COLORADO
CHILDREN'S
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COALITION

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Dear Immunization Provider:

Welcome to the second edition of The Immunization Competency Manual. The manual has been revised with feedback from users. There is updated information for 2005 and various editing and formatting changes.

CCIC is a Coalition of organizations and individuals from many public and private agencies dedicated to increasing the number of fully immunized children in Colorado. Educating health care providers is a very important part of our mission.

This manual is designed specifically for personnel who are new to the field of immunization delivery or are returning to immunization delivery after some time away from this area. Vaccines and immunization delivery are very complex subjects. This unique manual gives you an opportunity to study a variety of vaccine topics and then complete a self-administered exam to help you retain the details. The manual then becomes an office tool for future reference.

There are a variety of resources and vaccine experts available to assist you with vaccine challenges. You will find these resources listed throughout the manual.

Thank you for your efforts in supporting the campaign to fully immunize the children of Colorado.

We are always happy to receive your inquires and comments and feedback on this manual. Feel free to contact us at 303-864-5340. We also encourage you to join the Colorado Children's Immunization Coalition if you are not already a member.

Sincerely,

Marti Sharp

Marti Sharp, RN, MS
Executive Director

Colorado Children's Immunization Coalition

ACKNOWLEDGEMENT

It is with much gratitude that we thank William Atkinson, MD, MPH from the Centers of Disease Control and Prevention. Dr. Atkinson arranged for us to use large portions of Chapters Two and Three from *Epidemiology and Prevention of Vaccine-Preventable Diseases, 7th edition* (January 2003), commonly known as "The Pink Book." He also graciously allowed us the flexibility of simplifying the text. Donna L. Weaver, MN, RN, who wrote Appendix G of the Pink Book entitled, *Vaccine Administration,* allowed us the same flexibility and our gratitude extends to her as well.

Michigan's Department of Community Health, Division of Immunization, offered us their Provider Tool Kit 2002 from which we drew numerous presentation ideas and several documents. Our thanks to Rosemary F. Franklin for her work in getting us the material we needed.

In addition, we need to recognize several Colorado healthcare professionals for their contribution to this manual. Marti Sharp, RN, MS, Executive Director of the Colorado Children's Immunization Coalition (CCIC), had the overall vision for the manual including the active learning style that the question /answer format creates. Mary Stucky, RN, PNP, CCIC Immunization Grant Coordinator, wrote the questions/answers and along with Pam Smith and Jennifer Gamblin, wrote the original sections of the text and adapted the simplified information from "The Pink Book." Donita Kurtz, BSN, graciously agreed to devise the overall plan for the artwork for the immunity section and Stephanie Starck created the artwork used in the immunity section. We thank Joanne McConville for her proofreading corrections to the manual. Pat Rotharmel, BSN, Colorado Department of Public Health and Environment (CDPHE), assisted with all portions of the manual development. Pat along with Lisa Inhulsen, Staff Assistant for CCIC, took on the huge task of production and distribution of the manual.

As one can imagine, the manual required an extensive review process. All of the individuals in the previous paragraph were an integral part of this process. In addition, our gratitude must be extended to Bob Brayden, MD, Associate Professor of Pediatrics at the University of Colorado Health Sciences Center, Joni Reynolds RNC, MSN from the CDPHE Immunization Program and Opal Stalker, RN, CCIC Immunization Specialist and nurse at the Montezuma County Health Department for assisting as the review committee for this project.

PREFACE

Colorado Children's Immunization Coalition Presents
A Guide to Immunization for the Beginning Immunization Provider

We would like to extend a warm and sincere welcome to all who are just entering a course of immunization studies and to those of you who are using this tool to brush up on your immunization knowledge and skills. The following material is a beginner's level course in immunization covering the following topics and more:

- General vaccine information
- Vaccine administration
- Legal and documentation issues
- Vaccine storage and handling requirements
- Immunization strategies and best practices
- Talking with parents
- A comprehensive test and a skills checklist
- Resources and references

Users will become familiar with general immunization knowledge including the principles of active and passive immunity. You will also be able to identify correct sites and needle size for intramuscular and subcutaneous injections, understand schedules, and learn safe methods of restraint for the administration of vaccines. Strategies for raising practice immunization rates are covered. These include but are not limited to:

- Reducing barriers to full immunization
- Utilizing opportunities for simultaneous administration
- Implementing reminder/recall systems

This resource is NOT intended to be an exhaustive reference. The intended audience is the beginning provider; the material also can be used as a refresher course for the more experienced immunization provider. Since the materials provided here are limited, the practitioner must draw on their knowledge, refer to appropriate resources and be cautious about proceeding when uncertain.

You are encouraged to defer to an immunization expert when concerns arise regarding contraindications, dosages, accelerated schedules and other unfamiliar immunization issues.

As you work though the section materials you will notice that we have presented the information in a question/answer format. Key immunization information is set apart by a text box and presented in a question format. The answer to each question will follow within the text and is highlighted in bold print. We suggest that you read the question, then the bolded answer, then read the paragraph contents.

The training tool that follows is designed to educate and to allow for competency testing. The test at the back of the binder will assist you in testing your immunization competency. It is designed to be either self-administered or given by a preceptor and will be most useful if you study first and then test one section at a time.

The most important caution we can impart is to encourage you to train yourself to ask the questions…raise the red flags…and defer to the expert before proceeding. If within your practice you do not have access to an immunization expert, contact your local or state health department, or you may e-mail immunization questions to the Centers for Disease Control and Prevention at **nipinfo@cdc.gov** or call the CDC Immunization Information Hotline at **1-800-232-2522.**

A more comprehensive immunization manual is available through the Colorado Department of Public Health and Environment. Call 303-692-2363 for additional information.

Immunization information is updated frequently—make sure your resources and reference materials are current. The Colorado Children's Immunization Coalition will update this manual every summer. We suggest you assign an individual staff member to be responsible for this manual and for keeping it current.

It is our sincere hope that this competency tool will assist you as you expand your immunization knowledge and skill base, and encourage you as you join others in immunizing all our children.

Colorado Children's Immunization Coalition
Immunization Competency Manual
A Guide to Immunization for the Beginning Immunization Provider

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I. General Knowledge—Immunity and General Recommendations

Colorado Children's Immunization Coalition
Basic Principals of Vaccination

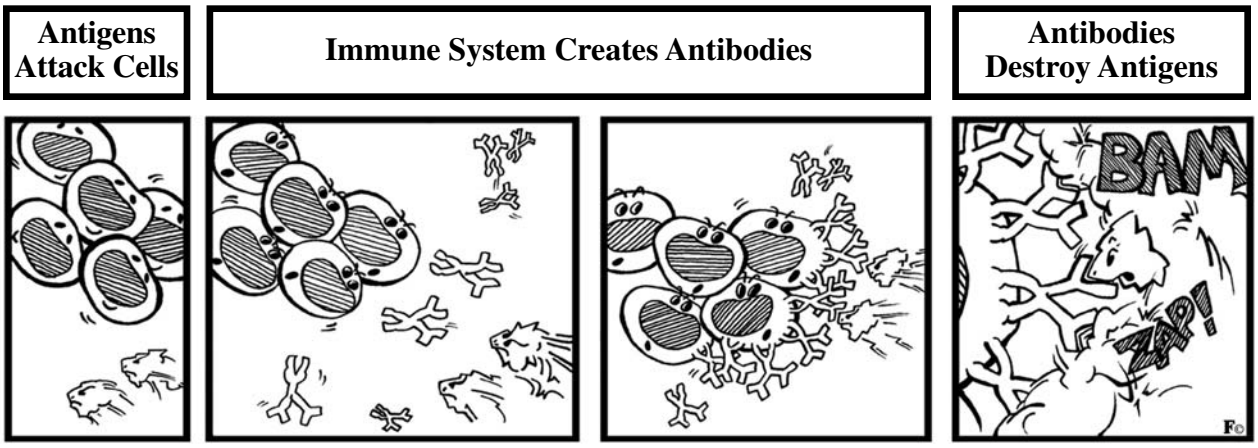
Immunity

Understanding the basic concepts of immunity will assist the learner in reviewing the general rules section of the *Pink Book*, which is heavily incorporated in this chapter. *Epidemiology and Prevention of Vaccine-Preventable Diseases 7th edition* (January 2003), commonly referred to as "the Pink Book," will become the framework for creating the "red flags" which will guide the student toward safe immunization practices. To purchase a copy of this book, call the Public Health Foundation toll free at 877-252-1200 or 800-418-7246. The cost is $29 plus shipping and handling.

Immunity is the body's ability to resist infection. To *immunize* means to make the body immune. To more fully understand the need for immunization, it's helpful to explore how the body's immune system operates.

The way the body accomplishes immunity is quite interesting. The body has a network of cells and organs, called the *immune system*, which defends the body from foreign substances. The immune system is extremely sophisticated in that it can tell the difference between the body's own healthy cells (or "self") and foreign invader cells, like viruses and bacteria (or "other"). The scientific term for "other" cell is *antigen.*

When the body's immune system notices this "other" cell, or antigen, it creates *antibodies.* Antibodies attack and destroy antigens. Antibodies in the bloodstream are called *circulating antibodies.*



An interesting fact about the immune system is that babies in the first year of life have some immunity to diseases. They receive limited protection (antibodies) from their mothers in the womb and through their mother's breast milk if they are breastfed. However, babies lose their mothers' antibodies after the first year. But, vaccinations help keep children immune from

disease by creating new antibodies. Thus, vaccines make the body think it is being attacked by disease and the body produces antibodies to fight it. These antibodies stay in children's bodies and protect them when they actually are exposed to the disease.

Antibodies can be produced actively, artificially or acquired passively. Each results in a different type of immunity, lasting for different amounts of time. There are also various kinds of vaccinations – live attenuated, inactivated and recombinant – which result in different kinds of immunity for the body. Let's look at each of these in more detail.

Types of Immunity

1. What is active immunity?

Active immunity results from the body's exposure to a naturally occurring or "wild-type" viral or bacterial strain. When this kind of foreign invader comes into the body, it generally leads to illness. The body then produces protective antibodies to fight off the invaders. Once the illness passes, the antibodies have produced *active immunity* or protection to the body. The antibodies continue to circulate in the blood and are stored in the bone marrow for many years. This protection after infection is known as immunologic memory. That way, if a similar antigen comes into the body in the future, the memory cells begin to duplicate and produce antibodies quickly and once again protect the body from foreign invaders. Generally, this wild type production of antibodies is the most risky way for a person to develop immunity against disease because they'll have to suffer through the disease fully the first time in order to develop future immunity to it.

2. What is artificial active immunity?

Artificial active immunity results from a person being vaccinated. Vaccines spur the body to produce an immune response similar to a wild-type viral or bacterial strain-produced response. However, vaccines do not expose the body to the wild disease and its potential complications. Thus, this is a safer and more predictable way for a person to develop active immunity.

Whether the individual is exposed to a wild strain or is vaccinated, the newly produced antibodies are specific to the virus or bacteria that spurred their creation and will have no effect on other viruses or bacteria. Let's look at an example of that. If a person is vaccinated against polio, their body will create antibodies to ward off polio antigens. If that same person is exposed to measles, their anti-polio antibodies will have no effect whatsoever against the measles antigens. That's why each person needs to be vaccinated against a variety of different diseases and illnesses.

3. What is passive immunity?

Passive immunity occurs when a specific antibody is introduced into the body from an outside source. The body is not stimulated to produce its own antibodies, but absorbs them from an external source. There are several ways this can happen. Passive immunity can be given to a person via the placenta during the last one or two months of pregnancy, through breast milk, or from a product such as immune globulin, human plasma, or animal anitisera.

There are pros and cons of passive immunity. The benefit of passive immunity is instant protection. Since the body is receiving already-formed antibodies and does not have to take the time to produce the antibodies itself, passive immunity provides immediate protection. This is especially helpful for infants, who would be especially vulnerable to disease without this protection absorbed from their mother's womb. The downside to passive immunity is that its protection is temporary and wears off over time. Unlike with active immunity, antibodies absorbed via passive immunity are not stored in the cell memory and over time, cannot be used to fend off the body from future invasion from the same antigens.

Types of Vaccines

4. What are live attenuated vaccines?

Live attenuated vaccines are a modified, weaker version of a "wild-type" bacteria or virus. The resulting vaccine retains the ability to replicate and produce immunity through the production of antibodies. Since live attenuated vaccines stimulate the immune system more strongly, people usually need only one or two doses of the vaccine. Although illness rarely occurs, if it does, it tends to be a mild illness without the possible serious complications that would occur with a wild-type pathogen.

Common live attenuated vaccines are:

- Measles, mumps, rubella (MMR) and
- Varicella
- LAIV (Live Attenuated Influenza Vaccine)

5. What are inactivated vaccines?

To produce an inactivated vaccine, the bacteria or virus is grown, and then inactivated (killed) through the use of chemicals or heat. The bacteria or viruses cannot replicate, thus the vaccine cannot cause disease. Since the vaccine cannot cause disease from infection, even people with immunodeficiency can receive inactivated vaccines. Further, other antibodies circulating in the blood do not affect an inactivated vaccine. An inactivated vaccine

always requires multiple doses. The first dose usually just "primes" the immune system. Even after multiple doses, antibodies fall over time. As a result, some inactivated vaccines require a booster dose later in life.

Common inactivated vaccines are:

- Diphtheria
- Hepatitis A
- Hepatitis B
- Hib
- Influenza
- Pertussis
- Polio
- Pneumococci
- Tetanus.

6. What are recombinant vaccines?

Recombinant vaccines are a new type of vaccine. They are genetically engineered and contain either live or killed antigens. Some recombinant vaccines have longer shelf lives, which will be helpful in using these vaccines in countries with extreme climates.

There are two recombinant vaccines currently available in the United States: Hepatitis B and live typhoid vaccine, which is a foreign travel vaccination.

7. What are inactive and active ingredients in vaccines?

Vaccines contain both active and inactive ingredients. **Active ingredients, such as adjuvents, are used to help the body to produce a vigorous immune response. Inactive ingredients, like stabilizers and preservatives, are not involved in promoting or enhancing the immune response.**

Selected References:

Epidemiology and Prevention of Vaccine-Preventable Diseases, 7th edition (January 2003), Department of Health and Human Services, Centers for Disease Control and Prevention.

Vaccinations: From Smallpox to Cancer. By Margaret O. Hyde and Elizabeth H. Forsyth, M.D. Franklin Watts, a Division of Grolier Publishing Company, New York, 2000.

www.immunizationinfo.org

www.vaccine.chop.edu

General Recommendations on Immunizations

The General Recommendations on Immunization is a document that addresses issues common to more than one vaccine. It is revised by the Advisory Committee on Immunization Practice (ACIP) every three to five years as needed. The most current revision was published in February 2002 (MMWR 2002; 51(RR-2):1-36). All persons who administer vaccine should have a copy of this document and be familiar with its contents. It can be downloaded from the MMWR web site at www.cdc.gov/mmwr or ordered in print version from the National Immunization Program at www.cdc.gov/nip.

This chapter discusses issues common in vaccination practices and is adapted from *Epidemiology and Prevention of Vaccine Preventable Diseases,* 7th edition (January 2003).

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 vaccine), simultaneous and non-simultaneous administration of different vaccines, and the intervals between subsequent doses of the same vaccine.

Antibody-Vaccine Interactions

1. Which type of vaccines are generally not affected by circulating antibodies and can be administered before, after or at the same time as other vaccines and antibody products?

General Rule

- ♦ Inactivated vaccines generally are not affected by circulating antibody to the antigen.
- ♦ Live attenuated vaccines may be affected by circulating antibody to the antigen.

The presence of circulating antibody against a vaccine antigen may reduce or completely eliminate an 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 antigens are not substantially affected by circulating antibodies, so they can be administered before, after or at the same time as the antibodies. Simultaneous administration of antibody (in the form of immune globulin) and vaccine is recommended for post-exposure prophylaxis of certain diseases, such as hepatitis B, rabies, and tetanus.

All live vaccines must duplicate in order to cause an immune response. Antibody against live injected vaccine antigen may interfere with replication. If a live injected vaccine (MMR or varicella) 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 two weeks (*i.e.,* an incubation period) before giving the antibody. If the interval between the vaccine and antibody is less than two 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. The necessary interval between an antibody-

containing product and MMR or varicella vaccine depends on the concentration of antibody in the product. A table listing the recommended intervals between antibody products and live vaccines entitled, *Suggested Intervals Between Administration of Immune Globulin Preparations for Different Indications and Measles-Containing Vaccine and Varicella Vaccine,* is included on page II-39. This is a complicated issue and most beginning immunization providers will find they need to consult their physician or experienced nurse before administering vaccine in this situation.

Simultaneous and Non-Simultaneous Administration

2. Which vaccines cannot be administered together?

General Rule

♦ **There is no contraindication to the simultaneous administration of any routine childhood vaccines.** The simultaneous administration of the most widely used live and inactivated vaccines does not result in decreased antibody responses or increased rates of adverse reaction. Pneumoccal polysaccharide vaccine (PPV23) and Pneumoccal conjugate (PCV7) should not be given the same day. See p. II-35 for details.

Simultaneous administration of all vaccines for which a child is eligible can be very important in childhood vaccination programs because it increases the chance that a child will be fully immunized at the appropriate age. A study during a recent measles outbreak 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.

Individual vaccines should not be mixed in the same syringe unless they are licensed for mixing by the FDA. Only the Aventis-Pasteur Hib/DTaP (TriHIBit™) vaccine is licensed for mixing in the same syringe.

3. If an MMR and Varicella vaccine are not administered together, how long should one wait to give the second vaccine?

Non-Simultaneous Administration of Different Vaccines

Live injected vaccines (MMR and varicella) that are not administered simultaneously should be separated by at least four weeks. This precaution is intended to reduce or eliminate interference from the vaccine given first on the vaccine given later. If two live injected vaccines are not administered simultaneously but are separated by less than four weeks, the vaccine given second should be repeated more than four weeks later or confirmed to be effective by blood testing of the recipient.

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

4. If a child had received one hepatitis B at birth and one at two months of age and is now presenting at three years old to complete the series, is it necessary to restart the hepatitis B series?

Interval Between Doses of the Same Vaccine

General Rule

♦ Increasing the timing between doses of a multidose vaccine does not decrease the effectiveness of the vaccine.

♦ Decreasing the interval between doses of a multidose vaccine may interfere with antibody response and protection.

Immunizations are recommended for members of the youngest age group at risk for a disease for whom efficacy, immunogenicity and safety of a vaccine have been demonstrated. Most vaccines in the childhood immunization schedule require two or more doses for stimulation of an adequate and persisting antibody response. Studies have shown that recommended ages and intervals between doses of the same antigen(s) provide optimal protection or have the best evidence of efficacy. *The General Recommendations on Immunization* show the recommended minimal ages and minimal intervals between immunizations for vaccines in the recommended childhood immunization schedule. It can be downloaded from the MMWR web site at www.cdc.gov/mmwr or refer to summary on page II-13 of this document.

Administering doses of a multidose vaccine at shorter than the recommended intervals might be necessary in circumstances where 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.

Vaccine doses administered up to four days before the minimum interval or age can be counted as valid. Doses administered five 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 be spaced after the invalid dose by a time greater than the recommended minimum interval. Refer to page II-13 of this document.

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. **It is not necessary to restart the series of any vaccine due to extended intervals between doses.**

5. Which vaccines require multiple doses and possible periodic boosting to maintain immunity?

Number of Doses

General Rule

♦ Live attenuated vaccines generally produce long lasting immunity with a single dose.

♦ Inactivated vaccines require multiple doses and may require periodic boosting to maintain immunity.

For live injected vaccines, the first dose usually provides protection. An additional dose is given to ensure seroconversion. For instance, 95% to 98% of recipients will respond to a single dose of measles vaccine. The second dose is given to assure 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 usually does not provide protection. 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, Hib vaccine does not require boosting because Hib disease is very rare in children older than five 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 (LOCAL, SYSTEMIC, ALLERGIC)

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.

6. Which is the most common type of adverse reaction?

Vaccines are intended to produce active immunity to specific antigens. An adverse reaction is an untoward effect caused by a vaccine that is not related to the vaccine's primary purpose of production of immunity. Adverse reactions are also called vaccine side effects. A vaccine adverse event refers to any adverse event that occurs following vaccination. An adverse event could be a true vaccine reaction, or just a coincidental event, with further research needed to distinguish between them.

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 in up to 50 percent of vaccine doses, depending on the type of vaccine. Local reactions are most common with inactivated vaccines, particularly those, such as DTaP, that contain adjuvants. 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.

7. How are generalized reactions like fever, malaise and headache classified?

Systemic adverse reactions are more generalized events, and include fever, weakness, myalgia (muscle pain), headache, loss of appetite and others. These symptoms are common and nonspecific, and may occur in vaccinated persons because of the vaccine, or may be caused by something unrelated to the vaccine, like a viral infection occurring at the same time.

Systemic adverse reactions are more common following live attenuated vaccines than inactivated 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 that replication, and are similar to a mild form of the natural disease. Systemic adverse reactions following live vaccines are usually mild, and occur a week or two after the vaccine was given (*i.e.,* after an incubation period of the vaccine virus).

8. How can the risk of an allergic reaction be minimized?

A third type of vaccine adverse reaction is a severe 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, a stabilizer, preservatives, or an antibiotic used to inhibit bacterial growth. Severe allergic reactions to vaccines may be life-threatening. Fortunately, they are very rare, occurring at a rate of less than one in half a million doses. **The risk of an allergic reaction may be minimized by good screening prior to vaccination.** An example of a good screen tool is found on page II-15.

REPORTING VACCINE ADVERSE EVENTS (REFER TO SECTION III, THIS RESOURCE)

CONTRAINDICATIONS AND PRECAUTIONS TO VACCINATION

9. What is the difference between a contraindication and a precaution to immunization?

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 itself. If the vaccine were given in the presence of that condition, the resulting adverse reaction could seriously harm the recipient. For instance, administering influenza vaccine to a person with a true anaphylactic allergy to egg 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 *may increase* the chance of a serious adverse reaction, or that may 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. Under normal circumstances, 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.

10. What are the conditions generally considered to be permanent contraindications?

There are very few true contraindication and precaution conditions. **Only two of these conditions are generally considered to be permanent: severe allergy to a vaccine component or severe allergic reaction following a prior dose of a vaccine, and encephalopathy within seven days of pertussis vaccination.**

11. What are the conditions considered permanent precautions to further doses of pertussis-containing vaccine?

Four conditions are considered permanent precautions to further doses of pertussis-containing vaccine: temperature >105° F; collapse or shock-like state (hypotonic hyporesponsive episode); persistent inconsolable crying lasting three or more hours occurring within 48 hours of a dose; or a seizure, with or without fever, occurring within three days of a dose.

