cell disease), human immunodeficiency virus (HIV) infection, or other immunocompromising conditions.

6a. Pneumococcal conjugate vaccine (PCV).
Routine vaccination:
• Administer a series of PCV13 vaccine at ages 2, 4, 6 months and a booster at age 12 through 15 months.
• For children aged 1 through 59 months who have received an age-appropriate series of 7-valent PCV (PCV7), administer a single supplemental dose of 13-valent PCV (PCV13).
Catch-up vaccination:
• Administer 1 dose of PCV13 to all healthy children aged 24 through 59months who are not completely vaccinated for their age.
• For other catch-up issues, see Figure 2.

Vaccination of persons with high-risk conditions:
• For children aged 24 through 71 months with certain underlying medical conditions (see footnote 6c), administer 1 dose of PCV13 at 7-10 weeks of age; or administer 2 doses of PCV13 at 8 weeks apart if fewer than 3 doses of PCV were previously received.
• A single dose of PCV13 may be administered to previously unvaccinated children aged 6 through 18 years who have at least one of the following functional asplenia (including sickle cell disease), HIV infection or an immunocompromising condition, cochlear implant or cerebrospinal fluid leak. See MMWR 2010;59 (No. RR-11), available at http://www.cdc.gov/mmwr/pdf/rr/rr5911.pdf.
• PCV20 can be given at least 8 weeks after the last dose of PCV to children aged 2 years or older with certain underlying medical conditions (see footnotes 6b and 6c).

6b. Pneumococcal polysaccharide vaccine (PPSV23).
(Minimum age: 2 years)
Vaccination of persons with high-risk conditions:
• Administer PPSV20 at least 8 weeks after the last dose of PCV to children aged 2 years or older with certain underlying medical conditions (see footnote 6c). A single revaccination with PPSV20 should be administered at 5 years to children with anatomic or functional asplenia (including sickle cell disease) or an immunocompromising condition.

6c. Medical conditions for which PPSV23 is indicated in children aged 2 years and older and for which use of PCV13 is not contraindicated:
• Immune competent children with chronic heart disease (particularly cyanotic congenital heart disease and cardiac failure), chronic lung disease (including asthma if treated with high-dose oral corticosteroid therapy), diabetes mellitus; cerebrospinal fluid leaks; or renal dysfunction.
• Children with anatomic or functional asplenia (including sickle cell disease and other hemoglobinopathies, congenital or acquired asplenia, or splenic dysfunction).
• Children with immunocompromising conditions such as HIV infection, chronic renal failure and nephrotic syndrome, diseases associated with treatment with immunosuppressive drugs or radiation therapy, including malignant neoplasms, immunosuppression following organ transplantation, congenital immunodeficiency.

7. Inactivated poliovirus vaccine (IPV). (Minimum age: 6 weeks)
Routine vaccination:
• Administer series of IPV at ages 2, 4, 6–18 months, with a booster at age 4–6 years. The final dose in the series should be administered on or after the fourth birthday and at least 6 months before the last dose.
Catch-up vaccination:
• In the absence of confirmed polio, minimum age and minimum intervals are only recommended if the person is at risk for imminent exposure to circulating poliovirus (i.e., travel to a polio-endemic region or during an outbreak).
• If 4 or more doses are administered before age 4 years, an additional dose should be administered at age 4 through 6 years.
• A fourth dose is not necessary if the third dose was administered at age 4 or older and at least 6 months after the previous dose.
• If both OPV and IPV were administered as part of a series, a total of 4 doses should be administered, regardless of the child’s current age.
• IPV is not routinely recommended for U.S. residents aged 18 years or older.

8. Influenza vaccines. (Minimum age: 6 months for inactivated influenza vaccine [IIV]; 2 years for live, attenuated influenza vaccine [LAIV])
Routine vaccination:
• Administer 2 doses of IIV at ages 2, 4–6, 18 months, with a booster at age 4–6 years. The first dose in the series should be administered on or after the fourth birthday and at least 6 months before the last dose.
Catch-up vaccination:
• In children aged 19 months of age and older, minimum age and minimum intervals are only recommended for children who are at risk for imminent exposure to circulating influenza virus (i.e., travel to a polio-endemic region or during an outbreak).
• For the purposes of calculating intervals between doses, 4 weeks = 28 days. Intervals of 4 months or greater are determined by calendar months.
• Information on travel vaccine requirements and recommendations is available at http://www.wte.cdc.gov/travel/page/vacinations.htm.

For additional information:
• For contraindications and precautions to use of vaccine and for additional information regarding vaccine, vaccination providers should consult the relevant AIP statement available online at http://www.cdc.gov/vaccines/pubs/aip-list.htm.

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### Recommended Adult Immunization Schedule—United States - 2013

Note: These recommendations must be read with the footnotes that follow containing number of doses, intervals between doses, and other important information.

<table>
<thead>
<tr>
<th>VACCINE ▼</th>
<th>AGE GROUP ▶</th>
<th>19-21 years</th>
<th>22-26 years</th>
<th>27-49 years</th>
<th>50-59 years</th>
<th>60-64 years</th>
<th>≥ 65 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Influenza 4,8</td>
<td>1 dose annually</td>
<td>Substitute 1-time dose of Tdap for Td booster; then boost with Td every 10 yrs</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Tetanus, diphtheria, pertussis (Td/Tdap) 1,4,8</td>
<td>2 doses</td>
<td>2 doses</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Influenza 4,8</td>
<td>1 dose annually</td>
<td>Substitute 1-time dose of Tdap for Td booster; then boost with Td every 10 yrs</td>
<td></td>
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</tr>
<tr>
<td>Measles, mumps, rubella (MMR) 1,4,8</td>
<td>1 or 2 doses</td>
<td>1 or 2 doses</td>
<td>1 dose</td>
<td></td>
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<tr>
<td>Human papillomavirus (HPV) Female 5,8</td>
<td>3 doses</td>
<td>3 doses</td>
<td>3 doses</td>
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<td></td>
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<tr>
<td>Human papillomavirus (HPV) Male 5,8</td>
<td>3 doses</td>
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<tr>
<td>Pneumococcal 13-valent conjugate (PCV13) 11,4,7</td>
<td>1 or more doses</td>
<td>2 doses</td>
<td>3 doses</td>
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<tr>
<td>Pneumococcal polysaccharide (PPSV23) 8,9</td>
<td>1 dose annually</td>
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<td>Meningococcal 11,4,7</td>
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<td>Zoster 4,8</td>
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<td>Hepatitis A 11,4,7</td>
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<tr>
<td>Hepatitis B 11,4,7</td>
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<td></td>
</tr>
</tbody>
</table>

*Covered by the Vaccine Injury Compensation Program

For all persons in this category who meet the age requirements and who lack documentation of vaccination or have no evidence of previous infection; zoster vaccine recommended regardless of prior episode of zoster

Recommended if some other risk factor is present (e.g., on the basis of medical, occupational, lifestyle, or other indication)

No recommendation

Report all clinically significant postvaccination reactions to the Vaccine Adverse Event Reporting System (VAERS). Reporting forms and instructions on filing a VAERS report are available at www.vaers.hhs.gov or by telephone, 800-822-7967. Information on how to file a Vaccine Injury Compensation Program claim is available at www.hrsa.gov/vaccinecompensation or by telephone, 800-338-2382. To file a claim for vaccine injury, contact the U.S. Court of Federal Claims, 717 Madison Place, N.W., Washington, D.C. 20005; telephone, 202-357-6400. Additional information about the vaccines in this schedule, extent of available data, and contraindications for vaccination is also available at www.cdc.gov/vaccines or from the CDC-INFO Contact Center at 800-CDC-INFO (800-232-4636) in English and Spanish, 8:00 a.m. - 8:00 p.m. Eastern Time, Monday - Friday, excluding holidays.

Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services.

The recommendations in this schedule were approved by the Centers for Disease Control and Prevention’s (CDC) Advisory Committee on Immunization Practices (ACIP), the American Academy of Family Physicians (AAFP), the American College of Physicians (ACP), American College of Osteopathic Physicians and Gynecologists (ACOG) and American College of Nurse-Midwives (ACNM).

For all vaccines being recommended on the Adult Immunization Schedule: a vaccine series does not need to be restarted, regardless of the time that has elapsed between doses. Licensed combination vaccines may be used whenever any components of the combination are indicated and when the vaccine’s other components are not contraindicated. For detailed recommendations on all vaccines, including those used primarily for travelers or that are issued during the year, consult the manufacturers’ package inserts and the complete statements from the Advisory Committee on Immunization Practices (www.cdc.gov/vaccines/pubs/acip-list.htm). Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services.
2. Influenza vaccination

• Annual vaccination against influenza is recommended for all persons aged 6 months and older.
• Persons aged 6 months to 4 years, and older persons aged 65 years and older, should receive influenza vaccine each year before the end of October.
• Young persons aged 2–9 years who have an increased risk of complications from influenza should receive influenza vaccine each year.
• Pregnant women should receive influenza vaccine each year.
• Vaccination of health-care personnel is recommended.

3. Tetanus, diphtheria, and acellular pertussis (Tdap) vaccination

• Administer one dose of Tdap vaccine to pregnant women during each pregnancy (preferred during 27–36 weeks’ gestation), regardless of age and number of prior doses of Tdap previously received.
• Administer Tdap to all other adults who have not previously received Tdap for whom vaccine status is unknown. Tdap can be administered regardless of interval since the most recent tetanus or diphtheria toxoid-containing vaccine.
• Adults with an unknown or incomplete history of completing a 3-dose primary vaccination series with Td-containing vaccines should begin or complete a primary vaccination series (including Tdap dose).
• For unvaccinated adults, administer the first 2 doses at least 4 weeks apart and the third 6–12 months after the second.
• For incompletely vaccinated (i.e., less than 3 doses), administer remaining doses.

Refer to the Advisory Committee on Immunization Practices (ACIP) statement for recommendations for administering Tdap as prophylaxis in sexual management (see footnote #1).

4. Varicella vaccination

• Adults aged 40 years or older without evidence of immunity to varicella (as defined below) should receive 2 doses of single-antigen varicella vaccine or a second dose if they have received only 1 dose.
• Special consideration for vaccination should be given to those who have close contact with persons at high risk for severe disease (e.g., health-care personnel and family contacts of persons with immunocompromising conditions) or are at high risk for exposure or transmission (e.g., children ≤18 years of age [adults should complete a primary varicella vaccination series (including Tdap dose) to achieve immune status], college students, military personnel, and adults living in households with children; nonpregnant women of childbearing age, and international travelers).
• Pregnant women should be advised for evidence of varicella immunity. Women who have not evidence of immunity should receive the first dose of varicella vaccine upon completion or termination of pregnancy and before discharge from the health-care facility. The second dose should be administered 4–8 weeks after the first dose.
• Evidence of immunity to varicella is indicated by the following:
  — documentation of 2 doses of varicella vaccine at least 4 weeks apart.
  — history of varicella based on diagnosis or verification of varicella by a health-care provider; historic of herpes zoster based on diagnosis or verification of herpes zoster disease by a health-care provider; or laboratory evidence of immunity or laboratory confirmation of disease.

5. Human papillomavirus (HPV) vaccination

Two vaccines are licensed for use in females, bivalent HPV vaccine (HPV2) and quadrivalent HPV vaccine (HPV4), and one HPV vaccine for use in males (HPV4).

• For females, either HPV4 or HPV2 is recommended in a 3-dose series for routine vaccination at ages 11 or 12 years, and for those aged 13 through 26 years with at least 1 dose of HPV previously received.
• For males, HPV4 is recommended in a 3-dose series for routine vaccination at age 11 or 12 years, and for those aged through 21 years, if not previously vaccinated. Males aged 22 through 26 years may be vaccinated.
• HPV4 is recommended for men who have sex with men (MSM) through age 26 years for those who did not get any or all doses when younger.
• Vaccination is recommended for immunocompromised persons (including those with HIV infection) through age 26 years for those who did not get any or all doses when younger.
• A complete series for either HPV4 or HPV2 consists of 3 doses. The second dose should be administered 1–2 months after the first dose; the third dose should be administered 6 months after the first dose (at least 4 weeks after the first dose).
• HPV vaccines are not recommended for use in pregnant women. However, pregnancy testing is not needed before vaccination. If a woman is found to be pregnant after initiating the vaccination series, no intervention is needed; the remainder of the 3-dose series should be delayed until after delivery.
• Although HPV vaccination is not specifically recommended for health-care personnel (HCP) based on their occupation, HCP should receive the HPV vaccine as recommended (see above).

6. Zoster vaccination

• A single dose of zoster vaccine is recommended for adults aged 60 years and older, regardless of whether they report a prior episode of herpes zoster. Although the vaccine is licensed by the Food and Drug Administration (FDA) for use among and can be administered to persons aged ≥60 years and older, ACIP recommends vaccination only for adults aged 60 years and older with chronic medical conditions that might make an episode of zoster more severe. (See age 2 years or older who are living in residential halls should be vaccinated if they have not received a dose on or after their 6th birthday.
• MCV4 is licensed for adults with any of the following indications who are aged 50 years or younger; and quadrivalent polychlorocysal varicella vaccine (VZV) is preferred for adults aged 50 years and older.
• Revaccination with MCV4 every 5 years is recommended for adults previously vaccinated with MCV4 or MCV5 who remain at increased risk for infection (e.g., adults with anatomic or functional asplenia or persistent complement component deficiencies).

7. Hepatitis A vaccination

• Vaccinate persons who are not immune to hepatitis A virus (HAV) infection and persons with any of the following indications:
  — men who have sex with men and persons who use injection or noninjection illicit drugs;
  — persons working with HIV-infected primates or with HAV in a research laboratory setting;
  — persons with chronic liver disease or persons who receive clotting factor concentrates;
  — persons traveling to or working in countries that have high or intermediate endemicity of hepatitis A, and
  — unvaccinated persons who anticipate close personal contact (e.g., household or regular babysitting) with an infant at adoption or birth during the first year of life from a country with high or intermediate endemicity. (See footnote #1 for more information on travel recommendations).
• The first dose of the 2-dose hepatitis A vaccine series should be administered as soon as adoption is planned, ideally 2 or more weeks before the arrival of the adoptee.
• Single-antigen vaccine formulations should be administered in a 1-dose schedule with 6–12 months (SpinVax) or 8–16 months (Pro-hep A) interval following the first dose. If the combination vaccine (Fluzone Hep A) is used, administer 2 doses at 1 and 6 months, alternatively, a 4-dose hepatitis A vaccine schedule may be used, administered on days 0, 7, and 21–30, followed by a booster dose at month 12.

8. Hepatitis B vaccination

• Vaccinate persons who are not immune to hepatitis B virus (HBV) infection and persons with any of the following indications:
  — sexually active persons who are not in long-term, mutually monogamous relationship (e.g., persons with more than one sex partner during the previous 6 months), persons seeking evaluation or treatment for a sexually transmitted disease (STD), current or recent injection drug use, and persons who receive clotting factor concentrates;
  — persons traveling to or working in countries that have high or intermediate endemicity of hepatitis A, and
  — unvaccinated persons who anticipate close personal contact (e.g., household or regular babysitting) with an infant at adoption or birth during the first year of life from a country with high or intermediate endemicity. (See footnote #1 for more information on travel recommendations).
• Vaccination of health-care personnel and public-service workers who are potentially exposed to blood or other infectious body fluids;
• persons with diabetes who are 60 years of age or younger as soon as feasible after diagnosis; persons with diabetes who are 60 years or older at the discretion of the treating clinician based on increased need for assisted blood glucose monitoring in long-term care facilities, likelihood of acquiring hepatitis B infection, its complications or chronic sequelae, and likelihood of immunosuppression; and
• persons with end-stage renal disease, including patients receiving hemodialysis, persons with HIV infection, and persons with chronic liver disease (including those with cirrhosis or hepatitis C virus infection);
• household contacts and sex partners of hepatitis B surface antigen-positive persons; clients and staff members of institutions for persons with developmental disabilities; and international travelers to countries with high or intermediate prevalence of chronic hepatitis B infection.

All adults in the following settings: STD treatment facilities, HIV testing and treatment facilities; facilities providing drug-abuse treatment and prevention services; health-care settings targeting service providers to injection-drug users or men who have sex with men; correctional facilities; end-stage renal disease programs and facilities for chronic hemodialysis patients, and institutions and nonresidential daycare facilities for persons with developmental disabilities.
• Administer missing doses to complete a 3-dose series of hepatitis B vaccine to those persons not vaccinated or not completely vaccinated.
• The second dose should be administered 1 month after the first dose; the third dose should be given at least 2 months after the second dose (at least 4 months after the first dose). If the combined hepatitis A and hepatitis B vaccine (Twinrix) is used, give the Hepatitis A dose at 0, 1, and 6 months, alternatively, a 4-dose Twinrix schedule, administered on days 0, 7, and 21–30 followed by a booster dose at month 12 may be used.
• Adult patients receiving hemodialysis or who have other immunocompromising conditions should receive 1 dose of 40 μg/mL (Recombivax HB) administered on a 3-dose schedule at 0, 1, and 6 months or 2 doses of 20 μg/mL (Engerix-B) administered simultaneously on a 4-dose schedule at 0, 1, 2, and 6 months.

14. Selected conditions for which Haemophilus influenzae type b (Hib) vaccine may be used

• 1 dose of Hib vaccine is considered for use in children with cell-mediated disease, leukemia, or HIV infection, or who have immunodeficiency or functional asplenia if they have not previously received Hib vaccine.

• Immunocompromising conditions

Inhanced vaccines: genetic or congenital immunodeficiency (e.g., severe combined immunodeficiency, primary hyper IgM syndrome, agammaglobulinemia), or in vivo live vaccines generally are avoided in persons with immune deficiencies or immunocompromising conditions. Information on specific conditions is available at http://www.cdc.gov/vaccines/pubs/acip-list.htm.
### Summary of Recommendations for Adult Immunization (Age 19 years & older)

<table>
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<th>Vaccine name and route</th>
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| **Influenza** Inactivated Influenza vaccine (IV) **Give IM or intradermally** Live attenuated influenza vaccine (LAIV) **Give intranasally** | For people through age 18 years, consult “Summary of Recommendations for Child/Teen Immunization” at www.immunize.org/catg.d/p2010.pdf.  
- Vaccination is recommended for all adults. (This includes healthy adults age 19–49yrs without risk factors.)  
- LAIV is approved only for healthy nonpregnant people age 2–49yrs.  
- Adults age 18 through 64yrs may be given any intramuscular IV product or, alternatively, the intradermal IV product (Fluzone Intradermal).  
- Adults age 65yrs and older may be given standard-dose IV or, alternatively, high-dose IV (Fluzone High-Dose).  
**Note**: Healthcare personnel who care for severely immunocompromised people (i.e., those who require care in a protected environment) should receive IV rather than LAIV. For information on other contraindications and precautions to LAIV, see far right column. | • Give 1 dose every year in the fall or winter.  
• Begin vaccination services as soon as vaccine is available and continue until the supply is depleted.  
• Continue to give vaccine to unvaccinated adults throughout the influenza season (including when influenza activity is present in the community) and at other times when the risk of influenza exists.  
• If 2 or more of the following live virus vaccines are to be given—LAIV, MMR, Var, HZV, and/or yellow fever—they should be given on the same day. If they are not, space them by at least 28d. | **Contraindications**  
• Previous anaphylactic reaction to this vaccine, to any of its components, including egg protein.  
• For LAIV only: pregnancy; chronic pulmonary (including asthma), cardiovascular (except hypertension), renal, hepatic, neurological/neuromuscular, hematologic, or metabolic (including diabetes) disorders; immunosuppression (including that caused by medications or HIV). For adults who experience only hives with exposure to eggs, give IV with additional safety precautions as found in the 2012 ACIP influenza recommendations, pages 613–618.*  
**Precautions**  
• Moderate or severe acute illness.  
• History of Guillain-Barré syndrome (GBS) within 6wks following previous influenza vaccination.  
For LAIV only: receipt of specific antivirals (i.e., amantadine, rimantadine, zanamivir, or oseltamivir) 48hrs before vaccination. Avoid use of these antiviral drugs for 14d after vaccination. |
| **Pneumococcal polysaccharide (PPSV)** **Give IM or SC**  
**Pneumococcal conjugate (PCV13)** **Give IM** | For people through age 18 years, consult “Summary of Recommendations for Child/Teen Immunization” at www.immunize.org/catg.d/p2010.pdf.  
- People age 65yrs and older.  
- People younger than age 65yrs who have chronic illness or other risk factors, including chronic cardiac or pulmonary disease (including asthma), chronic liver disease, alcoholism, diabetes, CSF leaks, cigarette smoking, as well as candidates for or recipients of cochlear implants and people living in special environments or social settings (including American Indian/Alaska Natives age 50 through 64yrs if recommended by local public health authorities).  
- Those at highest risk of serious pneumococcal infection, including people who  
  - Have anatomic or functional asplenia, including sickle cell disease.  
  - Have an immunocompromising condition, including HIV infection, leukemia, lymphoma, Hodgkin’s disease, multiple myeloma, generalized malignancy, chronic renal failure, or nephrotic syndrome.  
  - Are receiving immunosuppressive chemotherapy (including corticosteroids).  
  - Have received an organ or bone marrow transplant. | • Give 1 dose if unvaccinated or if previous vaccination history is unknown.  
• Give a 1-time revaccination to people  
  - Age 65yrs and older if 1st dose was given prior to age 65yrs and 5yrs have elapsed since dose #1.  
  - Age 19 through 64yrs who are at highest risk of fatal pneumococcal infection or rapid antibody loss (see the 3rd bullet in the box to left for listings of people at highest risk) and 5yrs have elapsed since dose #1.  
• Give 1 dose of PCV13 to people age 19yrs and older at highest risk of serious pneumococcal infection (see column to left), and to those who have CSF leaks, or are candidates for or recipient of cochlear implants. If previously vaccinated with PPSV, give PCV13 at least 12m following PPSV; if not previously vaccinated with PPSV, give PCV13 first, followed by PPSV in 8wks. | **Contraindication**  
Previous anaphylactic reaction to this vaccine, including (for PCV13) to any diphtheria toxoid-containing vaccine, or to any of its components.  
**Precaution**  
Moderate or severe acute illness. |

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*This document was adapted from the recommendations of the Advisory Committee on Immunization Practices (ACIP). To obtain copies of these recommendations, visit CDC’s website at www.cdc.gov/vaccines/pubs/ACIP-list.htm or visit the Immunization Action Coalition (IAC) website at www.immunize.org/acip.*

This table is revised periodically. Visit IAC’s website at www.immunize.org/adultrules to make sure you have the most current version.

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Technical content reviewed by the Centers for Disease Control and Prevention.
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| **MMR**  
(Measles, mumps, rubella)  
• People born in 1957 or later (especially those born outside the U.S.) should receive at least 1 dose of MMR if they have no laboratory evidence of immunity to each of the 3 diseases or documentation of a dose given on or after the first birthday.  
• People in high-risk groups, such as healthcare personnel (paid, unpaid, or volunteer), students entering college and other post-high school educational institutions, and international travelers, should receive a total of 2 doses.  
• People born before 1957 are usually considered immune, but evidence of immunity (serology or documented history of 2 doses of MMR) should be considered for healthcare personnel.  
• Women of childbearing age who do not have acceptable evidence of rubella immunity or vaccination. | • Give 1 or 2 doses (see criteria in 1st and 2nd bullets in box to left).  
• If dose #2 is recommended, give it no sooner than 4wks after dose #1.  
• If a pregnant woman is found to be rubella susceptible, give 1 dose of MMR postpartum.  
• If 2 or more of the following live virus vaccines are to be given—LAIV, MMR, Var, HZV, and/or yellow fever—they should be given on the same day. If they are not, space them by at least 28d.  
• Within 72hrs of measles exposure, give 1 dose as postexposure prophylaxis to susceptible adults.  
**Note:** Routine post-vaccination serologic testing is not recommended. | • Previous anaphylactic reaction to this vaccine or to any of its components.  
• Pregnancy or possibility of pregnancy within 4wks.  
• Severe immunodeficiency (e.g., hematologic and solid tumors; receiving chemotherapy; congenital immunodeficiency; long-term immunosuppressive therapy; or severely symptomatic HIV).  
**Note:** HIV infection is NOT a contraindication to MMR for those who are not severely immunocompromised (i.e., CD4+ T-lymphotoocyte counts are greater than or equal to 200 cells/µL) for 6 months.*  
**Precautions**  
• Moderate or severe acute illness.  
• If blood, plasma, and/or immune globulin were given in past 11m, see ACIP’s General Recommendations on Immunization* regarding time to wait before vaccinating.  
• History of thrombocytopenia or thrombotic purpura.  
**Note:** If TST (tuberculosis skin test) and MMR are both needed but not given on same day, delay TST for 4–6wks after MMR. |
| **Varicella**  
(chickenpox)  
*(Var)*  
• All adults without evidence of immunity.  
**Note:** Evidence of immunity is defined as written documentation of 2 doses of varicella vaccine; a history of varicella disease or herpes zoster (shingles) based on healthcare-provider diagnosis; laboratory evidence of immunity or confirmation of disease; and/or birth in the U.S. before 1980, with the exceptions that follow.  
- Healthcare personnel born in the U.S. before 1980 who do not meet any of the criteria above should be tested or given the 2-dose vaccine series. If testing indicates they are not immune, give the 1st dose of varicella vaccine immediately. Give the 2nd dose 4–8 wks later.  
- Pregnant women born in the U.S. before 1980 who do not meet any of the criteria above should either 1) be tested for susceptibility during pregnancy and if found susceptible, given the 1st dose of varicella vaccine postpartum before hospital discharge, or 2) not be tested for susceptibility and given the 1st dose of varicella vaccine postpartum before hospital discharge. Give the 2nd dose 4–8wks later. | • Give 2 doses.  
• Dose #2 is given 4–8wks after dose #1.  
• Dose #2 is delayed, do not repeat dose #1. Just give dose #2.  
• If 2 or more of the following live virus vaccines are to be given—LAIV, MMR, Var, HZV, and/or yellow fever—they should be given on the same day. If they are not, space them by at least 28d.  
• May use as postexposure prophylaxis if given within 5d.  
**Note:** Routine post-vaccination serologic testing is not recommended. | • Previous anaphylactic reaction to this vaccine or to any of its components.  
• Pregnancy or possibility of pregnancy within 4wks.  
• People on long-term immunosuppressive therapy or who are immunocompromised because of malignancy and primary or acquired immunodeficiency, including HIV/AIDS (although vaccination may be considered if CD4+ T-lymphotoocyte counts are greater than or equal to 200 cells/µL. See MMWR 2007;56:RR-4).  
**Precautions**  
• Moderate or severe acute illness.  
• If blood, plasma, and/or immune globulin were given in past 11m, see ACIP’s General Recommendations on Immunization* regarding time to wait before vaccinating.  
• Receipt of specific antivirals (i.e., acyclovir, famciclovir, or valacyclovir) 24hrs before vaccination, if possible; delay resumption of these antiviral drugs for 14d after vaccination. |
| **Zoster**  
(shingles)  
*(HZV)*  
*Give SC* | • People age 60yrs and older.  
• Give 1-time dose if unvaccinated, regardless of previous history of herpes zoster (shingles) or chickenpox.  
• If 2 or more of the following live virus vaccines are to be given—MMR, Var, HZV and/or yellow fever—they should be given on the same day. If they are not, space them by at least 28d.  
• Contraindications and precautions (mild illness is not a contraindication) | • Previous anaphylactic reaction to any component of zoster vaccine.  
• Primary cellular or acquired immunodeficiency.  
• Pregnancy.  
**Precautions**  
• Moderate or severe acute illness.  
• Receipt of specific antivirals (i.e., acyclovir, famciclovir, or valacyclovir) 24hrs before vaccination, if possible; delay resumption of these antiviral drugs for 14d after vaccination. |
# Summary of Recommendations for Adult Immunization (Age 19 years & older)

## Hepatitis A (HepA)

**Give IM**

Brands may be used interchangeably.

For people through age 18 years, consult “Summary of Recommendations for Child/Teen Immunization” at www.immunize.org/catg/p2010.pdf.

- All people who want to be protected from hepatitis A virus (HAV) infection and lack a specific risk factor.
- People who travel or work anywhere EXCEPT the U.S., Western Europe, New Zealand, Australia, Canada, and Japan.
- People with chronic liver disease; injecting and non-injecting drug users; men who have sex with men; people who receive clotting-factor concentrates; people who work with HAV in experimental lab settings; food handlers when health authorities or private employers determine vaccination to be appropriate.
- People who anticipate close personal contact with an international adoptee from a country of high or intermediate endemicity during the first 60 days following the adoptee’s arrival in the U.S.
- Adults age 40yrs or younger with recent (within 2 wks) exposure to HAV. For people older than age 40yrs with recent (within 2 wks) exposure to HAV, immune globulin is preferred over HepA vaccine.

**Schedule for vaccine administration**

- Give 2 doses, spaced 6–12m apart.
- If dose #2 is delayed, do not repeat dose #1. Just give dose #2.

### Contraindications and precautions

- **Contraindication**
  - Previous anaphylactic reaction to this vaccine or to any of its components.
  - **Precaution**
  - Moderate or severe acute illness.
  
  For Twinrix (hepatitis A and B combination vaccine [GSK]) for patients age 18yrs and older only: give 3 doses on a 0, 1, 6m schedule. There must be at least 4wks between doses #1 and #2, and at least 5m between doses #2 and #3. An alternative schedule can also be used at 0, 7d, 21–30d, and a booster at 12m.

## Hepatitis B (HepB)

**Give IM**

Brands may be used interchangeably.

For people through age 18 years, consult “Summary of Recommendations for Child/Teen Immunization” at www.immunize.org/catg/p2010.pdf.

- All adults who want to be protected from hepatitis B virus infection and lack a specific risk factor.
- Household contacts and sex partners of HBSAg-positive people; injecting drug users; sexually active people not in a long-term, mutually monogamous relationship; men who have sex with men; people with HIV; people seeking STD evaluation or treatment; hemodialysis patients and those with renal disease that may result in dialysis; diabetics younger than age 60yrs (diabetics age 60yrs and older may be vaccinated at the clinician’s discretion [see ACIP recommendations]); healthcare personnel and public safety workers who are exposed to blood; clients and staff of institutions for the developmentally disabled; inmates of long-term correctional facilities; certain international travelers; and people with chronic liver disease.

**Note:** Provide serologic screening for immigrants from endemic areas. If patient is chronically infected, assure appropriate disease management. For sex partners and household contacts of HBSAg-positive people, provide serologic screening and administer initial dose of HepB vaccine at same visit.

**Schedule for vaccine administration**

- Give 3 doses on a 0, 1, 6m schedule.
- Alternative timing options for vaccination include 0, 2, 4m; 0, 1, 4m; and 0, 1, 2, 12m (Engerix brand only).
- There must be at least 4wks between doses #1 and #2, and at least 8wks between doses #2 and #3. Overall, there must be at least 16wks between doses #1 and #3.
- Give adults on hemodialysis or with other immunocompromising conditions 1 dose of 40µg/mL (Recombivax HB) at 0, 1, 6m or 2 doses of 20 µg/mL. (Engerix-B) given simultaneously at 0, 1, 2, 6m.

### Schedule for those who have fallen behind:

If the series is delayed between doses, DO NOT start the series over. Continue from where you left off.

## Inactivated Polio (IPV)

**Give IM or SC**

For people through age 18 years, consult “Summary of Recommendations for Child/Teen Immunization” at www.immunize.org/catg/p2010.pdf.

- Not routinely recommended for U.S. residents age 18yrs and older.

**Note:** Adults living in the U.S. who never received or completed a primary series of polo vaccine need not be vaccinated unless they intend to travel to areas where exposure to wild-type virus is likely. Previously vaccinated adults can receive 1 booster dose if traveling to polo endemic areas or to areas where the risk of exposure is high.

**Schedule for vaccine administration**

- Refer to ACIP recommendations regarding unique situations, schedules, and dosing information.

### Contraindications

- **Contraindication**
  - Previous anaphylactic reaction to this vaccine or to any of its components.
  - **Precautions**
  - Moderate or severe acute illness.
  - Pregnancy.

## Hib (Haemophilus influenzae type b)

**Give IM**

For people through age 18 years, consult “Summary of Recommendations for Child/Teen Immunization” at www.immunize.org/catg/p2010.pdf.

- Not routinely recommended for healthy adults.
- Those adults at highest risk of serious Hib disease include people who 1) have anatomic or functional asplenia, 2) are undergoing an elective splenectomy, or 3) are recipients of hematopoietic stem cell transplant (HSCT).

**Schedule for vaccine administration**

- Give 1 dose of any Hib conjugate vaccine to adults in categories 1 or 2 (see 2nd bullet in column to left) if no history of previous Hib vaccine.
- For HSCT patients, regardless of Hib vaccination history, give 3 doses, at least 4wks apart, beginning 6–12m after transplant.

### Contraindications

- **Contraindication**
  - Previous anaphylactic reaction to this vaccine or to any of its components.
  - **Precaution**
  - Moderate or severe acute illness.

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- All previously unvaccinated women through age 26yrs and men through age 21yrs.  
- All previously unvaccinated men through age 26yrs who 1) have sex with men or 2) are immunocompromised as a result of infection (including HIV), disease, or medications or who lack either of the preceding risk factors but want to be vaccinated. | Give 3 doses on a 0, 2, 6m schedule. Use either HPV2 or HPV4 for women, and only HPV4 for men.  
- There must be at least 4wks between doses #1 and #2 and at least 12wks between doses #2 and #3. Overall, there must be at least 24wks between doses #1 and #3. If possible, use the same vaccine product for all three doses. | Contraindication  
Previous anaphylactic reaction to this vaccine or to any of its components.  
Precautions  
- Moderate or severe acute illness.  
- Pregnancy. |
- People with anatomic or functional asplenia or persistent complement component deficiency.  
- People who travel to or reside in countries in which meningococcal disease is hyperendemic or epidemic (e.g., the "meningitis belt" of Sub-Saharan Africa).  
- Microbiologists routinely exposed to isolates of N. meningitidis.  
- First year college students through age 21yrs who live in residence halls; see 5th bullet in the box to the right for details. | Give 2 initial doses of MCV4 separated by 2m to adults 55yrs and younger with risk factors listed in 1st bullet in column to left or if vaccinating adults with HIV infection in this age group. Give 1 dose of MPSV4 to adults 56yrs and older with risk factors.  
- Give 1 initial dose to all other adults with risk factors (see 2nd–4th bullets in column to left).  
- Give booster doses every 5yrs to adults with continuing risk (see the 1st–3rd bullets in column to left).  
- MCV4 is preferred over MPSV4 for people age 55yrs and younger. For people age 56yrs and older who anticipate multiple doses (see the 1st–3rd bullets in column to left) or who have received MCV4 previously, use MCV4. For all others, use MPSV4.  
- For first year college students age 19–21yrs living in residence halls, give 1 initial dose if unvaccinated and give booster dose if most recent dose was given when younger than age 16yrs. | Contraindication  
Previous anaphylactic reaction to this vaccine or to any of its components.  
Precaution  
- Moderate or severe acute illness. |
- People with anatomic or functional asplenia or persistent complement component deficiency.  
- People who travel to or reside in countries in which meningococcal disease is hyperendemic or epidemic (e.g., the "meningitis belt" of Sub-Saharan Africa).  
- Microbiologists routinely exposed to isolates of N. meningitidis.  
- First year college students through age 21yrs who live in residence halls; see 5th bullet in the box to the right for details. | Give 2 initial doses of MCV4 separated by 2m to adults 55yrs and younger with risk factors listed in 1st bullet in column to left or if vaccinating adults with HIV infection in this age group. Give 1 dose of MPSV4 to adults 56yrs and older with risk factors.  
- Give 1 initial dose to all other adults with risk factors (see 2nd–4th bullets in column to left).  
- Give booster doses every 5yrs to adults with continuing risk (see the 1st–3rd bullets in column to left).  
- MCV4 is preferred over MPSV4 for people age 55yrs and younger. For people age 56yrs and older who anticipate multiple doses (see the 1st–3rd bullets in column to left) or who have received MCV4 previously, use MCV4. For all others, use MPSV4.  
- For first year college students age 19–21yrs living in residence halls, give 1 initial dose if unvaccinated and give booster dose if most recent dose was given when younger than age 16yrs. | Contraindication  
Previous anaphylactic reaction to this vaccine or to any of its components.  
Precaution  
- Moderate or severe acute illness. |
- All people who lack written documentation of a primary series consisting of at least 3 doses of tetanus- and diphtheria-toxoid-containing vaccine.  
- A booster dose of Td or Tdap may be needed for wound management, so consult ACIP recommendations.*  
**For Tdap only:**  
- Adults who have not already received Tdap.  
- Healthcare personnel of all ages.  
- Give Tdap to pregnant women during each pregnancy (preferred during 27–36 weeks’ gestation), regardless of number of years since prior Td or Tdap.  
- For people who are unvaccinated or behind, complete the primary Td series (spaced at 0, 1–2m, 6–12m intervals); substitute a one-time dose of Tdap for one of the doses in the series, preferably the first.  
- Give Td booster every 10yrs after the primary series has been completed.  
- Tdap should be given regardless of interval since previous Td. | • Previous anaphylactic reaction to this vaccine or to any of its components.  
• For Tdap only, history of encephalopathy not attributable to an identifiable cause, within 7d following DTP/DTaP, or Tdap.  
**Precautions**  
• Moderate or severe acute illness.  
• Guillain-Barré syndrome within 6wks following previous dose of tetanus toxoid-containing vaccine.  
• History of arthus reaction following a prior dose of tetanus- or diphtheria toxoid-containing vaccine (including MCV4); defer vaccination until at least 10yrs have elapsed since the last toxoid-containing vaccine.  
• For Tdap only, progressive or unstable neurologic disorder, uncontrolled seizures, or progressive encephalopathy until a treatment regimen has been established and the condition has stabilized. |
Module 1
CASE STUDIES

These case studies serve as a review of Module 1.

Case #1

Jane is a 64 year old female who has recently been diagnosed with end stage renal failure. She presents to the community pharmacy for a refill of her prescription for prednisone 60mg daily. She states that she is now on hemodialysis and is currently being evaluated for listing on the kidney transplant list. During the transplant work up, it was documented that she has immunity to varicella. The pharmacist takes an immunization history and discovers that she has not received any vaccines in the past 10 years. Using the adult immunization schedule, make immunization recommendations for Jane.

Case #2

Maddy is a 7 month old child who is brought to the pharmacy by her mother with a prescription for amoxicillin to treat otitis media. The infant has had no contact with healthcare since birth and has received no vaccines except dose #1 of hepatitis B vaccine series administered just prior to hospital discharge. Devise an immunization schedule that would bring this child up to date with her immunizations.