12. What are the temporary contraindications to vaccination with live vaccines?

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 (live injected vaccines only).

Allergy

A severe allergic reaction following a dose of vaccine will virtually always contraindicate a subsequent dose of that vaccine. Severe allergies occur within minutes or hours of the vaccine, and require medical attention. Examples of severe allergic 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.

Persons may be allergic to the vaccine antigen, animal protein, antibiotics, preservatives, or stabilizers. The most common animal protein allergen is egg protein found in vaccines prepared using embryonated chicken eggs (e.g., influenza vaccines). Ordinarily, persons who are able to eat eggs or egg products safely can receive these vaccines; persons with histories of anaphylactic or anaphylactic-like allergy to eggs or egg proteins should not. Asking individuals whether they can eat eggs without adverse effects is a reasonable way to screen for those who might be at risk from receiving influenza vaccines.

Several recent studies have shown that children who have a history of severe allergy to eggs rarely have reactions to MMR vaccine. It appears now that it may be gelatin, not egg, that causes allergic reactions to MMR. As a result, in 1998, the Advisory Committee on Immunization Practices (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 anaphylactic reactions to Neomycin should not receive these vaccines.

Pregnancy

The concern about vaccinating pregnant women is with infection of the fetus, and is theoretical. There is no evidence that any live vaccine (including rubella) causes birth defects. However, since the theoretical possibility exists, live vaccines should not be given to pregnant women.

Since inactivated vaccines cannot replicate, they cannot cause fetal infection. Inactivated vaccines should be administered to pregnant women for whom they are indicated.

Immunosuppression

13. Which type of vaccines can always be given to an immunosuppressed person?

Live vaccines can cause severe or fatal reactions in immunosuppressed persons due to uncontrolled replication of the vaccine virus, particularly oral polio vaccine virus (and rarely measles vaccine virus). Severely immunosuppressed persons should not be given live vaccines for this reason. Varicella vaccine may be given to an eligible patient when an immunosuppressed person lives in the same house.

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 three months.

Persons receiving large doses of corticosteroids should not receive live vaccines. Aerosolized steroids, such as inhalers for asthma, alternate day, rapidly tapering, and short (<14 days) high dose schedules, topical formulations, and physiologic replacement schedules are not, however, contraindications to vaccination. This is a complicated issue and most beginning immunization providers will find they need to consult their physician or experienced nurse before administering vaccine in this situation.

Inactivated vaccines are not contraindicated for immunosuppressed persons. Inactivated vaccines cannot replicate, so are safe to use in immunosuppressed persons. However, response to the vaccine may be decreased. Additional recommendations for vaccination of immunosuppressed persons are detailed in the General Recommendations on Immunization www.cdc.gov/mmwr and in a specific Altered Immunocompetence ACIP statement www.cdc.gov/nip/publications/acip_list.htm.

HIV Infection

14. Which two live vaccines should susceptible household contacts of persons with HIV infection receive?

Persons infected with human immunodeficiency virus (HIV) may have no symptoms, or may be severely immunosuppressed. Live virus vaccines are usually contraindicated, and inactivated vaccines are not contraindicated.
Measles and varicella can be very severe illnesses in persons with HIV infection and are often associated with complications. **Susceptible household contacts (such as an unimmunized child in the home) of persons with HIV infection should receive MMR and varicella vaccines.**

Moderate or Severe Acute Illness

There is no evidence that an acute illness reduces vaccine at the time of vaccination efficacy or increases vaccine adverse events. 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.
Mild, common illnesses (such as otitis media, upper respiratory infections, colds, and diarrhea) are not contraindications to vaccination.

Recent Blood Products
Blood products may interfere with the replication of live injected vaccine viruses. Recent receipt of blood products is a precaution to MMR and varicella vaccines. This is a complicated issue and most beginning immunization providers will find they need to consult their physician or experienced nurse before

administering vaccine in this situation.
Varicella and MMR vaccines should be given 14 days prior to the blood product, or delayed until the antibody has degraded (see *Suggested Intervals Between Administration of Immune Globulin Preparations for Different Indications and Measles-Containing Vaccine and Varicella Vaccine* on page II-39). If MMR is given sooner than the minimum interval shown, the recipient should be tested for immunity or the dose repeated after the appropriate interval. This is a complicated issue and most beginning immunization providers will find they need to consult their physician or experienced nurse before administering vaccine in this situation.

Inactivated vaccines are not substantially affected by circulating antibody from blood products and are not contraindicated.

INVALID CONTRAINDICATIONS TO VACCINATION
Some health care providers inappropriately consider certain conditions or circumstances to be true contraindications or precautions to vaccinations. Such conditions or circumstances are known as invalid contraindications, and result in missed opportunities to administer needed vaccines. Some of the most common invalid contraindications are minor illnesses, conditions related to pregnancy and breast-feeding, allergies that are not anaphylactic in nature, and certain aspects of the patient's family history.

15. If a child has a mild acute illness such as a low-grade fever and upper respiratory infection, can he be immunized?

Minor Illness
Children with mild acute illnesses, such as low-grade fever, upper respiratory infection, colds, otitis media, and mild diarrhea can and should be vaccinated.

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. Further, there is no evidence that mild diarrhea reduces the success of immunization of infants in this country. 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.

16. If a child is presently taking an antibiotic such as Amoxicillin for an ear infection can he receive his vaccines today?

Antibiotic Therapy
Yes, the child can receive immunizations while taking antibiotics such as Amoxicillin. Antibiotics do not have an effect on the immune response to a vaccine. No commonly used antibiotic or antiviral will inactivate a live virus vaccine.

Disease Exposure or Convalescence
If a child is not 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.

17. What vaccines are contraindicated for breast-fed infants?

Pregnancy in the Household or Breast-feeding

All vaccines, including live vaccines (MMR and varicella) can be given to infants or children with pregnant household contacts, as well as to breast-feeding infants. Breast-feeding does not decrease the response to routine childhood vaccines.

Premature Birth

Vaccines should be started on schedule based on the child's chronological age. Premature infants have been shown to respond adequately to vaccines used in infancy.

Studies demonstrate that decreased seroconversion rates might occur among certain premature infants with low birth weights (*i.e.,* <2,000 grams) after administration of hepatitis B vaccine at birth. However, by one month chronological age, all premature infants, regardless of initial birthweight or gestational age are as likely to respond as adequately as older and larger infants. All premature infants born to hepatitis B surface antigen (HBsAg) positive mothers and mothers with unknown HBsAg status must receive immunoprophylaxis with hepatitis B vaccine and hepatitis B immunoglobulin (HBIG) within 12 hours after birth. If these infants weigh less than 2000 grams at birth, the initial vaccine dose should not be counted towards completion of the hepatitis B vaccine series, and three additional doses of hepatitis B vaccine should be administered beginning when the infant is one month of age.

Nonspecific Allergies, Allergies to Antibiotics Not in Vaccine, Non-severe Egg Allergies, and Allergies to Duck Antigens

Infants and children with non-specific allergies, duck or feather allergy, allergy to penicillin, 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.

Non-anaphylactic Allergy to Vaccine Component

Anaphylactic allergy to a vaccine component (such as egg or Neomycin) is a true contraindication to vaccination. Non-anaphylactic allergy to a vaccine constituent is not a contraindication to that vaccine.

Family History of Adverse Events Unrelated to Immunosuppression, or Family History of Seizures or SIDS

The only family history that is relevant in the decision to vaccinate a child is immunosuppression and only for oral polio virus vaccine. OPV should not be given to a child with a personal or family history of immunosuppression, because the vaccine virus could spread to the immunosuppressed contact. This is a complicated issue and most beginning immunization providers will find they need to consult their physician or experienced nurse before administering vaccine in this situation.

18. What vaccine cannot be administered at the same time as a TB skin test?

Need or Requirement for Tuberculosis Skin Test (PPD)

Infants and children who need TB skin tests can and should be immunized. **All vaccines, including MMR, can be given on the same day as a TB skin test, or any time after a TB skin test is applied.** For most vaccines, there are no TB skin test timing restrictions at all.

MMR vaccine may decrease the response to a TB skin test, potentially causing a false negative response in someone who actually has an infection with tuberculosis. MMR can be given the same day as a TB

skin test, but if MMR has been given and one or more days have elapsed, in most situations it is recommended to wait four to six weeks before giving a routine TB skin test. No information on the effect of varicella vaccine on a TB skin test is available. Until such information is available, it is prudent to apply the rules for spacing measles vaccine and TB skin testing to varicella vaccine.

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II. Vaccine Administration

Colorado Children's Immunization Coalition
Vaccine Administration

Overview

Appropriate vaccine administration is critical to vaccine effectiveness. The recommended site, route and dosage for each vaccine is based on clinical trials, practical experience and theoretical considerations. The following information is adapted from *Epidemiology and Prevention of Vaccine Preventable Diseases*, 7th edition (January 2003) and provides general guidelines for administration of vaccines for those who administer vaccines, as well as those in training, education and supervisory positions. This information should be used in conjunction with professional standards for medication administration, vaccine manufacturers' product guidelines, Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) General Recommendations on Immunization, the American Academy of Pediatrics' (AAP) Report of the Committee on Infectious Diseases Red Book, and state/agency-related policies and procedures.

An education plan that includes competency-based training on vaccine administration should be considered for all persons who administer vaccines to children and/or adults. Various immunization training resources can be located at any of the following web addresses: www.cdc.gov or www.immunize.org/iztech or www2.edserv.musc.edu/tide/menu.lasso

PREPARATION

1. What two factors should be considered when preparing a patient for vaccination?

➢ **PATIENT PREPARATION - Patients should be prepared for vaccination with consideration for their age and stage of development**. Parents/guardians and patients should be encouraged to take an active role before, during and after the administration of vaccines. Parents/guardians who elect not to directly participate during vaccine administration can wait in a nearby area.

- **Screening** - All patients should be screened for contraindications and precautions for each scheduled vaccine. Many state immunization programs and other organizations have developed and make available standardized screening tools. An example of a good immunization screening tool is on page II-15.

- **Vaccine Safety & Risk Communication** - Parents/guardians and patients are exposed through the media to information about vaccines, some of which is inaccurate or misleading. Health care providers should be prepared to discuss the benefits and risks of vaccines using Vaccine Information Statements (VISs) and other reliable resources. Establishing an open dialogue provides a safe, trust-building environment in which individuals can freely evaluate information, discuss vaccine concerns and make informed decisions regarding immunization.

2. List two issues that have contributed to the concerns and anxiety that patients/parents associate with vaccination.

■ **Vaccine safety issues and the need for multiple injections have increased the concerns and anxiety associated with immunizations.** Health care providers need to display confidence and establish an environment that promotes a sense of security and trust for the patient and family, utilizing a variety of techniques to minimize the stress and discomfort associated with receiving injections. This is particularly important when administering vaccines to children.

3. When considering patient positioning and restraint, what must the health care provider accommodate for?

- **Positioning & Comforting Restraint - To assure patient comfort and safety, the health care provider must make accommodations for age, activity level and the site of administration, when considering patient positioning and restraint.** For a child, the parent/guardian should be encouraged to hold the child during administration. If the parent is uncomfortable, another person may assist or the patient may be positioned safely on an examination table.

- **Pain Control** - Pain is a subjective phenomenon influenced by multiple factors, including an individual's age, anxiety level, previous health care experiences and culture. Consideration for these factors is important as the provider develops a planned approach to management of injection pain.

  ✓Topical anesthetics or a vapocoolant spray may be prescribed pre-vaccination to decrease pain at the injection site. These products should be used only for the ages recommended and as directed by the product manufacturer.

  ✓ Analgesic Agents - A non-aspirin-containing pain reliever may be considered to decrease discomfort and fever following vaccination. These products should be used only in age-appropriate doses.

4. Why do diversionary techniques used for vaccine administration pain control work?

✓ Diversionary Techniques - **Age-appropriate non-pharmacologic techniques may provide distraction from pain associated with injections.** Diversion can be accomplished through a variety of techniques. The Immunization Branch of the California Department of Health Services has developed a handout which describes various diversionary techniques entitled, *Comforting Restraint for Immunizations,* included in this section on page II-27.

✓ Dual Administrators - Some providers favor the technique of two individuals administering vaccines at the sametime at separate sites. The premise is that this procedure may decrease

anxiety from anticipation of the next injection(s). The effectiveness of this procedure in decreasing pain or stress associated with vaccine injections has not been widely evaluated.

➢**INFECTION CONTROL** –Health care providers should follow Standard Precautions to minimize the risks of spreading disease during vaccine administration.

5. What is the single most effective disease prevention activity?

■ **Handwashing** - **The single, most effective disease prevention activity is good handwashing.** Hands should be washed thoroughly with soap and water or cleansed with an alcohol-based waterless antiseptic between patients, before vaccine preparation or any time hands become soiled, e.g. diapering, cleaning excreta, etc.

■ **Gloving** - Gloves are not mandatory for vaccine administration unless there is potential for exposure to blood or body fluids or the provider has open lesions on the hands. It is important to remember that gloves cannot prevent needle stick injuries.

■ **Needle stick injuries** should be reported immediately to the site supervisor with appropriate care and follow-up given as directed by state/local guidelines.

6. How should empty vaccine vials be handled?

■ **Equipment Disposal** - *Used needles should not be detached from syringes, recapped or cut before disposal. All used syringe/needle devices should be placed in puncture proof-containers to prevent accidental needle sticks and reuse.* **Empty or expired vaccine vials are considered medical waste and should be disposed of according to state regulations.**

➢**VACCINE PREPARATION** - Proper vaccine handling and preparation is critical in maintaining the integrity of the vaccine during transfer from the manufacturer's vial to the syringe and ultimately to the patient.

■ **Equipment Selection**

- Syringe Selection - A separate needle and syringe should be used for each injection. A parenteral vaccine may be delivered in either a 1 ml or 3 ml syringe as long as the prescribed dosage is delivered. Syringe devices with sharps engineered sharps injury protection (SESIP) are available, and required by OSHA to reduce the incidence of needle stick injuries and potential disease transmission. Personnel should be involved in product evaluation and selection. Prior to use in the clinical area, staff should receive training with the device.

7. When selecting a needle for vaccine administration, what should the needle size be based on?

- **Needle Selection** - Vaccine must reach the desired tissue site for optimal immune response. Therefore, **needle selection should be based upon the prescribed route, size of the individual and viscosity of the vaccine** (see *Subcutaneous & Intramuscular Injections*

below). Typically vaccines are not highly viscous, and therefore, a fine gauge needle can be used (22-25 gauge).

8. What is the rule of thumb about vaccine expiration dates?

■ Inspecting Vaccine - Each vaccine vial should be carefully inspected for damage or contamination prior to use. The expiration date printed on the vial or box should be checked. **Vaccine can be used through the last day of the month indicated by the expiration date**. Vaccine past its expiration date should never be used.

■ Reconstitution - Some vaccines are prepared in a lyophilized form that requires reconstitution, which should be done according to manufacturer guidelines. Diluent solutions vary; only the specific diluent supplied for the vaccine should be used. Once the vaccine vial is uncapped, clean the rubber stopper of the vial with an alcohol wipe and allow to dry. Inject the entire content of the diluent vial into the vial of lyophilized vaccine and gently agitate to ensure thorough mixing. Once reconstituted, the vaccine must be administered within the time guidelines provided by the manufacturer or discarded. Changing the needle after reconstitution of the vaccine is not necessary unless the needle has become contaminated or bent. Continue with steps for filling the syringe.

■ Filling the Syringe -

- For vaccines that do not require reconstitution, uncap the vaccine vial, clean the rubber stopper of the vial with an alcohol wipe and allow to dry.
- If possible, tighten the needle on the syringe.
- Pull back on the plunger to fill the syringe with an amount of air equal to the amount of vaccine to be withdrawn.
- Remove the needle guard and place the guard where it will not become contaminated.
- With the vial upright, insert the needle directly into the center of the rubber stopper.
- Inject the air into the vial, keeping the bevel of the needle above the level of the vaccine to avoid producing air bubbles in the vaccine. The injected air will create positive pressure in the vial and allow removal of the vaccine without creating a vacuum.
- Invert the vial and withdraw the vaccine keeping the bevel of the needle within the solution to avoid drawing air into the syringe. For single dose vials, withdraw the entire vial contents. For multidose vials, withdraw the desired vaccine dose.
- Remove the vial and expel any air bubbles or excess air from the syringe by gently tapping the side of the syringe and advancing the plunger. Do not expel any of the vaccine.
- Recap the needle. Since the needle has not been injected into the patient, recapping at this

point is allowable.

9. Why is pre-filling a syringe discouraged?

■ **Prefilling syringes or loading vaccine into syringes to prepare for patients to be seen later is discouraged by ACIP because of the risks for vaccine contamination, administration errors and vaccine wastage.** In certain situations where only one vaccine will be administered (i.e. large influenza campaigns), filling several syringes shortly before administration may be considered. Storage and handling guidelines must be maintained and the syringes must be labeled with the name of the vaccine or antigen(s), lot number, and filling date.

10. It is important to label each vaccine that you draw up and how can this be accomplished?

■ **Labeling** - Once vaccines are drawn up, filled syringes should be identifiable in terms of the vaccine or antigen(s) in the syringe(s). **There are a variety of methods for identifying or labeling syringes (i.e. keep syringes with the appropriate vaccine vials, place the syringes in a label-partitioned tray, or use color-coded labels or preprinted labels). Some providers may choose to include the lot number and date of filling on the identification.**

ADMINISTRATION

Administering a vaccine by the recommended route is imperative. Delivering the vaccine into the appropriate tissue promotes optimal vaccine efficacy and diminishes the risk of severe local adverse reactions.

■ **Subcutaneous** (SC) injections are administered into the fatty tissue found below the dermis and above muscle tissue.

- Site - SC tissue can be found all over the body. The usual SC sites for vaccine administration are the thigh and the upper outer triceps region of the arm. If necessary, the upper outer triceps region can be used to administer SC injections to infants.

- Technique

  ✓ Following appropriate site assessment/selection, prep the injection site with an alcohol wipe. Using a circular motion, wipe from the center out and allow to dry.

11. How can one avoid reaching the muscle when administering a subcutaneous (SC) injection?

✓ **To avoid reaching the muscle, the fatty tissue is pinched up, the needle is inserted at a 45 degree angle and the vaccine is injected into the tissue.**

✓ Withdraw the needle and apply light pressure to the injection site for several seconds

with a dry cotton ball/gauze.

■ **Intramuscular** (IM) injections are administered into muscle tissue below the dermis and SC tissue.

12. Which intramuscular (IM) muscle site should never be used to administer vaccines?

- Site - Although there are several IM injection sites on the body, the recommended IM sites for vaccine administration are the vastus lateralis muscle (anterolateral thigh) and the deltoid muscle (upper arm). The site depends on the age of the individual and the degree of muscle development. The deltoid muscle site is most commonly used in older children and adults. The deltoid muscle can be used in toddlers if the muscle mass is adequate. **The buttock should never be used to administer vaccines because you can cause nerve damage and run the risk of reduced titers.**

- Technique

  ✓ Following appropriate site assessment/selection, prep the injection site with an alcohol wipe. Using a circular motion, wipe from the center out and allow to dry.

13. When administering an intramuscular (IM) immunization, how can injection into subcutaneous tissue be avoided?

✓ **To avoid injection into subcutaneous (SC) tissue when administering an intramuscular (IM) immunization, a 90 degree angle should be used and the skin of the selected vaccine administration site can be spread taut between the thumb and forefinger, isolating the muscle. Another technique, acceptable mostly for pediatric and geriatric patients, is to grasp the tissue and "bunch up" the muscle.**

✓ Insert the needle fully into the muscle at a 90 degree angle and inject the vaccine into the tissue.

✓ Withdraw the needle and apply light pressure to the injection site for several seconds with a dry cotton ball/gauze.

Aspiration - Aspiration is the process of pulling back on the plunger of the syringe prior to injection to ensure that the medication is not injected into a blood vessel. Although this practice is advocated by some experts, there is no research data documented to support the need for this procedure. If blood appears following aspiration, the needle should be withdrawn, a new site selected and the entire administration process restarted.

14. If more than one vaccine is administered in the same limb, how far apart must the two injections be placed?

Multiple Vaccinations - When administering multiple vaccines, NEVER mix vaccines in the same syringe unless approved for mixing by the Food and Drug Administration (FDA). **If more than one vaccine must be administered in the same limb, the injection sites should be separated by one to two inches so that any local reactions can be differentiated.** Vaccine doses range from 0.5 ml to 1 ml. The recommended maximum volume of medication for an IM site, varies among references and depends on the muscle mass of the individual. However, administering two IM vaccines into the same muscle would not exceed any suggested volume ranges for either the vastus lateralis or the deltoid muscle in any age group. The option to also administer a SC vaccine into the same limb, if necessary, is acceptable since a different tissue site is involved.

Nonstandard Administration - not using from the recommended route, site and dosage of vaccine is strongly discouraged and can result in inadequate protection. In situations where nonstandard administration has occurred, refer to the ACIP General Recommendation on Immunization, MMWR 2002; 51 (RR-2), for specific guidance.

SPECIAL SITUATIONS

15. What is the most important step to take when preparing an immunization injection for an individual with a bleeding disorder?

➢ Bleeding Disorders - Individuals with a bleeding disorder or who are receiving anticoagulation therapy may develop hematomas in IM injection sites. Prior to administration of IM vaccines the patient or family should be instructed about the risk of hematoma formation from the injection. Additionally, **a physician familiar with the patient's bleeding disorder or therapy should be consulted regarding the safety of administration by this route.** If the patient periodically receives hemophilia replacement factor or other similar therapy, IM vaccine administration should ideally be scheduled shortly after replacement therapy. A 23-gauge or finer needle should be used and firm pressure applied to the site for at least two minutes. The site should not be rubbed or massaged.

16. If a patient has a history of rare severe latex allergy, what should the immunization provider do first in considering the vaccine administration?

➢ Latex Allergy - Administration of a vaccine supplied in a vial or syringe that contains natural rubber (refer to product information) should not be administered to an individual with a history of a severe (anaphylactic) allergy to latex, unless the benefit of vaccination clearly outweighs the risk of an allergic reaction. These situations are rare**. Medical consultation and direction should be sought regarding vaccination.** A local or contact sensitivity to latex is not a contraindication to vaccination.

➢Limited Sites - Sometimes vaccination sites may be limited in an individual because of amputation, injury, orthopedic device or cast, etc. It may be necessary to consult the patient's primary health care provider to develop an individualized immunization schedule.

➢Syncopal or vasovagal response ("fainting") may occur during vaccine administration, especially with adolescents and adults. Because individuals may fall and sustain injury as a result, the provider may consider having the patient sit during injection(s). A syncopal or vasovagal response is not an allergic reaction, however, the provider should observe and administer supportive care until the patient is recovered.