Case #3

Jeff is a 22 year old male with a history of asthma. He Presents to the pharmacy in September to pick up his albuterol inhaler and asks if he is able to get the influenza vaccine this year. Upon further questioning, you discover that he has an egg allergy (he develops hives after eating eggs). What are your recommendations regarding the influenza vaccine for him?
Case #1

Jane is a 64 year old female who has recently been diagnosed with end stage renal failure. She presents to the community pharmacy for a refill of her prescription for prednisone 60mg daily. She states that she is now on hemodialysis and is currently being evaluated for listing on the kidney transplant list. During the transplant work up, it was documented that she has immunity to varicella. The pharmacist takes an immunization history and discovers that she has not received any vaccines in the past 10 years. Using the adult immunization schedule, make immunization recommendations for Jane.

*Based on Jane’s age and renal failure, she should receive an annual influenza vaccine, tetanus-diphtheria-acellular pertussis vaccine, zoster vaccine, pneumococcal vaccine, and hepatitis B vaccine series. Her prednisone therapy is a contraindication to the live attenuated zoster vaccine. She should receive the trivalent inactivated influenza vaccine rather than the live attenuated influenza vaccine for two reasons: 1) LAIV is indicated for healthy individuals aged 2-49 years; and 2) Jane is taking what is considered an immunosuppressing dose of a corticosteroid. Jane is outside the recommended age range for LAIV and a live vaccine could cause her harm because of her immunosuppression.*
Immunization Administration Training for Pharmacists

Module 1
CASE STUDIES ANSWERS

These case answers serve as a review of Module 1.

Case #2 (childhood case)

Maddy is a 7 month old child who is brought to the pharmacy by her mother with a prescription for amoxicillin to treat otitis media. The infant has had no contact with healthcare since birth and has received no vaccines except dose #1 of hepatitis B vaccine series administered just prior to hospital discharge. Devise an immunization schedule that would bring this child up to date with her immunizations.

<table>
<thead>
<tr>
<th>Timing</th>
<th>Vaccines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Today</td>
<td>Hepatitis B dose #2</td>
</tr>
<tr>
<td></td>
<td>DTaP dose #1</td>
</tr>
<tr>
<td></td>
<td>Hib dose #1</td>
</tr>
<tr>
<td></td>
<td>PCV13 dose #1</td>
</tr>
<tr>
<td></td>
<td>IPV dose#1</td>
</tr>
<tr>
<td></td>
<td>IIV3 or IIV4 dose #1 if season</td>
</tr>
<tr>
<td>4 weeks from today</td>
<td>DTaP dose #2</td>
</tr>
<tr>
<td></td>
<td>Hib dose #2</td>
</tr>
<tr>
<td></td>
<td>PCV13 dose #2</td>
</tr>
<tr>
<td></td>
<td>IPV dose #2</td>
</tr>
<tr>
<td></td>
<td>IIV3 or IIV4 dose #2 if season</td>
</tr>
<tr>
<td>8 weeks from today</td>
<td>Hepatitis B dose #3</td>
</tr>
<tr>
<td></td>
<td>DTaP dose #3</td>
</tr>
<tr>
<td></td>
<td>IPV dose #3</td>
</tr>
<tr>
<td></td>
<td>PCV13 dose #3</td>
</tr>
<tr>
<td>On the child’s first birthday</td>
<td>Hib dose #3</td>
</tr>
<tr>
<td></td>
<td>PCV13 dose #4</td>
</tr>
<tr>
<td></td>
<td>MMR dose #1</td>
</tr>
<tr>
<td></td>
<td>Varicella dose #1</td>
</tr>
<tr>
<td></td>
<td>Hepatitis A dose #1</td>
</tr>
<tr>
<td>When child is 15 months old</td>
<td>DTaP dose #4</td>
</tr>
<tr>
<td>When child is 18 months old</td>
<td>Hepatitis A dose #2</td>
</tr>
<tr>
<td>Continue immunizing according to the childhood immunization schedule with next doses due prior to entering school.</td>
<td></td>
</tr>
</tbody>
</table>

A schedule can be devised using the childhood immunization schedule and the catch-up schedule for individuals aged 4 months to 18 years. The goal is to get the infant age-appropriately immunized quickly. The infant has a mild illness treated with antibiotics. Neither of these events should delay immunization. This child is too old to initiate the rotavirus vaccine series. The maximum age for first dose is 14 weeks. The healthcare providers are careful not to get ahead of the recommended schedule which is easy to do if the provider fails to refer to the routine childhood immunization schedule while devising the catch-up schedule. The footnotes to the schedule help to explain and clarify it. The schedule has some flexibility in it to allow immunization at slightly different intervals than those identified in this schedule. A number of combination vaccines are available for infant immunization. Providers could also consider the combination vaccines that they stock when devising the immunization schedule. The interrupted hepatitis B vaccine series can be picked up where it was left off.

See Common Abbreviations Table included in Module 1 for the definitions of the abbreviations used in this table.
Ignoring the prolonged interval between doses 1 and 2. Note that live attenuated vaccines are not administered until the child is 12 months old which gives time for maternal antibodies to wane minimizing the possibility that they could interfere with the child’s response to the vaccine. Annual influenza immunization is recommended for all children older than 6 months of age. Live attenuated influenza vaccine cannot be used until the child is at least 2 years of age so this infant should receive IIV3 or IIV4. The first season that the child is vaccinated, she should receive two doses separated by 4 weeks. The influenza vaccine was put in this schedule during the first two visits. All these childhood vaccines can be administered during the same visit, however, should be administered using different needles/syringes (unless combination products), and should have different administration sites. The inactivated vaccines can be administered without regard to an interval between the different vaccines if necessary. At the 12 month visit, if the MMR and varicella vaccine are not administered in the same visit, they must be separated by 4 weeks.

Case #3

Jeff is a 22 year old male with a history of asthma. He presents to the pharmacy in September to pick up his albuterol inhaler and asks if he is able to get the influenza vaccine this year. Upon further questioning, you discover that he has an egg allergy (he develops hives after eating eggs). What are your recommendations regarding the influenza vaccine for him?

There is a new influenza vaccine available that is a trivalent, recombinant hemagglutinin vaccine (RIV3) which is egg free and is recommended by the Advisory Committee on Immunizations Practices to be administered to patients with egg allergies (indicated for patients age 18 through 49). Another acceptable option would be to refer the patient to a physician with expertise in Management of allergic conditions for further evaluation.
1. Which of the following antibody classes is the mediator of allergy and anaphylaxis?
   a. IgA
   b. IgE
   c. IgG
   d. IgM

2. Which of the following describes the role of helper T cells in mounting an immune response to a vaccine?
   a. Directly kills infected cells
   b. Produces large amounts of antigen specific antibodies
   c. Produce cytokines that stimulate B cells to produce antibodies
   d. Present antigen to antibodies

3. Which of the following is an advantage of passive immunity compared to active immunity?
   a. Passive immunity is long-lasting
   b. Passive immunity develops in response to infection or after giving a vaccine or toxoid
   c. Passive immunity protects almost immediately
   d. Passive immunity does not interfere with the development immune responses from live vaccines

4. Which of the following is NOT an example of active immunity?
   a. Infection with natural disease
   b. Administration of a live attenuated viral vaccine
   c. Administration of high titer immune globulin
   d. Administration of a recombinant immunogenic protein
Module 1
SELF-ASSESSMENT QUESTIONS

5. Mary received a blood transfusion following a recent motor vehicle accident. Response to which of the following vaccines will be most affected by this event?
   a. Pneumococcal polysaccharide vaccine
   b. Inactivated influenza vaccine (IIV)
   c. Measles vaccine
   d. Tetanus-diphtheria

6. A US born 65 year old was recently diagnosed with diabetes. His vaccine records indicate that he received his Tdap, pneumococcal, and influenza vaccines last fall (one year ago). What vaccines would you recommend for him?
   a. Influenza vaccine, zoster vaccine, and hepatitis B vaccine series
   b. Influenza vaccine, pneumococcal vaccine, and hepatitis B vaccine series
   c. Influenza vaccine and hepatitis vaccine series
   d. Influenza vaccine, pneumococcal vaccine, varicella vaccine, and hepatitis B vaccine series

7. Blake is a 5 year old child who was exposed to a potentially rabid animal 1 month ago and received rabies post-exposure prophylaxis which included a dose of rabies immune globulin and the rabies vaccine series. He now presents for a well-child visit that should include immunization prior to entering school. Which of the following is an appropriate time for him to receive his MMR and varicella vaccines?
   a. Today
   b. In one week
   c. Three months from today
   d. One year from completing the rabies vaccine series

8. Joe is a 28 year old accountant who traveled to Bangkok for a two-month visit two years ago. As part of his preparations for that trip he received a dose of hepatitis A vaccine. He has received only a Tdap booster for a finger laceration since his return. He is now planning a trip to Beijing and seeks your advice regarding hepatitis A vaccination. What do you recommend?
   a. He should receive a double dose of hepatitis A vaccine prior to his departure
   b. He should receive a half dose of hepatitis A vaccine now and another dose in 6 months
   c. He should start the hepatitis A series over and receive a dose now and another dose in 6 months
   d. He should receive a dose of hepatitis A vaccine now to complete the series

9. Which of the following represents a true contraindication to measles vaccine?
   a. History of thrombocytopenia
   b. Vaccine candidate’s mother is pregnant
   c. Vaccine candidate is pregnant
   d. Moderate or severe acute illness with or without fever
Module 1

SELF-ASSESSMENT QUESTIONS

10. A 26 year old female received the second dose in her series of varicella vaccine two weeks ago. Today she stepped on a rusty nail while working on her farm. Her last tetanus-diphtheria (Td) dose was six years ago. Which of the following immunization strategies is appropriate?
   a. No booster is necessary
   b. Give DTaP now
   c. Give Tdap now
   d. Give Td in two weeks

11. Which of the following is a contraindication to receiving live vaccines?
   a. Diabetic patient
   b. Allergy to penicillin
   c. Chronic liver disease
   d. Prednisone 40mg daily

12. Is the following statement true or false? Inactivated and live vaccines can be administered simultaneously or at any interval between doses.
   a. True
   b. False

13. Which of the following is a candidate for the HPV4 vaccine?
   a. 27 year old healthy female
   b. 27 year old male on prednisone 10mg daily
   c. 11 year old healthy boy
   d. 35 year old healthy male

14. What is the minimum age for administration of the first dose of PCV13?
   a. 6 weeks
   b. 10 weeks
   c. 2 months
   d. 4 months

15. For a post-kidney transplant patient on chronic immunosuppression with no history of pneumococcal vaccination which of the following is correct?
   a. PPSV23 alone is indicated when patients are 65 years old or older
   b. PCV13 alone is indicated when patients are 50 years old or older
   c. Single dose of PCV13 followed by a single dose of PPSV23 8 weeks later
   d. Single dose of PPSV23 followed by a single dose of PCV13 8 weeks later
16. For which of these individuals is pneumococcal polysaccharide vaccine recommended today?
   a. A 67 year old with type 2 diabetes who received PPSV23 on her 65th birthday
   b. A medical student prior to her pediatric clerkship
   c. A 23 year old healthy male who smokes
   d. A 14 month old child who completed the infant series for whom repair of a congenital heart defect is planned

17. A 65 year old female taking fluticasone MDI BID for asthma is not a candidate for the herpes zoster vaccine.
   a. True
   b. False

18. Which of the following vaccines is contraindicated for a pregnant woman?
   a. Tetanus, diphtheria, pertussis vaccine
   b. Pneumococcal vaccine
   c. Measles, mumps, and rubella vaccine
   d. Inactivated influenza vaccine

19. Which of the following vaccines is recommended for all healthcare workers?
   a. Annual influenza vaccine
   b. Pneumococcal vaccine
   c. Hepatitis A vaccine
   d. Zoster vaccine

20. For which of the following patients should the trivalent recombinant hemagglutinin influenza vaccine (RIV3) be administered?
   a. A 50 year old woman with asthma
   b. A 30 year old man with a history of anaphylaxis to eggs
   c. A 24 year old women with no comorbidities
   d. A 44 year old man with diabetes
Module 2: Preparing the Pharmacy to Provide Immunization Services

Learning Objectives: At the conclusion of this module, pharmacists should be able to:
1. Develop a plan to properly and safely store vaccines.
2. Implement and accurately complete the checklist for safe vaccine handling and storage.
3. Contact the appropriate manufacturer quality control office if a question arises regarding the integrity of a vaccine.
4. Educate other pharmacy staff about safe vaccine handling and storage.
5. Establish methods to access vaccine information resources.
6. Develop a record keeping system that complies with legal requirements.
7. Describe the benefits and use of immunization registries.
8. Develop a screening technique to identify patients needing immunization.
10. Develop an exposure plan for implementation in the pharmacy, including blood-borne pathogen directives and needle stick injury prevention.

✓ Appendix C: Vaccine Storage and Handling
✓ Appendix E: Vaccine Information Statements

Also included in Module 2 in a shaded box or on a shaded page are the following:
From the Immunization Action Coalition’s Vaccine Information for Healthcare Professionals website, www.immunize.org:
✓ Vaccine Handling Tips
✓ Vaccine Temperature Logs and Storage Troubleshooting Records for Freezer
✓ Vaccine Temperature Logs and Storage Troubleshooting Records for Refrigerator
✓ Emergency Response Worksheet
✓ Errors in Vaccine Storage and Handling
✓ Vaccines with Diluents: How to Use Them
✓ Screening Questionnaire for Adult Immunization
✓ Screening Questionnaire for Children and Teens Immunization

Adult Immunization Programs in Nontraditional Settings: Quality Standards and Guidance for Program Evaluation - A Report of the National Vaccine Advisory Committee and Use of Standing Orders Programs to Increase Adult Vaccination Rates - Recommendations of the ACIP, CDC MMWR, 3-2000.

From the Occupational Safety and Health Administration’s website, www.OSHA.gov:
✓ Model Plans and Programs for the OSHA Bloodborne Pathogens and Hazard Communications Standards
✓ Sample Blood and Body Fluid Exposure Report Form
✓ Sharps Injury Prevention Workbook, A-13 Sample Device Evaluation Form
This module contains the Immunization Implementation Plan (which can be found as the last pages of this module). The Immunization Implementation Plan will be referred to throughout the Immunization Administration Training, but particularly in Modules 2 and 6. This Plan will guide you as you prepare to implement an immunization administration program in your pharmacy. It is recommended that you complete this Plan as the items are discussed.

**Vaccine Storage and Handling**

Vaccines are fragile biological pharmaceuticals that are vulnerable to deviations in storage temperature. Vaccines that are improperly stored may fail to induce the expected immune responses when administered to patients. In addition, vaccines represent a significant investment in inventory for the pharmacy. Proper storage helps protect that investment.

Storage conditions will be described in each vaccine’s package insert. For proper vaccine storage, stand-alone units that only refrigerate or only freeze are recommended by the CDC. The CDC has prepared a “Storage and Handling Toolkit” that should be reviewed and utilized as a resource when preparing the pharmacy for vaccine storage (http://www.cdc.gov/Vaccines/recs/storage/toolkit/). Combination refrigerator/freezer units are less capable of simultaneously maintaining proper storage temperatures in both compartments. If a combination refrigerator/freezer must be used, vaccines should only be stored in the refrigerated section and a separate stand-alone freezer should be used for frozen vaccines. In order to meet vaccine storage requirements, the pharmacy must ensure the refrigerator and freezer are in proper working condition and can maintain the required temperatures. Refrigerator temperature is defined as between 2 and 8°C (36-46°F) and freezer temperature as -15°C (5°F) or colder. A warning sign should be kept by the refrigerator plug and the circuit breaker box stating that vaccines are located within the unit, and it should not be unplugged or the power interrupted. Vaccines should be kept in the center of the freezer or refrigerator compartment, not in the door due to temperature variations from frequent door openings. Keeping jugs of water, but not food, in the door compartment and to fill up empty space on shelves will help maintain a stable temperature as the refrigerator door is opened frequently or if the power goes out. Ice packs can be kept in the freezer for the same reasons. Recording refrigerator and freezer temperatures at least twice daily is a standard of practice. An action plan must be used when the temperature is out of range. That action plan may include adjusting the thermostat or having the unit repaired. The corrective action taken should be noted. If corrective action cannot be taken or is ineffective, vaccine should be moved to back up storage. Stock should be rotated so vaccines with the earliest dates are used first. Expiration dates are printed on the vial or container and vary with each vaccine. If a vaccine arrives in the pharmacy under questionable storage conditions, the vaccine should be stored appropriately but separate from the other stock. The vaccine manufacturer quality control office can offer advice regarding the situation.
Pharmacists are experts in medication storage. However, it is essential that all pharmacy staff and those involved in vaccine delivery understand the fragile nature of vaccines and know the storage requirements. Each pharmacy must designate an individual and back-up person to be in charge of vaccine inventory and storage.\(^1\) If there is any question or concern about the shipping or storage requirements, always contact the local health department or the vaccine manufacturer. Following the proper storage and handling guidelines for vaccines are essential in maximizing vaccine potency and reducing cost lost to vaccine mishandling.
Immunization Implementation Plan

Disclaimer: If you work for a pharmacy with an existing immunization program, many if not all of the items may have already been decided or implemented by your corporate office and/or management team. It is important to follow any company-specific pharmacy policies and procedures with regard to the administration of immunizations and other topics covered within this implementation plan.

Instructions to complete and/or information about the following items can be found throughout Module 2.

☐ Item 1. Plan for vaccine storage
  o Check refrigerator and freezer operation
  o Identify individual and back up to be responsible for storage and handling
  o Establish an emergency storage procedure
    o

☐ Item 2. Devise a system to notify primary care providers of the immunizations you administer to their patients (if necessary)
  Example systems include copying standardized letters to personal physicians, developing spreadsheets for email communication
    o

☐ Item 3. Develop or adopt immunization screening forms
    o

☐ Item 4. Copy or index internet links to appropriate Vaccine Information Statements (VIS)
    o
Item 5. Develop a filing and or record keeping system
   o Consider using the state’s immunization registry. If determined that you will participate in the registry, arrange training for your staff
   o Obtain supply of personal immunization records
   o Develop recall system for vaccine series
   o Develop system for recording occurrence and management of adverse reactions (more information about this can also be found in Module 3)

Item 6. Obtain vaccine information references
   o

Item 7. Write blood-borne pathogens exposure plan
   o

Item 8. Contact waste management company to plan sharps disposal
   o

Item 9. Immunize staff with hepatitis B vaccine
   o

Item 10. Order vaccine
   o
Item 11. Obtain supplies, including: (further information about this can also be found in Module 6)
- Sharps container
- Needles
- Syringes
- Alcohol wipes
- Adhesive bandages
- Gauze pads
- Emergency box
  - Epinephrine or epinephrine auto injector
  - Diphenhydramine injection
  - Tourniquet
  - Alcohol wipes
  - Emergency response procedure

Instructions to complete and/or information about the following items can be found throughout Module 3.

Item 12. Develop emergency management procedure

Instructions to complete and/or information about the following items can be found throughout Module 6. Many of the items listed in the Plan for this section will require you to find out the specific answer as it relates to your state. Depending on where you practice and what organization is hosting the live session associated with your Immunization Administration Training, the information may be provided to you. Time is allotted within Module 6 for you to find the answers to the specific items listed below and to complete the Immunization Implementation Plan.

Item 13. Determine the vaccines you are authorized to administer in the state where you practice pharmacy (ex. influenza, pneumococcal, all CDC-recommended vaccines, etc.)
• Item 14. Determine how you are authorized to administer immunizations

Your state regulation will likely fall into one of the following categories:
- Individual prescription from a prescriber for an individual patient
- Standing order
- Protocol
- Collaborative practice agreement
- Prescriptive authority

• Item 15. Develop a protocol (if this is a requirement). Included in the Module 6 handouts, you will find “Standing Orders for Administering Influenza Vaccine to Adults” from the ACIP. This document will assist you in developing a protocol if your state requires it.

• Item 16. Determine to whom you can administer immunizations (e.g. adults, children, etc.)

• Item 17. Determine the reporting requirements for immunization administration (e.g. to the patient’s prescriber, to the prescriber who authorized the immunization)
Item 18. Meet the training requirements for pharmacists
  o ACPE-accredited activity (specific # of hours)
  o Yearly update (# hours)
  o CPR
  o OSHA
    ▪ blood-borne pathogen training
    ▪ exposure control plan
    ▪ sharps injury log
    ▪ annual OSHA training plan, including documentation
  o Medicare Fraud, Waste and Abuse training
  o Register with Board of Pharmacy
  o Hepatitis B vaccine for all employees (must offer and document if decline)

Item 19. Understand your state’s vaccine registry
  o Are pharmacists required to report to the registry?
  o If yes, obtain training

Item 20. Determine the student pharmacists’ role in your practice related to immunization administration
  o Are student pharmacists allowed to administer vaccines?
  o Are there specific requirements different from pharmacists?

Item 21. Determine if administration of immunizations is included in your professional liability coverage

Item 22. Determine where in your pharmacy you will administer immunizations and design/arrange
Item 23. Determine workflow for your pharmacy practice
  o Student pharmacist role
  o Pharmacy technician role
  ________________________________________________________________
  ________________________________________________________________

Item 24. Develop promotional plan and implement plan
  (e.g. by appointment, clinics, on demand, through employers, etc.)
  ________________________________________________________________
  ________________________________________________________________

Item 25. Determine how adverse events will be handled in your practice
  o Which adverse events will be documented?
  o What is the timeframe for documentation?
  o Who will send the VAERS (Vaccine Adverse Event Reporting System)?
  o What is the follow-up protocol?
    ________________________________________________________________
    ________________________________________________________________

Item 26. Determine plans for reimbursement
  o Cash
  o Private Plans
  o Obtain Medicare provider number
  o Obtain CMS 1500 forms/roster billing forms or software
  o Determine the current product reimbursement for through Medicare Part B
  o Determine the current administration reimbursement through Medicare Part B
    ________________________________________________________________
APPENDIX C
Vaccine Storage & Handling

Checklist for Safe Vaccine Handling and Storage .................. C-1
Vaccine Handling Tips ........................................... C-3
Recording Refrigerator Temperatures ............................... C-4
Vaccine Storage Temperature Recommendations .................... C-5
Safeguard Your Power Supply ....................................... C-6
Vaccine Storage and Handling Resources ............................. C-7
Vaccine Manufacturer Contact Information ......................... C-8
### Establish Storage and Handling Policies

1. We have designated a primary vaccine coordinator and at least one back-up coordinator to be in charge of vaccine storage and handling at our facility.

2. Both the primary and back-up vaccine coordinator(s) have completely reviewed either CDC's online vaccine storage and handling guidance or equivalent training materials offered by our state health department's immunization program.

3. We have detailed, up-to-date, written policies for general vaccine management, including policies for routine activities and an emergency vaccine-retrieval-and-storage plan for power outages and other problems. Our policies are based on CDC's vaccine storage and handling guidance and/or on instruction from our state or local health department's immunization program.

4. We review these policies with all staff annually and with new staff, including temporary staff, when they are hired.

### Log In New Vaccine Shipments

5. We maintain a vaccine inventory log that we use to document the following:
   a. Vaccine name and number of doses received
   b. Date we received the vaccine
   c. Condition of vaccine when we received it
   d. Vaccine manufacturer and lot number
   e. Vaccine expiration date

### Use Proper Storage Equipment

6. We store vaccines in refrigerator and freezer units designed specifically for storing biologics, including vaccines. Alternatively, we keep frozen and refrigerated vaccines in separate, free-standing freezer and refrigerator units. At a minimum, we use a household-style unit with a separate exterior door for the freezer and separate thermostats for the freezer and refrigerator. We DO NOT use a dormitory-style unit (a small combination freezer-refrigerator unit with a freezer compartment inside the refrigerator).

7. We use only calibrated thermometers with a Certificate of Traceability and Calibration* that are recalibrated as recommended by the manufacturer.

8. We have planned back-up storage unit(s) in the event of a power failure or other unforeseen event. We perform regular maintenance to assure optimal functioning.

### Ensure Optimal Operation of Storage Units

9. We have a "Do Not Unplug" sign next to the electrical outlets for the refrigerator and freezer and a "Do Not Stop Power" warning label by the circuit breaker for the electrical outlets. Both include emergency contact information.

10. We keep the storage unit clean, dusting the coils and cleaning beneath it every 3–6 months.

### Maintain Correct Temperatures

11. We always keep at least one accurate calibrated thermometer (+/-1°C [+/-2°F]) with the vaccines in the refrigerator; ideally, we have a continuous-temperature logger and/or temperature-sensitive alarm system.

12. We maintain the refrigerator temperature at 35–46ºF (2–8ºC), and we aim for 40ºF (5ºC).

---

**Checklist for Safe Vaccine Storage and Handling**

Here are the most important things you can do to safeguard your vaccine supply. Are you doing them all? Review this list to see where you might make improvements in your vaccine management practices. Fill in each box with either **YES** or **NO**.

<table>
<thead>
<tr>
<th>Establish Storage and Handling Policies</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>YES</strong></td>
</tr>
<tr>
<td>1. We have designated a primary vaccine coordinator and at least one back-up coordinator to be in charge of vaccine storage and handling at our facility.</td>
</tr>
<tr>
<td><strong>YES</strong></td>
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<tr>
<td>2. Both the primary and back-up vaccine coordinator(s) have completely reviewed either CDC's online vaccine storage and handling guidance or equivalent training materials offered by our state health department's immunization program.</td>
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</tr>
<tr>
<td>3. We have detailed, up-to-date, written policies for general vaccine management, including policies for routine activities and an emergency vaccine-retrieval-and-storage plan for power outages and other problems. Our policies are based on CDC's vaccine storage and handling guidance and/or on instruction from our state or local health department's immunization program.</td>
</tr>
<tr>
<td><strong>YES</strong></td>
</tr>
<tr>
<td>4. We review these policies with all staff annually and with new staff, including temporary staff, when they are hired.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Log In New Vaccine Shipments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>YES</strong></td>
</tr>
<tr>
<td>5. We maintain a vaccine inventory log that we use to document the following:</td>
</tr>
<tr>
<td>a. Vaccine name and number of doses received</td>
</tr>
<tr>
<td>b. Date we received the vaccine</td>
</tr>
<tr>
<td>c. Condition of vaccine when we received it</td>
</tr>
<tr>
<td>d. Vaccine manufacturer and lot number</td>
</tr>
<tr>
<td>e. Vaccine expiration date</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Use Proper Storage Equipment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>YES</strong></td>
</tr>
<tr>
<td>6. We store vaccines in refrigerator and freezer units designed specifically for storing biologics, including vaccines. Alternatively, we keep frozen and refrigerated vaccines in separate, free-standing freezer and refrigerator units. At a minimum, we use a household-style unit with a separate exterior door for the freezer and separate thermostats for the freezer and refrigerator. We DO NOT use a dormitory-style unit (a small combination freezer-refrigerator unit with a freezer compartment inside the refrigerator).</td>
</tr>
<tr>
<td><strong>YES</strong></td>
</tr>
<tr>
<td>7. We use only calibrated thermometers with a Certificate of Traceability and Calibration* that are recalibrated as recommended by the manufacturer.</td>
</tr>
<tr>
<td><strong>YES</strong></td>
</tr>
<tr>
<td>8. We have planned back-up storage unit(s) in the event of a power failure or other unforeseen event. We perform regular maintenance to assure optimal functioning.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ensure Optimal Operation of Storage Units</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>YES</strong></td>
</tr>
<tr>
<td>9. We have a &quot;Do Not Unplug&quot; sign next to the electrical outlets for the refrigerator and freezer and a &quot;Do Not Stop Power&quot; warning label by the circuit breaker for the electrical outlets. Both include emergency contact information.</td>
</tr>
<tr>
<td><strong>YES</strong></td>
</tr>
<tr>
<td>10. We keep the storage unit clean, dusting the coils and cleaning beneath it every 3–6 months.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Maintain Correct Temperatures</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>YES</strong></td>
</tr>
<tr>
<td>11. We always keep at least one accurate calibrated thermometer (+/-1°C [+/-2°F]) with the vaccines in the refrigerator; ideally, we have a continuous-temperature logger and/or temperature-sensitive alarm system.</td>
</tr>
<tr>
<td><strong>YES</strong></td>
</tr>
<tr>
<td>12. We maintain the refrigerator temperature at 35–46ºF (2–8ºC), and we aim for 40ºF (5ºC).</td>
</tr>
</tbody>
</table>

---

*Certificate of Traceability and Calibration with calibration measurements traceable to a testing laboratory accredited by the International Organization of Standardization, to the standards of the National Institute of Standards and Technology, or to another internationally recognized standards agency.*

---

Immunization Action Coalition • 1573 Selby Ave. • St. Paul, MN 55104 • (651) 647-9009 • www.vaccineinformation.org • www.immunize.org
13. We keep extra containers of water in the refrigerator (e.g., in the door, on the floor of the unit where the vegetable bins were located) to help maintain cool temperatures.

14. We always keep at least one accurate calibrated thermometer (+/-1°C [+/-2°F]) with vaccines in the freezer.

15. We maintain the average temperature in the freezer at +5°F (-15°C), preferably colder but no colder than -58°F (-50°C).

16. We keep ice packs or ice-filled containers in the freezer to help maintain cold temperatures.

17. We post signs on the doors of the refrigerator and freezer that indicate which vaccines should be stored in the refrigerator and which in the freezer.

18. We do NOT store any food or drink in any vaccine storage unit.

19. We store vaccines in the middle of the refrigerator or freezer (never in the doors), with room for air to circulate.

20. We have removed all vegetable and deli bins from the storage unit.

21. If we are using a combination refrigerator-freezer unit, we do not store vaccines in front of the cold air outlet that leads from the freezer to the refrigerator (often near the top shelf).

22. We check vaccine expiration dates and rotate our supply of each type of vaccine so that we use the vaccines that will expire soonest.

23. We store vaccines in their original packaging in clearly labeled uncovered containers with slotted sides that allow air to circulate.

24. On days when our practice is open, we document refrigerator and freezer temperatures on the daily log twice a day — first thing in the morning and right before our facility closes.

25. We consistently record temperatures on the log in either Fahrenheit or Celsius. We NEVER mix in any way how we record our temperatures. For example, if the log prompts us to insert an "x" by the temperature that's preprinted on the log, we do not attempt to write in the actual temperature.

26. The logs show whom to call if the temperature in the storage unit goes out of range.

27. When we change the thermostat setting, we document it in the daily log sheet's note section.

28. If out-of-range temperatures occur in the unit, we document in the daily log sheet's note section who responded and when.

29. Trained staff (other than staff designated to record the temperatures) review the logs weekly.

30. We keep the temperature logs on file for at least 3 years.

31. In the event that vaccines are exposed to improper storage conditions, we take the following steps:
   a. We restore proper storage conditions as quickly as possible; if necessary, we move the vaccine to our planned back-up storage unit. We address the storage unit’s mechanical or electrical problems according to guidance from the manufacturer or repair service.
   b. In responding to improper storage conditions, we do NOT make frequent or large changes in thermostat settings. After changing the setting, we give the unit at least a day to stabilize its temperature.
   c. We temporarily label exposed vaccines “Do not use” and keep them separate from any unexposed vaccines. We do not use exposed vaccines until our state health department’s immunization program or the vaccine manufacturer gives us approval.
   d. We document exactly what happened, noting the temperature in the storage unit and the amount of time the vaccines were out of proper storage conditions. We contact our state health department’s immunization program or the vaccine manufacturer to determine how to handle the exposed vaccines.
   e. We follow the health department or manufacturer’s instructions and keep a record detailing the event. Where applicable, we mark the exposed vials with a revised expiration date provided by the manufacturer.

If we answer **YES** to all of the above, we give ourselves a pat on the back! If not, we assign someone to implement needed changes!
Appendix C

Vaccine Handling Tips
Outdated or improperly stored vaccines won’t protect patients!

Manage vaccine inventories.
Inventory your vaccine supplies at least monthly and before placing an order. Expired vaccine must never be used and is money wasted!

Always use the vaccine with the soonest expiration date first.
Move vaccine with the soonest expiration date to the front of the storage unit and mark it to be used first. Keep vaccine vials in their original boxes.

Store vaccine appropriately.†
Place vaccines in refrigerator or freezer immediately upon receiving shipment. Keep vaccine vials in their original packaging. Place vaccine in clearly labeled wire baskets or other open containers with a 2 3” separation between baskets and from wall of unit. Separate vaccines that have been supplied from your state’s Vaccines for Children program from vaccines that are privately purchased. Do not store vaccines in the door or on the floor of the unit.

Stabilize temperatures.
Store ice packs in the freezer and large bags of water in the refrigerator along with the vaccines. This will help maintain a stable, cold temperature in case of a power failure or if the refrigerator or freezer doors are opened frequently or left open. Frequent opening of either the refrigerator or freezer door can lead to temperature variations inside, which could affect vaccine efficacy. For this reason you should not store food or beverages in the refrigerator or freezer.

Safeguard the electrical supply to the refrigerator.
Make sure the refrigerator and freezer are plugged into outlets in a protected area where they cannot be disconnected accidentally. Label the refrigerator, freezer, electrical outlets, fuses, and circuit breakers on the power circuit with information that clearly identifies the perishable nature of vaccines and the immediate steps to be taken in case of interruption of power. If your building has auxiliary power, use the outlet supplied by that system.

†Refer to package insert for specific instructions on the storage of each vaccine. If you have questions about the condition of the vaccine upon arrival, you should immediately place the vaccine in recommended storage, mark it “do not use,” and then call your state health department or the vaccine manufacturer(s) to determine whether the potency of the vaccine(s) has been affected. For other questions, call the immunization program at your state or local health department.

Record your health department’s phone number here:

Technical content reviewed by the Centers for Disease Control and Prevention, December 2011.

Immunization Action Coalition • 1573 Selby Ave. • St. Paul, MN 55104 • (651) 647-9009 • www.immunize.org • www.vaccineinformation.org
Recording Refrigerator Temperatures

Record refrigerator temperatures twice a day.

- Acceptable temperatures are 35°F to 46°F.
- Unacceptable temperatures are below 35°F and above 46°F.

The numbers on the temperature log on the right correspond to step numbers below.

1. Start a new log at the beginning of every month. Write the month and year in the upper right corner of the Refrigerator Temperature Log.

   June 2020

   Month/Year
   Days 1-15

2. At the beginning and end of every clinic day, write your initials in the Staff Initials a.m. or p.m. space for that day. Then write the a.m. or p.m. time.

3. Read the current temperature on the refrigerator thermometer.

   - Temperature is acceptable
   - Temperature is NOT acceptable

   Write an X next to the current temperature on the log.

4. Read the MIN and MAX temperatures.

   - OR
   - MIN: 40°F
   - MAX: 35°F

   Temperatures are acceptable
   OR
   Temperatures are NOT acceptable

   Do nothing.
   Write the unacceptable temperature in the space provided.

   Write MIN or MAX next to the unacceptable temperature.

   Immediately follow the steps under Take Action!

5. At the end of every clinic day repeat steps 2, 3, 4.

   www.eziz.org

   California Department of Public Health Immunization Branch

   IMM-1629 (W/10)
Vaccine Storage Temperatures

- Store unopened and opened vaccines in their original box with the lid in place until administration. Many vaccines should be protected from light.

- Keep calibrated thermometers with *Certificates of Traceability and Calibration* in both the refrigerator and freezer. Read and document refrigerator and freezer temperatures in the morning AND at the end of the work day.

- Have a current emergency vaccine retrieval and storage plan. Exposure of a vaccine to temperatures outside the recommended range requires immediate corrective action. Contact the vaccine manufacturer and/or your state or local health department for guidance.

<table>
<thead>
<tr>
<th>Vaccine(s)</th>
<th>Diluent – Store Between:</th>
<th>Vaccine – Store Between:</th>
</tr>
</thead>
<tbody>
<tr>
<td>DTaP, DT, Tdap, Td</td>
<td>No diluent</td>
<td></td>
</tr>
<tr>
<td>Hepatitis A</td>
<td>No diluent</td>
<td></td>
</tr>
<tr>
<td>Hepatitis B</td>
<td>No diluent</td>
<td></td>
</tr>
<tr>
<td>Hib (ActHIB, Hiberix)</td>
<td>35°F &amp; 46°F (2°C &amp; 8°C)</td>
<td></td>
</tr>
<tr>
<td>Hib (PedvaxHIB)</td>
<td>No diluent</td>
<td></td>
</tr>
<tr>
<td>HPV</td>
<td>No diluent</td>
<td></td>
</tr>
<tr>
<td>Influenza (LAIV)</td>
<td>No diluent</td>
<td></td>
</tr>
<tr>
<td>Influenza (TIV)</td>
<td>No diluent</td>
<td></td>
</tr>
<tr>
<td>Meningococcal (MCV4 – Menactra)</td>
<td>No diluent</td>
<td></td>
</tr>
<tr>
<td>Meningococcal (MCV4 – Menveo)</td>
<td>35°F &amp; 46°F (2°C &amp; 8°C)</td>
<td></td>
</tr>
<tr>
<td>Meningococcal (MPSV4)</td>
<td>35°F &amp; 46°F (2°C &amp; 8°C)</td>
<td></td>
</tr>
<tr>
<td>Pneumococcal (PCV, PPSV)</td>
<td>No diluent</td>
<td></td>
</tr>
<tr>
<td>Polio (IPV)</td>
<td>No diluent</td>
<td></td>
</tr>
<tr>
<td>Rotavirus (RV-5 RotaTeq)</td>
<td>No diluent</td>
<td></td>
</tr>
<tr>
<td>Rotavirus (RV-1 Rotarix)</td>
<td>68°F &amp; 77°F (20°C &amp; 25°C)</td>
<td></td>
</tr>
<tr>
<td>MMR</td>
<td>35°F &amp; 46°F (2°C &amp; 8°C)</td>
<td>-58°F &amp; 46°F (-50°C &amp; 8°C)*</td>
</tr>
<tr>
<td>Varicella</td>
<td>35°F &amp; 77°F (2°C &amp; 25°C)</td>
<td>-58°F &amp; 5°F (-50°C &amp; -25°C)</td>
</tr>
<tr>
<td>Zoster</td>
<td>35°F &amp; 77°F (2°C &amp; -25°C)</td>
<td>-58°F &amp; 5°F (-50°C &amp; -25°C)</td>
</tr>
</tbody>
</table>

**Combination Vaccines**

<table>
<thead>
<tr>
<th>Vaccine(s)</th>
<th>Diluent – Store Between:</th>
<th>Vaccine – Store Between:</th>
</tr>
</thead>
<tbody>
<tr>
<td>DTaP-IPV (Kinrix)</td>
<td>No diluent</td>
<td>35°F &amp; 46°F (2°C &amp; 8°C)</td>
</tr>
<tr>
<td>DTaP-HepB-IPV (Pediarix)</td>
<td>No diluent</td>
<td></td>
</tr>
<tr>
<td>DTaP-IPV/Hib (Pentacel)</td>
<td>35°F &amp; 46°F (2°C &amp; 8°C)</td>
<td></td>
</tr>
<tr>
<td>HepA-HepB (Twinrix)</td>
<td>No diluent</td>
<td></td>
</tr>
<tr>
<td>Hib-HepB (Comvax)</td>
<td>No diluent</td>
<td></td>
</tr>
<tr>
<td>MMRV</td>
<td>35°F &amp; 46°F (2°C &amp; 8°C)</td>
<td>-58°F &amp; 5°F (-50°C &amp; -25°C)</td>
</tr>
</tbody>
</table>

*MMR may be stored in either refrigerator or freezer.*

For more information, see CDC’s *Vaccine Storage & Handling Guide* ([http://www.cdc.gov/vaccines/recs/storage/guide/vaccine-storage-handling.pdf](http://www.cdc.gov/vaccines/recs/storage/guide/vaccine-storage-handling.pdf))
Appendix C

Safeguard Your Power Supply

Protect plug and outlet

Plug in unit to a nearby outlet.