17. What should every facility have in place to prepare for an anaphylaxis after vaccine administration?

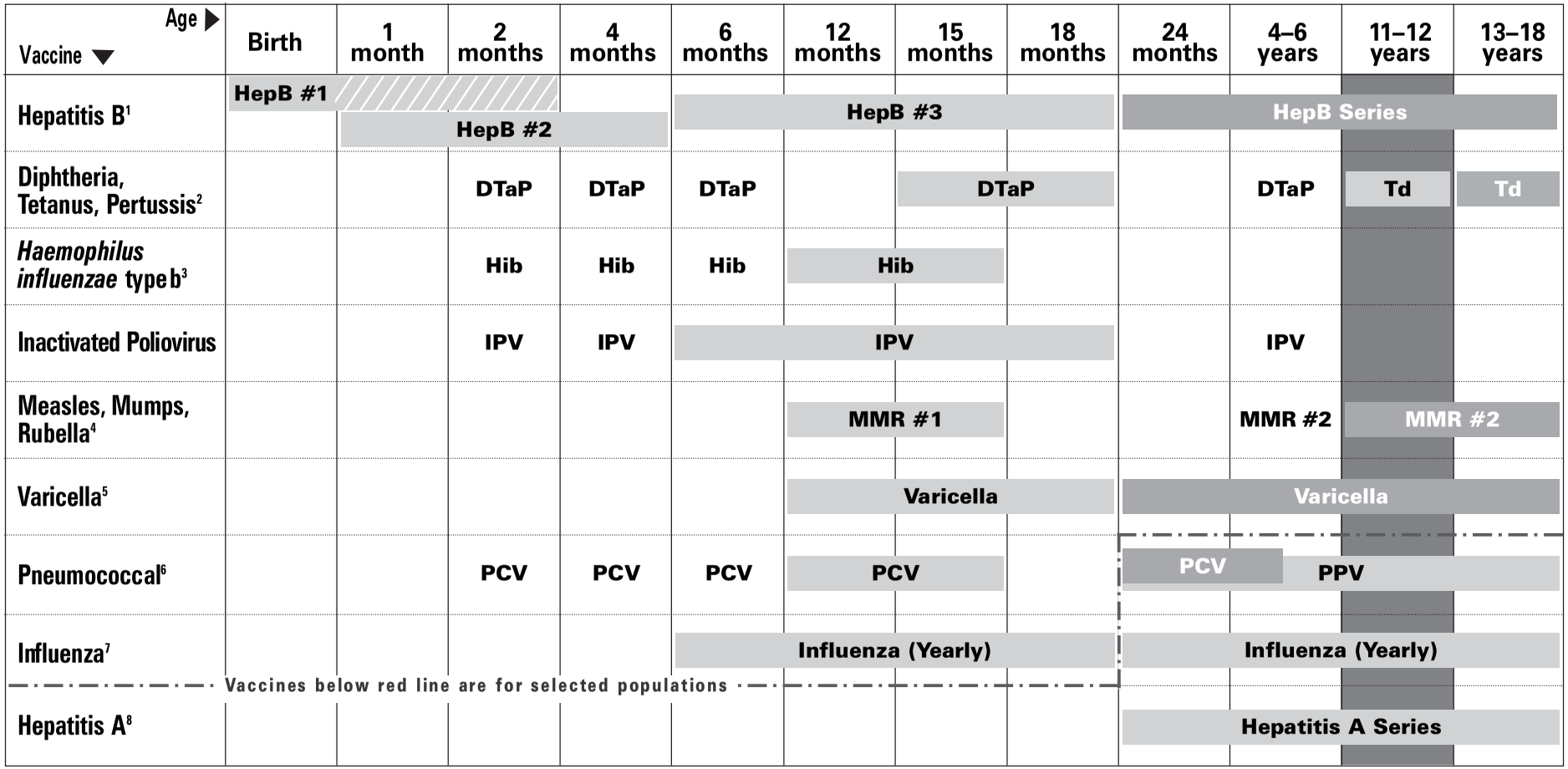
➢Anaphylaxis (a life-threatening, acute allergic reaction) - **Each facility that administers vaccines should have a protocol, procedures and equipment to provide initial care for suspected anaphylaxis.** Facility staff should be prepared to recognize and respond appropriately to this type of emergency situation. All staff should maintain current CPR certification. Emergency protocols, procedures and equipment/supplies should be reviewed periodically. For detailed information on medical management, refer to the *ACIP General Recommendations on Immunization and the AAP Red Book.* Although both fainting and allergic reactions are rare, some experts suggest observing patients for 15 – 20 minutes following vaccine administration.

➢Facilities that administer vaccines are encouraged to participate in state/local vaccine registries. The patient or parent should be provided with an immunization record that includes the vaccines administered with dates of administration.

SELECTED REFERENCES

CDC. *Epidemiology and Prevention of Vaccine-Preventable Diseases, 7th edition, Appendix G* (January 2003).

Recommended Childhood and Adolescent Immunization Schedule UNITED STATES • 2005



This schedule indicates the recommended ages for routine administration of currently licensed childhood vaccines, as of December 1, 2004, for children through age 18 years. Any dose not administered at the recommended age should be administered at any subsequent visit when indicated and feasible.

Indicates age groups that warrant special effort to administer those vaccines not previously administered. Additional vaccines may be licensed and recommended during the year. Licensed combination vaccines may be used whenever any components of the combination are indicated and other components of the vaccine are not contraindicated. Providers should consult the manufacturers' package inserts for detailed recommendations. Clinically significant adverse events that follow immunization should be reported to the Vaccine Adverse Event Reporting System (VAERS). Guidance about how to obtain and complete a VAERS form are available at www.vaers.org or by telephone, 800-822-7967.

- Range of recommended ages
- Preadolescent assessment
- Only if mother HBsAg(–)
- Catch-up immunization

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION

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The Childhood and Adolescent Immunization Schedule is approved by:
Advisory Committee on Immunization Practices www.cdc.gov/nip/acip
American Academy of Pediatrics www.aap.org
American Academy of Family Physicians www.aafp.org

Footnotes
Recommended Childhood and Adolescent Immunization Schedule
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1. **Hepatitis B (HepB) vaccine.** All infants should receive the first dose of HepB vaccine soon after birth and before hospital discharge; the first dose may also be administered by age 2 months if the mother is hepatitis B surface antigen (HBsAg) negative. Only monovalent HepB may be used for the birth dose. Monovalent or combination vaccine containing HepB may be used to complete the series. Four doses of vaccine may be administered when a birth dose is given. The second dose should be administered at least 4 weeks after the first dose, except for combination vaccines which cannot be administered before age 6 weeks. The third dose should be given at least 16 weeks after the first dose and at least 8 weeks after the second dose. The last dose in the vaccination series (third or fourth dose) should not be administered before age 24 weeks.

   Infants born to HBsAg-positive mothers should receive HepB and 0.5 mL of hepatitis B immune globulin (HBIG) at separate sites within 12 hours of birth. The second dose is recommended at age 1–2 months. The final dose in the immunization series should not be administered before age 24 weeks. These infants should be tested for HBsAg and antibody to HBsAg (anti-HBs) at age 9–15 months.

   Infants born to mothers whose HBsAg status is unknown should receive the first dose of the HepB series within 12 hours of birth. Maternal blood should be drawn as soon as possible to determine the mother's HBsAg status; if the HBsAg test is positive, the infant should receive HBIG as soon as possible (no later than age 1 week). The second dose is recommended at age 1–2 months. The last dose in the immunization series should not be administered before age 24 weeks.

2. **Diphtheria and tetanus toxoids and acellular pertussis (DTaP) vaccine.** The fourth dose of DTaP may be administered as early as age 12 months, provided 6 months have elapsed since the third dose and the child is unlikely to return at age 15–18 months. The final dose in the series should be given at age ≥4 years. **Tetanus and diphtheria toxoids (Td)** is recommended at age 11–12 years if at least 5 years have elapsed since the last dose of tetanus and diphtheria toxoid-containing vaccine. Subsequent routine Td boosters are recommended every 10 years.

3. ***Haemophilus influenzae* type b (Hib) conjugate vaccine.** Three Hib conjugate vaccines are licensed for infant use. If PRP-OMP (PedvaxHIB® or ComVax® [Merck]) is administered at ages 2 and 4 months, a dose at age 6 months is not required. DTaP/Hib combination products should not be used for primary immunization in infants at ages 2, 4 or 6 months but can be used as boosters after any Hib vaccine. The final dose in the series should be administered at age ≥12 months.

4. **Measles, mumps, and rubella vaccine (MMR).** The second dose of MMR is recommended routinely at age 4–6 years but may be administered during any visit, provided at least 4 weeks have elapsed since the first dose and both doses are administered beginning at or after age 12 months. Those who have not previously received the second dose should complete the schedule by age 11–12 years.

5. **Varicella vaccine.** Varicella vaccine is recommended at any visit at or after age 12 months for susceptible children (i.e., those who lack a reliable history of chickenpox). Susceptible persons aged ≥13 years should receive 2 doses administered at least 4 weeks apart.

6. **Pneumococcal vaccine.** The heptavalent **pneumococcal conjugate vaccine (PCV)** is recommended for all children aged 2–23 months and for certain children aged 24–59 months. The final dose in the series should be given at age ≥12 months. **Pneumococcal polysaccharide vaccine (PPV)** is recommended in addition to PCV for certain high-risk groups. See *MMWR* 2000;49(RR-9):1-35.

7. **Influenza vaccine.** Influenza vaccine is recommended annually for children aged ≥6 months with certain risk factors (including, but not limited to, asthma, cardiac disease, sickle cell disease, human immunodeficiency virus [HIV], and diabetes), healthcare workers, and other persons (including household members) in close contact with persons in groups at high risk (see *MMWR* 2004;53[RR-6]:1-40). In addition, healthy children aged 6–23 months and close contacts of healthy children aged 0–23 months are recommended to receive influenza vaccine because children in this age group are at substantially increased risk for influenza-related hospitalizations. For healthy persons aged 5–49 years, the intranasally administered, live, attenuated influenza vaccine (LAIV) is an acceptable alternative to the intramuscular trivalent inactivated influenza vaccine (TIV). See *MMWR* 2004;53(RR-6):1-40. Children receiving TIV should be administered a dosage appropriate for their age (0.25 mL if aged 6–35 months or 0.5 mL if aged ≥3 years). Children aged ≤8 years who are receiving influenza vaccine for the first time should receive 2 doses (separated by at least 4 weeks for TIV and at least 6 weeks for LAIV).

8. **Hepatitis A vaccine.** Hepatitis A vaccine is recommended for children and adolescents in selected states and regions and for certain high-risk groups; consult your local public health authority. Children and adolescents in these states, regions, and high-risk groups who have not been immunized against hepatitis A can begin the hepatitis A immunization series during any visit. The 2 doses in the series should be administered at least 6 months apart. See *MMWR* 1999;48(RR-12):1-37.

Recommended Immunization Schedule
for Children and Adolescents Who Start Late or Who Are More Than 1 Month Behind
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The tables below give catch-up schedules and minimum intervals between doses for children who have delayed immunizations. There is no need to restart a vaccine series regardless of the time that has elapsed between doses. Use the chart appropriate for the child's age.

CATCH-UP SCHEDULE FOR CHILDREN AGED 4 MONTHS THROUGH 6 YEARS

Vaccine	Minimum Age for Dose 1	Minimum Interval Between Doses			
		Dose 1 to Dose 2	Dose 2 to Dose 3	Dose 3 to Dose 4	Dose 4 to Dose 5
Diphtheria, Tetanus, Pertussis	6 wks	4 weeks	4 weeks	6 months	6 months[1]
Inactivated Poliovirus	6 wks	4 weeks	4 weeks	4 weeks[2]	
Hepatitis B[3]	Birth	4 weeks	8 weeks (and 16 weeks after first dose)		
Measles, Mumps, Rubella	12 mo	4 weeks[4]			
Varicella	12 mo				
Haemophilus influenzae type b[5]	6 wks	4 weeks if first dose given at age <12 months 8 weeks (as final dose) if first dose given at age 12-14 months No further doses needed if first dose given at age ≥15 months	4 weeks[6] if current age <12 months 8 weeks (as final dose)[6] if current age ≥12 months and second dose given at age <15 months No further doses needed if previous dose given at age ≥15 mo	8 weeks (as final dose) This dose only necessary for children aged 12 months–5 years who received 3 doses before age 12 months	
Pneumococcal[7]	6 wks	4 weeks if first dose given at age <12 months and current age <24 months 8 weeks (as final dose) if first dose given at age ≥12 months or current age 24–59 months No further doses needed for healthy children if first dose given at age ≥24 months	4 weeks if current age <12 months 8 weeks (as final dose) if current age ≥12 months No further doses needed for healthy children if previous dose given at age ≥24 months	8 weeks (as final dose) This dose only necessary for children aged 12 months–5 years who received 3 doses before age 12 months	

CATCH-UP SCHEDULE FOR CHILDREN AGED 7 YEARS THROUGH 18 YEARS

Vaccine	Minimum Interval Between Doses		
	Dose 1 to Dose 2	Dose 2 to Dose 3	Dose 3 to Booster Dose
Tetanus, Diphtheria	4 weeks	6 months	**6 months**[8] if first dose given at age <12 months and current age <11 years **5 years**[8] if first dose given at age ≥12 months and third dose given at age <7 years and current age ≥11 years **10 years**[8] if third dose given at age ≥7 years
Inactivated Poliovirus[9]	4 weeks	4 weeks	IPV[2,9]
Hepatitis B	4 weeks	8 weeks (and 16 weeks after first dose)	
Measles, Mumps, Rubella	4 weeks		
Varicella[10]	4 weeks		

Footnotes

Children and Adolescents Catch-up Schedules

UNITED STATES • 2005

1. **DTaP.** The fifth dose is not necessary if the fourth dose was administered after the fourth birthday.
2. **IPV.** For children who received an all-IPV or all-oral poliovirus (OPV) series, a fourth dose is not necessary if third dose was administered at age ≥4 years. If both OPV and IPV were administered as part of a series, a total of 4 doses should be given, regardless of the child's current age.
3. **HepB.** All children and adolescents who have not been immunized against hepatitis B should begin the HepB immunization series during any visit. Providers should make special efforts to immunize children who were born in, or whose parents were born in, areas of the world where hepatitis B virus infection is moderately or highly endemic.
4. **MMR.** The second dose of MMR is recommended routinely at age 4–6 years but may be administered earlier if desired.
5. **Hib.** Vaccine is not generally recommended for children aged ≥5 years.
6. **Hib.** If current age <12 months and the first 2 doses were PRP-OMP (PedvaxHIB® or ComVax® [Merck]), the third (and final) dose should be administered at age 12–15 months and at least 8 weeks after the second dose.
7. **PCV.** Vaccine is not generally recommended for children aged ≥5 years.
8. **Td.** For children aged 7–10 years, the interval between the third and booster dose is determined by the age when the first dose was administered. For adolescents aged 11–18 years, the interval is determined by the age when the third dose was given.
9. **IPV.** Vaccine is not generally recommended for persons aged ≥18 years.
10. **Varicella.** Administer the 2-dose series to all susceptible adolescents aged ≥13 years.

Report adverse reactions to vaccines through the federal Vaccine Adverse Event Reporting System. For information on reporting reactions following immunization, please visit www.vaers.org or call the 24-hour national toll-free information line 800-822-7967. Report suspected cases of vaccine-preventable diseases to your state or local health department.

For additional information about vaccines, including precautions and contraindications for immunization and vaccine shortages, please visit the National Immunization Program Web site at www.cdc.gov/nip or call the National Immunization Information Hotline at 800-232-2522 (English) or 800-232-0233 (Spanish).

Recommended and minimum ages and intervals between vaccine doses*

Vaccine and dose number	Recommended age for this dose	Minimum age for this dose	Recommended interval to next dose	Minimum interval to next dose
Hepatitis B-1†	Birth-2 months	Birth	1-4 months	4 weeks
Hepatitis B-2	1-4 months	4 weeks	2-17 months	8 weeks
Hepatitis B-3§	2 months	24 weeks	–	–
Diphtheria and tetanus toxoids and acellular pertussis (DTaP)-1	2 months	6 weeks	2 months	4 weeks
DTaP-2	4 months	10 weeks	2 months	4 weeks
DTaP-3	6 months	14 weeks	6-12 months	6 months¶**
DTaP-4	15-18 months	12 months	3 years	6 months¶
DTaP-5	4-6 years	4 years	–	–
Haemophilus influenzae type b (Hib)-1† ††	2 months	6 weeks	2 months	4 weeks
Hib-2	4 months	10 weeks	2 months	4 weeks
Hib-3	6 months	14 weeks	6-9 months	8 weeks
Hib-4	12-15 months	12 months	–	–
Inactivated poliovirus vaccine (IPV)-1	2 months	6 weeks	2 months	4 weeks
IPV-2	4 months	10 weeks	2-14 months	4 weeks
IPV-3	6-18 months	14 weeks	3-5 years	4 weeks
IPV-4	4-6 years	18 weeks	–	–
Pneumococcal conjugate vaccine (PCV)-1	2 months	6 weeks	2 months	4 weeks
PCV-2	4 months	10 weeks	2 months	4 weeks
PCV-3	6 months	14 weeks	6 months	8 weeks
PCV-4	12-15 months	12 months	–	–
Measles, mumps , and rubella (MMR)-1	12-15 months¶¶	12 months	3-5 years	4 weeks
MMR-2	4-6 years	13 months	–	–
Varicella***	12-18 months	12 months	4 weeks***	4 weeks***
Hepatitis A-1	≥2 years	2 years	6-18 months¶	6 months¶
Hepatitis A-2	≥30 months	30 months	–	–
Trivalent Inactivated Influenza Vaccine (TIV)†††	6-23 months	6 months	1 month	4 weeks
Live Attenuated Influenza Vaccine (LAIV)†††	–	5 years	6-10 weeks	6 weeks
Pneumococcal polysaccharide vaccine (PPV)-1	–	2 years	5 years	5 years
PPV-2	–	7 years§§§	–	–

* Combination vaccines are available. Using licensed combination vaccines is preferred over separate injections of their equivalent component vaccines (Source: 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];5). 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 antigens.

† A combination hepatitis B-Hib vaccine is available (Comvax©, manufactured by Merck Vaccine Division). This vaccine should not be administered to infants aged <6 weeks because of the Hib component.

§ Hepatitis B-3 should be administered ≥8 weeks after Hepatitis B-2 and 16 weeks after Hepatitis B-1, and it should not be administered before age 24 weeks.

¶ Calendar months.

** The minimum interval between DTaP-3 and DTaP-4 is recommended to be ≥6 months. However, DTaP-4 does not need to be repeated if administered ≥4 months after DTaP-3.

†† For Hib and PCV, children receiving the first dose of vaccine at age ≥7 months require fewer doses to complete the series (see 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]:1-7, and CDC. Preventing pneumococcal disease among infants and young children: recommendations of the Advisory Committee on Immunization Practices [ACIP], *MMWR* 2000; 49[No. RR-9];1-35).

§§ For a regimen of only polyribosylribitol phosphate-meningococcal outer membrane protein (PRP-OMP, Pedvax-Hib®, manufactured by Merck), a dose administered at age 6 months is not required.

¶¶ During a measles outbreak, if cases are occurring among infants aged <12 months, measles vaccination of infants aged ≥6 months can be undertaken as an outbreak control measure. However, doses administered at age <12 months should not be counted as part of the series. (Source: 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]:1-57).

*** Children aged 12 months - 12 years require only one dose of varicella vaccine. Persons aged ≥13 years should receive two doses separated by ≥4 weeks.

††† Two doses of influenza vaccine are recommended for children aged <9 years who are receiving the vaccine for the first time. Children aged <9 years who have previously received influenza vaccine and persons aged ≥9 years require only one dose per influenza season.

§§§ Second doses of PPV are recommended for persons at highest risk for serious pneumococcal infection and those who are likely to have a rapid decline in pneumococcal antibody concentration. Revaccination 3 years after the previous dose can be considered for children at highest risk for severe pneumococcal infection who would be aged <10 years at the time of revaccination. (See CDC. Prevention of pneumococcal disease: recommendations of the Advisory Committee on Immunization Practices [ACIP]. *MMWR* 1997;46[No. RR-8]:1-24).

Adapted from Table 1, ACIP General Recommendations on Immunization: *MMWR* 2002;51(No. RR-2) **November 2004**

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

Screening Questionnaire for Child and Teen Immunization

For parents/guardians: The following questions will help us determine which vaccines your child may be given today. If a question is not clear, please ask the nurse or doctor to explain it.

	Yes	No	Don't Know
1. Is the child sick today?	☐	☐	☐
2. Does the child have allergies to medications, food, or any vaccine?	☐	☐	☐
3. Has the child had a serious reaction to a vaccine in the past?	☐	☐	☐
4. Has the child had a seizure or a brain problem?	☐	☐	☐
5. Does the child have cancer, leukemia, AIDS, or any other immune system problem?	☐	☐	☐
6. Has the child taken cortisone, prednisone, other steroids, or anticancer drugs, or had x-ray treatments in the past 3 months?	☐	☐	☐
7. Has the child received a transfusion of blood or blood products, or been given a medicine called immune (gamma) globulin in the past year?	☐	☐	☐
8. Is the child/teen pregnant or is there a chance she could become pregnant during the next month?	☐	☐	☐
9. Has the child received vaccinations in the past 4 weeks?	☐	☐	☐

Form completed by: _____ Date: _____

Form reviewed by: _____ Date: _____

Did you bring your child's immunization record card with you? **yes** ☐ **no** ☐

It is important to have a personal record of your child's vaccinations. If you don't have a record card, ask the child's health care provider to give you one! Bring this record with you every time you seek medical care for your child. Make sure your health care provider records all your child's vaccinations on it. Your child will need this card to enter day care, kindergarten, junior high, etc.

www.immunize.org/catg.d/p4060scr.pdf • Item #P4060 (4/04)

Understanding the Screening Questionnaire for Child & Teen Immunization

The information below has been adapted from *Epidemiology & Prevention of Vaccine-Preventable Diseases,* WL Atkinson et al., editors, CDC, 8th edition, Feb. 2004, and the 2002 General Recommendations on Immunization, *MMWR* 2002;51(RR-2).

1. Is the child sick today?
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, or any vaccine?
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, or if a person has anaphylaxis after eating gelatin, do not administer MMR or varicella vaccine. Local reactions (e.g., a red eye following instillation of ophthalmic solution) are not contraindications. For an extensive table of vaccine components, see reference 3.