Secure plug with a guard/cover.

Post “Do Not Unplug” signs near outlet.

WARNING! Do Not Unplug

AVERTENCIA NO DESCONECTE EL REFRIGERADOR

Always avoid disruption of power

Do not use extension cords.

Do not plug more than one appliance into an outlet. This will prevent tripping of circuit breakers.

Do not use outlets that are controlled by wall switches.

Never unplug the vaccine refrigerator or freezer.

If you experience a power failure, do not open refrigerator/freezer doors. If it lasts more than 4-6 hours, call the VFC Program.

* VFC Program Office (877) 243-8832
* VFC Field Representative

www.eziz.org

California Department of Public Health, Immunization Branch

IMM-967 (8/09)
Selected Vaccine Storage & Handling Resources
(Materials from CDC, the Immunization Action Coalition and the California Department of Public Health’s EZ-IZ website.)

Vaccine Storage & Handling Guide [NEW] (Best practices. Storage and handling recommendations for all U.S. vaccines)
http://www.cdc.gov/vaccines/recs/storage/guide/vaccine-storage-handling.pdf

Emergency Response Worksheet (What to do in case of a power failure or another event that results in vaccine storage outside of the recommended temperature range)

Refrigerator Buying Guide (VFC requirements, tips, and a worksheet for buying a refrigerator for vaccine storage)
http://eziz.org/assets/docs/IMM-940.pdf

Setting Up Your Refrigerator and Freezer for Vaccine Storage
http://eziz.org/assets/docs/IMM-962.pdf (Refrigerator)
http://eziz.org/assets/docs/IMM-965.pdf (Freezer)

Storing Vaccines in Your Refrigerator and Freezer
http://eziz.org/assets/docs/IMM-963.pdf (Refrigerator)
http://eziz.org/assets/docs/IMM-966.pdf (Freezer)

Temperature Logs for Vaccines
http://www.immunize.org/catg.d/p3039f.pdf (Fahrenheit)
http://www.immunize.org/news.d/3039c.pdf (Celsius)

Transporting Refrigerated Vaccines (Guidelines for vaccine transport and short-term storage)
http://eziz.org/assets/docs/IMM-983.pdf
# Contact Information:
Selected Vaccine Manufacturers & Distributors

<table>
<thead>
<tr>
<th>Manufacturer/Website</th>
<th>Phone Number</th>
<th>Products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Centers for Disease Control Prevention</td>
<td>404-639-36</td>
<td>Distributor for diphtheria antitoxin, VIG, smallpox vaccine</td>
</tr>
<tr>
<td><a href="http://www.cdc.gov/ncidod/srp/drugs/drug-service.htm">www.cdc.gov/ncidod/srp/drugs/drug-service.htm</a></td>
<td></td>
<td></td>
</tr>
<tr>
<td><a href="http://www.cdc.gov/laboratory/drugservice/index.htm">www.cdc.gov/laboratory/drugservice/index.htm</a></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GlaxoSmith line</td>
<td>866-4 5-8222</td>
<td>Infanrix, inri, Pediari, Havrix, Engerix B, winrix, Hiberix, Cervarix, Fluari, Fluaval, Rotarix, Boostrix</td>
</tr>
<tr>
<td><a href="http://www.gskvaccines.com">www.gskvaccines.com</a></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Massachusetts Biological abs</td>
<td>61-4 4-3000</td>
<td>IGIM, d,</td>
</tr>
<tr>
<td><a href="http://www.umassmed.edu/massbiolabs/index.asp">www.umassmed.edu/massbiolabs/index.asp</a></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MedImmune, Inc.</td>
<td>8-633-4411</td>
<td>FluMist</td>
</tr>
<tr>
<td><a href="http://www.medimmune.com">www.medimmune.com</a></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Merck Co., Inc.</td>
<td>800-63-2590</td>
<td>Pedvax HIB, Comvax, Vaqta, Recombivax -HB, Gardasil, M-M-R II, Proquad, Afluria, Pneumovax 23, Rotarix, Variva, Zostavax, d</td>
</tr>
<tr>
<td><a href="http://www.merckvaccines.com">www.merckvaccines.com</a></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Biotest Pharmaceuticals</td>
<td>800-458-4244</td>
<td>HBIG</td>
</tr>
<tr>
<td><a href="http://www.biotestpharma.com/products/nabiHB.html">www.biotestpharma.com/products/nabiHB.html</a></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Novartis Vaccines</td>
<td>8-683-432</td>
<td>Fluvirin, Agriflu, Menveo, RabAvert (distributor for Iliaro)</td>
</tr>
<tr>
<td>Pfizer (Wyeth Vaccines)</td>
<td>800-438-1985</td>
<td>Prevnar 13</td>
</tr>
<tr>
<td><a href="http://www.pfizerpro.com/">www.pfizerpro.com/</a></td>
<td></td>
<td></td>
</tr>
<tr>
<td>sanofi Pasteur</td>
<td>800-822-2463</td>
<td>Daptacel, ripedia, Pentacel, ActHIB, Fluzone, Menomune, Menactra, IP, Imova, Decavac, enivac, Adacel, yphim Vi, F-Va</td>
</tr>
<tr>
<td><a href="http://www.vaccineshoppe.com">www.vaccineshoppe.com</a></td>
<td></td>
<td></td>
</tr>
<tr>
<td>alecris Biotherapeutics</td>
<td>800-520-280</td>
<td>HBIG, IGIM, RIG, IG</td>
</tr>
<tr>
<td><a href="http://www.alecris.com/talecris-biotherapeutics-us">www.alecris.com/talecris-biotherapeutics-us</a> home.htm</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

February 2012
Monitor temperatures closely!
1. Write your initials below in “Staff Initials,” and note the time in “Exact Time.”
2. Record temps twice each workday.
3. Record the min/max temps once each workday—preferably in the morning.
4. Put an “X” in the row that corresponds to the freezer’s temperature.
5. If any out-of-range temp, see instructions to the right.
6. After each month has ended, save each month’s log for 3 years, unless state/local jurisdictions require a longer period.

**Danger! Temperatures above 5°F are too warm! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!**

<table>
<thead>
<tr>
<th>Day of Month</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
<th>11</th>
<th>12</th>
<th>13</th>
<th>14</th>
<th>15</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staff Initials</td>
<td>AM</td>
<td>PM</td>
<td>AM</td>
<td>PM</td>
<td>AM</td>
<td>PM</td>
<td>AM</td>
<td>PM</td>
<td>AM</td>
<td>PM</td>
<td>AM</td>
<td>PM</td>
<td>AM</td>
<td>PM</td>
<td>AM</td>
</tr>
<tr>
<td>Exact Time</td>
<td>AM</td>
<td>PM</td>
<td>AM</td>
<td>PM</td>
<td>AM</td>
<td>PM</td>
<td>AM</td>
<td>PM</td>
<td>AM</td>
<td>PM</td>
<td>AM</td>
<td>PM</td>
<td>AM</td>
<td>PM</td>
<td>AM</td>
</tr>
<tr>
<td>Min/Max Temp</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Acceptable Temperatures**
- 5°F
- 4°F
- 3°F
- 2°F
- 1°F
- 0°F
- -1°F
- -2°F
- -3°F
- -4°F
- -58°F to -5°F

**Action**
Write any out-of-range temps (above 5°F or below -58°F) here.

Room Temperature

If you have a vaccine storage issue, also complete “Vaccine Storage Troubleshooting Record” found on page 3.

Take action if temp is out of range—too warm (above 5°F) or too cold (below -58°F).
1. Label exposed vaccine “do not use,” and store it under proper conditions as quickly as possible.
   Do not discard vaccines unless directed to by your state/local health department and/or the manufacturer(s).
2. Record the out-of-range temps and the room temp in the “Action” area on the bottom of the log.
3. Notify your vaccine coordinator, or call the immunization program at your state or local health department for guidance.
4. Document the action taken on the “Vaccine Storage Troubleshooting Record” on page 3.
Monitor temperatures closely!
1. Write your initials below in “Staff Initials,” and note the time in “Exact Time.”
2. Record temps twice each workday.
3. Record the min/max temps once each workday—preferably in the morning.
4. Put an “X” in the row that corresponds to the freezer’s temperature.
5. If any out-of-range temp, see instructions to the right.
6. After each month has ended, save each month’s log for 3 years, unless state/local jurisdictions require a longer period.

### Table: Temperature Log for Freezer – Fahrenheit

| Day of Month | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 |
|--------------|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|
| Staff Initials |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| Exact Time   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| Min/Max Temp (since previous reading) |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |

**Danger! Temperatures above 5°F are too warm!** Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!

- **5°F**
- **4°F**
- **3°F**
- **2°F**
- **1°F**
- **0°F**
- **-1°F**
- **-2°F**
- **-3°F**
- **-4°F**
- **-58°F to -5°F**

Write any out-of-range temps (above 5°F or below -58°F) here.

**Room Temperature**

If you have a vaccine storage issue, also complete “Vaccine Storage Troubleshooting Record” found on page 3.
**Vaccine Storage Troubleshooting Record**

Use this form to document any unacceptable vaccine storage event, such as exposure of refrigerated or frozen vaccines to temperatures that are outside the manufacturers’ recommended storage ranges. A fillable troubleshooting record (i.e., editable PDF or WORD document) can also be found at www.immunize.org/clinic/storage-handling.asp.

<table>
<thead>
<tr>
<th>Date &amp; Time of Event</th>
<th>Storage Unit Temperature</th>
<th>Room Temperature</th>
<th>Person Completing Report</th>
</tr>
</thead>
<tbody>
<tr>
<td>If multiple, related events occurred, see Description of Event below.</td>
<td>at the time the problem was discovered</td>
<td>at the time the problem was discovered</td>
<td></td>
</tr>
<tr>
<td>Date:</td>
<td>Temp when discovered:</td>
<td>Temp when discovered:</td>
<td>Name:</td>
</tr>
<tr>
<td>Time:</td>
<td>Minimum temp:</td>
<td>Maximum temp:</td>
<td>Comment (optional):</td>
</tr>
</tbody>
</table>

**Description of Event** *(If multiple, related events occurred, list each date, time, and length of time out of storage.)*

- General description (i.e., what happened?)
- Estimated length of time between event and last documented reading of storage temperature in acceptable range (35°F to 46°F [2°C to 8°C] for refrigerator; -58°F to 5°F [-50°C to -15°C] for freezer)
- Inventory of affected vaccines, including (1) lot #s and (2) whether purchased with public (for example, VFC) or private funds (Use separate sheet if needed, but maintain the inventory with this troubleshooting record.)
- At the time of the event, what else was in the storage unit? For example, were there water bottles in the refrigerator and/or frozen coolant packs in the freezer?
- Prior to this event, have there been any storage problems with this unit and/or with the affected vaccine?
- Include any other information you feel might be relevant to understanding the event.

**Action Taken** *(Document thoroughly. This information is critical to determining whether the vaccine might still be viable!)*

- When were the affected vaccines placed in proper storage conditions? (Note: Do not discard the vaccine. Store exposed vaccine in proper conditions and label it “do not use” until after you can discuss with your state/local health department and/or the manufacturer(s).)
- Who was contacted regarding the incident? (For example, supervisor, state/local health department, manufacturer—list all.)
- IMPORTANT: What did you do to prevent a similar problem from occurring in the future?

**Results**

- What happened to the vaccine? Was it able to be used? If not, was it returned to the distributor? (Note: For public-purchase vaccine, follow your state/local health department instructions for vaccine disposition.)

---

**Immunization Action Coalition**
1573 Selby Avenue • St. Paul, MN 55104 • 651-647-9009 • www.immunize.org • www.vaccineinformation.org
**Vaccine Storage Troubleshooting Record**

Use this form to document any unacceptable vaccine storage event, such as exposure of refrigerated or frozen vaccines to temperatures that are outside the manufacturers’ recommended storage ranges.

A fillable troubleshooting record (i.e., editable pdf or WORD document) can also be found at [www.immunize.org/clinic/storage-handling.asp](http://www.immunize.org/clinic/storage-handling.asp)

---

### Date & Time of Event

If multiple, related events occurred, see Description of Event below.

- **Date:** 7/16/2013
- **Time:** 8:00 am

### Storage Unit Temperature

- **Temp when discovered:** 55°F
- **Minimum temp:** 2°F
- **Maximum temp:** 57°F

### Room Temperature

- **Temp when discovered:** 77°F
- **Comment (optional):** temp is approx 57°F

### Person Completing Report

- **Name:** Nancy Nurse
- **Title:** VFC Coordinator
- **Date:** 7/15/13

---

### Description of Event

**(If multiple, related events occurred, list each date, time, and length of time out of storage.)**

- **General description (i.e., what happened?)**
- **Estimated length of time between event & last documented reading of storage temperature in acceptable range (35° to 46°F [2° to 8°C] for refrigerator; -58° to 5°F [-50° to -15°C] for freezer)**
- **Inventory of affected vaccines, including (1) lot #s and (2) whether purchased with public (for example, VFC) or private funds (Use separate sheet if needed, but maintain the inventory with this troubleshooting record)**
- **At the time of the event, have there been any storage problems with this unit and/or with the affected vaccine?**
- **Include any other information you feel might be relevant to understanding the event.**

When checked vaccine freezer (in lab) at 8:00 am on Tuesday, 7/16/2013, discovered freezer door slightly ajar. Digital readout on data logger read 55°F. Data logger located in center of freezer with probe in glycol. Review of computer readings (taken every 15 minutes) showed steady rise in temps from 2°F at 5:30 pm (7/15/2013) to 55°F reading discovered when arrived at clinic on Tuesday morning (7/16/2013). Readings hit 6°F at 11 pm (7/15) and 45°F at 2 am (7/16). Total time out of recommended storage temp of 5°F or below = 9 hours. (See attached document of continuous temp readings.) Freezer contained Varivax, ProQuad, and Zostavax (inventory attached).

Frozen packs stored on freezer floor and shelves in door. No recent adjustments to temp controls and no previous temp excursions noted with this freezer before 7/15.

### Action Taken

**(Document thoroughly. This information is critical to determining whether the vaccine might still be viable!)**

- **When were the affected vaccines placed in proper storage conditions? (Note: Do not discard the vaccine. Store exposed vaccine in proper conditions and label it “do not use” until after you can discuss with your state/local health department and/or the manufacturer[s])**
- **Who was contacted regarding the incident? (For example, supervisor, state/local health department, manufacturer—list all.)**
- **IMPORTANT: What did you do to prevent a similar problem from occurring in the future?**

Upon discovery, vaccines marked “Do Not Use” and stored in 2nd clinic freezer (in exam room #3) at 1°F. Also placed “Do Not Use” note on main freezer in lab. Notified Susie Supervisor about the issue. Contacted Victor Vaccine at My State Immunization Program at 8:30 am. Provided Victor with details of event and list of vaccines in freezer. Victor said to maintain vaccines in 2nd freezer and that he would check with Merck (manufacturer of all the affected vaccines) to determine next steps. Called Jim’s Appliance Repair to examine freezer. Repairman replaced freezer door gasket and recommended removal of ~½ of freezer packs in door because size and weight of packs potentially interfered with door closing completely. No problems identified with thermostat or other mechanical components.

Removed half of freezer packs located in shelf in door, per recommendation. Reset data logger on center shelf of freezer with probe in glycol. All staff received refresher training on ensuring freezer door is closed after each use, and a reminder sign was placed prominently on freezer door.

### Results

- **What happened to the vaccine? Was it able to be used? If not, was it returned to the distributor? (Note: For public-purchase vaccine, follow your state/local health department instructions for vaccine disposition.)**

After repair, monitored temps in empty freezer for 1 week, per state requirements. Freezer maintained 0–2°F temps for entire week. Submitted repair documentation and data logger readings to Victor Vaccine for approval and ordered replacement vaccines. Victor had checked with manufacturer. After reviewing history and stability data, manufacturer stated vaccine was acceptable for continued use. Discussed entire situation with Susie Supervisor and clinic director, Dr. Immunize, who agreed on continued use of vaccine. Vaccine to be labeled as “use first.”
# Temperature Log for Refrigerator – Fahrenheit

**Temperature Log for Refrigerator – Fahrenheit**

**DAYS 1–15**

Monitor temperatures closely!
1. Write your initials below in “Staff Initials,” and note the time in “Exact Time.”
2. Record temps twice each workday.
3. Record the min/max temps once each workday—preferably in the morning.
4. Put an “X” in the row that corresponds to the refrigerator’s temperature.
5. If any out-of-range temp, see instructions to the right.
6. After each month has ended, save each month’s log for 3 years, unless state/local jurisdictions require a longer period.

<table>
<thead>
<tr>
<th>Staff Initials</th>
<th>Exact Time</th>
<th>Min/Max Temp (since previous reading)</th>
</tr>
</thead>
<tbody>
<tr>
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</table>

**Danger! Temperatures above 46°F are too warm!** Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!

<table>
<thead>
<tr>
<th>Temperature</th>
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<tbody>
<tr>
<td>46°F</td>
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<td>45°F</td>
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<td>44°F</td>
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<td>43°F</td>
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<tr>
<td>42°F</td>
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<td>41°F</td>
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**Aim for 40°F**

<table>
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<tr>
<th>Temperature</th>
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<tr>
<td>40°F</td>
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<td>39°F</td>
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<td>37°F</td>
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<tr>
<td>36°F</td>
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<tr>
<td>35°F</td>
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</tbody>
</table>

**Danger! Temperatures below 35°F are too cold!** Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!

<table>
<thead>
<tr>
<th>Temperature</th>
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</thead>
<tbody>
<tr>
<td>Write any out-of-range temps (above 46°F or below 35°F) here:</td>
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</tbody>
</table>

**Room Temperature**

If you have a vaccine storage issue, also complete “Vaccine Storage Troubleshooting Record” found on page 3.

---

**Take action if temp is out of range—too warm (above 46°F) or too cold (below 35°F).**
1. Label exposed vaccine “do not use,” and store it under proper conditions as quickly as possible. Do not discard vaccines unless directed to by your state/local health department and/or the manufacturer(s).
2. Record the out-of-range temps and the room temp in the “Action” area on the bottom of the log.
3. Notify your vaccine coordinator, or call the immunization program at your state or local health department for guidance.
4. Document the action taken on the “Vaccine Storage Troubleshooting Record” on page 3.
Monitor temperatures closely!

1. Write your initials below in “Staff Initials,” and note the time in “Exact Time.”
2. Record temps twice each workday.
3. Record the min/max temps once each workday—preferably in the morning.
4. Put an “X” in the row that corresponds to the refrigerator’s temperature.
5. If any out-of-range temp, see instructions to the right.
6. After each month has ended, save each month’s log for 3 years, unless state/local jurisdictions require a longer period.

<table>
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<tr>
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<th>31</th>
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<tbody>
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<td>Staff Initials</td>
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<tr>
<td>Exact Time AM PM</td>
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<td>Min/Max Temp (since previous reading)</td>
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</tbody>
</table>

- **Danger! Temperatures above 46°F are too warm!** Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!
- **Aim for 40°F**
- **Acceptable Temperatures**
  - 46°F
  - 45°F
  - 44°F
  - 43°F
  - 42°F
  - 41°F
  - 40°F
  - 39°F
  - 38°F
  - 37°F
  - 36°F
  - 35°F

- **Danger! Temperatures below 35°F are too cold!** Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!

If you have a vaccine storage issue, also complete “Vaccine Storage Troubleshooting Record” found on page 3.
Use this form to document any unacceptable vaccine storage event, such as exposure of refrigerated vaccines to temperatures that are outside the manufacturers' recommended storage ranges.

A fillable troubleshooting record (i.e., editable PDF or WORD document) can also be found at www.immunize.org/clinic/storage-handling.asp.

**Date & Time of Event**
If multiple, related events occurred, see Description of Event below.

**Storage Unit Temperature**
at the time the problem was discovered

**Room Temperature**
at the time the problem was discovered

**Person Completing Report**

<table>
<thead>
<tr>
<th>Date:</th>
<th>Temp when discovered:</th>
<th>Temp when discovered:</th>
<th>Name:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time:</td>
<td>Minimum temp:</td>
<td>Maximum temp:</td>
<td>Comment (optional):</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Title:</td>
</tr>
</tbody>
</table>

**Description of Event** *(If multiple, related events occurred, list each date, time, and length of time out of storage.)*

- General description (i.e., what happened?)
- Estimated length of time between event and last documented reading of storage temperature in acceptable range (35° to 46°F [2° to 8°C] for refrigerator; -58° to 5°F [-50° to -15°C] for freezer)
- Inventory of affected vaccines, including (1) lot #s and (2) whether purchased with public (for example, VFC) or private funds (Use separate sheet if needed, but maintain the inventory with this troubleshooting record.)
- At the time of the event, what else was in the storage unit? For example, were there water bottles in the refrigerator and/or frozen coolant packs in the freezer?
- Prior to this event, have there been any storage problems with this unit and/or with the affected vaccine?
- Include any other information you feel might be relevant to understanding the event.

**Action Taken** *(Document thoroughly. This information is critical to determining whether the vaccine might still be viable!)*

- When were the affected vaccines placed in proper storage conditions? (Note: Do not discard the vaccine. Store exposed vaccine in proper conditions and label it “do not use” until after you can discuss with your state/local health department and/or the manufacturer[s].)
- Who was contacted regarding the incident? (For example, supervisor, state/local health department, manufacturer—list all.)
- IMPORTANT: What did you do to prevent a similar problem from occurring in the future?

**Results**

- What happened to the vaccine? Was it able to be used? If not, was it returned to the distributor? (Note: For public-purchase vaccine, follow your state/local health department instructions for vaccine disposition.)
**Vaccine Storage Troubleshooting Record** (check one)  
**Refrigerator**  □ Freezer  

Use this form to document any unacceptable vaccine storage event, such as exposure of refrigerated vaccines to temperatures that are outside the manufacturers’ recommended storage ranges.  
A fillable troubleshooting record (i.e., editable pdf or WORD document) can also be found at [www.immunize.org/clinic/storage-handling.asp](http://www.immunize.org/clinic/storage-handling.asp)

<table>
<thead>
<tr>
<th>Date &amp; Time of Event</th>
<th>Storage Unit Temperature</th>
<th>Room Temperature</th>
<th>Person Completing Report</th>
</tr>
</thead>
<tbody>
<tr>
<td>If multiple, related events occurred, see Description of Event below.</td>
<td>at the time the problem was discovered</td>
<td>at the time the problem was discovered</td>
<td>Name: Nancy Nurse</td>
</tr>
</tbody>
</table>

- **Date:** (see below)  
- **Time:** (see below)  
- **Minimum temp:** 38°F  
- **Maximum temp:** 53°F

**Description of Event** (If multiple, related events occurred, list each date, time, and length of time out of storage.)

- General description (i.e., what happened?)
- Estimated length of time between event & last documented reading of storage temperature in acceptable range (35°F to 46°F [2°C to 8°C] for refrigerator; -58°F to 5°F [-50°C to -15°C] for freezer)
- Inventory of affected vaccines, including (1) lot #s and (2) whether purchased with public (for example, VFC) or private funds (Use separate sheet if needed, but maintain the inventory with this troubleshooting record)
- At the time of the event, what else was in the storage unit? For example, were there water bottles in the refrigerator and/or frozen coolant packs in the freezer?
- Prior to this event, have there been any storage problems with this unit and/or with the affected vaccine?
- Include any other information you feel might be relevant to understanding the event.

At 8 am on Monday (6/24/13) morning when clinic opened, identified 4 temperature excursions over the weekend in refrigerator with readings as high as 54°F, 50°F, 49°F & 53°F in primary vaccine storage unit #1. Recordings taken every 15 min on calibrated digital data logger overnight.  
Data logger probe in glycol located in middle of refrigerator with vaccines.  
Total time out of range: approximately 3 hrs — maximum temp 53°F (see attached document of continuous temp readings)  
Inventory of vaccines: see attached  
Water bottles in refrigerator door. No vaccine stored in freezer. No problems with storage unit prior to Saturday night. Thunderstorms in area over weekend may have affected power.

**Results**

- What happened to the vaccine? Was it able to be used? If not, was it returned to the distributor? (Note: For public-purchase vaccine, follow your state/local health department instructions for vaccine disposition.)

Late on Monday, I talked with Victor regarding continued use of vaccine. Victor had checked with manufacturers which confirmed that vaccine is acceptable for use. He told me that vaccine could therefore be removed from quarantine. I discussed the entire situation with Susie Supervisor and Dr. Director (clinic medical director) who agreed that we could put vaccine back in use.
Vaccine Storage Troubleshooting Record (check one)  ☑Refrigerator  ☐ Freezer

Use this form to document any unacceptable vaccine storage event, such as exposure of refrigerated vaccines to temperatures that are outside the manufacturers’ recommended storage ranges.

A fillable troubleshooting record (i.e., editable pdf or WORD document) can also be found at www.immunize.org/clinic/storage-handling.asp

Date & Time of Event

<table>
<thead>
<tr>
<th>Date: 7/16/2013</th>
<th>Storage Unit Temperature</th>
<th>Room Temperature</th>
<th>Person Completing Report</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time: 8:00 am</td>
<td>Temp when discovered: 28°F</td>
<td>Temp when discovered: 77°F</td>
<td>Name: Nancy Nurse</td>
</tr>
<tr>
<td>Minimum temp: 28°F</td>
<td>Maximum temp: 42°F</td>
<td>Comment (optional): temp is approx</td>
<td>Title: VFC Coordinator</td>
</tr>
</tbody>
</table>

Description of Event (If multiple, related events occurred, list each date, time, and length of time out of storage.)

- General description (i.e., what happened?)
- Estimated length of time between event & last documented reading of storage temperature in acceptable range (35° to 46°F [2° to 8°C] for refrigerator; -58° to 5°F [-50° to -15°C] for freezer)
- Inventory of affected vaccines, including (1) lot #s and (2) whether purchased with public (for example, VFC) or private funds (Use separate sheet if needed, but maintain the inventory with this troubleshooting record)
- At the time of the event, what else was in the storage unit? For example, were there water bottles in the refrigerator and/or frozen coolant packs in the freezer?
- Prior to this event, have there been any storage problems with this unit and/or with the affected vaccine?
- Include any other information you feel might be relevant to understanding the event.

When checked main clinic fridge (in lab) at 8:00 am on Tuesday, 7/16/2013, digital readout on data logger read 28°F. Data logger located in center of fridge with probe in glycol. Review of computer readings (taken every 15 minutes) showed steady drop in temps from 42°F at 8:15 pm (7/15/2013) to 28°F reading discovered when arrived at clinic on Tuesday morning (7/16/2013). Readings hit 34°F at 11 pm (7/15) and 32°F at 2 am (7/16). Total time out of recommended storage temps = 9 hours, with 6 hours at freezing or below (see attached document of continuous temp readings). Inventory of vaccines attached.

When fridge thermostat repaired, monitored temps in empty fridge for 1 week, per state requirements. Fridge maintained 38°-40°F temps for entire week. Submitted repair documentation and data logger readings to Victor Vaccine for approval and ordered replacement vaccines. Victor had checked with manufacturers who confirmed that all vaccines in fridge EXCEPT MMR were no longer viable and should be returned per state policy guidelines. MMR may be used because pkg insert allows storage down to -58°F. Discussed entire situation with Susie Supervisor and clinic director, Dr. Director, who agreed on continued use of MMR. Will continue to monitor fridge closely to watch for pattern of temp fluctuations indicating potential problem with thermostat. If problems, contact Victor Vaccine for advice on purchasing new fridge meeting criteria for appropriate vaccine storage.

Results

- What happened to the vaccine? Was it able to be used? If not, was it returned to the distributor? (Note: For public-purchase vaccine, follow your state/local health department instructions for vaccine disposition.)

Upon discovery, vaccines marked “Do Not Use” and stored in 2nd clinic fridge (in exam room #3 at 41°F). Also placed “Do Not Use” note on main fridge in lab. Notified Susie Supervisor about the issue. Contacted Victor Vaccine at My State Immunization Program at 8:30 am. Provided Victor with details of event and list of vaccines in fridge. Victor said to maintain vaccines in 2nd fridge and that he would check with manufacturers to determine next steps.

Action Taken (Document thoroughly. This information is critical to determining whether the vaccine might still be viable!)

- When were the affected vaccines placed in proper storage conditions? (Note: Do not discard the vaccine. Store exposed vaccine in proper conditions and label it “do not use” until after you can discuss with your state/local health department and/or the manufacturer[s].)
- Who was contacted regarding the incident? (For example, supervisor, state/local health department, manufacturer—list all.)
- IMPORTANT: What did you do to prevent a similar problem from occurring in the future?

Called Jim’s Appliance Repair to examine fridge. Repairman found and replaced faulty thermostat in unit.

Reset data logger on center shelf in fridge with probe in glycol.
Emergency Response Worksheet

What to do in case of a power failure or another event that results in vaccine storage outside of the recommended temperature range

Follow these procedures:
1. Close the door tightly and/or plug in the refrigerator/freezer.
2. Ensure the vaccine is kept at appropriate temperatures. Make sure the refrigerator/freezer is working properly or move the vaccines to a unit that is. Do not discard the affected vaccines. Mark the vaccines so that the potentially compromised vaccines can be easily identified.
3. Notify the local or state health department or call the manufacturer (see manufacturers’ phone numbers below).
4. Record action taken.

Record this information*:
1. Temperature of refrigerator: current______ max.______ min.______
2. Temperature of freezer: current______ max.______ min.______
3. Air temperature of room where refrigerator is located:______
4. Estimated amount of time the unit’s temperature was outside normal range:
   refrigerator _______ freezer _______
5. Vaccines in the refrigerator/freezer during the event (use the table below)

* Using a recording thermometer is the most effective method of tracking the refrigerator and freezer temperatures over time. Visually checking thermometers twice a day is an effective method to identify inconsistent or fluctuating temperatures in a refrigerator and freezer.

Vaccines Stored in Refrigerator

<table>
<thead>
<tr>
<th>Vaccine, manufacturer, and lot #</th>
<th>Expiration date</th>
<th># of doses</th>
<th># of affected vials</th>
<th>Action taken</th>
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</table>

Vaccines Stored in Freezer

<table>
<thead>
<tr>
<th>Vaccine, manufacturer, and lot #</th>
<th>Expiration date</th>
<th># of doses</th>
<th># of affected vials</th>
<th>Action taken</th>
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</tbody>
</table>

Other Conditions
1. Prior to this event, was the vaccine exposed to temperatures outside the recommended range?  Y  N
2. Were water bottles in the refrigerator and ice packs in the freezer at the time of this event?  Y  N
3. Other:  ________________________________________________________________  ________________________________________________________________

Vaccines Stored in Freezer

<table>
<thead>
<tr>
<th>Vaccine, manufacturer, and lot #</th>
<th>Expiration date</th>
<th># of doses</th>
<th># of affected vials</th>
<th>Action taken</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

Other Resources

Local health department phone number ___________________________  State health department phone number ___________________________

Adapted by the Immunization Action Coalition, courtesy of the Michigan Department of Community Health

Technical content reviewed by the Centers for Disease Control and Prevention, October 2010.
Don’t Be Guilty of These Errors in Vaccine Storage and Handling

The following are frequently reported errors in vaccine storage and handling. Some of these errors are much more serious than others, but none of them should occur. Be sure your clinic or practice is not making errors such as these.

**Error #1: Designating only one person, rather than at least two, to be responsible for storage and handling of vaccines**

Since vaccines are both expensive and fragile, everyone in the office should know the basics of vaccine handling, including what to do when a shipment arrives and what to do in the event of an equipment failure or power outage. It’s very important to train at least one back-up person in all aspects of proper storage and handling of vaccines. The back-up and primary persons should be equally familiar with all aspects of vaccine storage and handling, including knowing how to handle vaccines when they arrive, how to properly record refrigerator and freezer temperatures, and should be prepared to lead the response to an equipment problem or power outage.

**Error #2: Refrigerating vaccine in a manner that could jeopardize its quality**

The temperature in the vegetable bins, on the floor, next to the walls, in the door, and near the cold air outlet from the freezer may differ significantly from the temperature in the body of the refrigerator: do not store your vaccines or place thermometers in these locations. Always store vaccines in their original packaging in the body of the refrigerator away from these locations, and place your thermometer with the vaccines. Place vaccine packages in such a way that air can circulate around the compartment. Never overpack a refrigerator compartment.

**Error #3: Storing food and drinks in the vaccine refrigerator**

Frequent opening of the refrigerator door to retrieve food items can adversely affect the internal temperature of the unit and damage vaccines.

**Error #4: Inadvertently leaving the refrigerator or freezer door open or having inadequate seals**

Remind staff to close the unit doors tightly each time they open them. Also, check the seals on the doors on a regular schedule, and if there is any indication the door seal may be cracked or not sealing properly, have it replaced. Replacing a seal is much less costly than replacing a box of pneumococcal conjugate or varicella vaccine.

**Error #5: Storing vaccine in a dorm-style refrigerator**

All vaccines should be stored in a refrigerator and/or freezer unit that is designed specifically for the storage of biologics or, alternatively, in a separate free-standing unit. A dorm-style combination refrigerator-freezer unit with just one exterior door has been shown to be unacceptable no matter where the vaccine was placed inside the unit. Small stand-alone refrigerator or freezer units are best for short-term storage needs.

**Error #6: Recording temperatures only once per day**

Temperatures fluctuate throughout the day. Temperatures in the refrigerator and freezer should be checked at the beginning and end of the day to determine if the unit is getting too cold or too warm. Ideally, you should have continuous thermometers that record temperatures all day and all night; those with alarms can alert you when temperatures go out of range. A less expensive alternative is to purchase maximum/minimum thermometers. Only thermometers with a Current Certificate of Traceability and Calibration should be used for vaccine storage. It’s also a good idea to record the room temperature on your temperature log in case there is a problem with the storage unit. This information may be helpful to the vaccine manufacturer and/or state immunization program in determining whether your vaccine is still usable.

**Error #7: Recording temperatures for only the refrigerator or freezer, rather than both**

It is essential to monitor and record temperatures in all refrigerators and freezers used to store vaccine. At all times you should have calibrated thermometers in the refrigerators as well as the freezers. Assure that your storage temperature monitoring is accurate by purchasing thermometers that have a Certificate of Traceability and Calibration and recalibrate them according to the manufacturer’s instructions. Your state immunization program may be able to provide more information on calibrated thermometers.

**Error #8: Documenting out-of-range temperatures on vaccine temperature logs but not taking action**

Documenting temperatures is not enough. Acting on the information is essential! So, what should you do? Notify your supervisor whenever you have an out-of-range temperature. Sometimes the solution is as simple as shutting a door left ajar or re-checking a freezer temperature that is slightly elevated as it goes through a normal, brief defrost cycle. Check the condition of the unit for problems. Are the seals on the door tight? Is there excessive lint or dust on the coils? After you have made any adjustment, document the date, time, temperature, and results of your action. Recheck the temperature every two hours. Call maintenance or a repair person if the temperature is still out of range. If the solution is not quick and easy, you will need to safeguard your vaccines by moving them to another storage unit that is functioning at the proper temperature. Label the affected vaccines “Do not use” and contact your state immunization program or vaccine manufacturer to find out if the affected vaccine is still usable. Be sure to notify your state’s VFC Program Coordinator if VFC vaccine was involved.

**Error #9: Discarding temperature logs at the end of every month**

It’s important that you keep your temperature logs for at least three years. As your refrigerator or freezer ages, you can track recurring problems. If out-of-range temperatures have been documented, you can determine how long and how often this has been happening and take appropriate action. It’s also a great way to demonstrate why you need a new refrigerator or freezer.

**Error #10: Discarding multi-dose vials 30 days after they are opened**

Don’t discard your multi-dose vials of vaccines prematurely. Almost all multi-dose vaccine vials contain a preservative and can be used until the expiration date on the vial unless there is actual contamination or the vials are not stored under appropriate temperatures. However, you must discard multi-dose vials of reconstituted vaccine (e.g., meningococcal polysaccharide, yellow fever) if they are not used within a defined period after reconstitution. Refer to the vaccine package inserts for detailed information.

**Error #11: Not having emergency plans for a power outage or natural disaster**

Every clinic should have a written Emergency Response Plan that identifies a refrigerator and freezer in another location (ideally, a storage unit with a back-up generator) in which to store vaccine in the event of a power outage or natural disaster. Consider arranging in advance for a local hospital or similar facility to be your back-up location if you should need it. Be sure back-up location staff understand vaccine storage and will allow you to supervise placement and verify storage temperatures so vaccine is not damaged.

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*A calibrated thermometer with a Certificate of Traceability and Calibration with calibration measurements traceable to a testing laboratory accredited by the International Organization of Standardization, to the Standards of the National Institute of Standards and Technology, or to another internationally recognized standards agency.

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Technical content reviewed by the Centers for Disease Control and Prevention, April 2011.

www.immunize.org/catg.d/p3036.pdf • Item #F3036 (4/11)
# Vaccines with Diluents: How to Use Them

The following vaccines must be reconstituted correctly before they are administered. Reconstitution means that the lyophilized (freeze-dried) vaccine powder or wafer in one vial must be reconstituted (mixed) with the diluent (liquid) in another. Only use the diluent provided by the manufacturer for that vaccine as indicated on the chart. ALWAYS check the expiration date on the diluent and vaccine. NEVER use expired diluent or vaccine.