3. Has the child had a serious reaction to a vaccine in the past?
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 pertussis-containing vaccines 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 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 seizure or a brain problem?
DTaP is contraindicated in children who have a history of encephalopathy within 7 days following DTP/DTaP. An unstable progressive neurologic problem is a precaution to the use of DTaP. For children with stable neurologic disorders (including seizures) unrelated to vaccination, or for children with a family history of seizure, vaccinate as usual but consider the use of acetaminophen or ibuprofen to minimize fever.

5. Does the child have cancer, leukemia, AIDS, or any other immune system problem?
Live virus vaccines (e.g., MMR, varicella, 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. Immunosuppressed children should not receive varicella vaccine or LAIV. For details, consult the ACIP recommendations (4, 5, 6).

6. 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, 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 only be given to healthy individuals ages 5–49 years.

7. 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, varicella) may need to be deferred, depending on several variables. Consult the most current ACIP recommendations or the 2003 *Red Book,* p. 423, for the most current information on intervals between immune globulin or blood product administration and MMR or varicella vaccination (1, 2).

8. 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, LAIV) are contraindicated prior to and during pregnancy because of the theoretical risk of virus transmission to the fetus (1,6). Sexually active young women who receive MMR or varicella vaccination should be instructed to practice careful contraception for one month following receipt of either vaccine (8, 9). Inactivated vaccines may be given to a pregnant woman whenever indicated.

9. Has the child received vaccinations in the past 4 weeks?
If two live virus parenteral vaccines (e.g., MMR, varicella) are not given on the same day, the doses must be separated by at least 28 days. Inactivated vaccines may be given at the same time or at any spacing interval.

References:

1. CDC. General recommendations on immunization. *MMWR* 2002; 51(RR-2).
2. AAP. *2003 Red Book: Report of the Committee on Infectious Diseases.* 26th ed. Elk Grove Village, IL: AAP, 2003.
3. Table of Vaccine Components: www.cdc.gov/nip/publications/pink/appendices/A/excipient2.pdf
4. CDC. Measles, mumps, and rubella—vaccine use and strategies for elimination of measles, rubella, and congenital rubella syndrome and control of mumps. *MMWR* 1998; 47 (RR-8).
5. CDC. Prevention of varicella: updated recommendations of the ACIP. *MMWR* 1999; 48 (RR-6).
6. CDC. Using live, attenuated influenza vaccine for prevention and control of influenza. *MMWR* 2003; 52 (RR-13).
7. CDC. Excerpt from Guidelines for preventing opportunistic infections among hematopoietic stem cell transplant recipients, *MMWR* 2000; 49 (RR-10), www.cdc.gov/nip/publications/hsct-recs.pdf
8. CDC. Notice to readers: Revised ACIP recommendation for avoiding pregnancy after receiving a rubella-containing vaccine. *MMWR* 2001; 50 (49).
9. CDC. Prevention of varicella. MMWR 1996; 45 (RR-11).

Injectable Vaccine Administration for Children

Vaccine	Stored	Route	Site*	Needle Gauge	Needle Length ⇳	Contraindications ⊕
DTaP	R	IM	Anterolateral Thigh **or** Deltoid#	22-25 g	1"	Anaphylactic reaction to prior dose
Hib	R	IM	Anterolateral Thigh **or** Deltoid	22-25 g	1"	Anaphylactic reaction to prior dose
Pneumococcal conjugate (PCV7)	R	IM	Anterolateral Thigh **or** Deltoid	22-25 g	1"	Anaphylactic reaction to prior dose
Hepatitis B (Hep B)	R	IM	Anterolateral Thigh **or** Deltoid	22-25 g	1"	Anaphylactic reaction to a prior dose or baker's yeast
Inactivated Polio Vaccine (IPV)	R	**SC**	Anterolateral Thigh **or** Lateral Upper Arm	23-25 g	5/8"	Anaphylactic reaction to a prior dose, neomycin, streptomycin, or polymyxin B
		or IM	Anterolateral Thigh **or** Deltoid	22-25 g	1"	
MMR	R‡	SC	Anterolateral Thigh **or** Lateral Upper Arm	23-25 g	5/8"	Anaphylactic reaction to a prior dose, neomycin or gelatin
Varicella (Var)	F	SC	Anterolateral Thigh **or** Lateral Upper Arm	23-25 g	5/8"	Anaphylactic reaction to a prior dose, neomycin or gelatin
Td (for use 7 yrs & older)	R	IM	Deltoid	22-25 g	1"	Anaphylactic reaction to a prior dose
Inactivated Influenza (TIV)	R	IM	Anterolateral Thigh **or** Deltoid	22-25 g	1"	Anaphylactic reaction to a prior dose or eggs

* Vaccines should never be administered in the buttocks

⇳ Professional judgment is appropriate when selecting needle length for use in all children, especially small infants or larger children.

⊕ This list is incomplete. See package insert for complete contraindication listing.

Use of the deltoid muscle in children 18 months and older (if adequate muscle mass is present) is an option for IM injections.

‡ Can freeze lypholized MMR powder but not MMR diluent. Key: R=Refrigerator F=Freezer

See Back: Injectable Vaccines for Selected Populations

Injectable Vaccines for Selected Populations**

Vaccine	Stored	Route	Site*	Needle Gauge	Needle Length⇳	Contraindications⊕
Hepatitis A (Hep A)	R	IM	Deltoid #	22-25g	1"	Anaphylactic reaction to prior dose, alum or 2-phenoxyethanol ±
Pneumococcal polysaccharide (PPV 23)	R	IM **or** SC	Anterolateral Thigh **or** Deltoid	22-25 g	1"	Anaphylactic reaction to prior dose
			Anterolateral Thigh **or** Lateral Upper Arm	23-25g	5/8"	
Meningococcal polysacchride (MPV)	R	SC	Anterolateral Thigh **or** Lateral Upper Arm	23-25g	5/8"	Anaphylactic reaction to prior dose

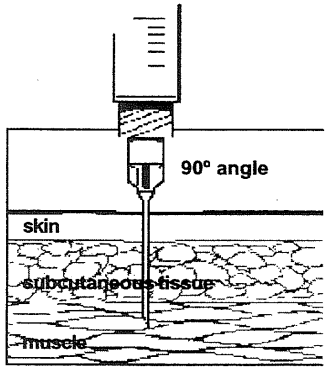
* Vaccines should never be administered in the buttocks
⇳ Professional judgment is appropriate when selecting needle length for use in all children, especially small infants or larger children.
⊕ This list is incomplete. See package insert for complete contraindication listing.
Use of the deltoid muscle in children 18 months and older (if adequate muscle mass is present) is an option for IM injections.
± Havrix® only
** Refer to Recommended Childhood and Adolescent Immunization Schedule (available in Child/Adolescent Immunization Section of the AIM Kit) for information on the selected populations.
Key: R=Refrigerator F=Freezer

How to Administer IM (Intramuscular) Injections

Administer these vaccines via IM (intramuscular) route: DTaP, DT, Td, Hib, hepatitis A, hepatitis B, influenza, PCV7. Administer IPV & PPV23 either IM or SC.

When you administer these vaccines, follow the age recommendations indicated in the current recommended immunization schedules.

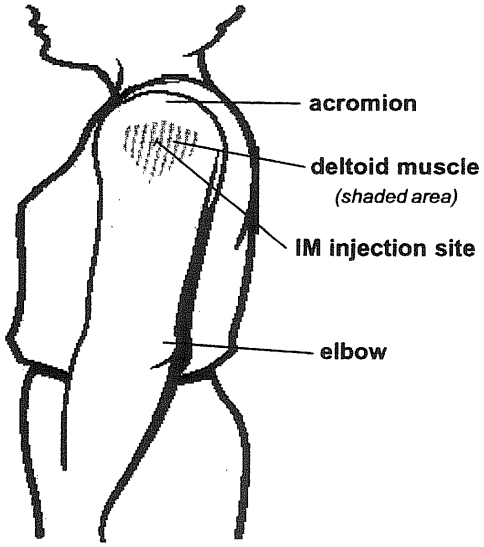
Patient's age	Site (see illustrations below)	Needle size*	Needle insertion
Infants (birth to 12 months of age)	Vastus lateralis muscle in anterolateral aspect of middle or upper thigh	7/8" to 1" needle, 23-25 gauge	Use a needle long enough to reach deep into the muscle. Insert needle at 90° angle to the skin with a quick thrust. Retain pressure on skin around injection site with thumb and index finger while needle is inserted. There are no data to document the necessity of aspiration, however, if performed and blood appears after negative pressure, the needle should be withdrawn and a new site selected.* Multiple injections given in the same extremity should be separated as far as possible (preferably 1" to 1½" with minimum of 1" apart). *American Academy of Pediatrics. *2000 Red Book: Report of the Committee on Infectious Diseases*:18.
Toddlers (12 to 36 months of age)	Vastus lateralis muscle preferred until deltoid muscle has developed adequate mass. Deltoid may be an option after 18 months of age	7/8" to 1" needle, 23-25 gauge	
Toddlers (>36 months of age), children, and adults	Densest portion of deltoid muscle - above armpit and below acromion	1" to 1 1/2" needle, 23-25 gauge	



IM site for infants and toddlers (birth to 36 months of age)

Insert needle at 90° angle into vastus lateralis muscle in anterolateral aspect of middle or upper thigh.

IM site for older toddlers, children, and adults



Insert needle at 90° angle into densest portion of deltoid muscle - above armpit and below acromion.

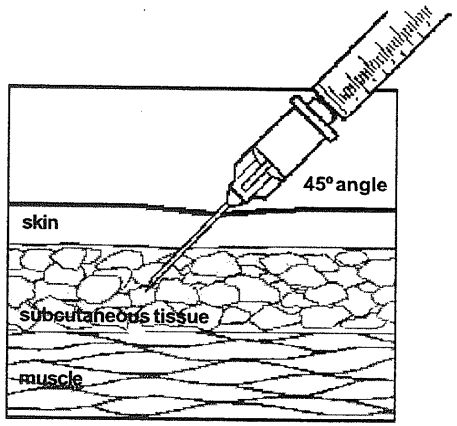
How to Administer SC (Subcutaneous) Injections

Administer these vaccines via SC (subcutaneous) route: MMR, varicella, meningococcal. Administer IPV & PPV23 either SC or IM.

When you administer these vaccines, follow the age recommendations indicated in the current recommended immunization schedules.

Patient's age	Site (see illustrations below)	Needle size*	Needle insertion
Infants (birth to 12 months of age)	Fatty area of the thigh or outer aspect of upper arm	5/8" needle, 23-25 gauge	Insert needle at 45° angle to the skin. Pinch up on SC tissue to prevent injection into muscle. There are no data to document the necessity of aspiration, however, if performed and blood appears after negative pressure, the needle should be withdrawn and a new site selected.* Multiple injections given in the same extremity should be separated as far as possible (preferably 1" to 1½" with minimum of 1" apart).
Toddlers (12 to 36 months of age)	Fatty area of the thigh or outer aspect of upper arm	5/8" needle, 23-25 gauge	
Children and adults	Outer aspect of upper arm	5/8" needle, 23-25 gauge	

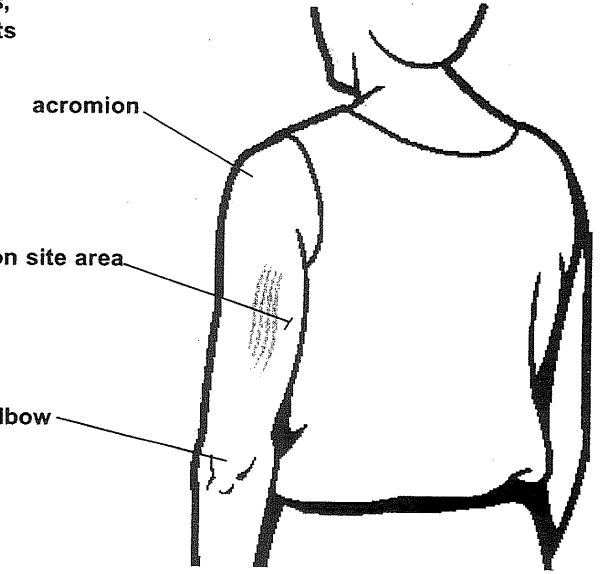
*American Academy of Pediatrics. *2000 Red Book: Report of the Committee on Infectious Diseases*:18.



SC site for infants and toddlers (birth to 36 months of age)

Insert needle at 45° angle into fatty area of anterolateral thigh or outer aspect of upper arm. Make sure you pinch up on SC tissue to prevent injection into muscle.

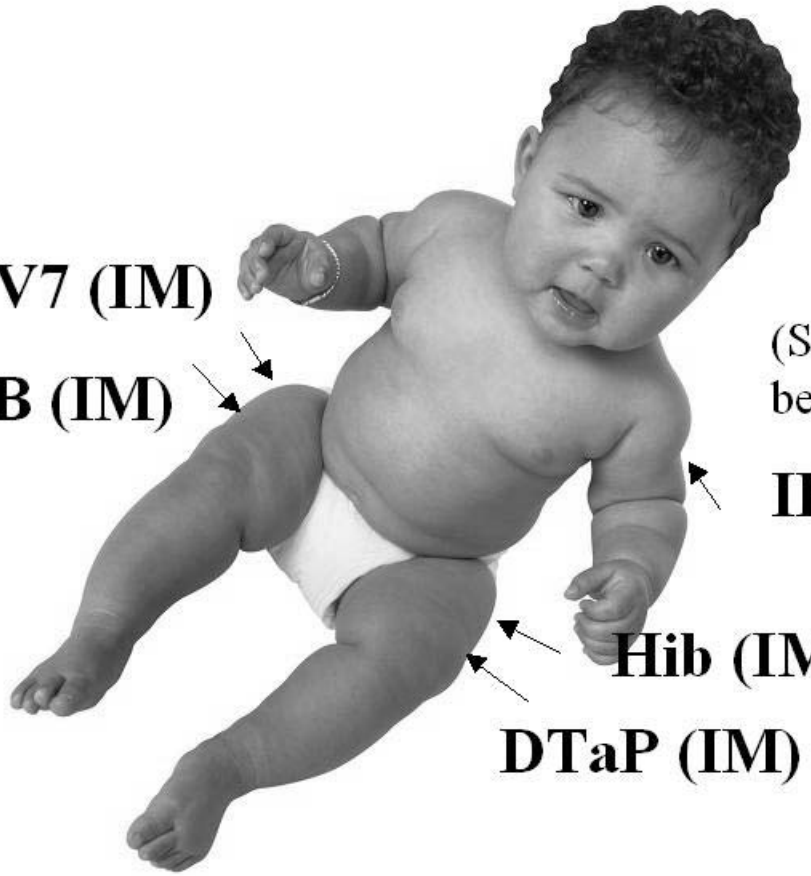
SC site for toddlers, children, and adults



Insert needle at 45° angle into outer aspect of upper arm. Make sure you pinch up on SC tissue to prevent injection into muscle.

Giving All the Doses

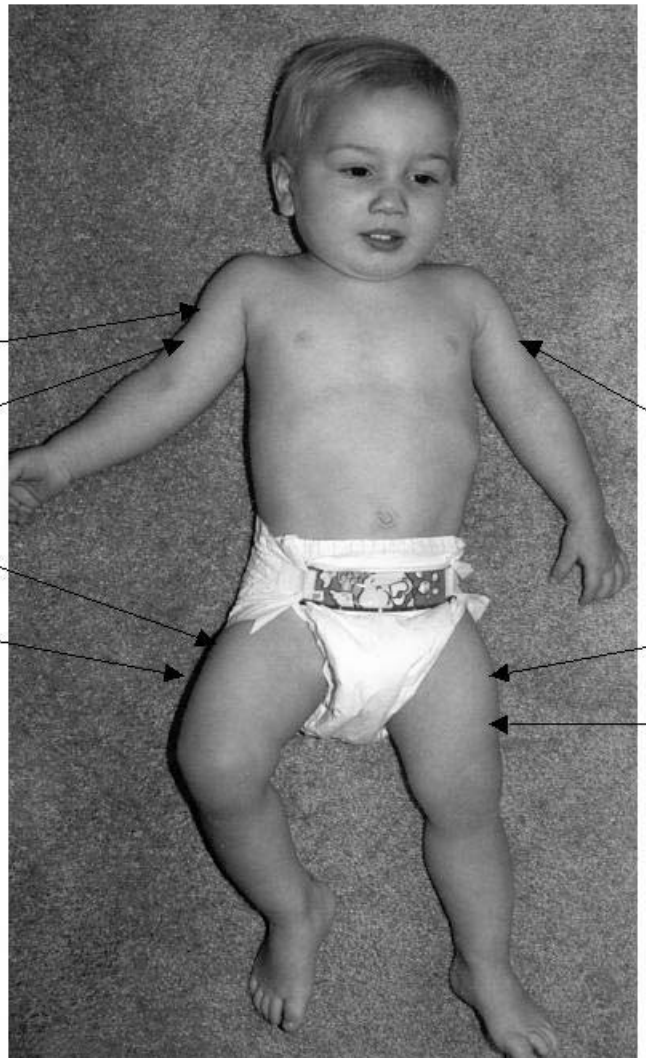
One way to give 5 doses at one visit



- Injection sites should be separated by 1 inch
- IM injections not recommended in infant's arms

Giving All the Doses

One way to give 7 doses (if needed) at one visit



IPV (SC)

MMR (SC)

DTaP (IM)

Hib (IM)

Varicella (SC)

PCV7 (IM)

HepB (IM)

The deltoid muscle is an option for IM injections in children 18 months and older with adequate muscle mass

COMFORTING RESTRAINT

FOR IMMUNIZATIONS

• The method:

This method involves the parent in embracing the child and controlling all four limbs. It avoids "holding down" or overpowering the child, but it helps you steady and control the limb of the injection site.

• For infants and toddlers:

Have parent hold the child on parent's lap.

1. One of the child's arms embraces the parent's back and is held under the parent's arm.
2. The other arm is controlled by the parent's arm and hand. For infants, the parent can control both arms with one hand.
3. Both legs are anchored with the child's feet held firmly between the parent's thighs, and controlled by the parent's other arm.

• For kindergarten and older children:

Hold the child on parent's lap or have the child stand in front of the seated parent.

1. Parent's arms embrace the child during the process.
2. Both legs are firmly between parent's legs.

IMMUNIZATION TECHNIQUES
Safe • Effective • Caring

Gray Davis, Governor—State of California
Grantland Johnson, Secretary—Health and Human Services Agency
Diana M. Bontá, R.N., Dr.P.H., Director—Department of Health Services
Immunization Branch • 2151 Berkeley Way • Berkeley, CA 94704

IMM-720 (12/01)

Summary of Rules for Childhood and Adolescent Immunization*

Adapted from ACIP, AAP, and AAFP by Immunization Action Coalition, March 2004

Vaccine	Ages usually given and other guidelines	If child falls behind	Precautions and contraindications
Hepatitis B *Give IM*	• Vaccinate all children 0 through 18yrs of age. • Vaccinate all newborns with monovalent vaccine prior to hospital discharge. Give dose #2 at 1–4m and dose #3 at 6–18m (the last dose in the infant series should not be given earlier than age 24wks). After the first dose, the series may be completed with single-antigen vaccine or up to 3 doses of Comvax (2m, 4m, 12–15m of age) or Pediarix (2m, 4m, 6m of age). Although not the preferred schedule, dose #1 can be given as late as age 2m of age if the mother has written documentation of HBsAg-negative status at the time of child's birth. • **If mother is HBsAg-positive:** give the newborn HBIG + dose #1 within 12hrs of birth, #2 at 1–2m, and #3 at 6m of age. • **If mother's HBsAg status is unknown:** give the newborn dose #1 within 12hrs of birth, #2 at 1–2m, and #3 at 6m of age. If mother is subsequently found to be HBsAg positive, give infant HBIG within 7d of birth. • May give with all other vaccines.	• Do not restart series, no matter how long since previous dose. • 3-dose series can be started at any age. • Minimum spacing for children and teens: 4wks between #1 & #2, and 8wks between #2 & #3. Overall there must be ≥16wks between #1 & #3 (e.g., 0-, 2-, 4m; 0-, 1-, 4m).	**Special Notes on Hepatitis B Vaccine** **Dosing of hepatitis B vaccines:** Vaccine brands are interchangeable for 3-dose schedules. For persons 0 through 19yrs of age, give 0.5 mL of either Engerix-B or Recombivax HB. **Alternative dosing schedule for unvaccinated adolescents age 11 through 15yrs:** Give 2 doses Recombivax HB 1.0mL (adult formulation) spaced 4–6m apart. (Engerix-B is not licensed for a 2-dose schedule.) **For premature infants:** Consult *2003 AAP Red Book* (p. 66–68) as hep B vaccination recommendations for premies may differ from routine infant schedule.
DTaP (Diphtheria, tetanus, acellular pertussis) *Give IM*	• Give at 2m, 4m, 6m, 15–18m, 4–6yrs of age. • May give dose #1 as early as 6wks of age. • May give #4 as early as 12m of age if 6m have elapsed since #3 and the child is unlikely to return at age 15–18m. • Do not give DTaP to children ≥7yrs of age (give Td). • May give with all other vaccines. • It is preferable but not mandatory to use the same DTaP product for all doses.	• #2 & #3 may be given 4wks after previous dose. • #4 may be given 6m after #3. • If #4 is given before 4th birthday, wait at least 6m for #5 (4–6yrs of age). • If #4 is given after 4th birthday, #5 is not needed.	**Contraindication for DTaP only:** Previous encephalopathy within 7d after DTP/DTaP. **Precautions for DTaP:** The following are precautions, not contraindications. When these conditions are present, the individual child's disease risk should be carefully assessed. In situations when the benefit outweighs the risk (e.g., community pertussis outbreak), vaccination should be considered. • Temperature ≥105°F (40.5°C) within 48hrs after previous dose. • Continuous crying lasting ≥3hrs within 48hrs after previous dose. • Previous convulsion within 3d after immunization. • Pale or limp episode or collapse within 48hrs after previous dose. • Unstable progressive neurologic problem (defer until stable).
DT *Give IM*	• Give to children <7yrs of age if child had a serious reaction to "P" in DTaP/DTP or if parents refuse the pertussis component. • May give with all other vaccines.		
Td *Give IM*	• Use Td, not tetanus toxoid (TT), for persons ≥7yrs of age for all indications. • A booster dose is recommended for children 11–12yrs of age if 5yrs have elapsed since last dose. Then boost every 10yrs. • May give with all other vaccines.	• For unvaccinated patients: give dose #1 now, give 2nd dose 4wks later, give 3rd dose 6m after #2, then give booster every 10yrs.	
MMR (Measles, mumps, rubella) *Give SC*	• Give #1 at 12–15m of age. Give #2 at 4–6yrs of age. • Make sure that all children and teens over 4–6yrs of age have received both doses of MMR. • If a dose was given before 12m of age, it doesn't count as the first dose, so give #1 at 12–15m of age with a minimum interval of 4wks between the invalid dose and dose #1. • May give with all other vaccines. • If MMR and Var (and/or yellow fever vaccine) are not given on the same day, space them ≥28d apart. • 2 doses of MMR are recommended for all children ≤18yrs of age. • Do not withhold vaccine from children of pregnant women.	• Dose should be given whenever it is noted that a child is behind. Exception: If MMR and Var (and/or yellow fever vaccine) are not given on the same day, space them ≥28d apart. • Dose #2 can be given at any time if at least 28d have elapsed since dose #1 and both doses are administered after 1yr of age.	• Pregnancy or possibility of pregnancy within 4 weeks. • If blood, plasma, and/or immune globulin were given in past 11m, see ACIP statement *General Recommendations on Immunization*† regarding time to wait before vaccinating. • HIV is NOT a contraindication unless severely immunocompromised. • Immunocompromised persons (e.g., because of cancer, leukemia, lymphoma). **Note:** For patients on high-dose immunosuppressive therapy, consult ACIP recommendations† regarding delay time. **Note:** MMR is not contraindicated if a PPD test was recently applied. If PPD and MMR not given on same day, delay PPD for 4–6wks after MMR.
Varicella (Var) (Chickenpox) *Give SC*	• Give at 12–18m of age. • Vaccinate all children ≥12m of age including all adolescents who have not had chickenpox. • May use as postexposure prophylaxis if given within 3–5d. • May give with all other vaccines. • If Var and MMR (and/or yellow fever vaccine) are not given on the same day, space them ≥28d apart. • Do not withhold vaccine from children of pregnant women.	• Do not give to children <12m of age. • Susceptible children <13yrs of age should receive 1 dose. • Susceptible persons ≥13yrs of age should receive 2 doses 4–8wks apart.	• Pregnancy or possibility of pregnancy within 4 weeks. • If blood, plasma, and/or immune globulin (IG or VZIG) were given in past 11m, see ACIP statement *General Recommendations on Immunization*† regarding time to wait before vaccinating. • Persons immunocompromised because of high doses of systemic steroids, cancer, leukemia, lymphoma, or immunodeficiency. **Note:** For patients with humoral immunodeficiency, HIV infection, or leukemia, or for patients on high doses of systemic steroids, see ACIP recommendations.† • For children taking salicylates, see ACIP recommendations.†

Do not give any vaccine if patient (1) has had an anaphylactic reaction to a prior dose of the vaccine or any of its components or (2) has a moderate or severe acute illness. (Minor illness is not a reason to postpone vaccination.)

Summary of Rules for Childhood and Adolescent Immunization* (continued)

Vaccine	Ages usually given and other guidelines	If child falls behind	Precautions and contraindications
Polio (IPV) *Give SC or IM*	• Give at 2m, 4m, 6–18m, and 4–6yrs of age. • May give #1 as early as 6wks of age. • Not routinely recommended for those ≥18yrs of age (except certain travelers). • May give with all other vaccines.	• All doses should be separated by at least 4wks. • If #3 of an all-IPV series is given at ≥4yrs of age, dose #4 is not needed.	Do not give any vaccine if patient (1) has had an anaphylactic reaction to a prior dose of the vaccine or any of its components or (2) has a moderate or severe acute illness. (Minor illness is not a reason to postpone vaccination.)
Hib (*Haemophilus influenzae* type b) *Give IM*	• HibTITER (HbOC) & ActHib (PRP-T): give at 2m, 4m, 6m, 12–15m (booster dose). • PedvaxHIB or Comvax (containing PRP-OMP): give at 2m, 4m, 12–15m. • Dose #1 of Hib vaccine may be given as early as 6wks of age but no earlier. • The last dose (booster dose) is given no earlier than 12m of age and a minimum of 8wks after the previous dose. • May give with all other vaccines. • Hib vaccines are interchangeable; however, if different brands of Hib vaccines are administered, a total of three doses are necessary to complete the primary series in infants. • Any Hib vaccine may be used for the booster dose. • Hib is not routinely given to children ≥5yrs of age.	**Rules for all Hib vaccines:** • If #1 was given at 12–14m, give a booster dose in 8wks. • Give only 1 dose to unvaccinated children ≥15m and <5yrs of age. **Rules for HibTITER and ActHib:** • #2 and #3 may be given 4 wks after previous dose. • If #1 was given at 7–11m, only 3 doses are needed; #2 is given 4–8wks after #1, then boost at 12–15m (and must be ≥8wks after dose #2). **Rules for PedvaxHIB and Comvax:** • #2 may be given 4wks after dose #1	
Hepatitis A *Give IM*	• Vaccinate children ≥2yrs old who live in areas with historically elevated rates of hepatitis A, as well as children who have specific risk factors. (See ACIP statement† and column to right for details.) • Children who travel outside of the U.S. (except to W. Europe, New Zealand, Australia, Canada, or Japan). • Dose #2 is given a minimum of 6m after dose #1. • Dose #1 may not be given earlier than 2yrs of age. • May give with all other vaccines.	• Do not restart series, no matter how long since previous dose. • Hepatitis A vaccine brands are interchangeable. • Consult your local/state public health authority for information regarding your city, county, or state hepatitis A rates. States with historically elevated rates (average ≥10 cases per 100,000 population from 1987-1997) include the following: AL, AZ, AK, CA, CO, ID, MO, MT, NV, NM, OK, OR, SD, TX, UT, WA, and WY.	
Influenza *Give IM or intranasally*	• Vaccinate all children ages 6–23 months. • Vaccinate children ≥24m of age with risk factors as defined by ACIP.† • Use trivalent inactivated influenza vaccine (TIV) for children 6–59m, and either TIV or live attenuated influenza vaccine (LAIV) for children ≥5yrs of age who have no contraindications. • Give 2 doses to first-time vaccinees <9yrs of age, separated by ≥4wks for TIV or ≥6wks for LAIV. • Give 0.25 mL dose (TIV) to infants 6–35m and 0.5 mL dose if age ≥3yrs. • May give with all other vaccines.	• If previously unvaccinated child <9 yrs does not receive 2nd dose during initial vaccination season, give only 1 dose the following season . **Special Note on Live Attenuated Influenza Vaccine (LAIV)** Do not give LAIV to children <5 yrs of age, children ≥5yrs of age with a chronic disease that constitutes an increased risk when exposed to wild influenza virus (e.g., asthma, heart and renal disease, diabetes), or children who are or who may have close contact with severely immunosuppressed persons (i.e., patients with hematopoietic stem cell transplants).	
Pneumococcal — **PCV** *Give IM*	• Give at 2m, 4m, 6m, and 12–15m of age. • Dose #1 may be given as early as 6wks of age. • For unvaccinated high-risk children (defined below) 24–59m of age, give 2 doses ≥8wks apart. If PPV not previously given, administer PPV ≥8wks after final dose of PCV. • For unvaccinated moderate-risk children (defined below) 24–59m of age, consider giving 1 dose. • May give 1 dose to unvaccinated healthy children 24–59m. • PCV is not routinely given to children ≥5yrs of age. • May give with all other vaccines.	• Minimum interval between doses for infants <12m of age is 4wks, for ≥12m of age is 8wks. • For infants 7–11m of age: If unvaccinated, give dose #1 now, give 2nd dose 4–8wks later, and boost at 12–15m. If infant has had 1 or 2 previous doses, give next dose now, and boost at 12–15m. • For children 12–23m: If not previously vaccinated or only one previous dose before 12m, give 2 doses ≥8wks apart. If child had 2 doses before 12m, give booster dose ≥8wks after previous dose.	
	High-risk children: Those with sickle cell disease; anatomic/functional asplenia; chronic cardiac, pulmonary, or renal disease; diabetes mellitus; CSF leak; HIV infection; or immunosuppression. **Moderate-risk children:** Children age 24–35m; children age 24–59m who attend group day care centers or are of Alaska Native, American Indian, or African American descent.		
Pneumococcal — **PPV** *IM or SC*	Give PPV to high-risk children ≥2yrs of age as recommended in the ACIP statement *Prevention of Pneumococcal Disease* (4/4/97).†		
Meningococcal *Give SC*	Vaccinate children ≥2yrs of age with risk factors. Discuss disease risk and vaccine availability with college students. Consult ACIP statement on meningococcal disease (6/30/00) for details.†		

* Licensed combination vaccines may be used whenever any components of the combination are indicated and the vaccine's other components are not contraindicated (except Trihibit, which may only be used as the 4th dose of the series). The following combination vaccines are currently licensed: Hib-HepB (Comvax), DTaP-HepB-IPV (Pediarix), DTaP-Hib (Trihibit), and HepA-HepB (Twinrix). Rules for use of combination vaccines consist of those applicable to each of the components.

† For more complete information, see the ACIP statements, which are published in the *MMWR*. To obtain them, visit www.cdc.gov/nip/publications/ACIP-list.htm or visit the Immunization Action Coalition's (IAC) website at www.immunize.org/acip For recommendations of the American Academy of Pediatrics (AAP), consult AAP's *2003 Red Book* and the journal *Pediatrics,* or visit www.immunize.org/aap To view the AAFP/AAP/CDC Recommended Childhood and Adolescent Immunization Schedule—U.S., visit www.immunize.org/cdc/child-schedule.pdf

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Common Immunization Acronyms

Adapted from *2002 AIM KIT* – Vaccine Storage and Resource Section (12/19/02 version)

AAFP	American Academy of Family Physicians
AAP	American Academy of Pediatrics
ACIP	Advisory Committee on Immunization Practices
AFIX	Assessment, Feedback, Incentives, eXchange of Information
CASA	Clinic Assessment Software Application
CD	Communicable Disease
CDC	Centers for Disease Control and Prevention
DT	Diphtheria and tetanus vaccine (pediatric)
DTP	Diphtheria, tetanus, and whole cell pertussis vaccine
DTaP	Diphtheria, tetanus, and acellular pertussis vaccine
e-IPV	Enhanced inactivated polio vaccine
FDA	Food and Drug Administration
HbsAg	hepatitis B surface antigen
HBIG	hepatitis B immune globulin
HBV	hepatitis B vaccine (also can mean hepatitis B virus)
HEDIS	Health Employer Data and Information Set
Hep A	hepatitis A virus (can also mean hepatitis A vaccine)
Hep B	hepatitis B vaccine (can also mean hepatitis B virus)
Hib	*Haemophilus influenzae* type b
HMO	Health Maintenance Organization
HRSA	Health Resources and Services Administration
LAIV	Live attenuated Influenza Vaccine
IAP	Immunization Action Plan
IG	Immune globulin
IPV	Inactivated polio vaccine
MMR	Measles, mumps, and rubella vaccine
MMWR	Morbidity Mortality Weekly Report
MSA	Medical Services Administration
NIIW	National Infant Immunization Week
NIP	National Immunization Program
NIS	National Immunization Survey
NVICP	National Vaccine Injury Compensation Program
OPV	Oral polio vaccine

DTAP-HEPB-IPV	Pediarix
PCV	Pneumococcal conjugate vaccine
PCV7	Pneumococcal conjugate vaccine –7 valent
PPV	Pneumococcal polysaccharide vaccine
PPV23	Pneumococcal polysaccharide vaccine–23 valent
Td	Tetanus and diphtheria vaccine (adult)
VAERS	Vaccine Adverse Event Reporting System
VAPP	Vaccine associated paralytic polio
VFC	Vaccines of Children
VIS	Vaccine Information Statement
VPD	Vaccine-preventable disease
VZV	Varicella zoster virus (chickenpox)
WIC	Women, Infant and Children (supplemental food program)
4:3:1:3:3	4 doses of DTaP vaccine, 3 doses of polio vaccine, 1 dose of MMR vaccine 3 doses of Hib vaccine, and 3 doses of hepatitis B vaccine

Hib Vaccination Schedule

Vaccine	Age at 1st dose (months)	Primary Series	Booster
HibTiTER or ActHIB	2-6	3 doses, 2 months apart	12-15 months*
	7-11	2 doses, 2 months apart	12-15 months*
	12-14	1 dose	2 months later
	15-59	1 dose	none
PedvaxHIB	2-6	2 doses, 2 months apart	12-15 months*
	7-11	2 doses, 2 months apart	12-15 months*
	12-14	1 dose	2 months later
	15-59	1 dose	none

***Minimum interval of 2 months between completion of primary series and booster dose.**

Schedule of Children Lapsed (Late) for Hib Vaccination

Current Age	Prior Hib Vaccination History	Recommended Regimen
7-11 months	1 dose of HibTITER or ActHIB	1 or 2 doses at 7-11 months, depending on age, booster at least 2 months later at 12-15 months
7-11 months	2 doses of HibTITER or ActHIB or 1 dose of PedvaxHIB	1 dose at 7-11 months, booster at least 2 months later at 12-15 months
12-14 months	2 doses before 12 months	1 dose at least 2 months after last dose
12-14 months	1 dose before 12 months	2 doses separated by 2 months
15-59 months	Any incomplete schedule	1 dose

Pneumococcal polysaccharide vaccine (PPV23) for children at least 2 years of age who have previously received the 7-valent conjugate vaccine (PCV7)

Population	Schedule for PPV23	Revaccination with PPV23
Healthy children	None❶	No
Children with sickle cell disease or anatomic or functional asplenia; immunocompromised❷, or who are infected with HIV	1 dose of PPV23 administered at least 2 years of age and at least 8 weeks after last dose of PCV7	Yes❸
Persons with chronic illnesses❹ or cochlear implants❺	1 dose of PPV23 administered at least 2 years of age and at least 8 weeks after the last dose of PCV7	Not recommended❻

❶ Health-care providers of Alaska Natives and American Indians should consider whether these children would benefit by the additional coverage provided by the expanded serotypes in PPV23. For more information see recommendations regarding Alaska Natives and American Indians in the MMWR, October 6, 2000/Vol. 49/No. RR-9.

❷ Immunocompromising conditions include congenital immunodeficiencies, renal failure and nephrotic syndrome, and diseases associated with immunosuppresive therapy or radiation therapy. For more information, see recommendations in Table 8 of the MMWR, October 6, 2000/Vol. 49/No. RR-9.

❸ Regardless of when administered, a second dose of PPV23 should not be administered fewer than 3 years after the previous PPV23 dose. If the patient is older than 10 years of age, one re-vaccination should be administered if at least 5 years have elapsed since the previous PPV23 dose. If the patient is 10 years of age or younger, one re-vaccination should be considered if 3-5 years have elapsed since the previous dose of PPV23. (See ACIP recommendations published in the MMWR 1997; Vol. 46/No. RR-8).

❹ Chronic illnesses include chronic cardiac disease, chronic pulmonary disease (excluding asthma), cerebrospinal fluid leaks, and diabetes mellitus. For more information, see recommendations in Table 8 of the MMWR, October 6, 2000/Vol. 49/No. RR-9.

❺ See "Public Health Web Notification: Cochlear Implant Recipients may be at Greater Risk for Meningitis" October 17, 2002, for recommendations.

❻ Persons with chronic illness receiving PPV23 and who are between 2 and 64 years of age should receive one additional dose of PPV23 at or after age 65 if 5 years have elapsed since the prior dose.

Recommendations state that no person should receive more than 2 doses of PPV23 in a lifetime. Pneumococcal polysaccharide vaccine (PPV23) and pneumococcal conjugate (PCV 7) vaccines **should not** be given simultaneously. If both vaccines are indicated, their administration should be separated by at least 8 weeks.

Recommended Dosages of Hepatitis B Vaccines

Hepatitis B Vaccine Recipient	Vaccine Brand (For specific prescribing information, precautions and contraindications, refer to the product inserts for each vaccine)			
	Engerix-B® (GlaxoSmithKline)		Recombivax HB® (Merck)	
	Pediatric Formulation	Adult Formulation	Pediatric/ Adolescent Formulation	Adult Formulation
	Blue Cap 10 μg (0.5ml)	Orange Cap 20 μg (1.0ml)	Yellow Cap 5 μg (0.5ml)	Green Cap 10 μg (1.0ml)
Newborns born to HBsAg (+) mothers	10 μg (0.5ml) & HBIG to be given within 12 hours of birth		5 μg (0.5ml) & HBIG to be given within 12 hours of birth	
Newborns born to mothers whose HBsAg status is unknown	10 μg (0.5ml) within 12 hours of birth; HBIG should also be given within 7 days if mom's status remains unknown or cannot be determined		5 μg (0.5ml) within 12 hours of birth; HBIG should also be given within 7 days if mom's status remains unknown or cannot be determined	
Children up to 10 years of age born to HBsAg (-) mothers	10 μg (0.5ml)		5 μg (0.5ml)[2]	
11-19 years	10 μg (0.5ml)		5 μg (0.5ml)[3]	
20 + years		20 μg (1.0ml)[1]		10 μg (1.0ml)

[1] **GlaxoSmithKline's Twinrix®** (hepatitis A and hepatitis B) is a combination vaccine approved for use for persons 18 years of age and older. It is recommended for administration at intervals of 0, 1 and 6 months. This combination vaccine may be given to any adult for whom either antigen is indicated and neither antigen is contraindicated.

[2] **Merck's Comvax®** (hepatitis B and Hib) is a combination vaccine recommended for administration at 2, 4 and 12-15 months of age. ***A single antigen dose of hepatitis B vaccine is recommended at birth.*** This combination vaccine may be given to any child for whom either antigen is indicated and neither antigen is contraindicated.

[3] **Merck's 2-dose (adolescent)** hepatitis B vaccine series (using the adult formulation of Recombivax HB® 10μg, 1.0ml) is approved only for adolescents 11-15 years of age. The second dose should be administered 4-6 months after the first dose. If the 2-dose regimen is used, documentation must indicate that the adolescent received 2 adult 10μg (1.0ml) doses of the Merck brand. If a child starts the hepatitis B series prior to age 11, starts the hepatitis B series between the ages of 11 and 15 with a hepatitis B vaccine other than the adult formulation of the Merck product, or completes the series after age 15, a 3-dose series should be administered.

Rev11/27/01

Suggested intervals between administration of immune globulin preparations for different indications and measles-containing vaccine and varicella vaccine*

Product/Indication	Dose, including mg immunoglobulin G (IgG)/kg body weight*	Suggested Interval before Measles or Varicella Vaccination
RSV monoclonal antibody (Synagis™)§	15 mg/kg intramuscularly (IM)	None
Tetanus (TIG)	250 units (10 mg IgG/kg) IM	3 months
Hepatitis A (IG)		
Contact prophylaxis	0.02 mL/kg (3.3 mg IgG/kg) IM	3 months
International travel	0.06 mL/kg (10 mg IgG/kg) IM	3 months
Hepatitis B IG	0.06 mL/kg (10 mg IgG/kg) IM	3 months
Rabies IG	20 IU/kg (22 mg IgG/kg) IM	4 months
Varicella IG	125 units/10kg (20-40 mg IgG/kg) IM (maximum 625 units)	5 months
Measles prophylaxis IG		
Standard (i.e., nonimmunocompromised contact)	0.25 mL/kg (40 mg IgG/kg) IM	5 months
Immunocompromised contact	0.50 mL/kg (80 mg IgG/kg) IM	6 months
Blood transfusion		
Red blood cells (RBCs), washed	10 mL/kg negligible IgG/kg) intervenously (IV)	None
RBCs, adenine-saline added	10 mL/kg (10 mg IgG/kg) IV	3 months
Packed RBCs (Hct 65%)†	10 mL/kg (60 mg IgG/kg) IV	6 months
Whole blood (Hct 35-50%)†	10 mL/kg (80-100 mg IgG/kg) IV	6 months
Plasma/platelet products	10 mL/kg (160 mg IgG/kg) IV	7 months
Cytomegalovirus intravenous immune globulin (IGIV)	150 mg/kg maximum	6 months
Respiratory syncytial virus prophylaxis IGIV	750 mg/kg	9 months
IGIV		
Replacement therapy for immune deficiencies¶	300-400 mg/kg IV¶	8 months
Immune thrombocytopenic purpura	400 mg/kg IV	8 months
Immune thrombocytopenic purpura	1000 mg/kg IV	10 months
Kawasaki disease	2 grams/kg IV	11 months

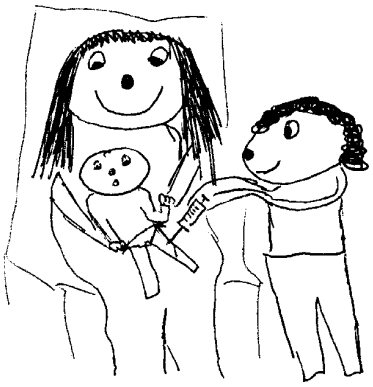
*This table is not intended for determining the correct indications and dosage for using immune globulin products. Unvaccinated persons might not be fully protected against measles during the entire recommended interval, and additional doses of immune globulin and/or measles vaccine might be indicated after measles exposure. Concentrations of measles antibody in an immune globulin preparation can vary by manufacturer's lot. Rates of antibody clearance after receipt of an immune globulin preparation might vary also. 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.
(**Source:** 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.)

§Contains antibody only to respiratory syncytial virus (RSV)

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

¶Measles and varicella vaccination is recommended for children with asymptomatic or mildly symptomatic human immunodeficiency virus (HIV) infection but is contraindicated for persons with severe immunosuppression from HIV or any other immunosuppressive disorder.

From ACIP "General Recommendations on Immunization" February 8, 2002



Vaccinations may hurt a little . . . but disease can hurt a lot!

After the Shots . . .

What to do if your child has discomfort

Your child may need extra love and care after getting vaccinated. Some vaccinations that protect children from serious diseases also can cause discomfort for a while. Here are answers to questions many parents have after their children have been vaccinated. If this sheet doesn't answer your questions, call your clinic or health care provider.

Clinic or health care provider phone number: _____

Call your clinic right away if you answer "yes" to any of the following questions:

- Does your child have a temperature about which your health care provider has told you to be concerned?
- Is your child pale or limp?
- Has your child been crying for more than 3 hours and just won't quit?
- Does your child have a strange cry that isn't normal (a high-pitched cry)?
- Is your child's body shaking, twitching, or jerking?
- Does your child have marked decrease in activity or decrease in responsiveness?

Check the back of this page for information on the proper dosage of medication you can give your child to reduce pain or fever.

I think my child has a fever. What should I do?

Check your child's temperature to find out if there is a fever. Do not use a mercury thermometer. If your child is younger than 3 years of age, taking a temperature with a rectal digital thermometer provides the best reading. Once your child is 4 or 5 years of age, you may prefer taking a temperature by mouth with an oral digital thermometer. Tympanic thermometers, which measure temperature inside the ear, are another option for older babies and children. If your child is older than 3 months of age, you can also take an underarm (axillary) temperature, although it is not as accurate.