<table>
<thead>
<tr>
<th>Vaccine product name</th>
<th>Manufacturer</th>
<th>Lyophilized vaccine (powder)</th>
<th>Liquid diluent (may contain vaccine)</th>
<th>Time allowed between reconstitution and use*</th>
<th>Diluent storage environment</th>
</tr>
</thead>
<tbody>
<tr>
<td>ActHIB (Hib)</td>
<td>sanofi pasteur</td>
<td>Hib</td>
<td>0.4% sodium chloride</td>
<td>24 hrs</td>
<td>Refrigerator</td>
</tr>
<tr>
<td>Hiberix (Hib)</td>
<td>GlaxoSmithKline</td>
<td>Hib</td>
<td>0.9% sodium chloride</td>
<td>24 hrs</td>
<td>Refrigerator or room temp</td>
</tr>
<tr>
<td>Imovax (RABHV)</td>
<td>sanofi pasteur</td>
<td>Rabies virus</td>
<td>Sterile water</td>
<td>Immediately</td>
<td>Refrigerator</td>
</tr>
<tr>
<td>M-M-R II (MMR)</td>
<td>Merck</td>
<td>MMR</td>
<td>Sterile water</td>
<td>8 hrs</td>
<td>Refrigerator or room temp</td>
</tr>
<tr>
<td>MenHibrix (Hib-MenCY)</td>
<td>GlaxoSmithKline</td>
<td>Hib-MenCY</td>
<td>0.9% sodium chloride</td>
<td>Immediately</td>
<td>Refrigerator or room temp</td>
</tr>
<tr>
<td>Menomune (MPSV4)</td>
<td>sanofi pasteur</td>
<td>MPSV4</td>
<td>Distilled water</td>
<td>30 min (single-dose vial) 35 days (multidose vial)</td>
<td>Refrigerator</td>
</tr>
<tr>
<td>Mveneo (MCV4)</td>
<td>Novartis</td>
<td>MenA</td>
<td>MenCWY</td>
<td>8 hrs</td>
<td>Refrigerator</td>
</tr>
<tr>
<td>Pentacel (DTaP-IPV/Hib)</td>
<td>sanofi pasteur</td>
<td>Hib</td>
<td>DTaP-IPV</td>
<td>Immediately (i.e., within 30 minutes or less)</td>
<td>Refrigerator</td>
</tr>
<tr>
<td>ProQuad (MMRV)</td>
<td>Merck</td>
<td>MMRV</td>
<td>Sterile water</td>
<td>30 min</td>
<td>Refrigerator or room temp</td>
</tr>
<tr>
<td>RabAvert (RABHV)</td>
<td>Novartis</td>
<td>Rabies virus</td>
<td>Sterile water</td>
<td>Immediately</td>
<td>Refrigerator</td>
</tr>
<tr>
<td>Rotarix (RV1)†</td>
<td>GlaxoSmithKline</td>
<td>RV1</td>
<td>Sterile water, calcium carbonate, and xanthan</td>
<td>24 hrs</td>
<td>Room temp</td>
</tr>
<tr>
<td>Varivax (VAR)</td>
<td>Merck</td>
<td>VAR</td>
<td>Sterile water</td>
<td>30 min</td>
<td>Refrigerator or room temp</td>
</tr>
<tr>
<td>YF-VAX (YF)</td>
<td>sanofi pasteur</td>
<td>YF</td>
<td>0.9% sodium chloride</td>
<td>60 min</td>
<td>Refrigerator or room temp</td>
</tr>
<tr>
<td>Zostavax (HZV)</td>
<td>Merck</td>
<td>HZV§</td>
<td>Sterile water</td>
<td>30 min</td>
<td>Refrigerator or room temp</td>
</tr>
</tbody>
</table>

Always refer to package inserts for detailed instructions on reconstituting specific vaccines. In general, follow these steps:

1. For single-dose vaccine products (exceptions are Menomune in the multidose vial and Rotarix†), select a syringe and a needle of proper length to be used for both reconstitution and administration of the vaccine. Following reconstitution, Menomune in a multidose vial will require a new needle and syringe for each dose of vaccine to be administered. For Rotarix, see the package insert.†

2. Before reconstituting, check labels on both the lyophilized vaccine vial and the diluent to verify the following:
   - that they are the correct two products to mix together
   - that the diluent is the correct volume (especially for Menomune in the multidose vial)
   - that neither vaccine nor diluent has expired

3. Reconstitute (i.e., mix) vaccine just prior to use‡ by
   - removing the protective caps and wiping each stopper with an alcohol swab
   - inserting needle of syringe into diluent vial and withdrawing entire contents
   - injecting diluent into lyophilized vaccine vial and rotating or agitating to thoroughly dissolve the lyophilized powder

4. Check the appearance of the reconstituted vaccine.
   - Reconstituted vaccine may be used if the color and appearance match the description on the package insert.
   - If there is discoloration, extraneous particulate matter, obvious lack of resuspension, or cannot be thoroughly mixed, mark the vial as “DO NOT USE,” return it to proper storage conditions, and contact your state or local health department immunization program or the vaccine manufacturer.

5. If reconstituted vaccine is not used immediately or comes in a multidose vial (i.e., multi-dose Menomune),
   - clearly mark the vial with the date and time the vaccine was reconstituted
   - maintain the product at 35°–46°F (2°–8°C); do not freeze
   - protect reconstituted vaccines from light
   - use only within the time indicated on chart above

---

* If the reconstituted vaccine is not used within this time period, it must be discarded.
† MMRV contains seven times as much varicella component as does the single antigen VAR.
‡ Rotarix vaccine is administered by mouth using the applicator that contains the diluent. It is not administered as an injection.
§ HZV contains fourteen times as much varicella component as does the single antigen VAR.

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Technical content reviewed by the Centers for Disease Control and Prevention

www.immunize.org/catg.d/p3040.pdf  •  Item #P3040 (12/12)
BEFORE ADVANCING: Complete Item 1 on the Immunization Implementation Plan

Pharmacy-Based Immunization Services

Pharmacists in the United States can administer vaccines to their patients. Each state has specific requirements. Therefore, pharmacists completing this course should assure that they are in compliance with regulations and rules governing the practice of pharmacy in their state. The National Vaccine Advisory Committee made recommendations for immunization outside the traditional clinic several years ago.
Adult Immunization Programs in Nontraditional Settings: Quality Standards and Guidance for Program Evaluation

A Report of the National Vaccine Advisory Committee

and

Use of Standing Orders Programs to Increase Adult Vaccination Rates

Recommendations of the Advisory Committee on Immunization Practices
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Adult Immunization Programs in Nontraditional Settings: Quality Standards and Guidance for Program Evaluation

A Report of the National Vaccine Advisory Committee

Summary
This report provides a summary of the National Vaccine Advisory Committee’s (NVAC) workshop on adult immunization programs in nontraditional settings, quality standards for such programs, and guidance for program evaluation. Throughout the United States, an increasing number of adults are receiving vaccine in nontraditional settings (e.g., pharmacies and churches). Immunization programs in nontraditional settings are often more accessible and convenient than a health-care provider’s office or a public health clinic, especially for medically underserved adults (e.g., economically disadvantaged, inner city, and minority populations). Medically underserved adults might be at particular risk for undervaccination because they are often without a medical home (i.e., a regular point of contact where their health-care needs are met). Immunization programs in nontraditional settings might enhance the capacity of the health-care system to effectively deliver vaccine to adults by increasing the number and types of sites where adults can receive vaccine. NVAC has recognized that strategies need to be developed to make vaccines available to all adults and that the number of immunization programs in nontraditional settings is increasing. Therefore, the Committee issues the following report, including quality standards and guidance for program evaluation.

BACKGROUND
Approximately 45,000 adults in the United States die annually of complications from influenza, pneumococcal infections, and hepatitis B — the primary vaccine-preventable diseases affecting adults. The total economic cost of treating these vaccine-preventable diseases among adults, excluding the value of years of life lost, exceeds $10 billion each year. Although effective vaccines to prevent these diseases are available, they are widely underutilized (1,2). This underutilization reflects a lack of emphasis on vaccines for adults in comparison with the more substantial emphasis on vaccines for children.
Influenza and pneumococcal vaccine coverage rates for adults aged ≥65 years vary by race and ethnicity (2). In 1997, influenza vaccine coverage rates ranged from 67.2% among non-Hispanic whites to 50.2% among non-Hispanic blacks (2). Pneumococcal vaccine coverage rates were even lower: 47.3% of white adults aged ≥65 years reported receiving pneumococcal vaccine compared with 34.1% of Hispanics and 29.7% of blacks (2). Disease burden also varies by race and ethnicity. Blacks have a threefold to fivefold increased risk for developing life-threatening invasive pneumococcal disease compared with whites (3–5).
A recommendation by a health-care provider is a key factor determining whether an adult patient will be vaccinated (6). Medically underserved adults (e.g., economically disadvantaged, inner city, and minority populations) might be at particular risk for underimmunization because they are often without a medical home (i.e., a regular point of contact where their health-care needs are met) and might not have regular access to a health-care provider (7–10). Therefore, to reach medically underserved adults, strategies to increase vaccine-seeking behavior are critically needed. One such strategy involves offering vaccine to adults in nontraditional settings (e.g., pharmacies and churches) that might be more accessible and convenient than the office of a health-care provider or a public health clinic. Immunization programs in nontraditional settings might enhance the capacity of the health-care system to effectively deliver vaccine to adults by increasing the number and types of settings in which adults can receive vaccine.

INTRODUCTION

Purpose of the National Vaccine Advisory Committee Workshop

The National Vaccine Program Office sponsored a public meeting of the National Vaccine Advisory Committee’s (NVAC) Adult Immunization Working Group on December 1–2, 1997, to explore adult immunization programs in nontraditional settings. The purpose of the workshop was

- to gain a better understanding of programs currently offering vaccines to adults in nontraditional settings,
- to identify potential benefits and challenges associated with administering vaccines in nontraditional settings,
- to identify additional nontraditional settings that could be explored and potentially used,
- to define areas where additional research is needed,
- to develop an effective immunization strategy integrating immunization programs in nontraditional settings with those in traditional settings, and
- to develop quality standards for immunization programs in nontraditional settings.

The workshop was limited to discussion regarding vaccines for adults because national vaccine coverage estimates for adults are substantially lower than the national goals established for this population, whereas coverage estimates for children approach or exceed national goals (2,7,11).

The purpose of this report is to provide a summary of discussions at the NVAC workshop so that persons who conduct or plan to conduct immunization programs in a nontraditional setting will have guidance regarding how to safely operate such a program. This report also highlights the importance of evaluating these programs by collecting data regarding associated benefits (e.g., increases in the number of adults vaccinated) and challenges (e.g., preventing fragmentation of care by reporting administration of vaccine to the primary-care provider of the vaccinee).
Influenza and pneumococcal vaccines constitute the majority of vaccines administered in nontraditional settings; therefore, this report focuses on these vaccines. If the types of vaccines administered in nontraditional settings increase, both the benefits and challenges could change.

Workshop Participants

Workshop participants included members of the NVAC Adult Immunization Working Group and representatives from approximately 50 organizations, including federal and state governments, community and professional organizations, and private companies. Participants were identified through discussions with staff at CDC, the Health Resources and Services Administration, the National Coalition for Adult Immunization (NCAI), and other organizations. NCAI is composed of nearly 100 professional medical and health-care associations, advocacy groups, voluntary organizations, vaccine manufacturers, and government agencies. Workshop presenters were selected to ensure that a spectrum of viewpoints was represented.

SUMMARY OF WORKSHOP PRESENTATIONS

Information regarding the U.S. Department of Health and Human Services’ Adult Immunization Action Plan (1), vaccine coverage rates, and incidence of morbidity and mortality attributable to vaccine-preventable diseases among adults was presented. The American College of Physicians (ACP) and the National Medical Association provided physicians’ perspectives of administration of vaccine in nontraditional settings. The benefits and challenges highlighted by these physicians were similar to those of other workshop participants. Benefits included increased access and convenience, reduced cost for vaccination, and increased awareness of the importance of vaccination. Challenges included ensuring that trained staff are available to treat potential adverse reactions to vaccines, keeping effective records, protecting health-care providers from liability, preventing fragmentation of care, and removing restrictive legal regulations.

NCAI and the National Council on Aging emphasized the importance of collaboration between public and private sectors and community-based organizations. A panel of representatives from community-based organizations providing services to traditionally underserved populations presented ways in which their clients might be more adequately cared for by the health-care profession (e.g., providing culturally and linguistically appropriate materials and outreach programs). Organizations that currently provide vaccines to adults in several nontraditional settings (including pharmacies, nontraditional clinical settings, retail establishments, dental care facilities, churches, the workplace, and the home) provided examples of the benefits and challenges experienced in these programs.

Examples of Adult Immunization Programs in Nontraditional Settings

The Health Care Financing Administration’s (HCFA) Horizons pilot project, a collaborative project between professional review organizations and nine historically black colleges and universities in eight southern states, was presented as an example of how the Federal government works with communities to provide vaccine in nontraditional settings. The goal of the Horizons project is to produce effective community-based
interventions for increasing vaccine coverage rates among black populations. Tennessee’s Horizons project has provided vaccines to adults in approximately 14 non-traditional settings, including shopping malls, senior citizen centers, nutrition sites, mobile units, grocery stores, voting sites, parks, and public housing projects.

Pharmacies in the United States are increasing their participation in vaccination activities (12). Pharmacists are functioning as a) vaccine advocates, by educating their clients about the importance of vaccines; b) vaccine facilitators, by hosting vaccine clinics at pharmacies; and c) vaccine administrators, by vaccinating their clients. The American Pharmaceutical Association and CDC’s National Immunization Program have developed a training course to prepare pharmacists for active participation in immunization programs (13). Twenty-six states have statutes that permit pharmacists to administer vaccine. Accessibility of pharmacists and the degree of trust between pharmacists and patients were suggested as factors that provide important opportunities for pharmacists to educate adults about the benefits of vaccines and, in some cases, administer vaccine.

Nurse practitioners, visiting nurses, and members of the National Black Nurses Association (NBNA) also are involved in immunization programs in nontraditional settings. Nurse practitioners, using mobile-community health centers, often provide care to traditionally underserved homeless and migrant workers and a large population of older adults who reside in rural or inner city areas. NBNA and the Visiting Nurses Association often staff immunization programs operating in nontraditional settings, including the workplace, pharmacies, and churches.

A representative from the American Association of Occupational Health Nurses noted that employers can be involved in workplace immunization activities on three levels: a) providing vaccines at the work site, administered by their own medical staff; b) contracting with health-care providers to administer vaccine at the work site; and/or c) including preventive care benefits (e.g., vaccinations) in health plans for employees. Employers generally are interested in increasing employee productivity; therefore, decreased employee absenteeism associated with receiving influenza vaccine should be highlighted (14). Potential barriers to workplace vaccination programs include employers being reluctant to disrupt work schedules or to offer vaccine to employees covered by health plans. Workplaces with a small number of employees might not be able to provide vaccination programs on their own but might be able to unite with other offices and provide vaccines in a centralized site within an office park.

New Settings and Incentives for Immunization Programs

Several additional nontraditional settings in which vaccines might be provided include soup kitchens, prisons, sheltered workshops for persons with disabilities, casinos, bingo halls, adult day care centers, major transit points, and polling stations on election days. Designation of mass immunization days (analogous to national immunization days for polio vaccination in endemic areas [15]) during which vaccinations are provided in several different settings was suggested. New incentive or endorsement programs that might increase the demand for vaccinations were also presented. For example, retail coupons and endorsement by sports teams were suggested as potential ways to enhance vaccine-seeking behavior among adults.
ACCESS AND CONVENIENCE

The most common benefits of administering vaccine in nontraditional settings noted by workshop presenters are increased access and convenience. Providing vaccines in settings readily accessible to adults who are most in need of the services is critical. For many adults, the need to use transportation to reach a health-care provider is a barrier to receiving preventive services (7,9). This barrier might be eliminated by offering preventive services (e.g., administration of vaccines) in a neighborhood retail establishment, church, or other convenient location. Eliminating the need for making an appointment in advance and avoiding the waiting time often associated with a clinic or office visit are factors that also might increase the vaccine-seeking behavior of some adults (8,9).

REDUCED COST FOR VACCINATIONS

The reduced cost of receiving vaccines in nontraditional settings compared with traditional settings is another potential benefit. The current cost of administering influenza and pneumococcal vaccines in a nontraditional setting is $10–$15 and $15–$20, respectively. Adults without health insurance might be willing to pay for a vaccine administered in a nontraditional setting when they would be unwilling or unable to pay the greater cost associated with a physician’s office visit (16,17). For adults who are covered by Medicare, HCFA has mandated reimbursement for health-care providers who administer influenza vaccine, regardless of the setting, even if the health-care provider is not a member of the vaccinee’s health-care plan.

INCREASED AWARENESS FOR VACCINATIONS AMONG ADULTS

An indirect benefit of administering vaccine in nontraditional settings is increased public awareness of the need for adult immunization. This benefit is realized in two ways. First, many immunization programs operating in nontraditional settings use direct marketing to inform the community about their services and why they are important. Although marketing strategies might be directed toward promoting a specific site, the actual benefit is likely a general increase in public awareness regarding the importance and availability of vaccines for adults. Secondly, immunization programs in nontraditional settings often elicit media attention, which might increase community awareness of the need for vaccination of adults.

CHALLENGES OF ADULT IMMUNIZATION PROGRAMS IN NONTRADITIONAL SETTINGS

ADVERSE REACTIONS TO VACCINES

Vaccine providers should be trained to manage adverse reactions that might occur. Concerns regarding postvaccination observation included: “Should direct observation
of vaccine recipients be routine? If so, what is the duration of observation? If a severe adverse reaction occurs, are trained and skilled personnel on site to respond appropriately?"

**Recordkeeping**

Important factors regarding recordkeeping include how to determine which adults are in need of vaccines and how to prevent inappropriate revaccination.* Immunization registries might play a role in resolving this issue; however, most existing immunization registries do not include information regarding adults. Until immunization registries routinely include this information, the primary-care provider and/or health department should be notified when a vaccine is administered in a nontraditional setting so that patient immunization records can be updated. In addition, vaccinees should be provided with wallet-sized vaccine records. These efforts will help ensure that adults are offered appropriately timed vaccines and that their vaccination status is accessible to their health-care provider in traditional or nontraditional settings and to other health-care providers who might offer them vaccines in nontraditional settings.

**Liability of Health-Care Providers**

Many workshop participants considered liability protection for health-care providers an important component of any adult immunization program. Health-care providers might be more likely to promote and administer vaccines if they could be assured of not being held liable for incidents of rare but serious adverse reactions to vaccines.

**Legal Regulations**

Workshop participants described several restrictive legal regulations regarding the administration of vaccines. In many states, legislation restricts who can administer vaccines and under what circumstances. In some areas, new immunization programs that might reach populations at high risk for disease could be hampered by restrictive legal regulations.

**Integrating Vaccine Programs in Nontraditional and Traditional Settings**

One challenge of offering vaccines in a setting that does not provide other preventive services is fragmentation of care. Workshop participants acknowledged the importance of having a medical home to ensure appropriate and comprehensive preventive care, early diagnosis, and optimal therapy. Immunization programs in nontraditional settings should facilitate identification of medical homes for medically underserved adults who need a health-care provider. To promote integration of preventive care

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*Influenza vaccine should not be routinely administered more than once during an influenza season (18). Revaccination with pneumococcal vaccine one time, at least 5 years after initial vaccination, is recommended for persons at highest risk for pneumococcal infection (e.g., persons who are immunocompromised or who are asplenic) and those most likely to have a rapid decline in antibody concentrations. In addition, for persons vaccinated before age 65 years, a second dose should be administered at age ≥65 years, provided that ≥5 years have elapsed since the first dose (19).
services when an adult with a regular primary-care provider is vaccinated in a nontraditional setting, the primary-care provider should be notified by the vaccine provider of the patient’s vaccination status. Vaccination status is often a marker for other healthcare needs. Therefore, adults seeking vaccines in nontraditional settings also might need other preventive health services (e.g., mammograms and lipid screenings). In addition, these programs need systematic procedures (e.g., providing lists of nearby physicians and offering to schedule appointments) to ensure that referrals to primary-care providers are offered when appropriate and that relevant health promotion and disease prevention literature are available on site.

Quality of Services

The mission of an immunization program and the motivation of the health-care providers who operate the program might affect the quality of services provided. Important components of quality care when administering vaccines in nontraditional settings include a) ability to handle adverse reactions, b) notification of the primary-care provider or health department when vaccines are administered, c) physician referral services, and d) providing education regarding other key preventive health measures.

FUTURE CONSIDERATIONS AND PRIORITIES

The conclusions reached by workshop participants were based primarily on expert opinion and anecdotal information. Both workshop participants and NVAC recognize the need for research targeted at providing data that addresses the effectiveness of immunization programs in nontraditional settings in reaching previously unvaccinated adults.

NVAC recommends that program evaluation be conducted to determine the impact of immunization programs in nontraditional settings on vaccine coverage rates and vaccine-preventive disease rates among adults. Specifically, the following concerns should be addressed:

• Determine characteristics of persons receiving vaccine in nontraditional settings, including demographic characteristics, previous vaccine-seeking behavior, and previous and anticipated future use of the traditional medical system. A survey of persons using nontraditional settings for vaccination could provide these data.

• Determine characteristics of programs successfully reaching hard-to-reach, previously unvaccinated adults. Demonstration projects, including various types of programs (e.g., those operated by service versus for-profit organizations) in different locations, including churches, work sites, and pharmacies, need to be assessed to determine which combination of features creates the most successful program.

• Catalogue the types of services provided. The catalogue could include the following features: reporting to primary-care physician, referral to physician, provision of educational materials regarding the importance of other preventive care measures, the number of programs offering each service, and the effect of these services on program operating costs.
• Determine if the nontraditional settings in which vaccines are administered are accessible locations and settings in which medically underserved populations feel comfortable receiving vaccine. This information could be obtained by surveying these adults.

• Determine the potential effect of liability protection on physician practice patterns by surveying physicians.

• Determine reasons nonphysician providers in some states are not allowed to administer vaccines in nontraditional settings. These reasons could be addressed by surveying state legislators and health officials.

GUIDANCE FROM NVAC FOR CONDUCTING ADULT IMMUNIZATION PROGRAMS IN NONTRADITIONAL SETTINGS

Although no formalized, coordinated effort to provide vaccinations in nontraditional settings exists at the national level, many adults are already receiving vaccine in these settings. To ensure the safety of persons receiving vaccines in these settings, NVAC has established seven quality standards for vaccine providers conducting or planning to conduct adult immunization programs in nontraditional settings. Quality standards for immunization programs in nontraditional settings generally coincide with the quality standards for programs in traditional settings. NVAC’s quality standards for immunization programs in nontraditional settings are consistent with existing adult immunization standards of the Advisory Committee on Immunization Practices (ACIP) (20), ACP (21), the Infectious Disease Society of America (22), and NCAI (23), with additional caveats specific to nontraditional settings.

Standard 1: Information and Education for Vaccinees

Before receiving vaccine, the vaccinee must be given information about the risks and benefits associated with vaccination, including the CDC-developed Vaccination Information Statements that address the risks and benefits for 12 commonly administered vaccines, including influenza and pneumococcal vaccines. This information should be culturally and linguistically appropriate and written at a reading level that can be easily understood. The vaccine provider should be available to accurately address questions and concerns posed by the vaccinee.

Vaccinees should also be informed regarding the importance of having a medical home and receiving other preventive medical services. In addition, health promotion and disease prevention literature should be available on site and offered to the vaccinee.

Standard 2: Vaccine Storage and Handling

Adherence to vaccine handling and storage recommendations included in vaccine package inserts is critical because mishandling and inappropriate storage can render vaccines ineffective. Influenza and pneumococcal vaccines are the primary vaccines administered in nontraditional settings. These vaccines should be stored at temperatures between 2 C and 8 C (38 F and 48 F), and records of storage temperature should
be maintained. Temperatures below freezing destroy the potency of these vaccines (24). Vaccine providers are responsible for ensuring appropriate storage of vaccines and should be trained accordingly. Storage procedures will become more complex if the types of vaccine offered in nontraditional settings increase.

**Standard 3: Immunization History**

Prevaccination screening interviews should be conducted and immunization histories of vaccinees obtained before administering vaccines. At a minimum, the following information should be obtained from the vaccinee: vaccines previously received, preexisting health conditions, allergies, and adverse events that occurred after previous vaccinations. Consulting the vaccinee’s medical record is the most reliable method of determining immunization status; however, this is not always feasible, especially among adults receiving vaccines in nontraditional settings. In many cases, the medical record might not be available or, if available, might not contain the most recent information, particularly if a vaccine was not administered by the vaccinee’s primary-care provider. Although repeated pneumococcal vaccination (especially within 24 months) might be associated with local adverse reactions more severe than those occurring after initial vaccination (19,25), ACIP and ACP recommend that the vaccine be offered when vaccination status cannot be determined (19,27).

**Standard 4: Contraindications**

Before administering vaccine, vaccine providers must assess the presence of contraindications. This assessment, part of the process of assessing the vaccinee’s immunization history (Standard 3), should be made during the prevaccination screening interview. If a contraindication to immunization exists, this information should be provided to the primary-care provider or local health department and the vaccinee.

Severe systemic hypersensitivity reactions (including anaphylaxis) to egg protein, gelatin, neomycin, or streptomycin are contraindications for vaccines that contain these products (e.g., influenza vaccines). Live virus vaccines are generally contraindicated for adults who are immunocompromised and for women who are pregnant. These important contraindications affect only a small number of adults. Adults who need vaccine are more likely to not be offered it because of misconceptions concerning contraindications (see Box).

**Standard 5: Recordkeeping**

Each time an adult receives a dose of vaccine, the following information should be recorded: vaccinee’s name, age, preexisting health conditions, type of vaccine, dose, site and route of administration, name of the vaccine provider, date vaccine was administered, manufacturer and lot number, and date that the next dose is due. If possible, this information should be recorded in the vaccinee’s medical file, sent to their primary-care provider, and given to the vaccinee. Retrievable files also should be maintained by the vaccine provider in compliance with general medical practice and state requirements.

Many adults do not have a primary-care provider and, even if they do, vaccine is often not administered by their primary-care provider. Geographic and occupational
mobility, changes in sources of health care, and economic factors often cause adults to see several health-care providers throughout their lifetime. As a result, vaccination records are often dispersed among a number of health-care providers. When vaccine is administered by a health-care provider other than the vaccinee’s primary-care provider (e.g., vaccine received in a nontraditional setting), a vaccine card with the information noted in this standard should be provided to the primary-care provider or local health department (if no such provider can be identified) and the vaccinee. When possible, reminder notices should be sent to adults alerting them of when they are due for another vaccination.

<table>
<thead>
<tr>
<th>True Contraindications</th>
<th>False Contraindications</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Do Not Administer Vaccine)</td>
<td>(Vaccine May be Administered)</td>
</tr>
<tr>
<td>• Anaphylactic reaction to a vaccine.</td>
<td>• Mild to moderate local reaction following a dosage of an injectable antigen.</td>
</tr>
<tr>
<td>• Anaphylactic reaction to a vaccine component.</td>
<td>• Low-grade or moderate fever following a previous vaccine dosage.</td>
</tr>
<tr>
<td>• Moderate or severe illness with or without fever.</td>
<td>• Mild acute illness with or without fever.</td>
</tr>
<tr>
<td>• Pregnancy.</td>
<td>• Current antimicrobial therapy.</td>
</tr>
<tr>
<td>• Compromised immune system.</td>
<td>• Convalescent phase of illness.</td>
</tr>
<tr>
<td></td>
<td>• Prematurity.</td>
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<tr>
<td></td>
<td>• Recent exposure to an infectious disease.</td>
</tr>
<tr>
<td></td>
<td>• History of penicillin or other nonspecific allergies or fact that relatives have such allergies.</td>
</tr>
<tr>
<td></td>
<td>• Pregnancy of mother or household contact.</td>
</tr>
<tr>
<td></td>
<td>• Unvaccinated household contact.</td>
</tr>
<tr>
<td></td>
<td>• Breast-feeding.</td>
</tr>
</tbody>
</table>

*This table is a modified version of the National Vaccine Advisory Committee’s Standards for Pediatric Immunization Practices (CDC. Standards for pediatric immunization practices: recommendations of the National Vaccine Advisory Committee. MMWR 1993;42[No. RR-5]). Please consult with CDC’s National Immunization Program for updates.*
Standard 6: Vaccine Administration

Health-care providers who administer vaccine must have the legal authority to do so and must be appropriately trained and licensed in all aspects of vaccine administration, including a) proper storage and handling of vaccines, b) information to be elicited from clients before vaccination (Standard 3), c) information to be given to clients before vaccination (Vaccine Information Statements), d) techniques for vaccine administration (20), and e) ability to handle adverse reactions.

Specific information regarding the recommended route of administration and appropriate dose is included in the package insert of each vaccine. Most vaccines are administered intramuscularly or subcutaneously. The dose indicated in the insert should be the dose administered. Administering one half of the recommended dose to potentially reduce the risk for adverse reaction has not been demonstrated to be an effective method of reducing adverse reactions and could result in inadequate protection against disease (26).

Standard 7: Adverse Events

Vaccine providers must be trained to recognize and treat adverse reactions, and the equipment needed to do so must be available on site. Vaccines are safe and effective; however, adverse events, ranging from minor, local reactions to severe systemic illness, occasionally occur following vaccination. Although severe, systemic reactions are rare, they can be life-threatening. Vaccine providers should be trained to use medications (epinephrine, atropine, and sodium bicarbonate) and conduct procedures necessary to maintain the airway and manage cardiovascular collapse (basic and advanced cardiopulmonary resuscitation [CPR], operation of a defibrillator, and use of a self-reinflating ventilating bag [Ambu bag] to provide positive pressure ventilation during resuscitation). Vaccine providers must be in close proximity to a telephone so that emergency medical personnel can be summoned immediately, if necessary.

Vaccinees should be monitored for adverse reactions after receiving vaccine. If a severe adverse reaction occurs while the vaccinee is on site or any time after receiving vaccine, the primary-care provider or local health department should be notified.

To improve knowledge about vaccines and vaccine-associated adverse reactions, all serious adverse events should be reported to the Vaccine Adverse Event Reporting System (VAERS) (21). VAERS reporting forms and assistance can be obtained by telephone (1-800-822-7967) or through the CDC Internet site at <http://www.cdc.gov/nip/vaers.htm>.

CONCLUSION

The ability of vaccines to save lives and prevent suffering extends beyond childhood. As with childhood vaccines, adult vaccines are a cost-effective means of preventing disease (27,28). To realize these benefits, vaccines must be made readily available to the public. Although rates of vaccine coverage among adults are increasing, many adults (especially among economically disadvantaged, inner city, and minority populations) are not receiving appropriate vaccinations (2). Enhancing educational efforts and increasing the number and types of programs (e.g., standing orders [29] and non-traditional settings) safely administering vaccine to adults might increase the number of adults receiving vaccines and the associated benefits.
Educating health-care providers and the public is the cornerstone of an effective vaccination strategy. The Adult Immunization Action Plan (1) emphasizes the need for physicians and other health-care providers to recognize both the severity of influenza and pneumococcal disease and the safety and effectiveness of vaccines so they consistently offer vaccines to their patients. Physicians’ recommendations influence patients’ decisions to receive vaccine, regardless of the patients’ initial attitude (6). However, some adults who need vaccination receive medical care but are not offered vaccine, whereas others might not have regular contact with traditional health-care settings. For these reasons, increased efforts to educate the public as well as health-care providers are needed. The 1994 NVAC report on adult immunization concluded that “better public understanding of the seriousness of vaccine-preventable diseases and the benefits of vaccination will be essential if there are to be improvements in adult immunization” (30).

An essential step toward creating an effective immunization infrastructure integrating traditional and nontraditional immunization programs is to determine the role each type of program has in the overall immunization strategy. Data from immunization programs in traditional and nontraditional settings are needed to assess who receives vaccine in which settings and why they choose that setting. Data characterizing persons who do not receive vaccine and their reasons for not getting vaccinated also are needed. These data will facilitate the development of a comprehensive immunization strategy to increase immunization coverage in all segments of the adult population.

Integration of nontraditional immunization programs with the existing health-care infrastructure provides the potential to increase vaccine coverage rates and decrease vaccine-preventable diseases among adults. To do so most effectively, the specific contributions of immunization programs in traditional and nontraditional settings need to be established, and the quality standards in this report need to be implemented. The efforts that effectively lowered vaccine-preventable disease rates among children now need to be targeted toward developing new and effective immunization programs that will make appropriate vaccines readily accessible to adults.

**References**

2. CDC. Influenza and pneumococcal vaccination levels among adults aged ≥65 years—United States. MMWR 1998;47:797–802.
7. CDC. Vaccination levels among Hispanic and Non-Hispanic whites aged ≥65 years—Los Angeles County, California, 1996. MMWR 1997;46:1165–8.
Use of Standing Orders Programs to Increase Adult Vaccination Rates

Recommendations of the Advisory Committee on Immunization Practices
Advisory Committee on Immunization Practices
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Use of Standing Orders Programs to Increase Adult Vaccination Rates

Recommendations of the Advisory Committee on Immunization Practices

Summary
The Advisory Committee on Immunization Practices recognizes the need for evidence-based policy to improve the delivery and receipt of immunization services recommended for adults (i.e., persons aged ≥18 years). Two recent, systematic reviews of the health services research literature recommended standing orders programs as an effective organizational intervention to improve vaccination coverage rates among adults. This report briefly reviews the evidence on the effectiveness of standing orders programs, describes standards for program implementation, and recommends initiating these programs to improve immunization coverage in several traditional and nontraditional settings.

INTRODUCTION
Standing orders programs authorize nurses and pharmacists to administer vaccinations according to an institution- or physician-approved protocol without a physician’s exam. These programs have documented improved vaccination rates among adults. Standing orders programs can be used in inpatient and outpatient facilities, long-term-care facilities, managed-care organizations, assisted living facilities, correctional facilities, pharmacies, adult workplaces, and home health-care agencies to vaccinate patient, client, resident, and employee populations. The Advisory Committee on Immunization Practices (ACIP) recommends standing orders for influenza and pneumococcal vaccinations (1,2). Recently, systematic literature reviews by the Task Force for Community Preventive Services (3) and the Southern California Evidence-Based Practice Center–RAND endorsed these programs for adult populations (4).

This report briefly reviews the evidence regarding the effectiveness of standing orders programs in improving adult vaccination coverage rates and recommends prioritizing these programs for influenza and pneumococcal vaccinations, to have the greatest impact on the burden of vaccine-preventable diseases in the United States. Standing orders programs are also recommended for other vaccines, including hepatitis B vaccine and diphtheria and tetanus toxoid vaccines, when feasible.

BACKGROUND
Epidemics of influenza occur during the winter months nearly every year and are responsible for an average of approximately 20,000 deaths per year in the United States (5,6). Influenza viruses cause disease in all age groups (7,8), but rates of serious morbidity and mortality are highest among persons aged ≥65 years and persons of any age who have medical conditions that place them at high risk for complications from influ-
Pneumococcal disease accounts for approximately 3,000 cases of meningitis, 50,000 cases of bacteremia, and 500,000 cases of pneumonia each year (1) and is responsible for more deaths than any other vaccine-preventable bacterial disease (12). Despite antimicrobial therapy and intensive medical care, the overall case-fatality rate for pneumococcal bacteremia is 15%–20% among adults (i.e., persons aged ≥18 years) (1). Among persons aged ≥65 years, case-fatality rates can be as high as 40% (13).

In recent years, a rapid emergence of antimicrobial resistance among pneumococci, especially to penicillin, has occurred. Increasing pneumococcal vaccination rates could help prevent invasive pneumococcal disease caused by vaccine-type, multidrug-resistant pneumococci. Outbreaks of pneumococcal disease caused by a single drug-resistant pneumococcal serotype have occurred in institutional settings, including nursing homes (14,15). In 1999, because of concerns about pneumococcal antimicrobial resistance and underuse of pneumococcal vaccine, the American Medical Association and several partner organizations issued a Quality Care Alert that supports ACIP’s recommendations for pneumococcal vaccination (16).

Health services research indicates that influenza and pneumococcal vaccines are underused in institutional settings, even after they became covered benefits of Medicare Part B (1981 for pneumococcal vaccine and 1993 for influenza vaccine) (17,18). Despite the availability of suitable vaccines, persons hospitalized with conditions for which influenza and pneumococcal vaccines are indicated are not usually assessed for vaccination status or vaccinated. Among persons who reported at least one hospitalization during the preceding year to the 1997 National Health Interview Survey, 83% of persons aged 18–64 years with medical conditions that put them at high risk and 55% of all persons aged ≥65 years reported not receiving pneumococcal vaccinations (CDC, unpublished data, 1999). Sixty-nine percent of persons aged 18–64 years with medical conditions that put them at high risk and 32% of all persons aged ≥65 years reported not receiving influenza vaccination (CDC, unpublished data, 1999). In 12 western states, 80% of Medicare beneficiaries hospitalized for pneumonia during September–December 1994 did not receive influenza vaccines; 65% did not receive pneumococcal vaccines (17). The 1995 National Nursing Home Survey estimated influenza and pneumococcal vaccination rates among residents in long-term–care facilities to be approximately 63% and 22%, respectively (18). These rates are far below the Healthy People 2010 objective of 90% for both vaccines among all persons aged ≥65 years (objective 14-29) (19). Coverage estimates for 1997 were approximately 64% for influenza vaccines and 28% for pneumococcal vaccines (CDC, unpublished data, 1999). Many long-term–care facilities have inadequate policies and procedures to prevent vaccine-preventable diseases among their vulnerable populations (20).

Several studies suggest that standing orders programs are more effective than other institution-based strategies in improving vaccination services. In one New York hospital, instituting a standing orders program for pneumococcal vaccination among persons aged ≥65 years and other patients at high risk increased the pneumococcal vaccination rate from 0% to 78% (21). In another study, pharmacists increased pneumococcal vaccination rates from 4.2% to 94% in one nursing facility and from 1.9% to 83% in a second facility, whereas the rates at a control facility increased from 0.9% to 4.0% (22). In a study of six small community hospitals in northern Minnesota, standing orders programs achieved an influenza vaccination rate of 40.3% among patients, compared with 17% using physician reminders and 9.6% using educational programs (23).
A study conducted in an ambulatory care clinic compared the use of nurse standing orders combined with other interventions, including patient and health-care provider reminders, with the use of patient and provider reminders alone. Pneumococcal vaccination rates per total patient population were 22%–25% for the nurse standing orders programs, compared with 5% when patient and provider reminders were used alone (24).

Based on the scientific evidence of effectiveness in improving vaccination rates in institutions, the Task Force for Community Preventive Services and the Southern California Evidence-Based Practice Center–RAND recommend standing orders programs for the vaccination of adults in hospitals, clinics, and nursing homes (3,4). Standing orders policies are acceptable to most primary-care physicians (25) and have resulted in higher vaccination rates than other vaccination delivery methods (4,26).