Here are some things you can do to help reduce fever:

- Give your child plenty to drink.
- Clothe your child lightly. Do not cover or wrap your child tightly.
- Give your child a fever-reducing medication such as acetaminophen (e.g., Tylenol®) or ibuprofen (e.g., Advil®, Motrin®). **Do not give aspirin.** Recheck your child's temperature after 1 hour.
- Sponge your child in 1–2 inches of lukewarm water.
- If your child's temperature is _____°F (_____°C) or higher or, if you have questions, call your clinic or health care provider.

My child has been fussy since getting vaccinated. What should I do?

After vaccination, children may be fussy due to pain or fever. You may want to give your child a medication such as acetaminophen (e.g., Tylenol®) or ibuprofen (e.g., Advil®, Motrin®) to reduce pain and fever. **Do not give aspirin.** If your child is fussy for more than 24 hours, call your clinic or health care provider.

My child's leg or arm is swollen, hot, and red. What should I do?

- Apply a clean, cool, wet washcloth over the sore area for comfort.
- For pain, give a medication such as acetaminophen (e.g., Tylenol®) or ibuprofen (e.g., Advil®, Motrin®). **Do not give aspirin.**
- If the redness or tenderness increases after 24 hours, call your clinic or health care provider.

My child seems really sick. Should I call my health care provider?

If you are worried **at all** about how your child looks or feels, call your clinic or health care provider!

www.immunize.org/catg.d/p4015.pdf • Item #P4015 (9/04)

Immunization Action Coalition • 1573 Selby Avenue • St. Paul, MN 55104 • (651) 647-9009 • www.immunize.org

Medications and Dosages to Reduce Pain and Fever

Important notes:

1. Ask your health care provider or pharmacist which formulation is best for your child.
2. Give dose based on your child's weight. If you don't know the weight, give dose based on your child's age. Do not give more medication than recommended.
3. If you have questions about dosing or any other concern, call your clinic or health care provider.
4. Always use a proper measuring device. For example:

- When giving infant drops, use only the dosing device (dropper or syringe) enclosed in the package.

- When giving children's suspension or liquid, use the dosage cup enclosed in the package. If you misplace the dosage cup, consult your health care provider or pharmacist for advice. (Kitchen spoons are not accurate measures.)

5. **WARNING:** If you're also giving your child over-the-counter (OTC) medications such as cold preparations, be aware that these may contain pain or fever reducers such as acetaminophen or ibuprofen. Be sure to read all OTC medication labels carefully to ensure your child is not receiving more acetaminophen or ibuprofen than recommended.

Acetaminophen Dosing Information (Tylenol® or another brand)

Give every 4–6 hours, as needed, no more than 5 times in 24 hours (unless directed to do otherwise by your health care provider).

Weight of child	Age of child	Infant drops 0.8 mL = 80 mg	Children's liquid or suspension 1 tsp (5 mL) = 160 mg	Children's tablets 1 tablet = 80 mg	Junior strength 1 tablet = 160 mg
6–11 lbs (2.7–5 kg)	0–3 mos	Advised dose*: _____			
12–17 lbs (5.5–7.7 kg)	4–11 mos	Advised dose*: _____	Advised dose*: _____		
18–23 lbs (8.2–10.5 kg)	12–23 mos	Advised dose*: _____	Advised dose*: _____		
24–35 lbs (10.9–15.9 kg)	2–3 yrs	1.6 mL	1 teaspoon (160 mg)	2 tablets	
36–47 lbs (16.4–21.4 kg)	4–5 yrs		1½ teaspoons (240 mg)	3 tablets	
48–59 lbs (21.8–26.8 kg)	6–8 yrs		2 teaspoons (320 mg)	4 tablets	2 tablets
60–71 lbs (27.3–32.3 kg)	9–10 yrs		2½ teaspoons (400 mg)	5 tablets	2½ tablets
72–95 lbs (32.7–43.2 kg)	11 yrs		3 teaspoons (480 mg)	6 tablets	3 tablets

*Ask your health care provider

Ibuprofen Dosing Information (Advil®, Motrin® or another brand)

Give every 6–8 hours, as needed, no more than 4 times in 24 hours (unless directed to do otherwise by your health care provider).

Weight of child	Age of child	Infant drops 1.25 mL = 50 mg	Children's liquid or suspension 1 tsp (5 mL) = 100 mg	Children's tablets 1 tablet = 50 mg	Junior strength 1 tablet = 100 mg
under 11 lbs (5 kg)	under 6 mos	Advised dose*: _____			
12–17 lbs (5.5–7.7 kg)	6–11 mos	1.25 mL			
18–23 lbs (8.2–10.5 kg)	12–23 mos	1.875 mL			
24–35 lbs (10.9–15.9 kg)	2–3 yrs		1 teaspoon (100 mg)	2 tablets	
36–47 lbs (16.4–21.4 kg)	4–5 yrs		1½ teaspoons (150 mg)	3 tablets	
48–59 lbs (21.8–26.8 kg)	6–8 yrs		2 teaspoons (200 mg)	4 tablets	2 tablets
60–71 lbs (27.3–32.3 kg)	9–10 yrs		2½ teaspoons (250 mg)	5 tablets	2½ tablets
72–95 lbs (32.7–43.2 kg)	11 yrs		3 teaspoons (300 mg)	6 tablets	3 tablets

*Ask your health care provider

ACIP recommends Meningococcal Conjugate (MCV4) Vaccine

The Advisory Committee on Immunization Practices (ACIP) recommends routine vaccination of young adolescents with the newly licensed Menactra™ **(Meningococcal** [Groups A,C,Y and W-135] **Conjugate Vaccine** (MCV4). ACIP recommends MCV4 for persons aged 11--12 years at the preadolescent health-care visit (at age 11--12 years), before high-school entry (at approximately age 15 years), for college freshmen living in dormitories and for other populations at increased risk (i.e., military recruits, travelers to areas in which meningococcal disease is hyperendemic or epidemic, microbiologists who are routinely exposed to isolates of Neisseria meningitidis, patients with anatomic or functional asplenia, and patients with terminal complement deficiency). In summary MCV4 is routinely recommended for these cohorts:

- Children at the pre-adolescent visit (11-12-year-old) and
- Adolescents at high school entry (15 –year-old) and
- All college freshmen living in dormitories and
- At risk individuals (military, travelers, microbiologists, immunodeficient patients).

The complete ACIP statement (which also includes administration information) can be located at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5407a1.htm.

Information regarding the Colorado state law requiring information at all public or nonpublic postsecondary education institutions to each incoming freshman student residing in student housing concerning meningococcal disease can be located at: http://www.cdphe.state.co.us/dc/Immunization/Forms/FORM-collegeCI.pdf.

For additional information, contact the Colorado Department of Public Health and Environment (303-692-2363) or VFC contact (303-692-2798).

""Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine (Tdap)"

The text for the section is "In May and in June, 2005 the FDA approved products that are booster vaccines for pertussis. The number of pertussiss (whooping cough) cases in the United States increased fourfold over the last three years, to 18,957 in 2004 and the proportion of these cases in persons 10 years of age and over has increased. Boostrix manufactured by GlaxoSmithKline is intended for young people aged 10 to 18 years and Sanofi-Aventis' ADACEL, was approved, for individuals from 11 to 64 years of age. Recommendations are under review by the Advisory Committee on Immunization Practices (ACIP). To monitor the status of these recommendations, you may visit the following WEB site.

http://aapredbook.aappublications.org/news/vaccstatus.pdf.

III. Legal & Documentation Issues

Colorado Children's Immunization Coalition

Legal and Documentation Issues

♦ Introduction: Health care providers who give vaccines need to understand and implement the legal and documentation required of them. In this section you will be introduced to the documentation, informed consent, and reporting processes required by law.

National Vaccine Injury Compensation Program

1. What is the National Vaccine Injury Compensation Program (NVICP) and what are the vaccines that the Program covers?

The National Vaccine Injury Compensation Program (NVICP) is a no-fault insurance program created by Congress in 1986. The program is funded with a federal excise tax that is paid on each dose of DTaP in any combination, DT, Td, OPV, IPV, MMR, Hib, hepatitis B, varicella and pneumococcal conjugate vaccine. Parents who believe that their children have been injured by a vaccine and wish to seek compensation cannot start a civil suit until they have gone through the NVICP process.

2. What is the process involved in filing a NVICP claim?

This process involves filing a claim which is then investigated by the program and judged according to whether the claim meets the requirements of the Vaccine Injury Table (see table this resource) or the claimant can prove that the vaccine caused the injury. If the claim is accepted, the parent is awarded compensation. If the parents accept compensation, they cannot then initiate a civil suit to seek another award. The advantages of the system include having the option of filing a claim without the services of an attorney and receiving quick decisions compared with the civil court process. Approximately 95% of successful claimants accept their compensation. Few of the remaining 5% who reject compensation elect to file a civil suit and it is rare for a civil court to overturn an NVICP decision.

Vaccine Information Statements

3. What is a Vaccine Information Statement (VIS)?

Vaccine Information Statements (VISs) are documents designed to inform and educate an adult or the parent or legal representative of a child receiving vaccine. VISs are available in English and numerous other languages. The answer to question #4 below lists the diseases for which you are required by law to provide a VIS. The Centers for Disease Control (CDC)

encourages that they be provided for every vaccine administered. You must provide the VISs prior to vaccination.

4. When are VISs required?

Effective October 1, 1994, **health care providers who administer any vaccine covered by the NVICP are required to give a copy of the relevant Vaccine Information Statements (VIS) to any adult or to the parent or legal representative of a child receiving the vaccine.** Vaccines included are as follows: any product containing diphtheria, tetanus, pertussis, measles, mumps, rubella, polio, Haemophilus influenzae type b (Hib), hepatitis B, varicella and pneumococcal conjugate. These requirements are the result of an amendment to the National Childhood Vaccine Injury Act (NCVIA). Health care providers are not required to obtain the signature of the patient, parent, or legal representative, acknowledging receipt of the VISs. However, health care providers in Colorado must document in the medical record that the VIS was given. A useful document that includes a parent signature block is included in this resource. See the *Vaccine Administration Record for Children and Teens* form which follows on page III-19 of this section.

VISs can be downloaded from www.cdc.gov/nip/publications/vis or you may call the Centers for Disease Control (CDC) 1-800-311-3435.

Record Keeping

5. What information must a health care provider who administers a vaccine document in every patient's permanent medical record?

Health care providers who administer a vaccine must record the following information in every patient's permanent medical record as required by the NCVIA, for each vaccine:

- **The date of administration of the vaccine**
- **The manufacturer and lot number of the vaccine**
- **The name, address and title of the health care provider administering the vaccine**
- **The version date on the relevant VIS given to the patient or patient representative**
- **The date the VIS was given to the patient**

Although it is not required, it is generally expected that the route and site of vaccine administration be documented in the medical record. Should a parent decline a vaccine or vaccines, it is important that the refusal be documented. You may either document the declination in the chart or use the form included in this section, entitled, *Refusal to Consent to Vaccination* on page III-29.

Liability Concerns Related to Adverse Events

6. Where can providers find a list of the vaccine adverse reactions that must be reported? What form is required?

Providers are required by law to report certain adverse reactions associated with vaccination to the U.S. Department of Health and Human Services. **These adverse events are listed in the Reportable Events Following Vaccination (vaccine injury table on page III-5 of this section). Adverse events should be reported on a Vaccine Adverse Event Reporting System (VAERS) form contained in this document on page III-27.** Both the table and the form are included in this resource.

The Addition of New Vaccines

7. How are new vaccines added for coverage under the NVICP?

On March 24, 1997, **a final rule was published which, in part, provided for the automatic addition of future vaccines recommended by the CDC for routine administration to children. However, Congress will still need to set an appropriate excise tax on any new vaccines recommended by the CDC before those vaccines are effectively covered under the Program.** Under current statutory language, eight years of retroactive coverage will be provided for those claiming injury or death resulting from a vaccine newly added to the NVICP.

Filing of Claims

8. Who may file a claim?

A claim may be made for any injury or death thought to be a result of a covered vaccine. These injuries may include, but are not limited to: anaphylaxis, paralytic polio, and encephalopathy. **The injured individual may file, or a parent, legal guardian or trustee may file on behalf of a child or an incapacitated person.**

Contacting the NVICP Program

9. To whom shall you direct your call for more information about the NVCIP?

The National Injury Compensation Program Internet Home Page can be found at the following address: www.hrsa.gov

The toll-free number for the National Vaccine Injury Compensation Program is **1-800-338-2382** to obtain an information packet detailing how to file a claim, criteria for eligibility, and the documentation required. For further information write to:

National Vaccine Injury Compensation Program
Parklawn Building, Room 8A-46
5600 Fishers Lane
Rockville, Maryland 20857

National Childhood Vaccine Injury Act Vaccine Injury Table

Effective December 1, 2004

Source: www.hrsa.gov/osp/vicp/table.htm

Vaccine	Adverse Event	Time Interval
I. Tetanus toxoid-containing vaccines (e.g., DTaP, DTP-Hib, DT; Td, or TT)	A. Anaphylaxis or anaphylactic shock (1)	0-4 hours
	B. Brachial neuritis (6)	2-28 days
	C. Any acute complication or sequela (including death) of above events (4)	Not applicable
II. Pertussis antigen-containing vaccines (e.g., DTaP, DTP, P, DTP-Hib)	A. Anaphylaxis or anaphylactic shock (1)	0-4 hours
	B. Encephalopathy (or encephalitis) (2)	0-72 hours
	C. Any acute complication or sequela (including death) of above events (4)	Not applicable
III. Measles, mumps and rubella virus-containing vaccines in any combination (e.g., MMR, MR, M, R)	A. Anaphylaxis or anaphylactic shock (1)	0-4 hours
	B. Encephalopathy (or encephalitis) (2)	5-15 days
	C. Any acute complication or sequela (including death) of above events (4)	Not applicable
IV. Rubella virus-containing vaccines (e.g., MMR, MR, R)	A. Chronic arthritis (5)	7-42 days
	B. Any acute complication or sequela (including death) of above event (4)	Not applicable
V. Measles virus-containing vaccines (e.g., MMR, MR, M)	A. Thrombocytopenic purpura (7)	7-30 days
	B. Vaccine-Strain Measles Viral Infection in an immunodeficient recipient (8)	0-6 months
	C. Any acute complication or sequela (including death) of above events (4)	Not applicable
VI. Polio live virus-containing vaccines (OPV)	A. Paralytic polio	
	— in a non-immunodeficient recipient	0-30 days
	— in an immunodeficient recipient	0-6 months
	— in a vaccine-associated community case	Not applicable
	B. Vaccine-strain polio viral infection (9)	
	— in a non-immunodeficient recipient	0-30 days
	— in an immunodeficient recipient	0-6 months
	— in a vaccine-associated community case	Not applicable
	C. Any acute complication or sequela (including death) of above events (4)	Not applicable
VII. Polio inactivated-virus containing vaccines (e.g., IPV)	A. Anaphylaxis or anaphylactic shock (1)	0-4 hours
	B. Any acute complication or sequela (including death) of above event (4)	Not applicable
VIII. Hepatitis B antigen- containing vaccines	A. Anaphylaxis or anaphylactic shock (1)	0-4 hours
	B. Any acute complication or sequela (including death) of above event (4)	Not applicable
IX. Hemophilus influenzae type b polysaccharide conjugate vaccines)	A. No condition specified for compensation	Not applicable
X. Varicella vaccine	A. No condition specified for compensation	Not applicable
XI. Rotavirus vaccine	A. No condition specified for compensation	Not applicable
XII. Vaccines containing live, oral, rhesus-based rotavirus	A. Intussusception	0-30 days
	B. Any acute complication or sequela (including death) of above event (4)	Not applicable
XIII. Pneumococcal conjugate vaccines	A. No condition specified for compensation	Not applicable
XIV. 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.*	A. No condition specified for compensation	Not applicable

* On December 1, 2004, the Secretary published a notice in the Federal Register announcing the addition of hepatitis A vaccines to the Vaccine Injury Table under Category XIV with an effective date of December 1, 2004. (69 Fed. Reg. 69945-46 (December 1, 2004)). See News: Hepatitis A Vaccines Added to the VICP for more information (http://www.hrsa.gov/osp/vicp/INDEX.HTM).

Qualifications and Aids to Interpretation

(1) **Anaphylaxis and anaphylactic shock** mean an acute, severe, and potentially lethal systemic allergic reaction. Most cases resolve without sequelae. Signs and symptoms begin minutes to a few hours after exposure. Death, if it occurs, usually results from airway obstruction caused by laryngeal edema or bronchospasm and may be associated with cardiovascular collapse. Other significant clinical signs and symptoms may include the following: Cyanosis, hypotension, bradycardia, tachycardia, arrhythmia, edema of the pharynx and/or trachea and/or larynx with stridor and dyspnea. Autopsy findings may include acute emphysema which results from lower respiratory tract obstruction, edema of the hypopharynx, epiglottis, larynx, or trachea and minimal findings of eosinophilia in the liver, spleen and lungs. When death occurs within minutes of exposure and without signs of respiratory distress, there may not be significant pathologic findings.

(2) **Encephalopathy.** For purposes of the Vaccine Injury Table, a vaccine recipient shall be considered to have suffered an encephalopathy only if such recipient manifests, within the applicable period, an injury meeting the description below of an acute encephalopathy, and then a chronic encephalopathy persists in such person for more than 6 months beyond the date of vaccination.

(i) An **acute encephalopathy** is one that is sufficiently severe so as to require hospitalization (whether or not hospitalization occurred).

(A) **For children less than 18 months of age** who present without an associated seizure event, an acute encephalopathy is indicated by a “significantly decreased level of consciousness” (see “D” below) lasting for at least 24 hours. Those children less than 18 months of age who present following a seizure shall be viewed as having an acute encephalopathy if their significantly decreased level of consciousness persists beyond 24 hours and cannot be attributed to a postictal state (seizure) or medication.

(B) **For adults and children 18 months of age or older,** an acute encephalopathy is one that persists for at least 24 hours and characterized by at least two of the following:

(1) A significant change in mental status that is not medication related; specifically a confusional state, or a delirium, or a psychosis;

(2) A significantly decreased level of consciousness, which is independent of a seizure and cannot be attributed to the effects of medication; and

(3) A seizure associated with loss of consciousness.

(C) Increased intracranial pressure may be a clinical feature of acute encephalopathy in any age group.

(D) A "significantly decreased level of consciousness" is indicated by the presence of at least one of the following clinical signs for at least 24 hours or greater (see paragraphs (2)(I)(A) and (2)(I)(B) of this section for applicable timeframes):

(1) Decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli);

(2) Decreased or absent eye contact (does not fix gaze upon family members or other individuals); or

(3) Inconsistent or absent responses to external stimuli (does not recognize familiar people or things).

(E) The following clinical features alone, or in combination, do not demonstrate an acute encephalopathy or a significant change in either mental status or level of consciousness as described above: Sleepiness, irritability (fussiness), high-pitched and unusual screaming, persistent inconsolable crying, and bulging fontanelle. Seizures in themselves are not sufficient to constitute a diagnosis of encephalopathy. In the absence of other evidence of an acute encephalopathy, seizures shall not be viewed as the first symptom or manifestation of the onset of an acute encephalopathy.

(ii) **Chronic encephalopathy** occurs when a change in mental or neurologic status, first manifested during the applicable time period, persists for a period of at least 6 months from the date of vaccination. Individuals who return to a normal neurologic state after the acute encephalopathy shall not be presumed to have suffered residual neurologic damage from that event; any subsequent chronic encephalopathy shall not be presumed to be a sequela of the acute encephalopathy. If a preponderance of the evidence indicates that a child's chronic encephalopathy is secondary to genetic, prenatal or perinatal factors, that chronic encephalopathy shall not be considered to be a condition set forth in the Table.

(iii) An encephalopathy shall not be considered to be a condition set forth in the Table if in a proceeding on a petition, it is shown by a preponderance of the evidence that the encephalopathy was caused by an infection, a toxin, a metabolic disturbance, a structural lesion, a genetic disorder or trauma (without regard to whether the cause of the infection, toxin, trauma, metabolic disturbance, structural lesion or genetic disorder is known). If at the time a decision is made on a petition filed under section 2111(b) of the Act for a vaccine-related injury or death, it is not possible to determine the cause by a preponderance of the evidence of an encephalopathy, the encephalopathy shall be considered to be a condition set forth in the Table.

(iv) In determining whether or not an encephalopathy is a condition set forth in the Table, the Court shall consider the entire medical record.

(3) **Seizure and convulsion.** For purposes of paragraphs (b)(2) of this section, the terms, "seizure" and "convulsion" include myoclonic, generalized tonic-clonic (grand mal), and simple and complex partial seizures. Absence (petit mal) seizures shall not be considered to be a condition set forth in the Table. Jerking movements or staring episodes alone are not necessarily an indication of seizure activity.

(4) **Sequela.** The term "sequela" means a condition or event which was actually caused by a condition listed in the Vaccine Injury Table.

(5) **Chronic Arthritis.For** purposes of the Vaccine Injury Table, chronic arthritis may be found in a person with no history in the 3 years prior to vaccination of arthropathy (joint disease) on the basis of:

A) Medical documentation, recorded within 30 days after the onset, of objective signs of acute arthritis (joint swelling) that occurred between 7 and 42 days after a rubella vaccination;

(B) Medical documentation (recorded within 3 years after the onset of acute arthritis) of the persistence of objective signs of intermittent or continuous arthritis for more than 6 months following vaccination:

(C) Medical documentation of an antibody response to the rubella virus.

For purposes of the Vaccine Injury Table, the following shall not be considered as chronic arthritis: Musculoskeletal disorders such as diffuse connective tissue diseases (including but not limited to rheumatoid arthritis, juvenile rheumatoid arthritis, systemic lupus erythematosus, systemic sclerosis, mixed connective tissue disease, polymyositis/dermatomyositis, fibromyalgia, necrotizing vasculitis and vasculopathies and Sjogren's Syndrome), degenerative joint disease, infectious agents other than rubella (whether by direct invasion or as an immune reaction), metabolic and endocrine diseases, trauma, neoplasms, neuropathic disorders, bone and cartilage disorders and arthritis associated with ankylosing spondylitis, psoriasis, inflammatory bowel disease, Reiter's syndrome, or blood disorders.

Arthralgia (joint pain) or stiffness without joint swelling shall not be viewed as chronic arthritis for purposes of the Vaccine Injury Table.