IMPLEMENTATION GUIDELINES

Successful standing orders programs begin by documenting a plan for the program’s infrastructure, key service-delivery components, and quality assurance. To ensure success, a committee should be formed that includes the organization’s medical director, nursing director, infection-control and quality-control personnel, and medical or nursing staff representatives. This committee should write protocols for the following procedures:

- Identifying persons eligible for vaccination based on their age, their vaccination status (e.g., persons previously unvaccinated or due for vaccination according to the recommended schedule), or the presence of a medical condition that puts them at high risk.
- Providing adequate information to patients or their guardians regarding the risks for and benefits of a vaccine and documenting the delivery of that information.
- Recording patient refusals or medical contraindications.
- Recording administration of a vaccine(s) and any postvaccination adverse events, according to institution- or physician-approved protocol.
- Providing documentation of vaccine administration to patients and their primary-care providers.

Standing orders protocols should also specify that vaccines be administered by health-care professionals trained to a) screen patients for contraindications to vaccination, b) administer vaccines, and c) monitor patients for adverse events, in accordance with state and local regulations. Vaccine information statements developed by and available from CDC can be useful for risk/benefit counseling before administering a vaccine. All health-care personnel administering vaccines or providing care to vaccinated persons should be trained to report adverse outcomes to the Vaccine Adverse Events Reporting System (VAERS). The appropriate VAERS forms and contact information should be readily available in all facilities delivering vaccines.

The standards for adult immunization practice established by the National Coalition for Adult Immunization recommend that standing orders programs include a standard personal and institutional immunization record to verify the immunization status of
patients and staff members and to reduce the risk for inappropriate revaccination (27). A patient’s primary-care provider should be able to override institutional standing orders when medically appropriate. Ongoing communication between the primary-care provider, vaccinee, and institutional staff members is recommended to reduce the possibility of inappropriate vaccinations.

None of the studies of standing orders programs for influenza and pneumococcal vaccination reported unnecessary or inappropriate vaccinations (3,4,21–23,26). If repeated pneumococcal vaccinations did occur, studies have indicated that the risk for adverse events beyond self-limited local reactions was minimal for a second dose administered 2–5 years after the primary dose (1,28). The risk for self-limited local injection site reactions does not represent a contraindication to revaccination with pneumococcal vaccine in recommended groups.

The policies and protocols for standing orders programs should include a quality assurance process to maintain appropriate standards of care. The feasibility and cost-effectiveness of standing orders programs in several settings need ongoing evaluation, with particular attention to safety and tracking of vaccinations (29). For example, preprinted admissions orders could improve the effectiveness of program staff members to assess the vaccination status of patients and to provide information about the risks for and benefits of administering vaccinations routinely upon admission to facilities.

Facility staff members should consider other potential benefits (e.g., sustainability over time) when developing standing orders programs (30). These programs could be adapted to other preventive services (e.g., mammography) to improve delivery of those services, and they could be used to improve clinic efficiency by reducing pressures on physicians’ time (3).

**CONCLUSION**

ACIP recommends that standing orders programs be used in long-term–care facilities under the supervision of a medical director to ensure the administration of recommended vaccinations for adults. ACIP also encourages the introduction of standing orders programs for vaccination of adults in other settings (e.g., inpatient and outpatient facilities, managed-care organizations, assisted living facilities, correctional facilities, pharmacies, adult workplaces, and home health-care agencies). Implementation of standing orders programs alone or combined with other effective interventions can help improve vaccination coverage by institutional providers (3,4,31). Because of the societal burden of influenza and pneumococcal disease, implementation of standing orders programs to improve adult vaccination coverage for these diseases should be a national public health priority.

**References**


Screening and Recordkeeping

Screening

Identification of patients in need of immunization is an important aspect of pharmacy-based immunization services. The childhood and adult immunization schedules should be used as a starting point. (Module 1) Indications, contraindications, and precautions for immunization can be identified using these schedules and each vaccine’s recommendation and report from the Advisory Committee on Immunization Practices. Age, comorbid diseases, and lifestyle are all indicators of need for immunization. Pharmacists have the information available that can be used to determine immunization indications. Age is a standard part of the pharmacy record. Diagnoses may be included or inferred based on the medication list. Indications for specific vaccines and patient populations will be covered in Modules 4 and 5.

Although the recommendations for vaccine use made by the Advisory Committee on Immunization Practices often are consistent and parallel with FDA labeling of vaccines, there are some exceptions where accepted immunization practices are different from what has been demonstrated in clinical trials upon which the package insert recommendations are written. For example, the ACIP strongly recommends that pregnant women receive inactivated influenza vaccine\(^2\), while the package insert expresses caution regarding the use of influenza vaccine in pregnant women.\(^3\)

The only general contraindication to immunization is an allergy to the vaccine or a component of the vaccine.\(^4\) Pregnancy is a contraindication for some vaccines (Module 1: Table 6), however; some are safe and recommended for pregnant individuals. Some precautions to immunization exist. Immunization may need to be deferred for patients who are immunocompromised. Patients who recently received immune globulins or blood products may require deferral of live vaccines. The length of the deferral depends on the type of immune globulin or blood product received (Module 1: Table 5). Individuals who are mildly ill can be immunized. Immunization can wait for patients who are moderately or severely ill.\(^4\) Hospital discharge is a good time for immunization. If a patient is in the pharmacy and well enough to go back home as opposed to being referred to an urgent care or emergency department, he is probably well enough to be immunized.

In order to systematically identify contraindications and precautions to immunization, many immunizers use screening questionnaires to determine a patient’s eligibility for immunization. The Immunization Action Coalition has a very useful screening tool. This form is also valuable for teaching as the consequences of patient answers to the screening questions are explained. Patients who present for immunization can be given the form and their answers reviewed with the immunizer prior to vaccine administration. Immunizers who are required to obtain written informed consent could use these screening forms for that purpose too.
# Screening Checklist for Contraindications to Vaccines for Adults

**For patients:** The following questions will help us determine which vaccines you may be given today. If you answer "yes" to any question, it does not necessarily mean you 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.

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Don’t Know</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Are you sick today?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Do you have allergies to medications, food, a vaccine component, or latex?</td>
<td></td>
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<tr>
<td>3. Have you ever had a serious reaction after receiving a vaccination?</td>
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<tr>
<td>4. Do you have a long-term health problem with heart disease, lung disease, asthma, kidney disease, metabolic disease (e.g., diabetes), anemia, or other blood disorder?</td>
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<tr>
<td>5. Do you have cancer, leukemia, HIV/AIDS, or any other immune system problem?</td>
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<tr>
<td>6. In the past 3 months, have you taken medications that weaken your immune system, such as cortisone, prednisone, other steroids, or anticancer drugs, or have you had radiation treatments?</td>
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<tr>
<td>7. Have you had a seizure or a brain or other nervous system problem?</td>
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<tr>
<td>8. During the past year, have you received a transfusion of blood or blood products, or been given immune (gamma) globulin or an antiviral drug?</td>
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<tr>
<td>9. For women: Are you pregnant or is there a chance you could become pregnant during the next month?</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>10. Have you received any vaccinations in the past 4 weeks?</td>
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</tr>
</tbody>
</table>

Form completed by: __________________________________________  Date: ________________
Form reviewed by: ____________________________________________  Date: ________________

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

It is important for you to have a personal record of your vaccinations. If you don’t have a personal record, ask your healthcare provider to give you one. Keep this record in a safe place and bring it with you every time you seek medical care. Make sure your healthcare provider records all your vaccinations on it.
Information for Health Professionals about the Screening Checklist for Contraindications To Vaccines for Adults

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 bottom of this page.

1. Are you sick today? [all vaccines]
   There is evidence that acute illness reduces vaccine efficacy or increases vaccine adverse events (1). However, as a precaution with moderate or severe acute illness, all vaccines should be delayed until the illness has improved. Mild illnesses (such as upper respiratory infections or diarrhea) are NOT contraindications to vaccination. Do not withhold vaccination if a person is taking antibiotics.

2. Do you have allergies to medications, food, a vaccine component, or latex? [all vaccines]
   If a person reports they have an allergy to an egg, ask if they can eat lightly cooked eggs (e.g., scrambled eggs). If they can, trivalent influenza vaccine (TIV) may be administered. If after eating eggs or egg-containing foods, they have a reaction consisting of only hives, TIV may be given and the person should be observed for at least 30 minutes. If a person experiences a serious systemic or anaphylactic reaction (e.g., hives and either swelling of the lips or tongue, acute respiratory distress, or collapse) after eating eggs, do not administer TIV or live attenuated influenza vaccine (LAIV). It is possible that they may be eligible to be given TIV, but only after they have seen a physician with expertise in the management of allergic conditions. If a person has anaphylaxis after eating gelatin, do not administer MMR or varicella vaccine. Local reactions are not contraindications. For a table of vaccines supplied in vials or syringes that contain latex, go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/lateral-table.pdf. For an extensive list of vaccine components, see reference 2.

3. Have you ever had a serious reaction after receiving a vaccination? [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). 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. Do you have a long-term health problem with heart disease, lung disease, asthma, kidney disease, metabolic disease (e.g., diabetes), anemia, or other blood disorder? [LAIV]
   People with any of these health conditions should not be given the intranasal live attenuated influenza vaccine (LAIV). Instead, they should be vaccinated with the inactivated influenza vaccine.

5. Do you have cancer, leukemia, HIV/AIDS, or any other immune system problem? [LAIV, MMR, VAR, ZOS]
   Live virus vaccines (e.g., LAIV, measles-mumps-rubella [MMR], varicella [VAR], zoster [ZOS]) are usually contraindicated in immunocompromised people. However, there are exceptions. For example, MMR vaccine is recommended and varicella vaccine should be considered for adults with CD4+ T-lymphocyte counts of greater than or equal to 200 cells/µL. Immunocompromised people should not receive LAIV. For details, consult the ACIP recommendations (3, 4, 5).

6. In the past 3 months, have you taken medications that weaken your immune system, such as cortisone, prednisone, other steroids, or anticancer drugs, or have you had radiation treatments? [LAIV, MMR, VAR, ZOS]
   Live virus vaccines (e.g., LAIV, MMR, VAR, ZOS) 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, 5).

To find specific vaccination schedules for stem cell transplant (bone marrow transplant) patients, see reference 6. LAIV can be given only to healthy non-pregnant people younger than age 50 years.

7. Have you had a seizure or a brain or other nervous system problem? [LAIV, Td/tdap]
   Tdap is contraindicated in people who have a history of encephalopathy within 7 days following DTP/DTaP given before age 7 years. An unstable progressive neurologic problem is a precaution to the use of Tdap. For people with stable neurologic disorders (including seizures) unrelated to vaccination, or for people with a family history of seizure, vaccinate as usual. A history of Guillain-Barré syndrome (GBS) is a consideration with the following: 1) Td/Tdap: if GBS has occurred within 6 weeks of a tetanus-containing vaccine and decision is made to continue vaccination, give Tdap instead of Td if no history of prior Tdap; 2) Influenza vaccine (TIV/LAIV): if GBS has occurred within 6 weeks of a prior influenza vaccine, vaccinate with TIV if at high risk for severe influenza complications.

8. During the past year, have you received a transfusion of blood or blood products, or been given immune (gamma) globulin or an antiviral drug? [LAIV, MMR, VAR]
   Certain live virus vaccines (e.g., LAIV, MMR, VAR) may need to be deferred, depending on several variables. Consult the most current ACIP recommendations for current information on intervals between antiviral drugs, immune globulin or blood product administration and live virus vaccines. (1)

9. For women: Are you pregnant or is there a chance you could become pregnant during the next month? [MMR, LAIV, VAR, ZOS]
   Live virus vaccines (e.g., MMR, VAR, ZOS, LAIV) are contraindicated one month before and during pregnancy because of the theoretical risk of virus transmission to the fetus. Sexually active women in their childbearing years who receive live virus vaccines should be instructed to practice careful contraception for one month following receipt of the vaccine. On theoretical grounds, inactivated poliovirus vaccine should not be given during pregnancy; however, it may be given if risk of disease is imminent and immediate protection is needed (e.g., travel to endemic areas). 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. (1, 3, 4, 5, 7, 8)

10. Have you received any vaccinations in the past 4 weeks? [LAIV, MMR, VAR, yellow fever]
    If the person to be vaccinated was given either LAIV or an injectable live virus vaccine (e.g., MMR, VAR, ZOS, 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 any spacing interval if they are not administered simultaneously.

References:
3. 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).
7. CDC. Notice to readers: Revised ACIP recommendation for avoiding pregnancy after receiving a rubella-containing vaccine, MMWR 2001; 50 (49).
**Screening Checklist for Contraindications to Vaccines for Children and Teens**

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

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
<th>Don’t Know</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Is the child sick today?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>2. Does the child have allergies to medications, food, a vaccine component, or latex?</td>
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<td>☐</td>
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</tr>
<tr>
<td>3. Has the child had a serious reaction to a vaccine in the past?</td>
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<tr>
<td>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?</td>
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<tr>
<td>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?</td>
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<td>6. If your child is a baby, have you ever been told he or she has had intussusception?</td>
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<td>☐</td>
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<tr>
<td>7. Has the child, a sibling, or a parent had a seizure; has the child had brain or other nervous system problems?</td>
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<tr>
<td>8. Does the child have cancer, leukemia, HIV/AIDS, or any other immune system problem?</td>
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<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>9. In the past 3 months, has the child taken medications that weaken their immune system, such as cortisone, prednisone, other steroids, or anticancer drugs, or had radiation treatments?</td>
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<td>☐</td>
</tr>
<tr>
<td>10. 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?</td>
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<tr>
<td>11. Is the child/teen pregnant or is there a chance she could become pregnant during the next month?</td>
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<td>☐</td>
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<tr>
<td>12. Has the child received vaccinations in the past 4 weeks?</td>
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</tbody>
</table>

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 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.
Information for Health Professionals about the Screening Checklist for Contraindications (Children & 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 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]
   If a person reports they have an allergy to egg, ask if they can eat lightly cooked eggs (e.g., scrambled eggs). If they can, trivalent influenza vaccine (TIV) may be administered. If after eating eggs or egg-containing foods, they have a reaction consisting of only hives, TIV may be given and the person should be observed for at least 30 minutes. If a person experiences a serious systemic or anaphylactic reaction (e.g., hives and either swelling of the lips or tongue, acute respiratory distress, or collapse) after eating eggs, do not administer TIV or live attenuated influenza vaccine (LAIV). It is possible that they may be eligible to be given TIV, but only after they have seen a physician with expertise in the management of allergic conditions. If a person has anaphylaxis after eating gelatin, do not administer LAIV, measles-mumps-rubella (MMR), MMR+varicella (MMRV), or varicella 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?** [VAR]
   Children with any of the health conditions listed above should not be given the inactivated, 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?** [LAV]
   Children who have had a wheezing episode within the past 12 months should not be given the live attenuated influenza vaccine (LAIV). These children should be vaccinated with the inactivated influenza vaccine.

6. **If your child is a baby, have you ever been told that he or she has had intussusception?** [Rotavirus]
   Infants who have a history of intussusception (i.e., the telescoping of one portion of the intestine into another) should not be given rotavirus vaccine.

7. **Has the child, a sibling, or a parent had a seizure? Has the child had brain or other nervous system problem?** [DTaP, Td, Tdap, TIV, LAV, MMRV] DTap and Tdap are contraindicated in children who have a history of encephalopathy within 7 days following DTP/DTaP. An unstable progressive neurological problem is a precaution to the use of DTap and Tdap, and a progressive neurological disorder in a teen is a precaution to the use of Td. For children with stable neurological 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 history [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.

8. **Does the child have cancer, leukemia, HIV/AIDS, or any other immune system problem?** [LAV, MMR, MMRV, VAR, RV, 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. 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 ACIP recommendations (4, 5, 6).

9. **In the past 3 months, has the child taken medications that weaken their immune system, such as cortisone, prednisone, other steroids, or anticancer drugs, or had radiation treatments?** [LAV, 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.

10. **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?** [LAV, MMR, MMRV, VAR]
    Certain live virus vaccines (e.g., LAV, 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).

11. **Is the child/teen pregnant or is there a chance she could become pregnant during the next month?** [LAV, 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).

12. **Has the child received vaccinations in the past 4 weeks?** [LAV, MMR, MMRV, VAR, 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:
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).
6. CDC. Prevention and Control of Influenza—Recommendations of ACIP at www.cdc.gov/mmwr/professionals/vaccination/
7. CDC. Prevention from Outbreaks of Certain Vaccine-Preventable Diseases. MMWR 1999; 48 (RR-10).
8. CDC. Notice to readers: Revised ACIP recommendations for intranasal live flu vaccine during pregnancy after receiving a rubella-containing vaccine. MMWR 2001; 50 (49).
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).
BEFORE ADVANCING: Complete Item 3 on the Immunization Implementation Plan

Vaccine Information Statements

Vaccine information statements (VIS) are patient education tools that immunizers are required to give patients or parents or guardians prior to administering a vaccine. Note that the dates that the VIS were given to the patient and the date of publication of the VIS are required elements for immunization recordkeeping. Recording the publication date of the VIS assures that the immunizer used the most current version.
APPENDIX E
Vaccine Information Statements

It’s Federal Law ..............................................E-1
Instructions for Use of VISs ..............................E-3
VIS Questions and Answers ..............................E-4
CDC’s Vaccine Information Statement Webpage.  ....E-8
Appendix E

It’s federal law!
You must give your patients current Vaccine Information Statements (VISs)

As healthcare professionals understand, the risks of serious consequences following vaccination are many hundreds or thousands of times less likely than the risks associated with the diseases that the vaccines protect against. Most adverse reactions from vaccines are mild and self-limited. Serious complications are rare, but they can have a devastating effect on the recipient, family members, and the providers involved with the care of the patient. We must continue the efforts to make vaccines as safe as possible.

Equally important is the need to furnish vaccine recipients (or the parents/legal representatives of minors) with objective information on vaccine safety and the diseases that the vaccines protect against, so that they are actively involved in making decisions affecting their health or the health of their children. When people are not informed about vaccine adverse events, even common, mild events, they can lose their trust in healthcare providers and vaccines. Vaccine Information Statements (VISs) provide a standardized way to present objective information about vaccine benefits and adverse events.

What are VISs?
VISs are developed by the staff of the Centers for Disease Control and Prevention (CDC) and undergo intense scrutiny by panels of experts for accuracy. Each VIS provides information to properly inform the adult vaccine recipient or the minor child’s parent or legal representative about the risks and benefits of each vaccine. VISs are not meant to replace interactions with healthcare providers, who should answer questions and address concerns that the recipient or the parent/legal representative may have.

Use of the VIS is mandatory!
Before a healthcare provider vaccinates a child or an adult with a dose of any vaccine containing diphtheria, tetanus, pertussis, measles, mumps, rubella, polio, hepatitis A, hepatitis B, Haemophilus influenzae type b (Hib), influenza, pneumococcal conjugate, meningococcal, rotavirus, human papillomavirus (HPV), or varicella (chickenpox) vaccine, the provider is required by the National Childhood Vaccine Injury Act (NCVIA) to provide a copy of the VIS to either the adult recipient or to the child’s parent/legal representative.

How to get VISs
All available VISs can be downloaded from the website of the Immunization Action Coalition at www.immunize.org/vis or from CDC’s website at www.cdc.gov/vaccines/pubs/vis/default.htm. Ready-to-copy versions may also be available from your state or local health department.

You can find VISs in more than 30 languages on the Immunization Action Coalition website at www.immunize.org/vis. To find VISs in alternative formats (e.g., audio, web-video), go to: www.immunize.org/vis/vis_sources.asp

Most current versions of VISs
As of February 22, 2012, the most recent versions of the VISs are as follows:

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>DTaP/DT</td>
<td>5/17/07</td>
</tr>
<tr>
<td>Hepatitis A</td>
<td>10/25/11</td>
</tr>
<tr>
<td>Hepatitis B</td>
<td>2/2/12</td>
</tr>
<tr>
<td>Hib</td>
<td>12/16/98</td>
</tr>
<tr>
<td>HPV (H. papillomavirus)</td>
<td>5/3/11</td>
</tr>
<tr>
<td>Gardasil</td>
<td>2/22/12</td>
</tr>
<tr>
<td>Influenza (inactive)</td>
<td>7/26/11</td>
</tr>
<tr>
<td>Influenza (live)</td>
<td>7/26/11</td>
</tr>
<tr>
<td>Japanese encephalitis</td>
<td>12/7/11</td>
</tr>
<tr>
<td>Meningococcal</td>
<td>10/14/11</td>
</tr>
<tr>
<td>Multi-vaccine VIS</td>
<td>9/18/08</td>
</tr>
</tbody>
</table>

(for 6 vaccines given to infants/children: DTaP, IPV, Hib, Hep B, PCV, RV)

Source: www.cdc.gov/vaccines/pubs/vis/vis-facts.htm
Top 10 Facts about VISs

Fact 1  It’s federal law!
Federal law requires that VISs must be used for the following vaccines when vaccinating patients of ALL ages:
- DTaP (includes DT)
- Td/Tdap
- Hib
- hepatitis A
- hepatitis B
- HPV
- influenza (inactivated and live vaccines)

According to CDC, every time one of these vaccines is given — regardless of what combination vaccine it is given in — regardless of whether it is given by a public health clinic or a private provider — regardless of how the vaccine was purchased — and regardless of the age of the recipient — the appropriate VIS must be given out prior to the vaccination. There are also VISs for vaccines not covered by NCVIA: anthrax, Japanese encephalitis, pneumococcal polysaccharide, rabies, shingles, smallpox, typhoid, and yellow fever. CDC recommends the use of VISs whenever these vaccines are given. The VIS must always be used if vaccine was purchased under CDC contract.

Fact 2  VISs are required for both public and private sectors
Federal law requires use of VISs in both the public and private sector settings and regardless of the source of payment for the vaccine.

Fact 3  VIS must be provided BEFORE vaccine is administered to the patient
The VIS provides information about the disease and the vaccine and should be given to the patient before vaccine is administered. It is also acceptable to hand out the VIS well before administering vaccines (e.g., at a prenatal visit or at birth for vaccines an infant will receive during infancy), as long as you still provide the VIS right before administering vaccines.

Fact 4  You must provide a current VIS for each dose of vaccine
The most current VIS must be provided before each dose of vaccine is given, including vaccines given as a series of doses. If five doses of a single vaccine are required, the patient (parent/legal representative) must have the opportunity to read the information on the VIS before each dose is given.

Fact 5  You must provide VISs for combination vaccines too
There is a VIS available for MMRV (ProQuad). An alternative VIS — the multi-vaccine VIS — is an option to providing single-vaccine VISs when administering one or more of these routine birth-through-6-month vaccines: DTaP, hepatitis B, Hib, pneumococcal (PCV), polio (IPV), or rotavirus (RV). The multi-vaccine VIS can also be used when giving combination vaccines (e.g., Pediarix, Pentacel, Convax) or when giving two or more routine vaccines at other pediatric visits (e.g., 12–15 months, 4–6 years). However, when giving combination vaccines for which no VIS exist (e.g., Twinrix), give out all relevant single VISs. For example, before administering Twinrix give your patient the VISs for both hepatitis A and hepatitis B vaccines.

Fact 6  VISs are available in other formats, including more than 30 languages
You may use laminated copies of VISs for patients and parents to read and return before leaving the clinic, but you must also offer the patient (parent/legal representative) a printed copy of the VIS to take home. If they prefer to download the VIS onto a mobile device, direct them to CDC’s VIS Mobile Downloads web page: www.cdc.gov/vaccines/Pubs/vis/vis-downloads.htm.

To download VISs in other languages, visit www.immunize.org/vis

Fact 7  Federal law does not require signed consent in order for a person to be vaccinated
Signed consent is not required by federal law (although some states may require them).

Fact 8  To verify that a VIS was given, providers must record in the patient’s chart (or permanent office log or file) the following information:
- The published date of the VIS
- The date the VIS is given to the patient
- Name, address (office address), and title of the person who administers the vaccine
- The date the vaccine is administered
- The vaccine manufacturer and lot number of each dose administered

Fact 9  VISs should not be altered before giving them to patients
Providers should not change a VIS or write their own VISs. It is permissible to add a practice’s name, address, or phone number to an existing VIS. Providers are encouraged to supplement the VIS with additional patient-education materials.

Fact 10  Provide VISs to all patients
For patients who don’t read or speak English, the law requires that providers ensure all patients (parent/legal representatives) receive a VIS, regardless of their ability to read English. If available, provide a translation of the VIS in the patient’s language. Translations of VISs in more than 30 languages are available from IAC. Go to www.immunize.org/vis for VISs in multiple languages as well as in other formats.

By using the VISs with your patients, you are helping to develop a better educated population and you are doing the right thing.
Instructions for the Use of Vaccine Information Statements

1. Provide a Vaccine Information Statement (VIS) when a vaccination is given.
   As required under the National Childhood Vaccine Injury Act (42 U.S.C. §300aa-26), all health care providers in the United States who administer, to any child or adult, any of the following vaccines – diphtheria, tetanus, pertussis, measles, mumps, rubella, polio, hepatitis A, hepatitis B, *Haemophilus influenzae* type b (Hib), trivalent influenza, pneumococcal conjugate, meningococcal, rotavirus, human papillomavirus (HPV), or varicella (chickenpox) – shall, prior to administration of each dose of the vaccine, provide a copy to keep of the relevant current edition vaccine information materials that have been produced by the Centers for Disease Control and Prevention (CDC):
   - to the parent or legal representative* of any child to whom the provider intends to administer such vaccine, or
   - to any adult† to whom the provider intends to administer such vaccine.

   If there is not a single VIS for a combination vaccine, use the VISs for all component vaccines.

   VISs should be supplemented with visual presentations or oral explanations as appropriate.

2. Record information for each VIS provided.
   Health care providers shall make a notation in each patient’s permanent medical record at the time vaccine information materials are provided, indicating:
   - (1) the edition date of the Vaccine Information Statement distributed, and
   - (2) the date the VIS was provided.

   This recordkeeping requirement supplements the requirement of 42 U.S.C. §300aa-25 that all health care providers administering these vaccines must record in the patient’s permanent medical record (or in a permanent office log):
   - (3) the name, address and title of the individual who administers the vaccine,
   - (4) the date of administration, and
   - (5) the vaccine manufacturer and lot number of the vaccine used.

**Applicability of State Law**
Health care providers should consult their legal counsel to determine additional State requirements pertaining to immunization. The Federal requirement to provide the vaccine information materials supplements any applicable State laws.

**Availability of Copies**
Copies are available in English and many other languages from CDC’s website at www.cdc.gov/vaccines/pubs/vis. Single camera-ready copies may also be available from State health departments.

**Current VIS Editions**
- **DTaP/DT:** 5/17/07
- **Hib:** 12/16/98
- **Hepatitis A:** 10/25/11†
- **Hepatitis B:** 2/2/12†
- **HPV (Cervarix):** 5/3/11†
- **HPV (Gardasil):** 2/2/12†
- **Influenza (inactivated):** 7/26/11†
- **Influenza (live):** 7/25/11†
- **MMR:** 3/13/08†
- **MMRV:** 5/21/10†

- **Meningococcal:** 10/14/11†
- **Pneumococcal (PCV13):** 4/16/10†
- **Polio:** 11/8/11†
- **Rotavirus:** 12/6/10†
- **Tdap/Td:** 1/24/12†
- **Varicella:** 3/13/08†
- **Multi-Vaccine*:** 9/18/08†

*Multipurpose vaccines (i.e., DTaP, hepatitis B, Hib, pneumococcal, polio, or rotavirus) are administered at the same visit.

Reference 42 U.S.C. §300aa-26

February 22, 2012

*Legal representative* is defined as a parent or other individual who is qualified under State law to consent to the immunization of a minor child or incompetent adult.

†In the case of an incompetent adult, relevant VISs shall be provided to the individual’s legal representative. If the incompetent adult is living in a long-term care facility, all relevant VISs may be provided at the time of admission, or at the time of consent if later than admission, rather than prior to each vaccination.
Vaccine Information Statements: Frequently Asked Questions

Are VISs "informed consent" forms?

No. People sometimes use the term “informed consent” loosely when referring to VISs.

There is no Federal requirement for informed consent. VISs are written to fulfill the information requirements of the National Childhood Vaccine Injury Act (NCVIA). But because they cover both benefits and risks associated with vaccinations, they provide enough information that anyone reading them should be adequately informed. Some states have informed consent laws. Check your state medical consent law to determine if there are any specific informed consent requirements relating to immunization. VISs can be used for informed consent as long as they conform to the appropriate state laws.

Should the VISs be used for adults getting vaccines as well as for children?

Yes. Under the NCVIA, anyone receiving a covered vaccine should be given the appropriate VIS. VISs for vaccines that may be administered to both children and adults are worded so they may be used by both. Apart from legal requirements, it is good practice to give the appropriate VIS every time a vaccine is administered, to anyone of any age.

The law states that vaccine information materials be given to a child’s legal representatives. How is "legal representative" defined?

A "legal representative" is a parent or other individual who is qualified under state law to consent to the immunization of a minor. There is not an overriding Federal definition.

Must the patient, parent, or legal representative physically take away a copy of each VIS, or can we simply let them read a copy and make sure they understand it?

Ideally each VIS should be taken home. They contain information that may be needed later (e.g., the recommended vaccine schedule, information about what to do in the case of an adverse reaction). Patients may choose not to take the VIS, but the provider should offer them the opportunity to do so.

When do providers have to start using a new VIS?

The date for a new VISs required use is announced when the final draft is published in the Federal Register. Ideally, providers will begin using a new VIS immediately,
particularly if the vaccine’s contraindications or adverse event profile have changed since the previous version.

**How should we comply with the law for patients who cannot read the VISs (e.g., those who are illiterate or blind)?**

The NCVIA allows providers to supplement the VISs with "visual presentations" or "oral explanations" as needed. VISs can be read to illiterate or blind patients, or videotapes can be used as supplements. At least one CD-ROM is being produced on which users can hear the VIS's read. The VISs available on CDC's website are compatible with screen reader devices.

**Why are the dates on some of the VISs so old? Are they obsolete? Why can’t they be updated every year?**

VISs are updated only when they need to be. For instance, a VIS would be updated if there were a change in ACIP recommendations that affects the vaccine’s adverse event profile, indications, or contraindications. VISs posted on the NIP website are always be the current versions. Annually changing the dates on VISs that haven’t changed otherwise could be confusing, because there would be multiple VISs in circulation that were identical but would have different dates.

**Sometimes a VIS will contain a recommendation that is at odds with the manufacturer's package insert. Why?**

VISs are based on the ACIP’s recommendations, which occasionally differ from those made by the manufacturer. These differences may involve adverse events. Package inserts generally tend to include all adverse events that were temporally associated with a vaccine during clinical trials, whereas ACIP tends to recognize only those shown to be causally linked to the vaccine. ACIP may also harmonize recommendations for similar vaccines produced by different manufacturers, for which approved indications differ slightly.

**What is the reading level of VISs?**

VIS’s generally test at about a 10th grade reading level, according to Fletch-Kincaid. However, traditional “grade level” measures may be somewhat misleading for VISs. In what may be a more useful indicator of readability, several VISs have been subjected to focus group testing among low-literacy parents in a variety of racial and ethnic groups (some not native English speakers), and were generally judged to be easy to read and understand. VISs are always reviewed for readability, within the constraints imposed by the need for technical accuracy.
How should we distribute VISs when the parent or legal representative of a minor is not present at the time the vaccination is given, for example during a school-based adolescent vaccination program?

CDC’s legal advisors have proposed two alternatives for this situation

- **Consent Prior to Administration of Each Dose of a Series.** With this alternative the VIS must be mailed or sent home with the student around the time of administration of each dose. Only those children for whom a signed consent is returned may be vaccinated. The program must place the signed consent in the patient's medical record.

- **Single Signature for Series.** This alternative is permissible only in those States where a single consent to an entire vaccination series is allowed under State law and in those schools where such a policy would be acceptable. The first dose of vaccine may be administered only after the parent or legal representative receives a copy of the VIS and signs and returns a statement that a) acknowledges receipt of the VIS and provides permission for their child to be vaccinated with the complete series of the vaccine (if possible, list the approximate dates of future doses) and b) acknowledges their acceptance of the following process regarding administration of additional doses

Prior to administration of each dose following the initial dose, a copy of the VIS will be mailed to the parent (or legal representative) who signs the original consent at the address they provide on this statement, or the VIS will be sent home with the student and

The vaccine information statements for the additional doses will be accompanied by a statement notifying the parent that, based on their earlier permission, the next dose will be administered to their child (state the date), unless the parent returns a portion of this statement by mail to an address provided, to arrive prior to the intended vaccination date, in which the parent withdraws permission for the child to receive the remaining dose.

The program must maintain the original consent signature and any additional dose veto statements in the patient's medical record. A record must be kept of the dates prior to additional doses that the VIS was mailed, or sent home with the adolescent.

Prior to administration of each additional dose, the provider should ask the adolescent whether he/she experienced any significant adverse events following receipt of earlier doses. If yes, the provider should consider consulting the parent or delaying the vaccination. The adolescent's response to questions about adverse reactions to previous doses should be kept in the medical record.
Questions concerning the Pediatric Multi-Vaccine VIS:

**May the existing, single-vaccine VISs still be used?**

Yes. The Multi-Vaccine VIS is an optional alternative to existing VISs. Providers wishing to continue using the individual VISs may do so. These will continue to be updated when recommendations change.

**May the Multi-Vaccine VIS be used with combination vaccines, such as Pediarix or Comvax?**

Yes. Just check the appropriate boxes on the first page as you would if you were administering the individual vaccines.

**When we record the edition date of the VISs on the patient’s medical record, do we record the date on the Multi-Vaccine VIS or the dates on the individual VISs?**

Record the date of the Multi-Vaccine VIS for each vaccine given. If there is ever a question, this will make it clear that this VIS was used, and not the individual VISs.

**Can the Multi-Vaccine VIS be used for children older than 6 months, or for adolescents or adults getting any of these vaccines?**

It may be used for older children getting two or more of these vaccines during the same visit (e.g., a 1-month old getting Hib and PCV or a 6-year old getting DTaP and IPV). It should not be used for adolescents or adults.

**Can the Multi-Vaccine VIS be used for catch-up doses?**

Yes, as long as the doses are given to children as part of the primary series or routine pediatric boosters.

**If a single-vaccine VIS is updated before the Multi-Vaccine VIS, may the multi continue to be used for that vaccine?**

Sometimes there can be delays in updating a VIS. If an individual VIS for a vaccine covered on the multi gets updated before the multi does, the multi may still be used. You may give the patient the new single VIS at the same time, or explain verbally or with other written materials any changes. This is most important if the changes involve contraindications or adverse events in these cases be certain the patient gets up-to-date information. It is less important if the update reflects other changes, such as changes in the routine schedule.
CDC’s Vaccine Information Statement Webpage
http://www.cdc.gov/vaccines/pubs/vis/default.htm

Vaccines & Immunizations
Vaccine Information Statements
At a glance:

Downloadable VISs:

Related Pages

Edition date.

HPV (Human Papillomavirus Vaccine) (2/22/12)
- HPV (Gardasil) [PDF-159KB] UPDATED
  - Do you still see the "old" edition?
- HPV (Cervarix)
- Other languages (including Spanish)

Influenza Vaccine - Live, Intranasal (7/26/11)
- Live, Intranasal FLU [PDF-113KB]

Go to Immunization Action Coalition site to access translations.

Jump to any VIS.

Learn about new VISs, upcoming VISs, other items of interest.

Download VIS Instructions

Get on mailing list for VIS updates.

If you download a new VIS and still get the previous version, click here.
Some immunizers maintain a small supply of VIS for the vaccines that they administer on hand. A color coding system can facilitate distribution of VIS. For example, trivalent inactivated influenza vaccine VIS can be printed on white paper, live attenuated influenza vaccine VIS can be printed on light blue paper, and zoster vaccine VIS is printed on yellow paper. Other immunizer print the VIS when a patient presents for immunization.

BEFORE ADVANCING: Complete Item 4 on the Immunization Implementation Plan

Recordkeeping

Immunization recordkeeping is particularly important as for many vaccines a single lifetime dose is all that is needed. No single repository of immunization records exists. However, immunization information systems are a step in that direction. Immunization information systems, also known as immunization registries, are confidential, population-based computerized systems that are being implemented in all states or public health jurisdictions to facilitate immunization recordkeeping for patients and providers and to allow healthcare providers to share immunization information. Most systems are web-based but have been designed for an individual jurisdiction. The National Vaccine Advisory Committee (NVAC) began the Initiative on Immunization Registries in 1998 to aid in the development of registries in the United States. One of the primary goals of immunization registry use is to reach and maintain high immunization coverage levels. Therefore, all registries should have the ability to reconcile an individual record with the current immunization schedule and identify vaccines or doses of vaccines within a series that may be needed.

Although immunization registries focus on childhood immunization, 70% of registries report the ability to track immunizations for all ages. The availability of reliable, readily accessible immunization records for adults facilitates clinical decision making and minimizes unnecessary reimmunization. Recording hepatitis A, hepatitis B, human papillomavirus, pneumococcal polysaccharide, tetanus/diphtheria or tetanus/diphtheria/acellular pertussis, and zoster vaccines for adults in a lifetime record that can be easily shared by all providers is an essential component of immunization delivery. Immunizing pharmacists should incorporate the use of immunization registries into their practices now or as soon as the registry in their state or jurisdiction can accommodate providers of adult immunizations. Pharmacists can contact their state immunization program for information on how to gain access to the immunization registry. Generally, only a computer, internet access, and a little training are required.

Recordkeeping requirements may vary by state so each pharmacy-based immunization program should assure that its recordkeeping plan is in compliance. In the absence of specific or less stringent guidelines, immunizers should record the vaccine, date administered, site of administration, vaccine manufacturer and lot number, VIS publication date and date given to the patient/parent or guardian, and the identification of the person administering the vaccine. Many pharmacists use their dispensing software for immunization records. They are
then integrated with the other patient-specific records for that individual. Electronic records are searchable, and reports can be generated. Records should be maintained as long as possible, and at a minimum, as long as pharmacy records are required by the state.

Any recordkeeping system used in the pharmacy should include a system for scheduling visits for all doses in a vaccine series or for return visits that might be needed in the event of a temporary deferral. A temporary deferral may be needed if the vaccine supply is exhausted or if the individual has a temporary contraindication to immunization (e.g. short term immunosuppression or pregnancy). The system can be as simple as a calendar with a task for pharmacy staff to call a patient to remind them to return for the next dose. An appointment system can be used such that when the patient receives a dose during a visit, an appointment for the next dose is made with a written reminder given to the patient.⁸

All patients should receive a personal record of their immunization. Immunization cards are available from state immunization programs or the Immunization Action Coalition (www.immunize.org). Additionally, if a patient identifies a primary care provider, a record of the immunization can be sent to that individual as well.⁹

BEFORE ADVANCING: Complete Item 5 on the Immunization Implementation Plan

Vaccine Information Resources

Finding Reliable Resources

Immunization information changes rapidly. Pharmacists must develop a strategy to keep up with the current immunization recommendations. The Advisory Committee on Immunization Practices makes reliable and widely accepted recommendations for immunization in the United States. The committee’s recommendations are published in Morbidity and Mortality Weekly Report (MMWR) and indexed on the Centers for Disease Control and Prevention Vaccine & Immunization page and the Immunization Action Coalition website.
### Item 9

**Recommended Electronic Sources for Vaccine Information**

<table>
<thead>
<tr>
<th>Site</th>
<th>Address</th>
<th>Content</th>
</tr>
</thead>
<tbody>
<tr>
<td>CDC</td>
<td><a href="http://www.cdc.gov">www.cdc.gov</a></td>
<td>Current information that is rapidly posted; for healthcare professional and public; contains information on most public health topics</td>
</tr>
<tr>
<td>CDC’s Vaccines &amp; Immunization</td>
<td><a href="http://www.cdc.gov/vaccines">http://www.cdc.gov/vaccines</a></td>
<td>CDC’s site for comprehensive immunization information; ACIP Recommendations and Reports, storage, safety, immunization program resources, education and training; resources for the public</td>
</tr>
<tr>
<td>Immunization Action Coalition</td>
<td><a href="http://www.immunize.org">www.immunize.org</a></td>
<td>Nonprofit organization with information promoting immunization and the appropriate use of vaccines; ACIP statement index; many handouts for patients including Vaccine Information Statements in multiple languages; educational handouts for staff; reference collections</td>
</tr>
<tr>
<td>National Foundation for Infectious Diseases</td>
<td><a href="http://www.nfid.org">www.nfid.org</a></td>
<td>Professional and patient resources designed to promote immunization throughout lifetime</td>
</tr>
<tr>
<td>National Network for Immunization Information</td>
<td><a href="http://www.immunizationinfo.org">www.immunizationinfo.org</a></td>
<td>Vaccine information, primarily childhood, compiled by an independent panel of experts for health professionals and patients</td>
</tr>
</tbody>
</table>

### Recommended Electronic Newsletters and Listservs

<table>
<thead>
<tr>
<th>Newsletter</th>
<th>Address</th>
<th>Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Morbidity and Mortality Weekly Report</td>
<td><a href="http://www.cdc.gov/mmwr">www.cdc.gov/mmwr</a></td>
<td>Click on “Free Subscription”</td>
</tr>
<tr>
<td>Immunization Action Coalition’s Immunize Express</td>
<td><a href="mailto:express@immunize.org">express@immunize.org</a></td>
<td>Type “subscribe” in the subject field</td>
</tr>
<tr>
<td>APhA Immunizing Pharmacists</td>
<td><a href="mailto:apha-immpharm-subscribe@yahooogroups.com">apha-immpharm-subscribe@yahooogroups.com</a></td>
<td>Send an email message to this address</td>
</tr>
</tbody>
</table>

**Abbreviations Used:** CDC, Centers for Disease Control and Prevention; ACIP, Advisory Committee on Immunization Practices
Another excellent resource for immunization information is the textbook, Epidemiology and Prevention of Vaccine Preventable Diseases. This text is often called “the Pink Book.” The chapters and appendices of the book are available on the CDC Vaccine & Immunization Web site. Individual chapters and the appendices can be downloaded or printed at no charge. The softbound print version of the book is available for $35. A new edition is published about every two years so it remains quite current.

Many immunizers depend on electronic newsletters to update them on new developments. Morbidity and Mortality Weekly Report is now published only electronically. Individuals can subscribe at no cost (Item 9). This electronic publication contains information on all public health topics. The table of contents can sent by email and it contains active links to the full text of each of the articles in the issue. If the reader sees no topics of interest, the message can just be deleted. The IAC Express is an electronic newsletter that is devoted to vaccines and vaccine-preventable diseases (Item 9). Many of the immunization news items in MMWR will be reprinted in the IAC Express. Again, the table of contents appears at the beginning of the message so that users can quickly determine if they have interest in the news items.

BEFORE ADVANCING: Complete Item 6 on the Immunization Implementation Plan

Bloodborne Pathogens Exposure Control

Immunization is a relatively low risk activity for bloodborne pathogens exposure. However because a risk exists, every pharmacy providing immunization services must have a bloodborne pathogens exposure control plan and provide engineering controls to minimize exposure. Pharmacies that are part of other entities or pharmacies providing point of service testing may already have a bloodborne pathogens exposure control plan. In this case, a review is needed to assure that it covers exposures associated with immunization and that the staff is aware of the plan.

The Occupational Safety and Health Administration (OSHA) is the main authority providing guidance on minimizing exposure. A state department of labor or a similar state organization may also have some oversight. Although a pharmacy may be subject to a variety of OSHA requirements, the focus of this module will be bloodborne pathogens exposure as this activity may bring exposures to which pharmacy staff may not have been previously subject. OSHA has a model exposure control plan template that can be used to cover immunization activities.

BEFORE ADVANCING: Working through the Model Exposure Control Plan (excerpts taken from http://www.osha.gov/Publications/osha3186.html) (following pages) will result in the completion of Item 7 on the Immunization Implementation Plan
Model Exposure Control Plan

http://www.osha.gov/Publications/osha3186.html

Part 1 Bloodborne Pathogens Standard

The following model for an Exposure Control Plan includes all elements required by the OSHA bloodborne pathogens standard (29 CFR 1910.1030). The intent of this model is to provide employers with an easy-to-use format that may be used as a template to develop a written exposure control plan tailored to the individual requirements of their establishments.

Model Exposure Control Plan

POLICY

The (Your facility name) is committed to providing a safe and healthful work environment for our entire staff. In pursuit of this goal, the following exposure control plan (ECP) is provided to eliminate or minimize occupational exposure to bloodborne pathogens in accordance with OSHA standard 29 CFR 1910.1030, "Occupational Exposure to Bloodborne Pathogens."

The ECP is a key document to assist our organization in implementing and ensuring compliance with the standard, thereby protecting our employees. This ECP includes:

- Determination of employee exposure
- Implementation of various methods of exposure control, including:
  - Universal precautions
  - Engineering and work practice controls
  - Personal protective equipment
  - Housekeeping
- Hepatitis B vaccination
- Post-exposure evaluation and follow-up
- Communication of hazards to employees and training
- Recordkeeping
- Procedures for evaluating circumstances surrounding exposure incidents

Implementation methods for these elements of the standard are discussed in the subsequent pages of this ECP.

PROGRAM ADMINISTRATION

- (Name of responsible person or department) is (are) responsible for implementation of the ECP. (Name of responsible person or department) will maintain, review, and update the ECP at least annually, and whenever necessary to include new or modified tasks and procedures. Contact location/phone number: __________.
Those employees who are determined to have occupational exposure to blood or other potentially infectious materials (OPIM) must comply with the procedures and work practices outlined in this ECP.

(Name of responsible person or department) will provide and maintain all necessary personal protective equipment (PPE), engineering controls (e.g., sharps containers), labels, and red bags as required by the standard. (Name of responsible person or department) will ensure that adequate supplies of the aforementioned equipment are available in the appropriate sizes. Contact location/phone number: __________.

(Name of responsible person or department) will be responsible for ensuring that all medical actions required by the standard are performed and that appropriate employee health and OSHA records are maintained. Contact location/phone number: __________.

(Name of responsible person or department) will be responsible for training, documentation of training, and making the written ECP available to employees, OSHA, and NIOSH representatives. Contact location/phone number: __________.

EMPLOYEE EXPOSURE DETERMINATION

The following is a list of all job classifications at our establishment in which all employees have occupational exposure:

<table>
<thead>
<tr>
<th>Job Title</th>
<th>Department/Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Example: Phlebotomists)</td>
<td>(Clinical Lab)</td>
</tr>
</tbody>
</table>

(use as many lines as necessary)

The following is a list of job classifications in which some employees at our establishment have occupational exposure. Included is a list of tasks and procedures, or groups of closely related tasks and procedures, in which occupational exposure may occur for these individuals:

Example:

<table>
<thead>
<tr>
<th>Job Title</th>
<th>Department/Location</th>
<th>Task/Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Housekeeper</td>
<td>Environmental Services</td>
<td>Handling Regulated Waste</td>
</tr>
</tbody>
</table>

(use as many lines as necessary)

NOTE: Part-time, temporary, contract and per diem employees are covered by the bloodborne pathogens standard. The ECP should describe how the standard will be met for these employees.

METHODS OF IMPLEMENTATION AND CONTROL

Universal Precautions All employees will utilize universal precautions.
Exposure Control Plan Employees covered by the bloodborne pathogens standard receive an explanation of this ECP during their initial training session. It will also be reviewed in their annual refresher training. All employees can review this plan at any time during their work shifts by contacting (Name of responsible person or department). If requested, we will provide an employee with a copy of the ECP free of charge and within 15 days of the request.

(Name of responsible person or department) is responsible for reviewing and updating the ECP annually or more frequently if necessary to reflect any new or modified tasks and procedures that affect occupational exposure and to reflect new or revised employee positions with occupational exposure.

Engineering Controls and Work Practices Engineering controls and work practice controls will be used to prevent or minimize exposure to bloodborne pathogens. The specific engineering controls and work practice controls used are listed below:

(For example: non-glass capillary tubes, SESIPs, needleless systems)

Sharps disposal containers are inspected and maintained or replaced by (Name of responsible person or department) every (list frequency) or whenever necessary to prevent overfilling.

This facility identifies the need for changes in engineering controls and work practices through (Examples: Review of OSHA records, employee interviews, committee activities, etc.)

We evaluate new procedures and new products regularly by (Describe the process, literature reviewed, supplier info, products considered)

Both front-line workers and management officials are involved in this process in the following manner: (Describe employees' involvement)

(Name of responsible person or department) is responsible for ensuring that these recommendations are implemented.

Personal Protective Equipment (PPE) PPE is provided to our employees at no cost to them. Training in the use of the appropriate PPE for specific tasks or procedures is provided by (Name of responsible person or department).

The types of PPE available to employees are as follows:

(gloves, eye protection, etc.)

PPE is located (List location) and may be obtained through (Name of responsible person or department). (Specify how employees will obtain PPE and who is responsible for ensuring that PPE is available.)
All employees using PPE must observe the following precautions:

- Wash hands immediately or as soon as feasible after removing gloves or other PPE.
- Remove PPE after it becomes contaminated and before leaving the work area.
- Used PPE may be disposed of in (List appropriate containers for storage, laundering, decontamination, or disposal.)
- Wear appropriate gloves when it is reasonably anticipated that there may be hand contact with blood or OPIM, and when handling or touching contaminated items or surfaces; replace gloves if torn, punctured or contaminated, or if their ability to function as a barrier is compromised.
- Utility gloves may be decontaminated for reuse if their integrity is not compromised; discard utility gloves if they show signs of cracking, peeling, tearing, puncturing, or deterioration.
- Never wash or decontaminate disposable gloves for reuse.
- Wear appropriate face and eye protection when splashes, sprays, spatters, or droplets of blood or OPIM pose a hazard to the eye, nose, or mouth.
- Remove immediately or as soon as feasible any garment contaminated by blood or OPIM, in such a way as to avoid contact with the outer surface.

The procedure for handling used PPE is as follows:

(may refer to specific procedure by title or number and last date of review; include how and where to decontaminate face shields, eye protection, resuscitation equipment)

Housekeeping Regulated waste is placed in containers which are closable, constructed to contain all contents and prevent leakage, appropriately labeled or color-coded (see the following section "Labels"), and closed prior to removal to prevent spillage or protrusion of contents during handling.

The procedure for handling sharps disposal containers is: (may refer to specific procedure by title or number and last date of review)

The procedure for handling other regulated waste is: (may refer to specific procedure by title or number and last date of review)

Contaminated sharps are discarded immediately or as soon as possible in containers that are closable, puncture-resistant, leak proof on sides and bottoms, and appropriately labeled or color-coded. Sharps disposal containers are available at (must be easily accessible and as close as feasible to the immediate area where sharps are used).
Bins and pails (e.g., wash or emesis basins) are cleaned and decontaminated as soon as feasible after visible contamination.

Broken glassware that may be contaminated is only picked up using mechanical means, such as a brush and dustpan.

**Laundry** The following contaminated articles will be laundered by this company:

Laundering will be performed by *(Name of responsible person or department)* at (time and/or location).

The following laundering requirements must be met:

- handle contaminated laundry as little as possible, with minimal agitation
- place wet contaminated laundry in leak-proof, labeled or color-coded containers before transport. Use (specify either red bags or bags marked with the biohazard symbol) for this purpose.
- wear the following PPE when handling and/or sorting contaminated laundry: *(List appropriate PPE)*

**Labels** The following labeling methods are used in this facility:

*Equipment to be Labeled*  
*Label Type (size, color)*  
*(specimens, contaminated laundry, etc.)* (red bag, biohazard label)

*(Name of responsible person or department)* is responsible for ensuring that warning labels are affixed or red bags are used as required if regulated waste or contaminated equipment is brought into the facility. Employees are to notify *(Name of responsible person or department)* if they discover regulated waste containers, refrigerators containing blood or OPIM, contaminated equipment, etc., without proper labels.

**HEPATITIS B VACCINATION**

*(Name of responsible person or department)* will provide training to employees on hepatitis B vaccinations, addressing safety, benefits, efficacy, methods of administration, and availability.

The hepatitis B vaccination series is available at no cost after initial employee training and within 10 days of initial assignment to all employees identified in the exposure determination section of this plan. Vaccination is encouraged unless: 1) documentation exists that the employee has previously received the series; 2) antibody testing reveals that the employee is immune; or 3) medical evaluation shows that vaccination is contraindicated.

However, if an employee declines the vaccination, the employee must sign a declination form.
Employees who decline may request and obtain the vaccination at a later date at no cost. Documentation of refusal of the vaccination is kept at (List location).

Vaccination will be provided by (List health care professional responsible for this part of the plan) at (location).

Following the medical evaluation, a copy of the health care professional's written opinion will be obtained and provided to the employee within 15 days of the completion of the evaluation. It will be limited to whether the employee requires the hepatitis vaccine and whether the vaccine was administered.

POST-EXPOSURE EVALUATION AND FOLLOW-UP

Should an exposure incident occur, contact (Name of responsible person) at the following number ____________________.

An immediately available confidential medical evaluation and follow-up will be conducted by (name of licensed health care professional). Following initial first aid (clean the wound, flush eyes or other mucous membrane, etc.), the following activities will be performed:

- Document the routes of exposure and how the exposure occurred.
- Identify and document the source individual (unless the employer can establish that identification is infeasible or prohibited by state or local law).
- Obtain consent and make arrangements to have the source individual tested as soon as possible to determine HIV, HCV, and HBV infectivity; document that the source individual's test results were conveyed to the employee's health care provider.
- If the source individual is already known to be HIV, HCV and/or HBV positive, new testing need not be performed.
- Assure that the exposed employee is provided with the source individual's test results and with information about applicable disclosure laws and regulations concerning the identity and infectious status of the source individual (e.g., laws protecting confidentiality).
- After obtaining consent, collect exposed employee's blood as soon as feasible after exposure incident, and test blood for HBV and HIV serological status.
- If the employee does not give consent for HIV serological testing during collection of blood for baseline testing, preserve the baseline blood sample for at least 90 days; if the exposed employee elects to have the baseline sample tested during this waiting period, perform testing as soon as feasible.

ADMINISTRATION OF POST-EXPOSURE EVALUATION AND FOLLOW-UP

(Name of responsible person or department) ensures that health care professional(s) responsible for employee's hepatitis B vaccination and post-exposure evaluation and follow-up are given a copy of OSHA's bloodborne pathogens standard.

(Name of responsible person or department) ensures that the health care professional evaluating an employee after an exposure incident receives the following:

Comment [m23]: The verbiage for the declination of hepatitis B vaccine series is at end of the template. Identify the location where the record will be kept.

Comment [m24]: Identify place for immunization services which certainly could be the pharmacy for which this plan covers. The administration of hepatitis B vaccine must be included in the immunization protocol.

Comment [m25]: Identify an individual

Comment [m26]: Identify an individual

Comment [m27]: Identify an individual. A pharmacy may wish to make arrangements to refer an exposed employee to a local hospital employee health service or occupational health specialist. However, the employee's personal physician could be used too.
• a description of the employee’s job duties relevant to the exposure incident
• route(s) of exposure
• circumstances of exposure
• if possible, results of the source individual’s blood test
• relevant employee medical records, including vaccination status

(Name of responsible person or department) provides the employee with a copy of the evaluating health care professional’s written opinion within 15 days after completion of the evaluation.

PROCEDURES FOR EVALUATING THE CIRCUMSTANCES SURROUNDING AN EXPOSURE INCIDENT

(Name of responsible person or department) will review the circumstances of all exposure incidents to determine:

• engineering controls in use at the time
• work practices followed
• a description of the device being used (including type and brand)
• protective equipment or clothing that was used at the time of the exposure incident (gloves, eye shields, etc.)
• location of the incident (O.R., E.R., patient room, etc.)
• procedure being performed when the incident occurred
• employee’s training

(Name of Responsible Person) will record all percutaneous injuries from contaminated sharps in a Sharps Injury Log.

If revisions to this ECP are necessary (Responsible person or department) will ensure that appropriate changes are made. (Changes may include an evaluation of safer devices, adding employees to the exposure determination list, etc.)

EMPLOYEE TRAINING

All employees who have occupational exposure to bloodborne pathogens receive initial and annual training conducted by (Name of responsible person or department). (Attach a brief description of their qualifications.)

All employees who have occupational exposure to bloodborne pathogens receive training on the epidemiology, symptoms, and transmission of bloodborne pathogen diseases. In addition, the training program covers, at a minimum, the following elements:

• a copy and explanation of the OSHA bloodborne pathogen standard
• an explanation of our ECP and how to obtain a copy
• an explanation of methods to recognize tasks and other activities that may involve exposure to blood and OPIM, including what constitutes an exposure incident
• an explanation of the use and limitations of engineering controls, work practices, and PPE
• an explanation of the types, uses, location, removal, handling, decontamination, and disposal of PPE
• an explanation of the basis for PPE selection
• information on the hepatitis B vaccine, including information on its efficacy, safety, method of administration, the benefits of being vaccinated, and that the vaccine will be offered free of charge
• information on the appropriate actions to take and persons to contact in an emergency involving blood or OPIM
• an explanation of the procedure to follow if an exposure incident occurs, including the method of reporting the incident and the medical follow-up that will be made available
• information on the post-exposure evaluation and follow-up that the employer is required to provide for the employee following an exposure incident
• an explanation of the signs and labels and/or color coding required by the standard and used at this facility
• an opportunity for interactive questions and answers with the person conducting the training session.

Training materials for this facility are available at (name location).

RECORDKEEPING

Training Records Training records are completed for each employee upon completion of training. These documents will be kept for at least three years at (Location of records).

The training records include:

• the dates of the training sessions
• the contents or a summary of the training sessions
• the names and qualifications of persons conducting the training
• the names and job titles of all persons attending the training sessions

Employee training records are provided upon request to the employee or the employee's authorized representative within 15 working days. Such requests should be addressed to (Name of responsible person or department).

Medical Records

Medical records are maintained for each employee with occupational exposure in accordance with 29 CFR 1910.1020, "Access to Employee Exposure and Medical Records."

(Name of responsible person or department) is responsible for maintenance of the required medical records. These confidential records are kept in (List location) for at least the duration of employment plus 30 years.

Employee medical records are provided upon request of the employee or to anyone having written consent of the employee within 15 working days. Such requests should be sent to (Name of responsible person or department and address).
**OSHA Recordkeeping**
An exposure incident is evaluated to determine if the case meets OSHA’s Recordkeeping Requirements (29 CFR 1904). This determination and the recording activities are done by (Name of responsible person or department).

**Sharps Injury Log**
In addition to the 1904 Recordkeeping Requirements, all percutaneous injuries from contaminated sharps are also recorded in a Sharps Injury Log. All incidences must include at least:

- date of the injury
- type and brand of the device involved (syringe, suture needle)
- department or work area where the incident occurred
- explanation of how the incident occurred.

This log is reviewed as part of the annual program evaluation and maintained for at least five years following the end of the calendar year covered. If a copy is requested by anyone, it must have any personal identifiers removed from the report.

**HEPATITIS B VACCINE DECLINATION (MANDATORY)**

I understand that due to my occupational exposure to blood or other potentially infectious materials I may be at risk of acquiring hepatitis B virus (HBV) infection. I have been given the opportunity to be vaccinated with hepatitis B vaccine, at no charge to myself. However, I decline hepatitis B vaccination at this time. I understand that by declining this vaccine, I continue to be at risk of acquiring hepatitis B, a serious disease. If in the future I continue to have occupational exposure to blood or other potentially infectious materials and I want to be vaccinated with hepatitis B vaccine, I can receive the vaccination series at no charge to me.

Signed: (Employee Name) ______________  Date: ______________
Hepatitis B vaccine series must be offered to all employees with bloodborne pathogen exposure. Some new or current employees may have already received the vaccine series. In this case, the immunization record should be collected. Employees with bloodborne pathogens exposure, current or new, must be offered the vaccine series at no cost to them. OSHA requires that they undergo antibody testing 1-2 months after completing the vaccine series. Those who did not mount a protective response must be offered a second three-dose vaccine series. OSHA regulations do not require an antibody test following the second hepatitis B vaccine series.

Use of the following documents can help pharmacies prepare to provide immunization services and keep their employees safe.

References:
Sample Blood and Body Fluid Exposure Report Form

Facility name: ________________________________________

Name of exposed worker: Last ______________________ First: ______________________ ID #: ______________________

Date of exposure: __________ / __________ / __________ Time of exposure: __________:________ AM   PM (Circle)

Job title/occupation: ______________________ Department/work unit: ______________________

Location where exposure occurred: ____________________________________________________________

Name of person completing form: ____________________________________________________________

Section I. Type of Exposure (Check all that apply.)

☐ Percutaneous (Needle or sharp object that was in contact with blood or body fluids)  (Complete Sections II, III, IV, and V.)

☐ Mucocutaneous (Check below and complete Sections III, IV, and VI.)
    ☐ Mucous Membrane  ☐ Skin

☐ Bite (Complete Sections III, IV, and VI.)

Section II. Needle/Sharp Device Information
(If exposure was percutaneous, provide the following information about the device involved.)

Name of device: ________________________________________  ☐ Unknown/Unable to determine

Brand/manufacturer: ________________________________________  ☐ Unknown/Unable to determine

Did the device have a sharps injury prevention feature, i.e., a “safety device”?  
☐ Yes  ☐ No  ☐ Unknown/Unable to determine

If yes, when did the injury occur?  
☐ Before activation of safety feature was appropriate  ☐ Safety feature failed after activation
☐ During activation of the safety feature  ☐ Safety feature not activated
☐ Safety feature improperly activated  ☐ Other: ______________________________________

Describe what happened with the safety feature, e.g., why it failed or why it was not activated: ______________________________________

Section III. Employee Narrative (Optional)

Describe how the exposure occurred and how it might have been prevented:
____________________________________________________________________________________
____________________________________________________________________________________
____________________________________________________________________________________

NOTE: This is not a CDC or OSHA form. This form was developed by CDC to help healthcare facilities collect detailed exposure information that is specifically useful for the facilities’ prevention planning. Information on this page (#1) may meet OSHA sharps injury documentation requirements and can be copied and filed for purposes of maintaining a separate sharps injury log. Procedures for maintaining employee confidentiality must be followed.
Section IV. Exposure and Source Information

A. Exposure Details: (Check all that apply.)

1. Type of fluid or material (For body fluid exposures only, check which fluid in adjacent box.)

   - Blood/blood products
   - Visibly bloody body fluid*
   - Non-visibly bloody body fluid*
   - Visibly bloody solution (e.g., water used to clean a blood spill)

   *Identify which body fluid
   - Cerebrospinal
   - Urine
   - Synovial
   - Amniotic
   - Sputum
   - Peritoneal
   - Pericardial
   - Saliva
   - Semen/vaginal
   - Pleural
   - Feces/stool
   - Other/Unknown

2. Body site of exposure. (Check all that apply.)

   - Hand/finger
   - Eye
   - Mouth/nose
   - Face
   - Arm
   - Leg
   - Other (Describe: ____________________________)

3. If percutaneous exposure:

   Depth of injury (Check only one.)
   - Superficial (e.g., scratch, no or little blood)
   - Moderate (e.g., penetrated through skin, wound bled)
   - Deep (e.g., intramuscular penetration)
   - Unsure/Unknown

   Was blood visible on device before exposure?  
   - Yes
   - No
   - Unsure/Unknown

4. If mucous membrane or skin exposure: (Check only one.)

   Approximate volume of material
   - Small (e.g., few drops)
   - Large (e.g., major blood splash)

   If skin exposure, was skin intact?  
   - Yes
   - No
   - Unsure/Unknown

B. Source Information

1. Was the source individual identified?  
   - Yes
   - No
   - Unsure/Unknown

2. Provide the serostatus of the source patient for the following pathogens.

<table>
<thead>
<tr>
<th>Pathogen</th>
<th>Positive</th>
<th>Negative</th>
<th>Refused</th>
<th>Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV Antibody</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HCV Antibody</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HbsAg</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3. If known, when was the serostatus of the source determined?

   - Known at the time of exposure
   - Determined through testing at the time of or soon after the exposure
Section V. Percutaneous Injury Circumstances

A. What device or item caused the injury?

<table>
<thead>
<tr>
<th>Device/Item</th>
<th>Attached to</th>
<th>Unattached</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hollow-bore needle</td>
<td>Syringe, IV tubing, tube holder, or IV tubing</td>
<td></td>
</tr>
<tr>
<td>Prefilled cartridge syringe needle</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Winged steel needle</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IV stylet</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phlebotomy needle</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spinal or epidural needle</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bone marrow needle</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Biopsy needle</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Huber needle</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other type of hollow-bore needle</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hollow-bore needle, type unknown</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Suture needle</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glass</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Capillary tube</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pipette (glass)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Slide</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Specimen/test/vacuum</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other: __________________________</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

B. Purpose or procedure for which sharp item was used or intended.

(For one procedure type and complete information in corresponding box as applicable.)

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Type of Line</th>
<th>Type of Injection</th>
<th>Type of Blood Sampling</th>
</tr>
</thead>
<tbody>
<tr>
<td>Establish intravenous or arterial access</td>
<td>Peripheral</td>
<td>IM injection</td>
<td>Venipuncture</td>
</tr>
<tr>
<td>Access established intravenous or arterial line</td>
<td>Central</td>
<td>Epidural/spinal anesthesia</td>
<td>Arterial puncture</td>
</tr>
<tr>
<td>Injection through skin or mucous membrane</td>
<td>Other</td>
<td>Other ID/SQ injection</td>
<td>Umbilical vessel</td>
</tr>
<tr>
<td>Obtain blood specimen (through skin)</td>
<td></td>
<td>Other procedure</td>
<td>Arterial puncture</td>
</tr>
<tr>
<td>Other specimen collection</td>
<td></td>
<td>Unknown</td>
<td>Dialysis/AV fistula site</td>
</tr>
<tr>
<td>Sutting</td>
<td></td>
<td></td>
<td>Finger/heelstick</td>
</tr>
<tr>
<td>Cutting</td>
<td></td>
<td></td>
<td>Other blood sampling</td>
</tr>
<tr>
<td>Other procedure</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unknown</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
C. When and how did the injury occur? (From the left hand side of page, select the point during or after use that most closely represents when the injury occurred. In the corresponding right hand box, select one or two circumstances that reflect how the injury happened.)

- During use of the item
- After use, before disposal of item
- During or after disposal of item
- Other (Describe): ____________________________
  ________________________________________________________________________
  ________________________________________________________________________
  ________________________________________________________________________
- Unknown

Select one or two choices:
- Patient moved and jarred device
- While inserting needle/sharp
- While manipulating needle/sharp
- While withdrawing needle/sharp
- Passing or receiving equipment
- Suturing
- Tying sutures
- Manipulating suture needle in holder
- Incising
- Palpating/Exploring
- Collided with co-worker or other during procedure
- Collided with sharp during procedure
- Sharp object dropped during procedure

Select one or two choices:
- Handling equipment on a tray or stand
- Transferring specimen into specimen container
- Processing specimens
- Passing or transferring equipment
- Recapping (missed or pierced cap)
- Cap fell off after recapping
- Disassembling device or equipment
- Decontamination/processing of used equipment
- During clean-up
- In transit to disposal
- Opening/breaking glass containers
- Collided with co-worker/other person
- Collided with sharp after procedure
- Sharp object dropped after procedure
- Struck by detached IV line needle

Select one or two choices:
- Placing sharp in container:
  __ Injured by sharp being disposed
  __ Injured by sharp already in container
  __ While manipulating container
  __ Over-filled sharps container
  __ Punctured sharps container
  __ Sharp protruding from open container
  __ Sharp in unusual location:
    __ In trash
    __ In linen/laundry
    __ Left on table/tray
    __ Left in bed/mattress
    __ On floor
    __ In clothing
    __ In pocket/clothing
    __ Other unusual location
    __ Collided with co-worker or other person
    __ Collided with sharp
    __ Sharp object dropped
    __ Struck by detached IV line needle
Section VI. Mucous Membrane Exposures Circumstances

A. What barriers were used by worker at the time of the exposure? (Check all that apply.)

- [ ] Gloves
- [ ] Goggles
- [ ] Eyeglasses
- [ ] Face Shield
- [ ] Mask
- [ ] Gown

B. Activity/Event when exposure occurred (Check one.)

- [ ] Patient spit/coughed/vomited
- [ ] Airway manipulation (e.g., suctioning airway, inducing sputum)
- [ ] Endoscopic procedure
- [ ] Dental procedure
- [ ] Tube placement/removal/manipulation (e.g., chest, endotracheal, NG, rectal, urine catheter)
- [ ] Phlebotomy
- [ ] IV or arterial line insertion/removal/manipulation
- [ ] Irrigation procedure
- [ ] Vaginal delivery
- [ ] Surgical procedure (e.g., all surgical procedures including C-section)
- [ ] Bleeding vessel
- [ ] Changing dressing/wound care
- [ ] Manipulating blood tube/bottle/specimen container
- [ ] Cleaning/transporting contaminated equipment
- [ ] Other: __________________________________________________________
- [ ] Unknown

Comments:

____________________________________________________________________
____________________________________________________________________
____________________________________________________________________
____________________________________________________________________
____________________________________________________________________
____________________________________________________________________
____________________________________________________________________
____________________________________________________________________
____________________________________________________________________
____________________________________________________________________
Date

Dear (e.g., staff member, healthcare worker, employee):

[Name of organization] is conducting a survey to evaluate a device with an engineered sharps injury prevention feature. Your feedback on this product is important in order to identify safer devices that allow us to better serve our workforce.

Please complete the attached form, which will only take a few minutes. All of your responses are confidential. Once they are collected, there is no connection between your name and the survey you complete. Your responses will be combined with others in order to determine the acceptability of this new device.

If you need help completing this survey or have any questions, please ask __________. When you have completed the survey, please return it to ___________. Thank you in advance for providing this information.
### Sample Device Evaluation Form

**Product:** [Filled in by healthcare facility]  
**Date:** ________________________

**Department/ Unit:** _______________  
**Position/ Title:** _______________

1. **Number of times you used the device.**
   - □ 1-5  
   - □ 6-10  
   - □ 11-25  
   - □ 26-50  
   - □ More than 50

2. **Please mark the box that best describes your experiences with the device. If a question is not applicable to this device, do not fill in an answer for that question.**

<table>
<thead>
<tr>
<th>Patient/ Procedure Considerations</th>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Neither Agree nor Disagree</th>
<th>Agree</th>
<th>Strongly Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Needle penetration <strong>is</strong> comparable to the standard device.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
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<td>b. Patients/residents <strong>do not</strong> perceive more pain or discomfort with this device.</td>
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<td>c. Use of the device <strong>does not</strong> increase the number of repeat sticks of patient.</td>
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<tr>
<td>d. The device <strong>does not</strong> increase the time it takes to perform the procedure.</td>
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<tr>
<td>e. Use of the device <strong>does not</strong> require a change in procedural technique.</td>
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<tr>
<td>f. The device is compatible with other equipment that must be used with it.</td>
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<td>g. The device can be used for the same purposes as the standard device.</td>
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<tr>
<td>h. Use of the device <strong>is not</strong> affected by my hand size.</td>
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<tr>
<td>i. Age or size of patient/resident <strong>does not</strong> affect use of this device.</td>
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<tr>
<th>Experience with the Safety Feature</th>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Neither Agree nor Disagree</th>
<th>Agree</th>
<th>Strongly Agree</th>
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<td>j. The safety feature <strong>does not</strong> interfere with procedural technique.</td>
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<td>k. The safety feature is easy to activate.</td>
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<td>l. The safety feature <strong>does not</strong> activate before the procedure is completed.</td>
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<td>m. Once activated, the safety feature remains engaged.</td>
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<td>n. I <strong>did not</strong> experience any injury or near miss of injury with the device.</td>
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### Special Questions about this Particular Device

[To be added by healthcare facility]

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### Overall Rating

Overall, this device is effective for both patient/resident care and safety.

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3. **Did you participate in training on how to use this product?**
   - ☐ No (Go to question 6.)
   - ☐ Yes (Go to next question.)

4. **Who provided this instruction?** *(Check all that apply.)*
   - ☐ Product representative
   - ☐ Staff development personnel
   - ☐ Other_______________________

5. **Was the training you received adequate?**
   - ☐ No
   - ☐ Yes

6. **Was special training needed in order to use the product effectively?**
   - ☐ No
   - ☐ Yes

7. **Compared to others of your gender, how would you describe your hand size?**
   - ☐ Small
   - ☐ Medium
   - ☐ Large

8. **What is your gender?**
   - ☐ Female
   - ☐ Male

9. **Which of the following do you consider yourself to be?**
   - ☐ Left-handed
   - ☐ Right-handed

10. **Please add any additional comments below.**

______________________________________________________________________

**THANK YOU FOR COMPLETING THIS SURVEY**

Please return this form to: ________________________________________________________

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*Sharps Injury Prevention Workbook: A-13 Sample Device Evaluation Form*
Module 2
CASE STUDIES

These cases serve as a review of Module 2.

Case #1
Ray is a newly licensed pharmacist who has been given the responsibility of setting up a pharmacy-based immunization service for Red Pharmacy with three other pharmacists. The pharmacy plans to offer influenza, pneumococcal polysaccharide, and zoster vaccines to adults and expand to all vaccines over the next two years. What steps should he take to prepare the pharmacy? Address vaccine storage, information resource, and occupational safety.

Case #2
Joe is a 68 year old male who presents for a prescription refill at Red Pharmacy. Joe is a nurse at the local hospital. Ray offers immunization services to him. What screening questions should be utilized to determine immunization indications, contraindications, and precautions? Which immunizations would be indicated for Joe today?

What recordkeeping should be done with this immunization encounter?

Case #3
You are the primary vaccinating pharmacist at a local pharmacy. As you are checking your vaccine refrigerator temperatures in the morning, you notice that the temperature is at 50 degrees Fahrenheit. What are your next steps?
Module 2

CASE STUDIES ANSWERS

These case answers serve as a review of Module 2.

Case #1

Ray is a newly licensed pharmacist who has been given the responsibility of setting up a pharmacy-based immunization service for Red Pharmacy with three other pharmacists. The pharmacy plans to offer influenza, pneumococcal polysaccharide, and zoster vaccines to adults and expand to all vaccines over the next two years. What steps should he take to prepare the pharmacy? Address vaccine storage, information resource, and occupational safety.

Influenza and pneumococcal vaccines are refrigerated, and zoster vaccine must be stored frozen. A standard household refrigerator with a separate sealed freezer compartment or a commercial type refrigerator is acceptable. A separate freezer could be purchased. A dorm style refrigerator is not acceptable for vaccine storage. The storage equipment must not be used to store food or beverages. Prior to storing vaccine in the refrigerator or freezer, the temperature inside should be checked several times a day for several days. Module 6 will present additional vaccine storage tips, like keeping jugs of water in the refrigerator and ice packs in the freezer to help maintain temperature if the door is opened frequently or if the power goes out. An individual and at least one other person should be given primary responsibility for overseeing vaccine storage and handling. Full time pharmacy technicians may be specially suited for this task. He could be charged with putting away the vaccine order when it arrives, rotating stock, ordering vaccines when supplies are low, and checking the temperature in the refrigerator and freezer at least twice daily. That person could also develop and maintain an emergency storage plan in the event of prolonged power outage or other disaster.

Reliable vaccine information resources are available on the internet and published. The state in which the pharmacy is located may have specific education requirements for immunizing pharmacists. Compliance with these requirements may guide the choice of resources. The table from Module 2 can be used to bookmark a few immunization information sites. Ray could subscribe to both MMWR and IAC Express to keep himself up to date and plans to share information that will influence their practice with the other pharmacy staff.

The pharmacy needs a bloodborne pathogens exposure control plan. Ray checks with the state’s department of labor or equivalent organization to determine the requirements that could differ from the OSHA requirements outlined in Module 2. He used the model exposure control plan from Module 2 taking on primary responsibility for administration.
Immunization Administration Training for Pharmacists

Module 2
CASE STUDIES ANSWERS

These case answers serve as a review of Module 2.

and education. He decided that all four immunizing pharmacists would have input regarding choice of safety injection devices and sharps containers. The technician who is in charge of vaccine storage will be in charge of changing sharps containers and storing them in the back room until the waste disposal company picks them up. The immunizing pharmacists and the technician have bloodborne pathogens exposure and will require education and hepatitis B immunization. Ray set up an education session with the local hospital that already has an educational program for bloodborne pathogens annual training. He will maintain records of the training for the staff for at least 3 years. Ray, one other pharmacist and the technician have already received the hepatitis B vaccine series. Ray collects their immunization records and decides to keep them with their personnel files. Ray initiates hepatitis B vaccine series for the other two pharmacists. He gets a prescription from the physician who will sign the immunization protocol for the hepatitis B vaccine series because this vaccine is not included in the current protocol. He plans to check their vaccine responses 1-2 months after completing the vaccine series. If either of the pharmacists fails to respond, a second series will be completed.