(6) **Brachial neuritis** is defined as dysfunction limited to the upper extremity nerve plexus (i.e., its trunks, divisions, or cords) without involvement of other peripheral (e.g., nerve roots or a single peripheral nerve) or central (e.g., spinal cord) nervous system structures. A deep, steady, often severe aching pain in the shoulder and upper arm usually her-

alds onset of the condition. The pain is followed in days or weeks by weakness and atrophy in upper extremity muscle groups. Sensory loss may accompany the motor deficits, but is generally a less notable clinical feature. The neuritis, or plexopathy, may be present on the same side as or the opposite side of the injection; it is sometimes bilateral, affecting both upper extremities. Weakness is required before the diagnosis can be made. Motor, sensory, and reflex findings on physical examination and the results of nerve conduction and electromyographic studies must be consistent in confirming that dysfunction is attributable to the brachial plexus. The condition should thereby be distinguishable from conditions that may give rise to dysfunction of nerve roots (i.e., radiculopathies) and peripheral nerves (i.e., including multiple mononeuropathies), as well as other peripheral and central nervous system structures (e.g., cranial neuropathies and myelopathies).

(7) **Thrombocytopenic purpura** is defined by a serum platelet count less than 50,000/mm^3. Thrombocytopenic purpura does not include cases of thrombocytopenia associated with other causes such as hypersplenism, autoimmune disorders (including alloantibodies from previous transfusions) myelodysplasias, lymphoproliferative disorders, congenital thrombocytopenia or hemolytic uremic syndrome. This does not include cases of immune (formerly called idiopathic) thrombocytopenic purpura (ITP) that are mediated, for example, by viral or fungal infections, toxins or drugs. Thrombocytopenic purpura does not include cases of thrombocytopenia associated with disseminated intravascular coagulation, as observed with bacterial and viral infections. Viral infections include, for example, those infections secondary to Epstein Barr virus, cytomegalovirus, hepatitis A and B, rhinovirus, human immunodeficiency virus (HIV), adenovirus, and dengue virus. An antecedent viral infection may be demonstrated by clinical signs and symptoms and need not be confirmed by culture or serologic testing. Bone marrow examination, if performed, must reveal a normal or an increased number of megakaryocytes in an otherwise normal marrow.

(8) **Vaccine-strain measles viral infection** is defined as a disease caused by the vaccine-strain that should be determined by vaccine-specific monoclonal antibody or polymerase chain reaction tests.

(9) **Vaccine-strain polio viral infection** is defined as a disease caused by poliovirus that is isolated from the affected tissue and should be determined to be the vaccine-strain by oligonucleotide or polymerase chain reaction. Isolation of poliovirus from the stool is not sufficient to establish a tissue specific infection or disease caused by vaccine-strain poliovirus.

For additional information call our public information line at 1-800-338-2382.

Health Resources and Services Administration
U.S. Department of Health and Human Services
Parklawn Building
5600 Fishers Lane
Rockville, Maryland 20857

Q&A: Vaccine Information Statements

1. What Vaccine Information Statements (VISs) must be used?

The relevant VIS must be provided to the vaccinee (or to the parent or legal representative) for *any vaccine covered by the National Childhood Vaccine Injury Act (NCVIA)*. As of January 2002, these VISs are: **DTaP, Td, MMR, Polio, Hepatitis B, *Haemophilus influenzae* type b (Hib), Varicella,** and **Pneumococcal conjugate** vaccine. Rotavirus is also covered by the NCVIA, but the vaccine is not in use.

Use of VISs for vaccines not covered by the NCVIA is strongly encouraged. Other VISs that are available are **Hepatitis A, Influenza, Pneunococcal polysaccharide, Lyme disease, Anthrax, Meningococcal,** and **Smallpox.**

2. What is the difference between VISs, Important Information Statements (IIS's), and Vaccine Information Materials (VIM's)?

Technically, the law designates statements describing vaccines covered by the NCVIA as Vaccine Information Statements. Important Information Statement is a term that was used for these statements in the past, and is still sometimes used to describe statements for vaccines not covered by NCVIA (e.g., hepatitis A, influenza). From 1991 to 1994 multi-page "Vaccine Information Pamphlets" (VIP's) were used for MMR, DTP, Td, and Polio. Vaccine Information Materials is a generic term that has been used to describe any of these statements. For convenience sake, we now use the term VIS for *all* current information statements.

3. How can I tell if the VISs I am using are the most up-to-date versions?

Check the NIP's website at http://www.cdc.gov/nip/publications/VIS/. The VISs posted there will be current.

4. Can providers develop their own vaccine information materials?

All public and private providers who administer the vaccines covered by the NCVIA are required to use the CDC-developed VISs. In 1994, an amendment to the act deleted the language that allowed providers to substitute their own materials for the VISs. However, providers may still *supplement* the VISs with materials of their own.

5. May immunization projects add state or local health department identification to the VISs?

Yes. But any other addition to these documents or variations from their language or format must have the prior written approval of the Director of CDC's National Immunization Program.

6. How are VISs distributed?

Camera-ready copies and explanatory information are sent to all Immunization Projects. The Immunization Projects are responsible for printing and distributing VISs to their public health clinics. They will also be asked to print and distribute single camera-ready copies to all providers who administer vaccine in their state or metro area. Funds have been included in the Immunization Project grants for printing and distribution of the VISs. Some private provider organizations also print and sell copies of the VISs.

The VISs are also available on the internet (see "Where can I get the VISs," below). These are identical to the printed VISs, and may be downloaded and printed out by Immunization Projects or providers and used as camera-ready copy.

7. Must VISs be used for adults as well as for children?

Yes. Under the NCVIA, anyone receiving a covered vaccine should be given the appropriate VIS.

8. Are VISs "informed consent" forms?

No. Informed consent requirements are determined by state law. The VISs were written to fulfill the information requirements of the NCVIA, and are not informed consent documents. However, because the materials cover both benefits and risks associated with vaccinations, they provide enough information that anyone reading them should be adequately informed.

Nevertheless, you should consult your state law to determine if there are any specific "informed consent" requirements relating to immunization. The requirements could include *procedural* requirements (e.g., whether informed consent is required prior to vaccination, whether it may be oral or must be in writing, whether state law requires a signature prior to vaccination) or *substantive* requirements (e.g., the types of information the state would require to be included in any informed consent).

NOTE: VISs must still be used, even if state law requires use of other informed consent materials.

9. What are the recordkeeping requirements regarding VISs?

Health care providers are **not** required to obtain the signature of the patient, parent or legal representative acknowledging receipt of the VISs. However, to document that the VIS was given, health care providers must note in each patient's permanent medical record at the time a VIS is provided: (1) the date printed on the VIS and (2) the date the VIS is given to the vaccine recipient, or the parent or legal representative.

In addition, the NCVIA still requires that health care providers note in the patient's permanent medical record:

(1) the date of administration of the vaccine
(2) the manufacturer and lot number of the vaccine
(3) the name and address of the health care provider administering the vaccine (This should be the address where the record is kept. If immunizations are given in a shopping mall, for example, the address would be the clinic where the permanent record will reside.)

10. What does "legal representative" mean?

A "legal representative" is a parent or other individual who is qualified *under state law* to consent to the immunization of a minor.

11. Must a VIS be given out *every time* a vaccine is administered?

Yes. A VIS must be given out with every vaccination, including each dose of a multi-dose series. This is done for several reasons. The statement might have been updated between visits, or the health status of the child could have changed (*e.g.*, he or she may have an evolving neurological disorder).

12. Must the patient, parent, or legal representative physically take away a copy of each VIS, or is it acceptable to simply let them read a copy and ensure that they understand it?

It is desirable for the person getting the shot or their representative to actually take the VISs home, because they include information that may be needed later (*e.g.*, the recommended schedule for the vaccines, information concerning what to look for and do after the vaccination, and what to do if there is a serious reaction). Even if some patients may elect not to take the VISs home, the provider should offer them the opportunity to do so.

13. How should we comply with the law for patients who are illiterate or blind?

The NCVIA requires providers to supplement the VISs with "visual presentations" or oral "explanations" as needed. If patients are unable to read the VISs, it is up to the provider to ensure that they have the information. VISs can be read to these patients, or videotapes (or other media) can be used as supplements.

14. Are the VISs available in languages other than English?

There are currently no "official" CDC translations of the VISs. Several states have translated them, however, and sharing of translations among states is encouraged. Projects or providers may translate the VISs into other languages. These do not have to be approved by CDC. (See "Where can I get the VISs," below.)

Translations currently exist on the web in Arabic, Armenian, Cambodian, Chinese, Croatian (Serbian), Farsi, French, German, Haitian Creole, Hmong, Japanese, Korean, Laotian, Portugese, Punjabi, Romanian, Russian, Samoan, Serbo-Croatian, Somali, Spanish, Tagalog, Thai, Turkish & Vietnamese.

The Truth about Using VISs

Many health care providers have heard misconceptions about the use of Vaccine Information Statements (VISs). A VIS is a two-sided information sheet developed by the Centers for Disease Control and Prevention (CDC) informing vaccine recipients (or, if a minor, the parents or legal representatives), of the benefits and risks of a vaccine. The National Childhood Vaccine Injury Act of 1986, a federal law, requires VISs be given out whenever certain vaccines are given. Here are true statements about VISs to counter the most common myths.

Myth: VISs are only required when vaccinating children.
Truth: Federal law requires that VISs be used when vaccinating patients of all ages, not just children.

Myth: You must provide a VIS when giving the first dose of a vaccine series, but it's optional for subsequent doses.
Truth: The most current VIS must be provided before each dose of vaccine is given, including those given in a series. If three doses are required, then three VISs must be given. (A child or adult's medical history may have changed between doses and the information read earlier may no longer apply.)

Myth: VISs must be used for vaccines supplied via the public sector (e.g., VFC); they're optional for vaccines purchased privately.
Truth: VISs are required when certain vaccines are administered, regardless of their source. These vaccines include DTaP, Td, MMR, polio, hepatitis B, Hib, pneumococcal conjugate, and varicella.

Myth: VISs for influenza, hepatitis A, pneumococcal polysaccharide, meningococcal, and anthrax are completely optional.
Truth: While VISs for these diseases are available, they are not required by the federal law but are required if a provider is administering vaccine purchased through a CDC contract. For example, if a clinic gets flu vaccine from the state health department for VFC-eligible children, they must use the most current VIS for influenza.

Myth: If there isn't enough time to have the patient read the VIS before the shots are given, you can give him or her a copy to read at home.
Truth: The idea of a VIS is to provide information about the vaccine and the disease just before the patient will receive the vaccine. It is acceptable, however, to supplement the usual process by giving out VISs at additional times (e.g., pre-natal visits or at birth).

Myth: Federal law requires a signature of the patient (parent/legal representative) that he or she received the appropriate VIS.
Truth: Signatures are no longer required by federal law (although some states may have a separate requirement). To verify that a VIS was given, providers must record in the patient's chart (or permanent office log or file) the following information:
- Which VIS was given (that is, for which vaccine)
- Publication date on the VIS (must be the current version)
- Date the VIS was given

The biggest myth about VISs is that they are just "busy work" and don't have any real benefit. The truth is, by using the VISs with your patients, you are helping to foster **a better educated patient population** and you're doing the right thing.

Myth: Providers can modify a VIS to better suit their practices.
Truth: 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 other educational materials.

Myth: It's too complicated to use the VISs with patients who don't read or speak English so it's okay to omit their use.
Truth: The law requires that providers ensure all patients (parents/legal representatives) receive the appropriate VIS, regardless of their ability to read English. You may also choose to read them aloud or play one of the videotapes that are available. VISs are also available in 27 languages from IAC's website at www.immunize.org/vis

Myth: Since there aren't VISs for combination vaccines, a VIS can't be given when using these vaccines.
Truth: When giving combination vaccines for which no VIS exists (e.g., Comvax), give out all relevant single VISs. In the case of Comvax, give both Hepatitis B and Hib VISs.

Myth: Merely giving the patient or parent a laminated copy of the VIS to read prior to immunization is adequate under the law.
Truth: If you do this, you must also give the patient or parent a copy of the VIS to take home.

Myth: VISs are merely a bureaucratic hassle and complicate the provider's job in vaccinating his/her patients.
Truth: Providing VISs does take some work, but patients and providers both benefit. The patient/parent who is provided with a VIS feels he or she has a part in the decision-making process. The patient may also identify a valid personal contraindication to immunization after reading the VIS. Finally, the VIS provides many answers to patients' questions about common and uncommon side effects of each vaccine, thereby saving staff time.

Myth: It's too difficult to know the most current VIS information and requirements and it's not all that important anyway.
Truth: The federal law requires that you give the patient the most current version. All current VISs are available from CDC's National Immunization Program (www.cdc.gov/nip), the CDC's Immunization Information Hotline at (800) 232-2522, and your state health department. And, of course, you can always find the most up-to-date information on VISs by visiting the IAC website: www.immunize.org/vis

www.immunize.org/catg.d/p2028.pdf • Item #P2028 (07/02)

Documenting Immunizations and Informed Consent

The National Childhood Vaccine Injury Act (NCVIA) requires all health care providers in the United States who administer any vaccine containing diphtheria, tetanus, pertussis, measles, mumps, rubella, polio, hepatitis B, Hib, pneumococcal conjugate and varicella antigen to document the information detailed below:

Vaccine Administration Record For Children and Teens

Patient name: _____
Birthdate: _____
Clinic chart number: _____

Vaccine administrator: Before administering any vaccine, make sure the parent or guardian understands the risks and benefits of the vaccines and that their questions have been answered to their satisfaction. Make sure to give the parent or guardian an updated shot record at every visit.

1 4 2 2 4 3

Vaccine and route (Circle type given)	Date dose & VIS given	Dose	Site given (LA, RA, LT, RT)	Vaccine manufacturer	Vaccine lot number	Expiration date	VIS rev. date*	Signature of vaccine administrator
Hepatitis B-1 (IM)		mcg						
Hepatitis B-2 (IM)		mcg						
Hepatitis B-3 (IM)		mcg						
DTaP DT Td- 1 (IM)								
DTaP DT Td- 2 (IM)								
DTaP DT Td- 3 (IM)								
DTaP DT Td- 4 (IM)								
DTaP DT Td- 5 (IM)								
DTaP/Hib DTP/Hib- 4 (IM)								

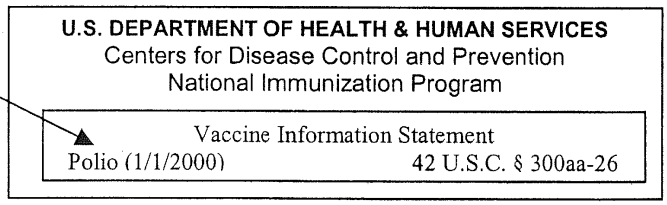
1 The date of vaccine administration must be charted. See number 4 for more information on VIS.

2 The lot number of the vaccine used and the manufacturer name must be documented for each immunization administered. This information would be needed in the case of an adverse event or vaccine recall.

3 The name, address, and title of the person who administered the vaccine must be charted. The address of the health care office may be pre-printed or stamped onto the record.

4 Federal law requires the health care provider to provide a copy of the most current version of the appropriate VIS. By noting the date of the VIS in the patient's medical record, the provider is indicating that the patient or parent received information about the vaccine and consented to vaccine administration. It is also showing that the most current VIS was used.
To document that the Vaccine Information Statement (VIS) was given, the provider must note in the client's permanent record at the time the VIS is provided: (1) the date the VIS was given to the vaccine recipient, or the parent or legal guardian and (2) the version date printed on the VIS.

The version date is located on the bottom of the back of each VIS. VIS are updated when there are changes in the information and the latest versions can be obtained from the local health department.



(Back of vaccine information statement)

Provider Name _____

Provider Address _____ **City** _____ **ZIP** _____

Immunization Administration Record Sheet/ Approved Colorado Certificate of Immunization

Colorado Department of Public Health and Environment

Name _____ DOB _____ Parent _____

Address _____ City _____ ZIP _____ Phone _____

VFC Qualified: ☐ Yes ☐ No If Yes, check one: ☐ Medicaid, ☐ American Indian or Alaskan Native, ☐ No Insurance,
☐ Has health insurance that does not pay for vaccines (applies only to FQHCs and rural health centers)

I have read or have had explained to me the information contained in the Vaccine Information Statement(s) about the disease(s) and the vaccine(s). I have had a chance to ask questions which were answered to my satisfaction. I believe I understand the benefits and risks of the vaccine(s) and request that the vaccine(s) indicated below be given to me or to the person named above for whom I am authorized to make this request.

Vaccine	Signature[1]	Immun. Date	Site Given[2]	Manufacturer/ Lot Number	VIS & Date[3]	Date VIS Given[4]	Administered By (Name/Title)
Hep B-1							
Hep B-2							
Hep B-3							
DTaP/DTP/DT-1							
DTaP/DTP/DT-2							
DTaP/DTP/DT-3							
DTaP/DTP/DT-4							
DTaP/DTP/DT-5							
Hib-1							
Hib-2							
Hib-3							
Hib-4							
IPV/OPV-1							
IPV/OPV-2							
IPV/OPV-3							
IPV/OPV-4							
MMR-1							
MMR-2							
Hep A-1							
Hep A-2							
Var-1							
Var-2							
Varicella Disease:	yes ☐ Date:_____ **(Record dates Varicella vaccines were given OR date of disease occurrence.)**						

(continues on back)

[1]**Signature:** Parent, guardian, emancipated student/consenting minor, adult
[2]**Site Given Legend: RA**=Right Arm, **LA**=Left Arm, **RT**=Right Thigh, **LT**=Left Thigh, **O**=Oral
[3]**VIS & Date:** Type & revision date of Vaccine Information Statement given to parent *e.g.,* MMR 1/15/03
[4]**Date VIS Given:** Date of which patient, parent or guardian was given Vaccine Information Sheet

August 2004

Name _____ DOB _____

I have read or have had explained to me the information contained in the Vaccine Information Statement(s) about the disease(s) and the vaccine(s). I have had a chance to ask questions which were answered to my satisfaction. I believe I understand the benefits and risks of the vaccine(s) and request that the vaccine(s) indicated below be given to me or to the person named above for whom I am authorized to make this request.

Vaccine	Signature[1]	Immun. Date	Site Given[2]	Manufacturer/ Lot Number	VIS & Date[3]	Date VIS Given[4]	Administered By (Name/Title)
Td-1							
Td-2							
Td-3							
Pneumococcal Conjugate-1							
Pneumococcal Conjugate-2							
Pneumococcal Conjugate-3							
Pneumococcal Conjugate-4							
Pneumococcal Polysaccharide							
Meningococcal							
Meningococcal							
Influenza							

[1]**Signature:** Parent, guardian, emancipated student/consenting minor, adult
[2]**Site Given Legend: RA**=Right Arm, **LA**=Left Arm, **RT**=Right Thigh, **LT**=Left Thigh, **O**=Oral
[3]**VIS & Date:** Type & revision date of Vaccine Information Statement given to parent *e.g.,* MMR 1/15/03
[4]**Date VIS Given:** Date of which patient, parent or guardian was given Vaccine Information Sheet

TO THE BEST OF MY KNOWLEDGE, THE PERSON NAMED ABOVE HAS RECEIVED THE IMMUNIZATIONS REQUIRED FOR SCHOOL/CHILD CARE ENTRY

DO NOT SIGN UNLESS MINIMUM IMMUNIZATION REQUIREMENTS FOR AGE OR GRADE ARE MET

Signed _____ Title _____ Date _____
(Physician, nurse or school health authority)

STATEMENT OF EXEMPTION TO IMMUNIZATION LAW (DECLARACIÓN RESPECTO A LAS EXENCIONES DE LA LEY DE VACUNACIÓN)

IN THE EVENT OF AN OUTBREAK, EXEMPTED PERSONS MAY BE SUBJECT TO EXCLUSION FROM SCHOOL AND TO QUARANTINE.
SI SE PRESENTA UN BROTE DE LA ENFERMEDAD, ES POSIBLE QUE A LAS PERSONAS EXENTAS SE LES PONGA EN CUARENTENA O SE LES EXCLUYA DE LA ESCUELA.

MEDICAL EXEMPTION: The physical condition of the above named person is such that immunization would endanger life or health or is medically contraindicated due to other medical conditions.
EXENCIÓN POR RAZONES MÉDICAS: El estado de salud de la persona arriba citada es tal que la vacunación significa un riesgo para su salud o incluso su vida; o bien, las vacunas están contraindicadas debido a otros problemas de salud.

Medical exemption *to the following vaccine(s):*
La exención por razones médicas *aplica a la(s) siguiente(s) vacuna(s):*

Signed (Firma) _____ Date (Fecha)_____ _____
Physician (Médico)

RELIGIOUS EXEMPTION: Parent or guardian of the above named person or the person himself/herself is an adherent to a religious belief opposed to immunizations.
EXENCIÓN POR MOTIVOS RELIGIOSOS: El padre o tutor de la persona arriba citada, o la persona misma, pertenece a una religión que se opone a la inmunización.

Religious exemption *to the following vaccine(s):*
Exención por motivos religiosos *de la(s) siguiente(s) vacuna(s):*

Signed (Firma) _____ Date (Fecha)_____ _____
Parent, guardian, emancipated student/consenting minor
(Padre, tutor, estudiante emancipado o consentimiento del menor)

PERSONAL EXEMPTION: Parent or guardian of the above named person or the person himself/herself is an adherent to a personal belief opposed to immunizations.
EXENCIÓN POR CREENCIAS PERSONALES: Las creencias personales del padre o tutor de la persona arriba citada, o la persona misma, se oponen a la inmunización.

Personal exemption *to the following vaccine(s):*
Exención por creencias personales *de la(s) siguiente(s) vacuna(s):*

Signed (Firma) _____ Date (Fecha)_____ _____
Parent, guardian, emancipated student/consenting minor
(Padre, tutor, estudiante emancipado o consentimiento del menor)

CDPHE-IMM IARS RC14#2

Vaccine Administration Record for Children and Teens

Patient name: _____

Birthdate: _____

Chart number: _____

Before administering any vaccines, give the parent/guardian all appropriate copies of Vaccine Information Statements (VISs) and make sure they understand the risks and benefits of the vaccine(s). Update the patient's personal record card or provide a new one whenever you administer vaccine.

Vaccine	Type of Vaccine* (generic abbreviation)	Date given (mo/day/yr)	Route	Site given (RA, LA, RT, LT)	Vaccine		Vaccine Information Statement		Signature/ initials of vaccinator
					lot #	mfr.	Date on VIS§	Date given§	
Hepatitis B† (e.g., HepB, Hib-HepB, DTaP-HepB-IPV)			IM						
			IM						
			IM						
			IM						
Diphtheria, Tetanus, Pertussis† (e.g, DTaP, DT, DTaP-Hib, DTaP-HepB-IPV, Td)			IM						
			IM						
			IM						
			IM						
			IM						
			IM						
			IM						
***Haemophilus influenzae* type b**† (e.g., Hib, Hib-HepB, DTaP-Hib)			IM						
			IM						
			IM						
			IM						
Polio† (e.g, IPV, DTaP-HepB-IPV)			IM•SC						
			IM•SC						
			IM•SC						
			IM•SC						
Pneumococcal conjugate (PCV)			IM						
			IM						
			IM						
			IM						
Measles, Mumps, Rubella (MMR)			SC						
			SC						
Varicella (Var)			SC						
			SC						
Hepatitis A** (HepA)			IM						
			IM						
Influenza** (Flu)			IM						
			IM						
			IM						
			IM						
			IM						
Other**									
Other**									

*Record the generic abbreviation for the type of vaccine given (e.g., DTaP-Hib, PCV), *not* the trade name.