Case #2

Joe is a 68 year old male who presents for a prescription refill at Red Pharmacy. Joe is a nurse at the local hospital. Ray offers immunization services to him. What screening questions should be utilized to determine immunization indications, contraindications, and precautions? Which immunizations would be indicated for Joe today.

The screening questionnaire for adult immunization should be utilized to identify contraindications and precautions for immunization for this patient and an immunization history should be elicited. The adult immunization schedule can be used to guide decisions on appropriate vaccines. Based on his age and being a healthcare worker, annual inactivated influenza vaccine or the high-dose influenza vaccine, a single pneumococcal polysaccharide vaccine, the hepatitis B vaccine series, and a single zoster vaccine are recommended. All vaccines may be administered on the same day as long as different needles and syringes are used and the injections are separated by 1 inch. He should also receive a single dose of tetanus-diphtheria-acellular pertussis (Tdap) now and a tetanus-diphtheria (Td) vaccine every 10 years. If he has received a pneumococcal vaccine since age 65 years, he would not need another dose. Since he was born prior to 1957, the MMR vaccine would not be indicated. The Vaccine Information Statements for each of the indicated vaccines should be given to the patient.
What recordkeeping should be done with this immunization encounter?

Immunization administration records should be maintained in the pharmacy in compliance with the state law or current standard of practice. Immunizers should record the vaccine, date administered, site of administration, vaccine manufacturer and lot number, VIS publication date and date given to the patient/parent or guardian, and the identification of the person administering the vaccine. The patient should be given a personal immunization record. If possible, the vaccines should be entered into the state’s immunization registry. The pharmacist should inform the patient’s physician or primary care provider by direct communication (email message, faxed or mailed letter). Alternatively, Ray could instruct the patient to show the physician his personal immunization record during his next clinic visit.

Case #3

You are the primary vaccinating pharmacist at a local pharmacy. As you are checking your vaccine refrigerator temperatures in the morning, you notice that the temperature is at 50 degrees Fahrenheit. What are your next steps?

The pharmacies emergency policy and procedure should be utilized. Determine if the refrigerator is not functioning properly due to the door being left ajar or accidentally being unplugged. The vaccines need to be moved to a refrigerator that is able to store them at the appropriate temperatures if the current refrigerator is not working properly. All vaccines should remain refrigerated until the health department or the vaccine manufacturers inform the pharmacy that they are unusable. Mark the vaccines so that the potentially compromised vaccines can be easily identified and do not use any of them until the state health department’s immunization program or the vaccine manufacturer gives approval. Call the manufacturers and notify the local or state health department. Record all of the actions taken on the emergency response worksheet.
Module 2
SELF-ASSESSMENT QUESTIONS

The self-assessment questions below address the information contained in Module 2. The questions will be the same questions as what will appear in the final examination for Immunization Fundamentals Modules 1-3.

1. Which of the following is true regarding the safe storage of vaccines?
   a. The temperature log is checked by the employee that thinks of it first each day
   b. Policies are developed on vaccine storage and kept in a binder for people to review as they feel necessary
   c. The vaccines that are utilized the most should be stored in the door of the refrigerator for easy access
   d. The refrigerator temperature is consistently maintained between 35 and 46 degrees Fahrenheit

2. Which of the following is appropriate for the storage and handling of zoster vaccine?
   a. Must be stored in the refrigerator
   b. May be refrigerated and used within 30 days of reconstitution
   c. Must be stored frozen, reconstituted with supplied diluent and used within 30 minutes
   d. Must be stored frozen but may be thawed and refrozen up to ten times

3. Which of the following describe appropriate storage conditions for inactivated vaccines?
   a. Must not be frozen
   b. Are stored at room temperature
   c. Are not affected by storage temperature
   d. Should be stored in the door of the refrigerator

4. Which of the following vaccines should NOT be stored frozen?
   a. Pneumococcal polysaccharide vaccine
   b. Varicella vaccine
   c. Zoster vaccine
   d. MMR vaccine
Module 2
SELF-ASSESSMENT QUESTIONS

5. Which of the following is an advantage of immunization in nontraditional settings, such as a pharmacy?
   a. Increased access and convenience for the patient
   b. Higher cost of immunization to the patient
   c. Consolidated immunization records for every patient
   d. Decreased public awareness regarding vaccinations

6. Which of the following describes the benefits of using standing orders for immunization?
   a. Makes immunization less costly
   b. Increases immunization coverage among adults in a variety of practice settings
   c. Limits liability of all healthcare providers
   d. Is generally perceived as substandard practice by immunization policy making bodies

7. Which of the following activities does the National Vaccine Advisory Committee urge all vaccinators in nontraditional settings to perform?
   a. Immunize all eligible patients, but provides no guidelines for recordkeeping
   b. Immunize only patients without a medical home
   c. Immunize all eligible patients and refer them to the physician who signed the protocol
   d. Immunize all eligible patients and assist those in need with the identification of a medical home

8. The freezer and refrigerator temperatures need to be checked once daily, first thing in the morning.
   a. True
   b. False
Module 2
SELF-ASSESSMENT QUESTIONS

9. Which of the following vaccines may be given to a pregnant female (>20 weeks’ gestation), when indicated?
   a. Measles vaccine
   b. Varicella vaccine
   c. Live attenuated influenza vaccine (LAIV)
   d. Tetanus, diphtheria, and acellular pertussis (Tdap)

10. Mike is a 32 year old male who suffered serious injuries in a car accident four days ago. He received fresh frozen plasma prior to going to surgery for an emergency splenectomy. Response to which of the following vaccines is most likely to be affected by this event?
   a. Varicella vaccine
   b. Pneumococcal polysaccharide vaccine
   c. Meningococcal conjugate vaccine
   d. Haemophilus influenza type b vaccine

11. For which of the following patients should inactivated influenza vaccination be deferred today?
   a. A 67 year old female who has just been diagnosed with hypertension and is starting hydrochlorothiazide
   b. A 73 year old male who is being discharged from the hospital following a COPD exacerbation
   c. A 62 year old male who is being admitted to the intensive care unit with pneumonia
   d. A 56 year old female who was started yesterday on a 7 day course of valacyclovir

12. Which of the following is true regarding Vaccine Information Statements (VIS)?
   a. The VIS can serve as the “informed consent” for vaccination
   b. They are meant to prevent questions to health care providers regarding vaccines
   c. They are updated every month
   d. They are designed to provide information about vaccines or, in the case of a minor, the child’s parent or guardian about the risks and benefits of each vaccine
Module 2

SELF-ASSESSMENT QUESTIONS

13. Which of the following is the appropriate strategy for giving the Vaccine Information Statement (VIS) to patients?
   a. The VIS should be given to patients 1 week prior to the immunization visit to allow time for review
   b. The VIS can be posted in the clinic for the patient to read while they wait
   c. The VIS should be given to the patient prior to immunization so the patient has time to review it and ask questions
   d. The VIS are required for only immunization of pediatric patients

14. Which of the following items should be included in immunization records for vaccines administered in the pharmacy?
   a. The vaccine and date administered, site of administration, vaccine manufacturer and lot number, VIS publication date with the date given to the patient/parent or guardian, and the identification of the person administering the vaccine
   b. The date administered, site of administration, vaccine manufacturer and lot number, and the VIS publication date with the date given to the patient/parent or guardian
   c. The vaccine and date administered, site of administration, and the site of vaccine storage, vaccine manufacturer and lot number, VIS publication date with the date given to the patient/parent or guardian
   d. The vaccine and date administered, vaccine manufacturer and lot number, and the VIS publication date with the date given to the patient/parent or guardian

15. Which of the following best describes immunization registries?
   a. All registries are used exclusively for tracking childhood immunizations
   b. All children born in the United States have their immunizations recorded in an immunization registry
   c. The value of the registry is that it allows all health care providers to access immunization records to facilitate clinical decision making
   d. Immunization registries are used only to measure immunization coverage rates
Module 2
SELF-ASSESSMENT QUESTIONS

16. The recommendations for prevention of vaccine preventable diseases made by the Advisory Committee on Immunization Practices (ACIP) are published in which of the following?
   a. The New England Journal of Medicine
   b. Morbidity and Mortality Weekly
   c. The Annals of Internal Medicine
   d. Immunofacts

17. Which of the following most accurately describes the federally-mandated training for employees with blood and body fluid exposure?
   a. Initial training and annual retraining are required for bloodborne pathogens
   b. Use of safer injection devices may be included in initial training only
   c. A handout alone can be used for retraining
   d. A standardized training program can be used for all employees with exposure

18. Which of the following is true regarding bloodborne pathogen exposure and immunizations?
   a. Providing immunizations is a high risk activity for exposure
   b. Every pharmacy providing immunizations must have a bloodborne pathogen exposure control plan
   c. No extra immunizations or training need to be offered to employees that provide immunizations
   d. The FDA is the main authority providing guidance on minimizing exposure

19. Which of the following should be completed in all pharmacies that provide immunizations?
   a. Recapping needles after immunizations are administered to prevent needlesticks
   b. Wearing gowns, masks, and goggles when giving vaccines
   c. Training employees about bloodborne pathogens and the pharmacies bloodborne exposure control plan
   d. Posting an orange biohazard symbol on the refrigerator door that is used to store vaccines

20. How should the disposal of sharps containers be handled?
   a. Arranged with the local waste management company
   b. Done when the container is full to the top
   c. Always taken care of with the regular garbage
   d. They are of little concern because of the puncture-proof nature of the containers
Module 3:
Vaccine Safety and Vaccine Adverse Events

Learning Objectives: At the conclusion of this module, pharmacists should able to:
1. Report an adverse event utilizing the Vaccine Adverse Event Reporting System (VAERS).
2. Describe the role of the Vaccine Injury Compensation Program.
3. Anticipate and manage common adverse events associated with vaccines and vaccination.
4. Develop an emergency plan for anaphylaxis associated with vaccine administration.
5. Discuss the safety of vaccines with patients, including how vaccines are developed and monitored to ensure their safety.

- Chapter 4: Vaccine Safety
- Appendix D-19 and D-22: Vaccine Administration, Medical Management of Vaccine Reactions, Children & Teens; Adults
- Appendix: Vaccine Safety

Vaccine Adverse Events

The immunization safety paradigm appropriately has little tolerance for risk. Vaccines are used to keep healthy people healthy. Vaccine safety is taken very seriously.
Vaccine Safety

Vaccine safety is a prime concern for the public, manufacturers, immunization providers, and recipients of vaccines. This chapter describes how vaccines licensed for use in the United States are monitored for safety, and presents general information about the provider’s role in immunization safety. Further information about contraindications and precautions for individual vaccines, such as pregnancy and immunosuppression, and about potential adverse events associated with the vaccine is contained in the chapter on General Recommendations on Immunization, and in the chapters on specific vaccines.

The Importance of Vaccine Safety Programs

Vaccination is among the most significant public health success stories of all time. However, like any pharmaceutical product, no vaccine is completely safe or completely effective. While almost all known vaccine adverse events are minor and self-limited, some vaccines have been associated with very rare but serious health effects. The following key considerations underscore the need for an active and ongoing vaccine safety program.

Decreases in Disease Risks

Today, vaccine-preventable diseases are at or near record lows. Many people no longer see reminders of the severity and potential life threatening complications of these diseases. Recent outbreaks of vaccine–preventable diseases show that even vaccinated people are at risk for disease if there is not adequate vaccine coverage in the population. At the same time, approximately 28,000 reports of adverse events following vaccination in the United States are received by the Vaccine Adverse Event Reporting System (VAERS) each year (these include both true adverse reactions and events that occur coincidentally after vaccination) (CDC unpublished data). As a result, parents and providers in the United States are more likely to know someone who has experienced an adverse event following immunization than they are to know someone who has experienced a vaccine-preventable disease. The success of vaccination has led to increased public attention on potential health risks associated with vaccines.

Public Confidence

Maintaining public confidence in immunizations is critical for preventing a decline in vaccination rates that can result in outbreaks of disease. While the majority of parents believe in the benefits of immunization and have their children vaccinated, some have concerns about the safety of vaccines. Public concerns about the safety of whole-cell
pertussis vaccine in the 1980s resulted in decreased vaccine coverage levels and the return of epidemic disease in Japan, Sweden, United Kingdom, and several other countries. In the United States, similar concerns led to increases both in the number of lawsuits against manufacturers and the price of vaccines, and to a decrease in the number of manufacturers willing to produce vaccines. Close monitoring and timely assessment of suspected vaccine adverse events can distinguish true vaccine reactions from coincidental unrelated events and help to maintain public confidence in immunizations.

A higher standard of safety is generally expected of vaccines than of other medical interventions because in contrast to most pharmaceutical products, which are administered to ill persons for curative purposes, vaccines are generally given to healthy persons to prevent disease. Public tolerance of adverse reactions related to products given to healthy persons, especially healthy infants and children, is substantially lower than for reactions to products administered to persons who are already sick. This lower tolerance of risk for vaccines translates into a need to investigate the possible causes of very rare adverse events following vaccinations.

Adding to public concern about vaccines is the fact that immunization is mandated by many state and local school entry requirements. Because of this widespread use, safety problems with vaccines can have a potential impact on large numbers of persons. The importance of ensuring the safety of a relatively universal human-directed “exposure” like immunizations is the basis for strict regulatory control of vaccines in the United States by the Food and Drug Administration (FDA).

**Sound Immunization Recommendations and Policy**

Public health recommendations for vaccine programs and practices represent a dynamic balancing of risks and benefits. Vaccine safety monitoring is necessary to accurately weigh this balance and adjust vaccination policy. This was done in the United States with smallpox and oral polio vaccines as these diseases neared global eradication. Complications associated with each vaccine exceeded the risks of the diseases, leading to discontinuation of routine smallpox vaccinations in the United States (prior to actual global eradication) and a shift to a safer inactivated polio vaccine. Sound immunization policies and recommendations affecting the health of the nation depend upon the ongoing monitoring of vaccines and continuous assessment of immunization benefits and risks.
Methods of Monitoring Vaccine Safety

Prelicensure
Vaccines, like other pharmaceutical products, undergo extensive safety and efficacy evaluations in the laboratory, in animals, and in sequentially phased human clinical trials prior to licensure. Phase I human clinical trials usually involve anywhere from 20 to 100 volunteers and focus on detecting serious side effects. Phase II trials generally enroll hundreds of volunteers. These trials might take a few months, or last up to 3 years. Phase II trials determine the best dose for effectiveness and safety and the right number of doses. Next, the vaccine moves into Phase III trials, which may last several years. A few hundred to several thousand volunteers may be involved. Some volunteers receive another already-licensed vaccine, allowing researchers to compare one vaccine with another for adverse health effects—anything from a sore arm to a serious reaction. If the vaccine is shown to be safe and effective in Phase III, the manufacturer applies for a license from the FDA. The FDA licenses the vaccine itself (the “product license”) and licenses the manufacturing plant where the vaccine will be made (the “establishment license”). During the application, the FDA reviews everything: the clinical trial results, product labeling, the manufacturing plant itself, and the manufacturing protocols.

FDA licensure occurs only after the vaccine has met rigorous standards of efficacy and safety, and when its potential benefits in preventing disease clearly outweigh any risks. However, while rates of common vaccine reactions, such as injection-site reactions and fever, can be estimated before licensure, the comparatively small number of patients enrolled in these trials generally limits detection of rare side effects or side effects that may occur many months after the vaccine is given. Even the largest prelicensure trials (more than 10,000 persons) are inadequate to assess the vaccine’s potential to induce possible rare side effects. Therefore, it is essential to monitor reports of vaccine-associated adverse events once the vaccine has been licensed and released for public use.

Fundamental to preventing safety problems is the assurance that any vaccines for public use are made using Good Manufacturing Practices and undergo lot testing for purity and potency. Manufacturers must submit samples of each vaccine lot and results of their own tests for potency and purity to the FDA before releasing them for public use.
Postlicensure

Because rare reactions, delayed reactions, or reactions within subpopulations may not be detected before vaccines are licensed, postlicensure evaluation of vaccine safety is critical. The objectives of postlicensure surveillance are to:

■ identify rare reactions not detected during prelicensure studies;

■ monitor increases in known reactions;

■ identify risk factors or preexisting conditions that may promote reactions;

■ identify whether there are particular vaccine lots with unusually high rates or certain types of events; and

■ identify signals of possible adverse reactions that may warrant further study or affect current immunization recommendations.

Historically, postlicensure monitoring of vaccine safety has relied on healthcare providers and the public to report side effects, and on “ad hoc” research studies to investigate possible rare associations between vaccines and identified health conditions of interest to scientists. Today, Phase IV trials and large-linked databases (LLDBs) have been added to improve the capability to study rare risks of specific immunizations. Phase IV studies can be an FDA requirement for licensure. These trials include tens of thousands of volunteers and may address questions of long-term effectiveness and safety or examine unanswered questions identified in Phase III clinical trials. In 2001, the Clinical Immunization Safety Assessment (CISA) Network was established which works to increase understanding of vaccine reactions at the individual patient level.

The Vaccine Adverse Event Reporting System

The National Childhood Vaccine Injury Act of 1986 mandated that healthcare providers who administer vaccines, and vaccine manufacturers report certain adverse health events following specific vaccinations. The Vaccine Adverse Event Reporting System (VAERS) is a national reporting system, jointly administered by CDC and FDA. VAERS was created in 1990 to unify the collection of all reports of adverse events after vaccination. VAERS is a passive reporting system and accepts reports from health professionals, vaccine manufacturers, and the general public. Reports are submitted via mail and fax as well as the Internet. All reports, whether submitted directly to VAERS or via state or local public health authorities or manufacturers, are coded and entered into the VAERS database. VAERS receives about 28,000 US reports per year.
(more than 371,000 as of December 31, 2010 [CDC unpublished data]). Though this seems like a very large number, it is relatively small compared with the approximately 100 million doses of childhood vaccines distributed during the past decade, as well as the millions of additional doses given to adults.

VAERS seeks to capture all clinically significant medical events occurring postvaccination, even if the reporter is not certain that the incident is vaccine related. Healthcare providers are encouraged to report to VAERS any clinically significant adverse events after immunization. From 2006 through 2010, US VAERS reports were received from healthcare providers (34.8%), manufacturers (26.1%), unknown or other reporters (24.5%), patients or parents (10.3%), and state and local health departments (4.4%).

Data collected on the VAERS reporting form include information about the patient, the vaccination(s) given, the reported health effect (called an adverse event—which may or may not be caused by vaccine), and the person reporting the event. Serious adverse event reports are defined as those involving hospitalization or prolongation of hospitalization, death, or reported life-threatening illness, permanent disability or congenital anomaly. All reports classified as serious are followed up to obtain additional medical information in order to provide as full a picture of the case as possible. For serious reports, letters to obtain information about recovery status are mailed to the reporters at 60 days and 1 year after vaccination. All records submitted to VAERS directly or as part of follow-up activities are protected by strict confidentiality requirements.

Despite some limitations, VAERS has been able to fulfill its primary purpose of detecting new or rare vaccine adverse events, increases in rates of known side effects, and patient risk factors for particular types of adverse events. Examples include tracking reports of intussusception after a rotavirus vaccine that is no longer used in the US, and tracking the syncope reports after adolescent vaccines. Additional studies are required to confirm signals detected by VAERS because not all reported adverse events are causally related to vaccine. (See “Reporting Suspected Side Effects to VAERS” for detailed information on submitting reports.) In addition, VAERS often provides early safety data after a vaccine is licensed or during a public health emergency.

VAERS data with personal identifiers removed are publicly available on the Internet at http://vaers.hhs.gov, or at http://wonder.cdc.gov/vaers.html at no cost.
Adverse Event Classifications and Assessment of Causality

Adverse events following vaccination can be classified by frequency (common, rare), extent (local, systemic), severity (hospitalization, disability, and death), causality, and preventability (intrinsic to vaccine, faulty production, faulty administration). Vaccine adverse events can be classified as follows:

- **Vaccine-induced**: Due to the intrinsic characteristic of the vaccine preparation and the individual response of the vaccinee. These events would not have occurred without vaccination (e.g., vaccine-associated paralytic poliomyelitis after oral polio vaccine).

- **Vaccine-potentiated**: The event would have occurred anyway, but was precipitated by the vaccination (e.g., first febrile seizure in a predisposed child).

- **Programmatic error**: Due to technical errors in vaccine storage, preparation, handling, or administration.

- **Coincidental**: The reported event was not caused by vaccination but happened by chance occurrence or due to underlying illness.

It is natural to suspect a vaccine when a health problem occurs following vaccination, but in reality a causal association may or may not exist. More information would be needed to establish a causal relationship. An adverse health event can be causally attributed to vaccine more readily if: 1) the health problem occurs during a plausible time period following vaccination; 2) the adverse event corresponds to those previously associated with a particular vaccine; 3) the event conforms to a specific clinical syndrome whose association with vaccination has strong biologic plausibility (e.g., anaphylaxis) or occurs following the natural disease; 4) a laboratory result confirms the association (e.g., isolation of vaccine strain varicella virus from skin lesions of a patient with rash); 5) the event recurs on re-administration of the vaccine (“positive rechallenge”); 6) a controlled clinical trial or epidemiologic study shows greater risk of a specific adverse event among vaccinated versus unvaccinated (control) groups; or 7) a finding linking an adverse event to vaccine has been confirmed by other studies.

Vaccine Safety Datalink

In 1990, CDC established the Vaccine Safety Datalink (VSD) project to address gaps in the scientific knowledge of rare vaccine side effects. This project involves partnerships with 10 large managed care organizations (MCOs) to monitor vaccine safety. MCOs’ site locations as of February 2011 are Group Health Cooperative of Puget Sound, Seattle, Washington; Kaiser Permanente Northwest, Portland,
Oregon; Kaiser Permanente Medical Care Program of Northern California, Oakland, California; Southern California Kaiser Permanente Health Care Program, Los Angeles, California; HealthPartners Research Foundation, Minneapolis, Minnesota; Marshfield Clinic Research Foundation, Marshfield, Wisconsin; Kaiser Permanente Colorado, Denver, Colorado; and Harvard Pilgrim Health Care, Boston, Massachusetts; Kaiser Permanente of Georgia, Atlanta, GA; and Kaiser Permanente of Hawaii, Honolulu, Hawaii.

Each participating organization gathers data on vaccination (vaccine type, date of vaccination, concurrent vaccinations), medical outcomes (outpatient visits, inpatient visits, urgent care visits), birth data, and census data.

The VSD project allows for planned immunization safety studies, as well as timely investigations of hypotheses that arise from review of medical literature, reports to VAERS changes in immunization schedules, or the introduction of new vaccines.

In 2005, the Vaccine Safety Datalink (VSD) project team launched an active surveillance system called Rapid Cycle Analysis (RCA). Its goal is to monitor adverse events following vaccination in near real time, so the public can be informed quickly of possible risks. RCA data come from participating managed care organizations that include more than 9.2 million people annually, representing nearly 3% of the United States population. The RCA data contain no personal identifiers. Further information about VSD is available at http://www.cdc.gov/vaccinesafety.vsd

Clinical Immunization Safety Assessment Network

The most recent addition to the postlicensure vaccine safety monitoring system is the Clinical Immunization Safety Assessment (CISA) Network, which is designed to improve scientific understanding of vaccine safety issues at the individual patient level. The CISA network’s goal is to evaluate persons who have experienced certain adverse health events following vaccination. The results of these evaluations will be used to gain a better understanding of how such events might occur and to develop protocols or guidelines for healthcare providers to help them make the right assessments and manage similar situations. In addition, the CISA centers serve as regional information resources where complex clinical vaccine safety questions can be referred by healthcare providers. Prior to the creation of the CISA network, no coordinated facilities in the United States investigated and managed vaccine side effects on an individual level for the purposes of providing patient care and systematically collecting and evaluating the experiences.

Vaccine Safety Datalink (VSD)

- Involves partnerships with 10 large managed care organizations
- Links vaccination and health records
- Allows for planned immunization safety studies
- Allows for investigations of hypotheses that arise from review of medical literature, reports to VAERS changes in immunization schedules, or the introduction of new vaccines

Clinical Immunization Safety Assessment (CISA) Network

- Improve understanding of vaccine safety issues at individual level
- Evaluate persons who experience adverse health events
- Gain better understanding of events
- Develop protocols for healthcare providers
Established in 2001, the CISA network consists of six centers of excellence with vaccine safety expertise working in partnership with CDC. These centers are Johns Hopkins University in Baltimore, Maryland; Boston University Medical Center in Boston, Massachusetts; Columbia Presbyterian Hospital in New York City; Vanderbilt University in Nashville, Tennessee; Northern California Kaiser in Oakland, and Stanford University in Palo Alto, California. For more information about CISA, visit http://www.cdc.gov/vaccinesafety/Activities/cisa.html.

**Vaccine Analytic Unit**

The Vaccine Analytic Unit (VAU) complements the other critical CDC vaccine safety surveillance systems (VAERS, VSD, and CISA). CDC established the VAU in 2003 in collaboration with the U.S. Department of Defense (DoD) and with input from the FDA to evaluate longer term safety of vaccines administered to young adults of military age. The VAU uses data from the Defense Medical Surveillance System (DMSS) for its investigations. The DMSS is a unique source of active surveillance data, and contains medical, vaccination and deployment information for US military personnel (active component is approximately 1.4 million individuals).

In 2006, VAU published its National Vaccine Advisory Committee (NVAC) approved research agenda for investigating potential anthrax vaccine (AVA) adverse events. Recently, the scope of the VAU’s research focus has broadened beyond AVA and biodefense vaccines to encompass all vaccines used in the military population, with a goal of improving military and civilian health. In addition to playing an important role in monitoring the safety of new vaccines administered to military personnel, such as the 2009 H1N1 pandemic influenza vaccine, and military-specific vaccines, such as AVA, it provides the opportunity to study vaccines that are infrequently administered in civilians (e.g., yellow fever vaccine, smallpox vaccine and Japanese encephalitis vaccine). Current projects focus on specific vaccines (AVA, Tdap, Menactra) and specific potential vaccine-associated diseases (autoimmune thyroid disease, diabetes, Guillain Barré syndrome).

**Vaccine Injury Compensation**

The topic of vaccine safety was prominent during the mid-1970s, with increases in lawsuits filed on behalf of those presumably injured by the whole-cell pertussis component of diphtheria-tetanus-pertussis (DPT) vaccine. Legal decisions were reached and damages awarded despite the lack of scientific evidence to support vaccine injury claims. As a result of the liability, prices soared and many manufacturers halted vaccine production. A vaccine shortage resulted, and
public health officials became concerned about the return of epidemic disease. To respond to these concerns, Congress passed the National Childhood Vaccine Injury Act (NCVIA) in 1986.

As a result of the NCVIA, the National Vaccine Injury Compensation Program (VICP) was established. This program is intended to compensate individuals who experience certain health events following vaccination on a “no fault” basis. “No fault” means that persons filing claims are not required to prove negligence on the part of either the healthcare provider or manufacturer to receive compensation. The program covers all routinely recommended childhood vaccinations, although adults who receive a covered vaccine may also file a claim. Claims may be based on a Vaccine Injury Table (Table) (Appendix F), which lists the adverse events associated with vaccines and provides a rebuttable presumption of causation, or by proving by preponderant evidence that the vaccine caused an injury not on the Table. This Table was developed initially by Congress and has been modified by the Secretary of the Department of Health and Human Services over time to better reflect current science regarding which serious adverse events are reasonably certain to be caused by vaccines. The Table was created to provide swift compensation to those possibly injured by vaccines. As more information becomes available from research on vaccine side effects, the Table will continue to be amended.

VICP has achieved its policy goals of providing compensation to those injured by rare adverse events and liability protection for vaccine manufacturers and administrators. Further information about the VICP is available at www.hrsa.gov/vaccinecompensation/.

During the 2009 H1N1 influenza pandemic, the government implemented a new compensation program called Countermeasures Injury Compensation Program (CICP). This program provides compensation for certain individuals who are seriously injured by countermeasures as specified in a declaration by the Secretary of HHS. Both security (bioterrorism) and pandemic countermeasures are covered. The CICP currently covers serious adverse events caused by pandemic influenza vaccines including the 2009 monovalent H1N1 influenza vaccine that was widely distributed in the 2009 influenza season and any pandemic influenza vaccines in clinical trials such as H5, H7, H9, etc. The CICP also currently covers serious adverse events caused by anthrax, smallpox, and botulism vaccines, including those used by the Department of Defense. Covered countermeasures within the CICP are not limited to vaccines and may include certain medications or devices used to diagnose, prevent, or treat the covered condition (currently pandemic influenza,
The Immunization Provider’s Role

Even though federal regulations require vaccines to undergo years of testing before they can be licensed, and vaccines are monitored continually for safety and efficacy, immunization providers still play a key role in helping to ensure the safety and efficacy of vaccines. They do this through proper vaccine storage and administration, timing and spacing of vaccine doses, observation of precautions and contraindications, management of vaccine side effects, reporting of suspected side effects to VAERS, and educating patients and parents about vaccine benefits and risks. Each of these steps is described only briefly here. Further information is available elsewhere in this book or in resource materials from CDC or other organizations.

Vaccine Storage and Administration

To achieve the best possible results from vaccines, immunization providers should carefully follow the recommendations found in each vaccine’s package insert for storage, handling, and administration. Other steps to help ensure vaccine safety include: 1) inspecting vaccines upon delivery and monitoring refrigerator and freezer temperatures to ensure maintenance of the cold chain; 2) rotating vaccine stock so the oldest vaccines are used first; 3) never administering a vaccine later than the expiration date; 4) administering vaccines within the prescribed time periods following reconstitution; 5) waiting to draw vaccines into syringes until immediately prior to administration; 6) never mixing vaccines in the same syringe unless they are specifically approved for mixing by the FDA; and 7) recording vaccine and administration information, including lot numbers and injection sites, in the patient’s record. If errors in vaccine storage and administration occur, corrective action should be taken immediately to prevent them from happening again and public health authorities should be notified. More information on vaccine storage and handling is available in Appendix C and in CDC’s Vaccine Storage and Handling Toolkit, available on the CDC Vaccines and Immunizations website at www.cdc.gov/vaccines.

Timing and Spacing

Timing and spacing of vaccine doses are two of the most important issues in the appropriate use of vaccines. To ensure optimal results from each immunization, providers should follow the currently recommended immunization schedules for children, adolescents, and adults. Decreasing
the timing intervals between doses of the same vaccine may interfere with the vaccine’s antibody response. For more specific information on timing and spacing of vaccines see Chapter 2, General Recommendations on Immunization. A table showing recommended minimum ages and intervals between vaccine doses is contained in Appendix A.

Providers should also remember the following:

- Administering all needed vaccines during the same visit is important because it increases the likelihood that children will be fully immunized as recommended. Studies have shown that vaccines are as effective when administered simultaneously as they are individually and carry no greater risk for adverse reactions.

- Some vaccines, such as pediatric diphtheria and tetanus, produce increased rates of side effects when given too frequently. Good recordkeeping, maintaining careful patient histories, and adherence to recommended schedules can decrease the chances that patients receive extra doses of vaccines.

Contraindications and Precautions

Contraindications and precautions to vaccination are conditions that indicate when vaccines should not be given. A contraindication is a condition in a recipient that increases the chance of a serious adverse reaction. In general, a vaccine should not be administered when a contraindication is present. A precaution is a condition in a recipient that might increase the chance or severity of an adverse reaction or compromise the ability of the vaccine to produce immunity. Normally, vaccination is deferred when a precaution is present. Situations may arise when the benefits of vaccination outweigh the risk of a side effect, and the provider may decide to vaccinate the patient. Most contraindications and precautions are temporary and the vaccine may be given at a later time. More information about contraindications can be found in the Advisory Committee on Immunization Practices (ACIP) statements for individual vaccines. Recommendations for immunizing persons who are immunocompromised can be found in Appendix A. Information on allergic reactions to vaccines can be found in the American Academy of Pediatrics Red Book.

Screening for contraindications and precautions is key to preventing serious adverse reactions to vaccines. Every provider who administers vaccines should screen every patient before giving a vaccine dose. Sample screening questionnaires can be found in Chapter 2, General Recommendations on Immunization. Many conditions are often inappropriately regarded as contraindications to vaccination. In most cases, the following are not considered contraindications:
Invalid Contraindications to Vaccination

- Minor illness
- Mild/moderate local reaction or fever following a prior dose
- Antimicrobial therapy
- Disease exposure or convalescence
- Pregnant or immunosuppressed in the household
- Premature birth
- Breastfeeding
- Allergies to products not in vaccine

Managing Vaccine Side Effects

Providers should use their best clinical judgment regarding specific management of suspected vaccine side effects. Allergic reactions to vaccines are estimated to occur after vaccination of children and adolescents at a rate of one for every 1.5 million doses of vaccine. All providers who administer vaccines should have procedures in place and be prepared for emergency care of a person who experiences an anaphylactic reaction. Epinephrine and equipment for maintaining an airway should be available for immediate use. All vaccine providers should be familiar with the office emergency plan and should be certified in cardiopulmonary resuscitation.

Reporting Suspected Side Effects to VAERS

Healthcare providers are required by the National Childhood Vaccine Injury Act of 1986 to report certain adverse events to VAERS and are encouraged to report any adverse event even if they are not sure a vaccine was the cause. A table listing reportable events is available at http://vaers.hhs.gov/reportable.htm and is contained in Appendix F. Reporting can be done in one of three ways:

1. Online through a secure website:
   https://vaers.hhs.gov/esub/step1

2. If a reporter is unable to report by Internet, they may fax a completed VAERS form* to 877-721-0366.

3. Mail a completed VAERS form* to
   VAERS
   P.O. Box 1100
   Rockville, MD 20849-1100

*A one-page VAERS form can be downloaded from http://vaers.hhs.gov/resources/vaers_form.pdf or can be requested by telephone at 800-822-7967 or by fax at 877-721-0366.
When providers report suspected vaccine reactions to VAERS, they provide valuable information that is needed for the ongoing evaluation of vaccine safety. CDC and FDA use VAERS information to ensure the safest strategies of vaccine use and to further reduce the rare risks associated with vaccines.

**Benefit and Risk Communication**

Parents, guardians, legal representatives, and adolescent and adult patients should be informed of the benefits and risks of vaccines in understandable language. Opportunity for questions should be provided before each vaccination. Discussion of the benefits and risks of vaccination is sound medical practice and is required by law.

The National Childhood Vaccine Injury Act requires that vaccine information materials be developed for each vaccine covered by the Act. These materials, known as “Vaccine Information Statements (VISs),” must be provided by all public and private vaccination providers before each dose of vaccine. Copies of VISs are available from state health authorities responsible for immunization, or they can be obtained from CDC’s website at www.cdc.gov/vaccines/pubs/vis/default.htm or from the Immunization Action Coalition at http://www.immunize.org. Translations of VISs into languages other than English are available from certain state immunization programs and from the Immunization Action Coalition website. Further information about VISs and their use is contained in Appendix E.

Healthcare providers should anticipate questions that parents or patients may have regarding the need for or safety of vaccination. A few may refuse certain vaccines, or even reject all vaccinations. Some persons might have religious or personal objections to vaccinations. Having a basic understanding of how patients view vaccine risk and developing effective approaches to dealing with vaccine safety concerns when they arise are imperative for vaccination providers. Healthcare providers can accomplish this by assessing patients’ specific concerns and information needs, providing them with accurate information, and referring them to credible sources for more information. The CDC’s website contains extensive and up-to-date information on vaccine safety issues http://www.cdc.gov/vaccines/.

When a parent or patient initiates discussion regarding a vaccine concern, the healthcare provider should discuss the specific concern and provide factual information, using language that is appropriate. Effective, empathetic vaccine risk communication is essential in responding to misinformation and concerns. The Vaccine Information Statements provide an outline for discussing vaccine benefits and risk.
Other vaccine resources are available at http://www.cdc.gov/vaccinesafety/.

Rather than excluding from their practice those patients who question or refuse vaccination, the more effective public health strategy for providers is to identify common ground and discuss measures to be followed if the patient’s decision is to defer vaccination. Healthcare providers can reinforce key points regarding each vaccine, including safety, and emphasize risks encountered by unimmunized children. Parents should be informed about state laws pertaining to school or child care entry, which might require that unimmunized children stay home from school during outbreaks. Documentation of these discussions in the patient’s record, including the refusal to receive certain vaccines (i.e., informed refusal), might reduce any potential liability if a vaccine-preventable disease occurs in the unimmunized patient.

Acknowledgement
The editors thank Pamela Bryant of the Immunization Safety Office, CDC, for her update and critical review of this chapter.

Selected References


VAERS website available at www.vaers.hhs.gov.
Medical Management of Vaccine Reactions in Children and Teens

All vaccines have the potential to cause an adverse reaction. To minimize adverse reactions, patients should be carefully screened for precautions and contraindications before vaccine is administered. Even with careful screening, reactions can occur. These reactions can vary from trivial and inconvenient (e.g., soreness, itching) to severe and life threatening (e.g., anaphylaxis). If reactions occur, staff should be prepared with procedures for their management. The table below describes procedures to follow if various reactions occur.

<table>
<thead>
<tr>
<th>Reaction</th>
<th>Symptoms</th>
<th>Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Localized</td>
<td>Soreness, redness, itching, or swelling at the injection site</td>
<td>Apply a cold compress to the injection site. Consider giving an analgesic (pain reliever) or antipruritic (anti-itch) medication.</td>
</tr>
<tr>
<td></td>
<td>Slight bleeding</td>
<td>Apply an adhesive compress over the injection site.</td>
</tr>
<tr>
<td></td>
<td>Continuous bleeding</td>
<td>Place thick layer of gauze pads over site and maintain direct and firm pressure; raise the bleeding injection site (e.g., arm) above the level of the patient’s heart.</td>
</tr>
<tr>
<td>Psychological fright and syncope (fainting)</td>
<td>Fright before injection is given</td>
<td>Have patient sit or lie down for the vaccination.</td>
</tr>
<tr>
<td></td>
<td>Extreme paleness, sweating, coldness of the hands and feet, nausea, light-headedness, dizziness, weakness, or visual disturbances</td>
<td>Have patient lie flat or sit with head between knees for several minutes. Loosen any tight clothing and maintain an open airway. Apply cool, damp cloths to patient’s face and neck.</td>
</tr>
<tr>
<td></td>
<td>Fall, without loss of consciousness</td>
<td>Examine the patient to determine if injury is present before attempting to move the patient. Place patient flat on back with feet elevated.</td>
</tr>
<tr>
<td></td>
<td>Loss of consciousness</td>
<td>Check the patient to determine if injury is present before attempting to move the patient. Place patient flat on back with feet elevated. Call 911 if patient does not recover immediately.</td>
</tr>
<tr>
<td>Anaphylaxis</td>
<td>Sudden or gradual onset of generalized itching, erythema (redness), or urticaria (hives); angioedema (swelling of the lips, face, or throat); severe bronchospasm (wheezing); shortness of breath; shock; abdominal cramping; or cardiovascular collapse</td>
<td>See “Emergency Medical Protocol for Management of Anaphylactic Reactions in Children and Teens” on the next page for detailed steps to follow in treating anaphylaxis.</td>
</tr>
</tbody>
</table>
Emergency medical protocol for management of anaphylactic reactions in children and teens

1. If itching and swelling are confined to the injection site where the vaccination was given, observe patient closely for the development of generalized symptoms.

2. If symptoms are generalized, activate the emergency medical system (EMS; e.g., call 911) and notify the on-call physician. This should be done by a second person, while the primary nurse assesses the airway, breathing, circulation, and level of consciousness of the patient.

3. Drug Dosing Information:
   a. **First-line treatment:** Administer aqueous epinephrine 1:1000 dilution (i.e., 1 mg/mL) intramuscularly; the standard dose is 0.01 mg/kg body weight, up to 0.3 mg maximum single dose in children and 0.5 mg maximum in adolescents (see chart on next page).
   b. **Secondary treatment option:** For hives or itching, you may also administer diphenhydramine either orally or by intramuscular injection; the standard dose is 1–2 mg/kg body weight, up to 30 mg maximum dose in children and 50 mg maximum dose in adolescents (see chart on next page).

4. Monitor the patient closely until EMS arrives. Perform cardiopulmonary resuscitation (CPR), if necessary, and maintain airway. Keep patient in supine position (flat on back) unless he or she is having breathing difficulty. If breathing is difficult, patient’s head may be elevated, provided blood pressure is adequate to prevent loss of consciousness. If blood pressure is low, elevate legs. Monitor blood pressure and pulse every 5 minutes.

5. If EMS has not arrived and symptoms are still present, repeat dose of epinephrine every 5–15 minutes for up to 3 doses, depending on patient’s response.

6. Record all vital signs, medications administered to the patient, including the time, dosage, response, and the name of the medical personnel who administered the medication, and other relevant clinical information.

7. Notify the patient’s primary care physician.
For your convenience, approximate dosages based on weight and age are provided in the charts below. Please confirm that you are administering the correct dose for your patient.

### First-Line Treatment: Epinephrine (the recommended dose for epinephrine is 0.01 mg/kg body weight)

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Range of weight (lb)</th>
<th>Range of weight (kg)*</th>
<th>Epinephrine Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infants and Children</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1–6 months</td>
<td>9–19 lb</td>
<td>4–8.5 kg</td>
<td>0.05 mL (or mg)</td>
</tr>
<tr>
<td>7–36 months</td>
<td>20–32 lb</td>
<td>9–14.5 kg</td>
<td>0.1 mL (or mg)</td>
</tr>
<tr>
<td>37–59 months</td>
<td>33–39 lb</td>
<td>15–17.5 kg</td>
<td>0.15 mL (or mg)</td>
</tr>
<tr>
<td>5–7 years</td>
<td>40–56 lb</td>
<td>18–25.5 kg</td>
<td>0.2–0.25 mL (or mg)</td>
</tr>
<tr>
<td>8–10 years</td>
<td>57–76 lb</td>
<td>26–34.5 kg</td>
<td>0.25–0.3 mL† (or mg)</td>
</tr>
<tr>
<td>Teens</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11–12 years</td>
<td>77–99 lb</td>
<td>35–45 kg</td>
<td>0.35–0.4 mL (or mg)</td>
</tr>
<tr>
<td>13 years &amp; older</td>
<td>100+ lb</td>
<td>46+ kg</td>
<td>0.5 mL (or mg)‡</td>
</tr>
</tbody>
</table>

Note: If body weight is known, then dosing by weight is preferred. If weight is not known or not readily available, dosing by age is appropriate.

* Rounded weight at the 50th percentile for each age range
† Maximum dose for children
‡ Maximum dose for teens

### Secondary Treatment Option: Diphenhydramine (the recommended dose for diphenhydramine [Benadryl] is 1–2 mg/kg body weight)

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Range of weight (lb)</th>
<th>Range of weight (kg)*</th>
<th>Diphenhydramine Dose</th>
</tr>
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<td>46+ kg</td>
<td>50 mg§</td>
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* Rounded weight at the 50th percentile for each age range
† Maximum dose for children
‡ Maximum dose for teens
§ Maximum dose for teens

Sources

These standing orders for the medical management of vaccine reactions in child and teenage patients shall remain in effect for patients of the ___________________________ until rescinded or until __________ date _________.

Medical Director’s signature ___________________________ Effective date __________

www.immunize.org/catg.d/p3082a.pdf • Item #P3082a (7/11)
## Medical Management of Vaccine Reactions in Adult Patients

All vaccines have the potential to cause an adverse reaction. In order to minimize adverse reactions, patients should be carefully screened for precautions and contraindications before vaccine is administered. Even with careful screening, reactions may occur. These reactions can vary from trivial and inconvenient (e.g., soreness, itching) to severe and life threatening (e.g., anaphylaxis). If reactions occur, staff should be prepared with procedures for their management. The table below describes procedures to follow if various reactions occur.

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<td>See “Emergency Medical Protocol for Management of Anaphylactic Reactions in Adults” on the next page for detailed steps to follow in treating anaphylaxis.</td>
</tr>
</tbody>
</table>

(continued on page 2)
Supplies you may need at a community immunization clinic

- **First-line treatment:** Aqueous epinephrine 1:1000 (i.e., 1 mg/mL) dilution, in ampules, vials of solution, or prefilled syringes, including epinephrine autoinjectors (e.g., EpiPen). If EpiPens are stocked, at least three adult EpiPens (0.30 mg) should be available.
- **Secondary treatment option:** Diphenhydramine (Benadryl) injectable (50 mg/mL solution) or oral (12.5 mg/5 mL liquid, 25 or 50 mg capsules/tablets)
- **Second-line treatment:** Syringes: 1 and 3 cc, 22 and 25g, 1”", 1½”, and 2” needles for epinephrine and diphenhydramine (Benadryl)
- **Third-line treatment:** Alcohol wipes
- **Fourth-line treatment:** Tourniquet
- **Fifth-line treatment:** Adult airways (small, medium, and large)
- **Sixth-line treatment:** Adult size pocket mask with one-way valve
- **Seventh-line treatment:** Oxygen (if available)
- **Eighth-line treatment:** Stethoscope
- **Ninth-line treatment:** Sphygmomanometer (blood pressure measuring device) with adult-size and extra-large cuffs
- **Tenth-line treatment:** Tongue depressors
- **Eleventh-line treatment:** Flashlight with extra batteries (for examination of the mouth and throat)
- **Twelfth-line treatment:** Wristwatch with ability to count seconds
- **Thirteenth-line treatment:** Cell phone or access to onsite phone

Emergency medical protocol for management of anaphylactic reactions in adults

1. If itching and swelling are confined to the injection site where the vaccination was given, observe patient closely for the development of generalized symptoms.
2. If symptoms are generalized, activate the emergency medical system (EMS; e.g., call 911) and notify the on-call physician. This should be done by a second person, while the primary nurse assesses the airway, breathing, circulation, and level of consciousness of the patient.
3. Drug Dosing Information:
   a. **First-line treatment:** Administer aqueous epinephrine 1:1000 dilution intramuscularly, 0.01 mL/kg/dose (adult dose ranges from 0.3 mL to 0.5 mL, with maximum single dose of 0.5 mL).
   b. **Secondary treatment option:** For hives or itching, you may also administer diphenhydramine either orally or by intramuscular injection; the standard dose is 1–2 mg/kg, up to 50 mg maximum single dose.
4. Monitor the patient closely until EMS arrives. Perform cardiopulmonary resuscitation (CPR), if necessary, and maintain airway. Keep patient in supine position (flat on back) unless he or she is having breathing difficulty. If breathing is difficult, patient’s head may be elevated, provided blood pressure is adequate to prevent loss of consciousness. If blood pressure is low, elevate legs. Monitor blood pressure and pulse every 5 minutes.
5. If EMS has not arrived and symptoms are still present, repeat dose of epinephrine every 5–15 minutes for up to 3 doses, depending on patient’s response.
6. Record all vital signs, medications administered to the patient, including the time, dosage, response, and the name of the medical personnel who administered the medication, and other relevant clinical information.
7. Notify the patient’s primary care physician.

Sources

These standing orders for the medical management of vaccine reactions in adult patients shall remain in effect for patients of the __________ until rescinded or until __________.

<table>
<thead>
<tr>
<th>Medical Director’s signature</th>
<th>Effective date</th>
</tr>
</thead>
</table>

www.immunize.org/catg.d/p3082.pdf • Item #P3082 (4/11)
APPENDIX F
Vaccine Safety

The Vaccine Adverse Event Reporting System (VAERS) .................. F-1
Table of Reportable Events Following Vaccination ....................... F-2
The Vaccine Injury Compensation Program (VICP) ....................... F-4
The VICP Vaccine Injury Table ........................................... F-6
The Vaccine Adverse Event Reporting System (VAERS)

VAERS is a national vaccine safety surveillance program co-sponsored by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). VAERS collects and analyzes information from reports of adverse events following immunization. Since 1990, VAERS has received over 371,000 reports, most of which describe mild side effects such as fever. Very rarely, people experience serious adverse events following immunization. By monitoring such events, VAERS can help to identify important new safety concerns.

WHO? Anyone can submit a VAERS report. Most reports are sent in by vaccine manufacturers and health care providers, but state immunization programs, vaccine recipients or their parent/guardian, and others may also submit reports.

WHAT? VAERS encourages reporting of any clinically significant adverse event that occurs after the administration of any vaccine licensed in the United States.

The National Childhood Vaccine Injury Act requires health care providers to report:
- Any event listed by the vaccine manufacturer as a contraindication to subsequent doses of the vaccine,
- Any event listed in the Reportable Events Table that occurs within the specified time period after the vaccination.

(A copy of the Reportable Events Table can be found on the following page, or obtained by calling VAERS at 1-800-822-7967 or by downloading it from http://vaers.hhs.gov/resources/vaersmaterialspublications.)

HOW? There are three ways to report to VAERS:

- **Online.** Complete a VAERS online form at https://vaers.hhs.gov/esub/step1. Before you begin, review the Instructions for Completing the VAERS On-Line Form at http://vaers.hhs.gov/esub/help. The VAERS On-Line form has a 20 minute limit to complete each step, and your information will be erased if you time out. You will receive a warning after 15 minutes. Information supplied on this form is transmitted securely to VAERS.

- **Fax.** Download a VAERS form at http://vaers.hhs.gov/resources/vaers_form.pdf, or request a form by sending an e-mail to info@vaers.org, by calling 800-822-7967, or by faxing a request to 877-721-0366. Review the Instructions for Completing the VAERS Paper Form at http://vaers.hhs.gov/helpinstructions. Fax the completed form to 877-721-0366.

- **Mail.** Download a VAERS form at http://vaers.hhs.gov/resources/vaers_form.pdf, or request a form by sending an e-mail to info@vaers.org, by calling 800-822-7967, or by faxing a request to 877-721-0366. Review the Instructions for Completing the VAERS Paper Form at http://vaers.hhs.gov/helpinstructions. Mail the completed form to VAERS, P.O. Box 1100, Rockville, MD 20849-1100. A pre-paid postage stamp is included on the back of the form.
### VAERS Table of Reportable Events Following Vaccination*

<table>
<thead>
<tr>
<th>Vaccine/Toxoid</th>
<th>Event and Interval from Vaccination</th>
</tr>
</thead>
</table>
| **Tetanus in any combination:** DTaP, DTP, DTP-Hib, DT, Td, TT, Tdap, DTaP-IPV, DTaP-IPV/Hib, DTaP-HepB-IPV | A. Anaphylaxis or anaphylactic shock (7 days)  
B. Brachial neuritis (28 days)  
C. Any acute complications or sequelae (including death) of above events (interval - not applicable)  
D. Events described in manufacturer’s package insert as contraindications to additional doses of vaccine (interval - see package insert) |
| **Pertussis in any combination:** DTaP, DTP, DTP-Hib, Tdap, P, DTaP-IPV, DTaP-IPV/Hib, DTaP-HepB-IPV | A. Anaphylaxis or anaphylactic shock (7 days)  
B. Encephalopathy or encephalitis (7 days)  
C. Any acute complications or sequelae (including death) of above events (interval - not applicable)  
D. Events described in manufacturer’s package insert as contraindications to additional doses of vaccine (interval - see package insert) |
| **Measles, mumps and rubella in any combination:** MMR, MR, M, MMRV, R | A. Chronic arthritis (42 days)  
B. Any acute complications or sequelae (including death) of above event (interval - not applicable)  
C. Events described in manufacturer’s package insert as contraindications to additional doses of vaccine (interval - see package insert) |
| **Rubella in any combination:** MMR, MMRV, MR, R | A. Thrombocytopenic purpura (7-30 days)  
B. Vaccine-strain measles viral infection in an immunodeficient recipient (6 months)  
C. Any acute complications or sequelae (including death) of above events (interval - not applicable)  
D. Events described in manufacturer’s package insert as contraindications to additional doses of vaccine (interval - see package insert) |
| **Measles in any combination:** MMR, MMRV, MR, M | A. Paralytic polio  
- o in a non-immunodeficient recipient (30 days)  
- o in an immunodeficient recipient (6 months)  
- o in a vaccine-associated community case (interval - not applicable)  
B. Vaccine-strain polio viral infection  
- o in a non-immunodeficient recipient (30 days)  
- o in an immunodeficient recipient (6 months)  
- o in a vaccine-associated community case (interval - not applicable)  
C. Any acute complication or sequelae (including death) of above events (interval - not applicable)  
D. Events described in manufacturer’s package insert as contraindications to additional doses of vaccine (interval - see package insert) |
| **Oral Polio (OPV)** | A. Anaphylaxis or anaphylactic shock (7 days)  
B. Any acute complication or sequelae (including death) of the above event (interval - not applicable)  
C. Events described in manufacturer’s package insert as contraindications to additional doses of vaccine (interval - see package insert) |
| **Inactivated Polio:** IPV, DTaP-IPV, DTaP-IPV/Hib, DTaP-HepB-IPV | A. Anaphylaxis or anaphylactic shock (7 days)  
B. Any acute complication or sequelae (including death) of the above event (interval - not applicable)  
C. Events described in manufacturer’s package insert as contraindications to additional doses of vaccine (interval - see package insert) |
| **Hepatitis B in any combination:** HepB, HepA-HepB, DTaP-HepB-IPV, Hib-HepB | A. Anaphylaxis or anaphylactic shock (7 days)  
B. Any acute complications or sequelae (including death) of the above event (interval - not applicable)  
C. Events described in manufacturer’s package insert as contraindications to additional doses of vaccine (interval - see package insert) |
<p>| <strong>Hemophilus influenzae type b in any combination (conjugate): Hib, Hib-HepB, DTP-Hib, DTaP-IPV/Hib</strong> | Events described in manufacturer’s package insert as contraindications to additional doses of vaccine (interval – see package insert) |
| <strong>Varicella in any combination:</strong> VAR, MMRV | Events described in manufacturer’s package insert as contraindications to additional doses of vaccine (interval – see package insert) |
| <strong>Rotavirus (monovalent or pentavalent) RV1, RV5</strong> | Events described in manufacturer’s package insert as contraindications to additional doses of vaccine (interval – see package insert) |
| <strong>Pneumococcal conjugate (7-valent or 13-valent) PCV7, PCV13</strong> | Events described in manufacturer’s package insert as contraindications to additional doses of vaccine (interval – see package insert) |</p>
<table>
<thead>
<tr>
<th>Vaccine/Toxoid</th>
<th>Event and Interval from Vaccination</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hepatitis A in any combination: HepA, HepA-HepB</td>
<td>Events described in manufacturer’s package insert as contraindications to additional doses of vaccine (interval – see package insert)</td>
</tr>
<tr>
<td>Influenza (trivalent inactivated influenza or live attenuated influenza): TIV, LAIV</td>
<td>Events described in manufacturer’s package insert as contraindications to additional doses of vaccine (interval – see package insert)</td>
</tr>
<tr>
<td>Meningococcal: MCV4, MPSV4</td>
<td>Events described in manufacturer’s package insert as contraindications to additional doses of vaccine (interval – see package insert)</td>
</tr>
<tr>
<td>Human Papillomavirus (quadrivalent or bivalent): HPV4, HPV2</td>
<td>Events described in manufacturer’s package insert as contraindications to additional doses of vaccine (interval – see package insert)</td>
</tr>
</tbody>
</table>

* Effective date: November 10, 2008. The Reportable Events Table (RET) reflects what is reportable by law (42 USC 300aa-25) to the Vaccine Adverse Event Reporting System (VAERS) including conditions found in the manufacturers package insert. In addition, healthcare professionals are encouraged to report any clinically significant or unexpected events (even if you are not certain the vaccine caused the event) for any vaccine, whether or not it is listed on the RET. Manufacturers are also required by regulation (21CFR 600.80) to report to the VAERS program all adverse events made known to them for any vaccine.
The Vaccine Injury Compensation Program (VICP)

The VICP is a no-fault alternative to the traditional tort system for resolving vaccine injury claims. It was established as part of the National Childhood Vaccine Injury Act of 1986, after a rash of lawsuits against vaccine manufacturers and healthcare providers threatened to cause vaccine shortages and reduce vaccination rates.

The VICP is administered jointly by the U.S. Department of Health and Human Services (HHS), the U.S. Court of Federal Claims (the Court), and the U.S. Department of Justice (DOJ). The VICP is located in the HHS, Health Resources and Services Administration (HRSA), Healthcare Systems Bureau, Division of Vaccine Injury Compensation.

Briefly, an individual claiming a vaccine-related injury or death files a petition for compensation with the Court, and may be represented by an attorney. A HHS physician reviews the petition to determine whether it meets the medical criteria for compensation. A recommendation is provided to the Court. The HHS position is presented before a “special master,” who makes the decision for compensation under the VICP. A decision may be appealed to a judge of the Court, then to the Federal Circuit Court of Appeals, and eventually to the U.S. Supreme Court.

A petitioner may file a claim in civil court against the vaccine company and/or the vaccine administrator only after first filing a claim under the VICP and then rejecting the decision of the Court.

Who Can File a Claim?

- You may file a claim if you received a vaccine covered by the VICP and believe that you have been injured by this vaccine.
- You may also file a claim if you are a parent or legal guardian of a child or disabled adult who received a vaccine covered by the VICP and believe that the person was injured by this vaccine.
- You may file a claim if you are the legal representative of the estate of a deceased person who received a vaccine covered by the VICP and believe that the person’s death resulted from the vaccine injury.
- You may file a claim if you are not a United States citizen.
- Some people who receive vaccines outside of the U.S. may be eligible for compensation. See the VICP website for more details.
- In addition, to be eligible to file a claim, the effects of the person’s injury must have:
  1. lasted for more than 6 months after the vaccine was given; or
  2. resulted in a hospital stay and surgery; or
  3. resulted in death.

There is no age restriction on who may file a claim. Anyone receiving a vaccine covered by the VICP, no matter their age, can file a claim or have one filed on their behalf.

To learn how to file a claim, see the VICP website at http://www.hrsa.gov/vaccinecompensation/filing_claim.htm.

Vaccines covered by VICP are diphtheria, tetanus, pertussis, Hib, hepatitis A, hepatitis B, human papillomavirus, trivalent influenza, measles, mumps, rubella, meningococcal, polio, pneumococcal conjugate, rotavirus, and varicella, in any combination. (Additional vaccines may be added in the future.)
The **Vaccine Injury Table** makes it easier for some people to get compensation. The Table lists and explains injuries and conditions that are presumed to be caused by vaccines. It also lists time periods in which the first symptom of these injuries and conditions must occur after receiving the vaccine. If the first symptom of these injuries/conditions occurs within the listed time periods, it is presumed that the vaccine was the cause of the injury or condition unless another cause is found. For example, if a patient received the tetanus vaccine and had a severe allergic reaction (anaphylaxis) within hours after receiving the vaccine, then it is presumed that the tetanus vaccine caused the injury, if no other cause is found.

If an injury or condition is not on the Table or if it did not occur within the time period on the Table, the petitioner must prove that the vaccine caused the injury or condition. Such proof must be based on medical records or opinion, which may include expert witness testimony.

A copy of the Vaccine Injury Table is on the following page, or can be found online at [http://www.hrsa.gov/vaccinecompensation/table.htm](http://www.hrsa.gov/vaccinecompensation/table.htm). A comprehensive explanation of terms used in the table accompanies the online version.

February 2 11

For more information, visit the VICP website at [http://www.hrsa.gov/vaccinecompensation](http://www.hrsa.gov/vaccinecompensation).
# Appendix F

## National Childhood Vaccine Injury Act

### Vaccine Injury Table

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Illness, disability, injury or condition covered</th>
<th>Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration</th>
</tr>
</thead>
</table>
| **I. Vaccines containing tetanus toxoid** (e.g., DTaP, DTP, DT, Td, TT) | A. Anaphylaxis or anaphylactic shock  
B. Brachial neuritis  
C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed. | 4 hours  
2-28 days  
Not applicable |
| **II. Vaccines containing whole cell pertussis bacteria, extracted or partial cell pertussis bacteria, or specific pertussis antigen(s) (e.g., DTP, DTaP, P, DTP-Hib).** | A. Anaphylaxis or anaphylactic shock  
B. Encephalopathy (or encephalitis)  
C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed. | 4 hours  
72 hours  
Not applicable |
| **III. Measles, mumps and rubella vaccine or any of its components (e.g., MMR, MR, M, R)** | A. Anaphylaxis or anaphylactic shock  
B. Encephalopathy (or encephalitis)  
C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed. | 4 hours  
5-15 days (not less than 5 days and not more than 15 days)  
Not applicable |
| **IV. Vaccines containing rubella virus** (e.g., MMR, MR, R) | A. Chronic arthritis  
B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed. | 7-42 days  
Not applicable |
| **V. Vaccines containing measles virus** (e.g., MMR, MR, M) | A. Thrombocytopenic purpura  
B. Vaccine-Strain Measles Viral Infection in an immunodeficient recipient  
C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed. | 7-30 days  
6 months  
Not applicable |
| **VI. Vaccines containing polio live virus (OPV)** | A. Paralytic polio  
--- in a non-immunodeficient recipient  
--- in an immunodeficient recipient  
--- in a vaccine assoc. community case  
B. Vaccine-strain polio viral infection  
--- in a non-immunodeficient recipient  
--- in an immunodeficient recipient  
--- in a vaccine assoc. community case | 30 days  
6 months  
Not applicable  
30 days  
6 months |
<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Illness, disability, injury or condition covered</th>
<th>Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.</td>
<td>Not applicable</td>
<td></td>
</tr>
</tbody>
</table>
| VII. Vaccines containing polio inactivated (e.g., IPV) | A. Anaphylaxis or anaphylactic shock  
B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed. | 4 hours  
Not applicable                                                                                                                                 |
| VIII. Hepatitis B vaccines                  | A. Anaphylaxis or anaphylactic shock  
B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed. | 4 hours  
Not applicable                                                                                                                                 |
| IX. Hemophilus influenza type b polysaccharide conjugate vaccines | No Condition Specified                                                                                                      | Not applicable                                                                                                   |
| X. Varicella vaccine                        | No Condition Specified                                                                                                      | Not applicable                                                                                                   |
| XI. Rotavirus vaccine                       | No Condition Specified                                                                                                      | Not applicable                                                                                                   |
| XII. Pneumococcal conjugate vaccines        | No Condition Specified                                                                                                      | Not applicable                                                                                                   |
| XIII. Hepatitis A vaccines                  | No Condition Specified                                                                                                      | Not applicable                                                                                                   |
| XIV. Trivalent influenza vaccines           | No Condition Specified                                                                                                      | Not applicable                                                                                                   |
| XV. Meningococcal vaccines                 | No Condition Specified                                                                                                      | Not applicable                                                                                                   |
| XVI. Human papillomavirus (HPV) vaccines   | No Condition Specified                                                                                                      | Not applicable                                                                                                   |
| XII. Any new vaccine recommended by the Centers for Disease Control and Prevention for routine administration to children, after publication by Secretary, HHS of a notice of coverage | No Condition Specified                                                                                                      | Not applicable                                                                                                   |

*Effective date: July 22, 2011* See Revisions to the Vaccine Injury Table, www.hrsa.gov/vaccinecompensation/tablerevisionsd6222011.pdf
Taking Vaccine Safety Seriously

Currently, Americans experience low rates of vaccine-preventable diseases but have grown to distrust vaccines. First, suspicion of the diphtheria-tetanus-pertussis vaccines emerged. Fearing litigation, many vaccine manufacturers stopped researching, developing, and manufacturing vaccines. The National Childhood Vaccine Injury Act of 1986 was instituted to decrease the liability exposure of manufacturers and clinicians. Although now determined to be fraudulent research, a report of a syndrome of colitis and autism following measles-mumps-rubella vaccine clearly undermined the public’s confidence in that combination vaccine. In order to keep vaccines as safe as possible, the Food and Drug Administration (FDA) Modernization Act of 1997 called for a review of all drug products containing mercury. Some drugs included were vaccines containing thimerosal. In partnership with the FDA, vaccine manufacturers reformulated these childhood vaccines without thimerosal. Concurrently, allegations of a link between thimerosal exposure from vaccines and autism were made. No real biologically plausible hypothesis was ever put forward. Only a temporal association was made. Following extensive study and examination of the evidence by the Institute of Medicine, no links between autism and thimerosal exposure can be made.

Management of Syncope with Immunization

With the recent additions to the adolescent immunization schedule, an increase in the incidence of syncope has been noted. Females aged 11-18 years of age have had the largest increase. Historically, female adolescents have also demonstrated a higher incidence of fainting than males.

Syncope occurs in a setting of fear or distress—for some individuals, this can be an immunization episode. Syncope results from sympathetic nervous system stimulation followed by a sudden bout of hypotension that results in loss of consciousness. Fainting itself is not dangerous. The real issue with fainting is secondary injury that can occur with a fall as the individual loses consciousness. Serious head injury and death have been reported with syncope following immunization. The ACIP made recommendations for vaccine administration that include a 15 minute observation period following immunization. An immunized patient should be encouraged to sit quietly or lie down if symptomatic for at least 15 minutes.

The main goal of syncope management is to prevent injury. A pharmacist should have the person to be immunized in a seated position with no table or furniture in front of the individual and with sufficient floor space to move the patient to a supine position. The pharmacist should be alert for presyncopal signs, including pallor, sweating, anxiety, perspiration, cool and clammy skin, hypotension, and bradycardia. Quick attention to lying these patients down may even prevent syncope. The patient should remain lying down until (s)he has completely recovered. Patients with possible injury must be referred for medical follow up.

Differentiating syncope from seizure is an important clinical distinction. Approximately one fourth of fainting patients will exhibit tonic-clonic jerking. Inexperienced health care providers may have difficulty distinguishing a syncopal episode from a seizure. The situation and the surrounding events can assist the clinician in making the
decision. Patients with seizure may have an aura and will generally be unconscious for minutes while a fainting patient will regain consciousness very quickly.

The clinician’s competent management may change the outcome of the fainting episode. It has been postulated that if the fainting patient is cared for by a confident, knowledgeable, and calm healthcare provider, this situation may prevent the fainting behavior from becoming habitual.5

Anaphylaxis

Anaphylaxis following immunization is very rare—about one case per 1.5 million doses of vaccine. However, immunizing pharmacists must be ready to respond because anaphylaxis can be unpredictable. Anaphylaxis is mediated by IgE. Therefore, the patient has to have been previously exposed to the allergen. The antigen does not have to be in the same form though. For example, an individual who is allergic to eggs may have had an exposure to eggs in his/her diet and then experience an anaphylactic reaction when receiving an influenza vaccine.

Anaphylaxis typically occurs within minutes of exposure to the allergen. Signs and symptoms include flushing, facial edema, urticaria, itching, swelling of the mouth or throat, wheezing, difficulty breathing, and gastrointestinal symptoms.6, 7 Quickly recognizing and initiating treatment can prevent anaphylaxis from progressing to cardiovascular collapse.7 Rapid recognition of anaphylaxis is critical. If a patient has symptoms consistent with anaphylaxis with sudden onset and rapid progression, life-threatening compromise of breathing or circulation, and skin or mucosal changes, anaphylaxis is very probable.8 Skin and mucosal changes that might be present include urticaria, flushing, or angioedema. The patient should lie down immediately with legs elevated, and the emergency medical system (EMS) should be activated—call 911. The pharmacist should remain with the patient continually monitoring for circulation, airway, and breathing. If a breathing patient is unconscious, the patients should be placed in the recovery position.8 Cardiopulmonary resuscitation should be started as soon as possible if needed. Epinephrine is the most important emergency medication. Early treatment results in the best outcomes so epinephrine should be administered promptly. If the clinician has any doubt regarding the situation, epinephrine should be used.7 Epinephrine can be repeated every 10-20 minutes up to 3 doses if needed to improve symptoms and increase blood pressure. The patient should be transported to an emergency care facility as soon as possible.

Diphenhydramine may be administered to the patient with anaphylaxis. The typical dose for an adult is 1-2 mg/kg up to 100 mg, and it may be administered orally or intramuscularly depending on the patient’s situation.

A written record of the event should be made and sent to both the patient’s primary care physician and the Vaccine Adverse Event Reporting System (VAERS, http://vaers.hhs.gov/esub/index). The report should also be maintained in the pharmacy immunization records.

Practical preparation can improve the safety of patients immunized in the pharmacy. Epinephrine is a prescription drug and its use must be specified in the immunization protocol as allowed by state law. An emergency box
can be assembled using the items listed in the emergency management procedure (Appendix D). A copy of
the procedure should be in the box also. The box should be sealed and labeled with its contents and with the
expiration date of the item with the shortest date. The box should then be stored in the immunization area of
the pharmacy. This emergency response protocol will be used very rarely, if ever, in the course of immunizing
patients. Pharmacists should maintain their competency by reviewing the protocol at least annually. The review
could be scheduled with recertification of basic life support skills or with bloodborne pathogens training.

References:
1. Deer B. How the case against the MMR vaccine was fixed. BMJ 2011;342:77-82.
6. Centers for Disease Control and Prevention. General recommendations on immunization. Recommendations of the
8. Soar J, on behalf of the multidisciplinary Guideline Development Group. Emergency treatment of anaphylaxis in
Case #1
Courtney, a 12 year old female accompanied by her mother, presents for human papillomavirus immunization. The girl has a history of “passing out” with vaccinations. She appears very nervous and her mother is trying to reassure her. What steps can be taken to minimize the dangers of syncope in this situation?

The pharmacist administered the human papillomavirus vaccine to Courtney. Courtney faints shortly upon trying to stand up to go to the waiting area. Her mother catches her and with the help of the pharmacist they lower her to the floor. As the patient is losing consciousness, her arms and head jerk a few times. The mother asks about a possible seizure. What steps should be taken at this time?

Case #2
Cathy is a 24 year old with asthma who presents for her annual influenza vaccine. Her asthma is controlled with inhaled corticosteroids and long acting bronchodilator. She uses her rescue inhaler at least twice each week. She has received the vaccine in the past but has not had it for the past few seasons as she did not have medical insurance. The pharmacist administers the influenza vaccine after screening for contraindications and asking her to review the Vaccine Information Statement. Cathy notices her lips swelling and begins to cough almost immediately. The pharmacist also notices hives on her face and arms. What response is needed at this time?

Case #3
JJ is a 24 year old male that was in the pharmacy for an influenza vaccination (inactivated influenza vaccine) yesterday. He calls the pharmacy today asking that the influenza vaccine be added to his allergy profile because the area that the vaccine was administered is now red and swollen. He also states that he got the “flu” from the vaccine (he is achy all over). What recommendations do you provide to JJ?
Module 3
CASE STUDIES ANSWERS

These case answers serve as a review of Module 3.

Case #1
Courtney, a 12 year old female accompanied by her mother, presents for human papillomavirus immunization. The girl has a history of “passing out” with vaccinations. She appears very nervous and her mother is trying to reassure her. What steps can be taken to minimize the dangers of syncope in this situation?

The girl should be screened for eligibility for the human papillomavirus vaccine series. The mother and girl should be given a Vaccine Information Statement. Recognition of the risk of syncope is particularly important. Female adolescents have higher rates of fainting in general and also with immunization. The girl should be seated with no furniture in front of her or preferably lying down for immunization. The vaccine should be prepared for administration out of sight of the patient. The vaccine is administered intramuscularly in the deltoid. The patient and mother should be instructed to remain seated/lying down for at least 15 minutes. If the girl experiences presyncopeal signs of pallor, sweating, anxiety, perspiration, cool and clammy skin, hypotension, and bradycardia, she should quickly be assisted to a supine position. Cool, damp cloths may be applied to the patient’s face and neck. The immunization encounter should be recorded in accord with the pharmacy recordkeeping system and in an immunization information system (immunization registry).

The pharmacist administered the human papillomavirus vaccine to Courtney. Courtney faints shortly upon trying to stand up to go to the waiting area. Her mother catches her and with the help of the pharmacist they lower her to the floor. As the patient is losing consciousness, her arms and head jerk a few times. The mother asks about a possible seizure. What steps should be taken at this time?

Courtney should regain consciousness very quickly after she lies down. She should be placed flat on her back with her feet elevated. The girl should remain lying down until she is fully recovered. She should be examined to determine if injury is present before attempting to move her. If there is any question of injury associated with fainting, she should be referred for care. The jerking motion noted requires no treatment and is often seen as a patient faints. If she would not recover immediately, then 911 should be called. The pharmacist should report this event to the Vaccine Adverse Event Reporting System. Syncope following human papillomavirus vaccine is not on the VAERS Table of Reportable Events Following Vaccination. However, clinicians, parents, patients are encouraged to report any clinically significant event that follows immunization. Reports can be made online or on paper. Forms are available in a variety of references or can be downloaded from the VAERS website.
Module 3
CASE STUDIES ANSWERS

These case answers serve as a review of Module 3.

Case #2
Cathy is a 24 year old with asthma who presents for her annual influenza vaccine. Her asthma is controlled with inhaled corticosteroids and long acting bronchodilator. She uses her rescue inhaler at least twice each week. She has received the vaccine in the past but has not had it for the past few seasons as she did not have medical insurance. The pharmacist administers the influenza vaccine after screening for contraindications and asking her to review the Vaccine Information Statement. Cathy notices her lips swelling and begins to cough almost immediately. The pharmacist also notices hives on her face and arms. What response is needed at this time?

The pharmacist should evaluate the patient immediately - circulation, airway, breathing. The patient is coughing so no cardiopulmonary resuscitation is needed at this time. The pharmacist should remain with the patient. He should instruct someone in the pharmacy to activate the emergency medical system (EMS) - Call 911. The pharmacist should open the emergency box and quickly review the response protocol if needed. Epinephrine 0.3-0.5 mg should be administered intramuscularly as soon as possible. Diphenhydramine 50 mg could be administered intramuscularly. The epinephrine dose could be repeated in 20 minutes if needed. The patient should be transported to an emergency department as soon as possible. The pharmacist should record the incident and send a copy to the patient’s physician. A VAERS report should be made as described above.

Case #3
JJ is a 24 year old male that was in the pharmacy for an influenza vaccination (inactivated influenza vaccine) yesterday. He calls the pharmacy today asking that the influenza vaccine be added to his allergy profile because the area that the vaccine was administered is now red and swollen. He also states that he got the “flu” from the vaccine (he is achy all over). What recommendations do you provide to JJ?

He is experiencing a localized reaction to the inactivated influenza vaccine. He can apply a cold compress to the injection site and can take an analgesic (acetaminophen or ibuprofen) to help with the swelling and pain. If it remains swollen and red, he should be advised to call the pharmacy or his physician (24-48 hours). The influenza vaccine that he received is inactivated and thus does not cause active influenza. The analgesic recommended above should help to alleviate the systemic symptoms. If they do not resolve or worsen he should be advised to contact his physician. He should not be considered to be “allergic” to the influenza vaccine and should continue to receive it in the future.
Module 3
SELF-ASSESSMENT QUESTIONS

The self-assessment questions below address the information contained in Module 3. The questions will be the same questions as what will appear in the final, self-assessment examination required to obtain your CE Statement of Credit upon completion of Modules 1-7. Because there are 100 questions and you have a time limit, it is suggested that you print these questions, answer them on your own, and save them to refer to when you are completing the final, self-assessment examination.

1. Why is the safety of vaccines held to a higher standard than for most medications?
   a. The public is willing to accept a high degree of risk to avoid most infectious diseases
   b. They are administered to healthy people to prevent disease rather than to sick people to cure disease
   c. The risks associated with vaccines are perceived by the individual to be voluntary risks
   d. The diseases prevented by vaccination are generally not life threatening

2. Which of the following are true regarding vaccine postlicensure surveillance?
   a. A main goal is to identify risk factors or preexisting conditions that may promote reactions
   b. Phase III trials are an example of postlicensure surveillance
   c. A main goal is to identify common adverse reactions
   d. The vaccine is generally tested in animals during this period

3. Which of the following scenarios are health care professionals encouraged to use VAERS for reporting?
   a. Only serious, life threatening adverse reactions
   b. Serious adverse reactions for which causation is firmly established
   c. Any clinically significant adverse event after vaccination
   d. Only adverse reactions that have not been previously reported

4. Which of the following is specifically listed as a VAERS reportable event for measles vaccine?
   a. Thrombocytopenic purpura
   b. Encephalopathy
   c. Brachial neuritis
   d. Chronic arthritis
Module 3

SELF-ASSESSMENT QUESTIONS

5. Which of the following describes the Vaccine Injury Compensation Program?
   a. Absolves the immunization provider from personal negligence
   b. Protects the immunization provider and vaccine manufacturer from personal liability
   c. Covers all licensed vaccines
   d. Requires that the injured party prove negligence

6. Which of the following is specifically listed as a VAERS reportable event for pertussis vaccine?
   a. Thrombocytopenic purpura
   b. Encephalopathy
   c. Brachial neuritis
   d. Chronic arthritis

7. What should be done prior to administering vaccines to patients with a history of syncope with immunizations?
   a. Have the patient lie down for the vaccination
   b. Not administer the vaccine, history of syncope is a contraindication to pharmacy based immunization
   c. Draw up the vaccine in front of them so they can get more comfortable with it
   d. Have the parent leave the room

8. Which of the following mediators is important for the development of anaphylaxis?
   a. IgA
   b. IgG
   c. IgE
   d. IgD

9. Which manifestation of anaphylaxis is epinephrine used to treat?
   a. Hypotension
   b. Arrhythmias
   c. Hemorrhage
   d. Decreased oxygen saturation

10. Anaphylaxis generally will not occur until 1-2 hours after the administration of a vaccine.
    a. True
    b. False