†For combination vaccines, fill in the row for each individual antigen composing the combination.

§Record the publication date of each VIS as well as the date it is given to the patient. According to federal law, VISs must be given to patients (or parent/guardian of a minor child) before administering each dose of DTaP, Td, Hib, polio, MMR, varicella, PCV, or HepB vaccine, or combinations thereof.

**Influenza, pneumococcal polysaccharide (PPV23), hepatitis A, and/or meningococcal vaccines are recommended for certain high-risk children.

www.immunize.org/catg.d/p2022b.pdf • Item #P2022 (4/03)

Vaccine Administration Record for Children and Teens

Patient name: Victoria Johnson

Birthdate: December 2, 2002

Chart number: 1234567

Before administering any vaccines, give the parent/guardian all appropriate copies of Vaccine Information Statements (VISs) and make sure they understand the risks and benefits of the vaccine(s). Update the patient's personal record card or provide a new one whenever you administer vaccine.

Vaccine	Type of Vaccine* (generic abbreviation)	Date given (mo/day/yr)	Route	Site given (RA, LA, RT, LT)	Vaccine		Vaccine Information Statement		Signature/ initials of vaccinator
					lot #	mfr.	Date on VIS§	Date given§	
Hepatitis B† (e.g., HepB, Hib-HepB, DTaP-HepB-IPV)	HepB	12/02/02	IM	RT	0651M	MRK	7/11/01	12/02/02	JTA
	Hib-HepB	2/02/03	IM	RT	1051M	MRK	7/11/01	2/02/03	DCP
	Hib-HepB	4/02/03	IM	RT	1051M	MRK	7/11/01	4/02/03	DCP
	Hib-HepB	12/02/03	IM	RT	1051M	MRK	7/11/01	12/02/03	DLW
Diphtheria, Tetanus, Pertussis† (e.g, DTaP, DT, DTaP-Hib, DTaP-HepB-IPV, Td)	DTaP	2/02/03	IM	LT	647A2	GSK	7/30/01	2/02/03	DCP
	DTaP	4/02/03	IM	LT	647A2	GSK	7/30/01	4/02/03	DCP
	DTaP	6/02/03	IM	LT	647A2	GSK	7/30/01	6/02/03	DLW
	DTaP	3/02/04	IM	RA	647A2	GSK	7/30/01	3/02/04	RLV
			IM						
			IM						
			IM						
***Haemophilus influenzae* type b**† (e.g., Hib, Hib-HepB, DTaP-Hib)	Hib-HepB	2/02/03	IM	RT	1051M	MRK	12/16/98	2/02/03	DCP
	Hib-HepB	4/02/03	IM	RT	1051M	MRK	12/16/98	4/02/03	DCP
	Hib-HepB	12/02/03	IM	RT	1051M	MRK	12/16/98	12/02/03	DLW
			IM						
Polio† (e.g, IPV, DTaP-HepB-IPV)	IPV	2/02/03	IM•SC	LT	U0123-4	AVP	1/01/00	2/02/03	DCP
	IPV	4/02/03	IM•SC	LT	U0123-4	AVP	1/01/00	4/02/03	DCP
	IPV	3/02/04	IM•SC	LT	U0123-4	AVP	1/01/00	3/02/04	DLW
			IM•SC						
Pneumococcal conjugate (PCV)	PCV	2/02/03	IM	LT	489-835	WYE	9/30/02	2/02/03	DCP
	PCV	4/02/03	IM	RT	489-835	WYE	9/30/02	4/02/03	DCP
	PCV	6/02/03	IM	LT	489-835	WYE	9/30/02	6/02/03	DLW
	PCV	3/02/04	IM	LA	501-245	WYE	9/30/02	3/02/04	RLV
Measles, Mumps, Rubella (MMR)	MMR	12/02/03	SC	LA	0857M	MRK	1/15/03	12/02/03	DLW
			SC						
Varicella (Var)	Var	12/02/03	SC	LA	0799M	MRK	12/16/98	12/02/03	DLW
			SC						
Hepatitis A** (HepA)			IM						
Influenza** (Flu)									
			IM						
			IM						
Other**									
Other**									

Hib-HepB (Comvax)

1 shot, 2 different VIS dates

How to record Hib-HepB combination vaccine

*Record the generic abbreviation for the type of vaccine given (e.g., DTaP-Hib, PCV), *not* the trade name.

†For combination vaccines, fill in the row for each individual antigen composing the combination.

§Record the publication date of each VIS as well as the date it is given to the patient. According to federal law, VISs must be given to patients (or parent/guardian of a minor child) before administering each dose of DTaP, Td, Hib, polio, MMR, varicella, PCV, or HepB vaccine, or combinations thereof.

**Influenza, pneumococcal polysaccharide (PPV23), hepatitis A, and/or meningococcal vaccines are recommended for certain high-risk children.

www.immunize.org/catg.d/p2022b.pdf • Item #P2022 (4/03)

Vaccine Administration Record for Children and Teens

Patient name: Sam Smith

Birthdate: December 2, 2002

Chart number: 2345678

Before administering any vaccines, give the parent/guardian all appropriate copies of Vaccine Information Statements (VISs) and make sure they understand the risks and benefits of the vaccine(s). Update the patient's personal record card or provide a new one whenever you administer vaccine.

Vaccine	Type of Vaccine* (generic abbreviation)	Date given (mo/day/yr)	Route	Site given (RA, LA, RT, LT)	Vaccine		Vaccine Information Statement		Signature/ initials of vaccinator
					lot #	mfr.	Date on VIS§	Date given§	
Hepatitis B† (e.g., HepB, Hib-HepB, DTaP-HepB-IPV)	HepB	12/02/02	IM	RT	0651M	MRK	7/11/01	12/02/02	JTA
	DTaP-HepB-IPV	2/02/03	IM	RT	635A2	GSK	7/11/01	2/02/03	DCP
	DTaP-HepB-IPV	4/02/03	IM	RT	712A2	GSK	7/11/01	4/02/03	DCP
	DTaP-HepB-IPV	06/02/03	IM	RT	712A2	GSK	7/11/01	06/02/03	DLW
Diphtheria, Tetanus, Pertussis† (e.g, DTaP, DT, DTaP-Hib, DTaP-HepB-IPV, Td)	DTaP-HepB-IPV	2/02/03	IM	RT	635A2	GSK	7/30/01	2/02/03	DCP
	DTaP-HepB-IPV	4/02/03	IM	RT	712A2	GSK	7/30/01	4/02/03	DCP
	DTaP-HepB-IPV	6/02/03	IM	RT	712A2	GSK	7/30/01	6/02/03	DLW
	DTaP-Hib	3/02/04	IM	RA	P0897AA	AVP	7/30/01	3/02/04	RLV
			IM						
			IM						
			IM						
***Haemophilus influenzae* type b**† (e.g., Hib, Hib-HepB, DTaP-Hib)	Hib	2/02/03	IM	LT	UA744AA	AVP	12/16/98	2/02/03	DCP
	Hib	4/02/03	IM	LT	UA744AA	AVP	12/16/98	4/02/03	DCP
	Hib	6/02/03	IM	LT	UA744AA	AVP	12/16/98	6/02/03	DLW
	DTaP-Hib	3/02/04	IM	RA	7172AA	AVP	12/16/98	3/02/04	RLV
Polio† (e.g, IPV, DTaP-HepB-IPV)	DTaP-HepB-IPV	2/02/03	IM•SC	RT	635A2	GSK	1/01/00	2/02/03	DCP
	DTaP-HepB-IPV	4/02/03	IM•SC	RT	712A2	GSK	1/01/00	4/02/03	DCP
	DTaP-HepB-IPV	6/02/03	IM•SC	RT	712A2	GSK	1/01/00	6/02/03	DLW
			IM•SC						
Pneumococcal conjugate (PCV)	PCV	2/02/03	IM	LT	489-835	WYE	9/30/02	2/02/03	DCP
	PCV	4/02/03	IM	RT	489-835	WYE	9/30/02	4/02/03	DCP
	PCV	6/02/03	IM	LT	489-835	WYE	9/30/02	6/02/03	DLW
	PCV	3/02/04	IM	LA	501-245	WYE	9/30/02	3/02/04	RLV
Measles, Mumps, Rubella (MMR)	MMR	12/02/03	SC	RA	0857M	MRK	1/15/03	12/02/03	DLW
			SC						
Varicella (Var)	Var	12/02/03	SC	LA	0799M	MRK	12/16/98	12/02/03	DLW
			SC						
Hepatitis A** (HepA)			IM						
Influenza** (Flu)									
			IM						
			IM						
Other**									
Other**									

DTaP-HepB-IPV (Pediarix)

DTaP-Hib (Trihibit)

1 shot, 2 lot #s

1 shot, 3 different VIS dates

How to record DTaP-HepB-IPV and DTaP-Hib combination vaccines

*Record the generic abbreviation for the type of vaccine given (e.g., DTaP-Hib, PCV), *not* the trade name.

†For combination vaccines, fill in the row for each individual antigen composing the combination.

§Record the publication date of each VIS as well as the date it is given to the patient. According to federal law, VISs must be given to patients (or parent/guardian of a minor child) before administering each dose of DTaP, Td, Hib, polio, MMR, varicella, PCV, or HepB vaccine, or combinations thereof.

**Influenza, pneumococcal polysaccharide (PPV23), hepatitis A, and/or meningococcal vaccines are recommended for certain high-risk children.

www.immunize.org/catg.d/p2022b.pdf • Item #P2022 (4/03)

Vaccine Administration Record for Children and Teens

Patient name: Jack Jones

Birthdate: October 15, 1989

Chart number: 3456789

Before administering any vaccines, give the parent/guardian all appropriate copies of Vaccine Information Statements (VISs) and make sure they understand the risks and benefits of the vaccine(s). Update the patient's personal record card or provide a new one whenever you administer vaccine.

Vaccine	Type of Vaccine* (generic abbreviation)	Date given (mo/day/yr)	Route	Site given (RA, LA, RT, LT)	Vaccine		Vaccine Information Statement		Signature/ initials of vaccinator
					lot #	mfr.	Date on VIS§	Date given§	
Hepatitis B† (e.g., HepB, Hib-HepB, DTaP-HepB-IPV)	HepB (1.0 ml)	6/02/02	IM	RA	0651M	MRK	7/11/01	6/02/02	TAA
	HepB (1.0 ml)	1/02/03	IM	RA	0651M	MRK	7/11/01	1/02/03	TAA
			IM						
			IM						
Diphtheria, Tetanus, Pertussis† (e.g, DTaP, DT, DTaP-Hib, DTaP-HepB-IPV, Td)	DTP	12/15/89	IM	RT	326-912	LED	1/01/88	12/15/89	DCP
	DTP	2/15/90	IM	RT	326-912	LED	1/01/88	2/15/90	DCP
	DTP	4/15/90	IM	RT	326-912	LED	1/01/88	4/15/90	DLW
	DTP	4/15/91	IM	RA	326-912	LED	1/01/88	4/15/91	RLV
	DTP	4/15/94	IM	RA	326-912	LED	10/15/91	4/15/94	JTA
			IM						
			IM						
***Haemophilus influenzae* type b**† (e.g., Hib, Hib-HepB, DTaP-Hib)	Hib	12/15/89	IM	LT	1492L	MRK	6/01/89	12/15/89	DCP
	Hib	2/15/90	IM	LT	1492L	MRK	6/01/89	2/15/90	DCP
	Hib	10/15/90	IM	LT	1492L	MRK	6/01/89	10/15/90	DLW
			IM						
Polio† (e.g, IPV, DTaP-HepB-IPV)	OPV	12/15/89	IM•SC	Oral	0678A	LED	3/01/83	12/15/89	DCP
	OPV	2/15/90	IM•SC	Oral	0678A	LED	3/01/83	2/15/90	DCP
	OPV	4/15/91	IM•SC	Oral	0896A	LED	3/01/83	4/15/91	RLV
	OPV	4/15/94	IM•SC	Oral	0987A	LED	10/15/91	4/15/94	JTA
Pneumococcal conjugate (PCV)			IM						
			IM						
			IM						
			IM						
Measles, Mumps, Rubella (MMR)	MMR	1/15/91	SC	RA	0857M	MRK	1/01/88	1/15/91	DLW
	MMR	10/15/01	SC	LA	0946M	MRK	1/01/88	10/15/01	PWS
Varicella (Var)	Var	10/15/01	SC	LA	0799M	MRK	12/16/98	10/15/01	PWS
			SC						
Hepatitis A** (HepA)			IM						
Influenza** (Flu)									
			IM						
Other**									
Other**									

2-dose adult HepB for adolescents

How to record adult HepB vaccine given to 11-15 year olds

*Record the generic abbreviation for the type of vaccine given (e.g., DTaP-Hib, PCV), *not* the trade name.

†For combination vaccines, fill in the row for each individual antigen composing the combination.

§Record the publication date of each VIS as well as the date it is given to the patient. According to federal law, VISs must be given to patients (or parent/guardian of a minor child) before administering each dose of DTaP, Td, Hib, polio, MMR, varicella, PCV, or HepB vaccine, or combinations thereof.

**Influenza, pneumococcal polysaccharide (PPV23), hepatitis A, and/or meningococcal vaccines are recommended for certain high-risk children.

www.immunize.org/catg.d/p2022b.pdf • Item #P2022 (4/03)

WEBSITE: www.vaers.org E-MAIL: info@vaers.org FAX: 1-877-721-0366

VACCINE ADVERSE EVENT REPORTING SYSTEM

VAERS

24 Hour Toll-Free Information 1-800-822-7967
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only

VAERS Number _____

Date Received _____

Patient Name:

Last First M.I.

Address

City State Zip

Telephone no. (____) _____

Vaccine administered by (Name):

Responsible Physician _____

Facility Name/Address

City State Zip

Telephone no. (____) _____

Form completed by (Name):

Relation to Patient ☐ Vaccine Provider ☐ Patient/Parent ☐ Manufacturer ☐ Other

Address *(if different from patient or provider)*

City State Zip

Telephone no. (____) _____

1. State	2. County where administered	3. Date of birth mm / dd / yy	4. Patient age	5. Sex ☐ M ☐ F	6. Date form completed mm / dd / yy

7. Describe adverse events(s) (symptoms, signs, time course) and treatment, if any

8. Check all appropriate:
- ☐ Patient died (date mm / dd / yy)
- ☐ Life threatening illness
- ☐ Required emergency room/doctor visit
- ☐ Required hospitalization (_____days)
- ☐ Resulted in prolongation of hospitalization
- ☐ Resulted in permanent disability
- ☐ None of the above

9. Patient recovered ☐ YES ☐ NO ☐ UNKNOWN

10. Date of vaccination mm / dd / yy
Time _____ AM PM

11. Adverse event onset mm / dd / yy
Time _____ AM PM

12. Relevant diagnostic tests/laboratory data

13. Enter all vaccines given on date listed in no. 10

	Vaccine (type)	Manufacturer	Lot number	Route/Site	No. Previous Doses
a.					
b.					
c.					
d.					

14. Any other vaccinations within 4 weeks prior to the date listed in no. 10

	Vaccine (type)	Manufacturer	Lot number	Route/Site	No. Previous doses	Date given
a.						
b.						

15. Vaccinated at:
- ☐ Private doctor's office/hospital
- ☐ Public health clinic/hospital
- ☐ Military clinic/hospital
- ☐ Other/unknown

16. Vaccine purchased with:
- ☐ Private funds
- ☐ Public funds
- ☐ Military funds
- ☐ Other/unknown

17. Other medications

18. Illness at time of vaccination (specify)

19. Pre-existing physician-diagnosed allergies, birth defects, medical conditions (specify)

20. Have you reported this adverse event previously?
- ☐ No
- ☐ To health department
- ☐ To doctor
- ☐ To manufacturer

Only for children 5 and under

22. Birth weight _____ lb. _____ oz.

23. No. of brothers and sisters

21. Adverse event following prior vaccination (check all applicable, specify)

	Adverse Event	Onset Age	Type Vaccine	Dose no. in series
☐ In patient				
☐ In brother or sister				

Only for reports submitted by manufacturer/immunization project

24. Mfr./imm. proj. report no.

25. Date received by mfr./imm.proj.

26. 15 day report? ☐ Yes ☐ No

27. Report type ☐ Initial ☐ Follow-Up

Health care providers and manufacturers are required by law (42 USC 300aa-25) to report reactions to vaccines listed in the Table of Reportable Events Following Immunization. Reports for reactions to other vaccines are voluntary except when required as a condition of immunization grant awards.

Form VAERS-1(FDA)

"Fold in thirds, tape & mail — DO NOT STAPLE FORM"

NO POSTAGE
NECESSARY
IF MAILED
IN THE
UNITED STATES
OR APO/FPO

BUSINESS REPLY MAIL
FIRST-CLASS MAIL PERMIT NO. 1895 ROCKVILLE, MD

POSTAGE WILL BE PAID BY ADDRESSEE

VAERS
P.O. Box 1100
Rockville MD 20849-1100

DIRECTIONS FOR COMPLETING FORM

(Additional pages may be attached if more space is needed.)

GENERAL

- Use a separate form for each patient. Complete the form to the best of your abilities. Items 3, 4, 7, 8, 10, 11, and 13 are considered essential and should be completed whenever possible. Parents/Guardians may need to consult the facility where the vaccine was administered for some of the information (such as manufacturer, lot number or laboratory data.)
- Refer to the Reportable Events Table (RET) for events mandated for reporting by law. Reporting for other serious events felt to be related but not on the RET is encouraged.
- Health care providers other than the vaccine administrator (VA) treating a patient for a suspected adverse event should notify the VA and provide the information about the adverse event to allow the VA to complete the form to meet the VA's legal responsibility.
- These data will be used to increase understanding of adverse events following vaccination and will become part of CDC Privacy Act System 09-20-0136, "Epidemiologic Studies and Surveillance of Disease Problems". Information identifying the person who received the vaccine or that person's legal representative will not be made available to the public, but may be available to the vaccinee or legal representative.
- Postage will be paid by addressee. Forms may be photocopied (must be front & back on same sheet).

SPECIFIC INSTRUCTIONS

Form Completed By: To be used by parents/guardians, vaccine manufacturers/distributors, vaccine administrators, and/or the person completing the form on behalf of the patient or the health professional who administered the vaccine.

Item 7: Describe the suspected adverse event. Such things as temperature, local and general signs and symptoms, time course, duration of symptoms, diagnosis, treatment and recovery should be noted.

Item 9: Check "YES" if the patient's health condition is the same as it was prior to the vaccine, "NO" if the patient has not returned to the pre-vaccination state of health, or "UNKNOWN" if the patient's condition is not known.

Item 10 and 11: Give dates and times as specifically as you can remember. If you do not know the exact time, please indicate "AM" or "PM" when possible if this information is known. If more than one adverse event, give the onset date and time for the most serious event.

Item 12: Include "negative" or "normal" results of any relevant tests performed as well as abnormal findings.

Item 13: List ONLY those vaccines given on the day listed in Item 10.

Item 14: List any other vaccines that the patient received within 4 weeks prior to the date listed in Item 10.

Item 16: This section refers to how the person who gave the vaccine purchased it, not to the patient's insurance.

Item 17: List any prescription or non-prescription medications the patient was taking when the vaccine(s) was given.

Item 18: List any short term illnesses the patient had on the date the vaccine(s) was given (i.e., cold, flu, ear infection).

Item 19: List any pre-existing physician-diagnosed allergies, birth defects, medical conditions (including developmental and/or neurologic disorders) for the patient.

Item 21: List any suspected adverse events the patient, or the patient's brothers or sisters, may have had to previous vaccinations. If more than one brother or sister, or if the patient has reacted to more than one prior vaccine, use additional pages to explain completely. For the onset age of a patient, provide the age in months if less than two years old.

Item 26: This space is for manufacturers' use only.

SAMPLE

Refusal to Consent to Vaccination

Child's Name: _____ Child's ID# _____

Parent's Name(s): _____

My child's health care provider, _____, has advised me that my child (named above) should receive the following vaccines:

- ❑ Hepatitis B vaccine
- ❑ Diphtheria, Tetanus, acellular Pertussis (DTaP) vaccine
- ❑ Diphtheria Tetanus (DT or Td) vaccine
- ❑ *Haemophilus influenzae* type B (Hib) vaccine
- ❑ Pneumococcal vaccine
- ❑ Polio (IPV) vaccine
- ❑ Measles, mumps, rubella (MMR) vaccine
- ❑ Varicella (chickenpox) vaccine
- ❑ Influenza (flu) vaccine
- ❑ Meningococcal vaccine
- ❑ Hepatitis A vaccine
- ❑ Other _____

My child's health care provider has explained to me and I understand the following:

- The **purpose** of the recommended vaccination
- The **risks and benefits** of the recommended vaccination
- A **possible consequence** of not allowing my child to receive the recommended vaccination is contracting the illness the vaccine is intended to prevent.
- My doctor, the American Academy of Pediatrics, the American Academy of Family Physicians, and the Centers for Disease Control and Prevention (CDC) have all strongly recommended that the vaccine(s) be given.

The health care provider has answered all of my questions.

I know that I may change my mind and accept vaccination for my child in the future.

I accept sole responsibility for any consequences as a result of my child not being vaccinated.

I acknowledge that I have read this document in its entirety and fully understand it.

_____ _____
Parent/Guardian Signature Date

_____ _____
Witness Date

IV. Vaccine Storage and Handling

Colorado Children's Immunization Coalition

Vaccine Storage and Handling

♦ Introduction: This chapter will cover basic storage and handling of vaccines and includes a new type of temperature log, developed by the Immunization Action Coalition (IAC), that shades the "out of range" storage temperatures for the user. At the end of the chapter there is a checklist that each office should use to assess the completeness of their vaccine storage and handling procedures. We ask that you complete this checklist for your practice.

1. Why is it so important to store vaccine properly?

Proper vaccine storage is of critical importance. **Outdated and improperly handled vaccines will not protect patients**. Remember, vaccines you administer must be potent in order for them to be effective. Another reason to protect your vaccine supply is that vaccines are very expensive. An example is the PCV7 vaccine with a cost of $58 per dose.

2. Where should vaccines not be stored in the refrigerator?

Refrigerate vaccine immediately when it is received.* Store varicella LAIV (Live attenuated influenza vaccine) vaccine in the freezer. **Do not store vaccine in the door of the refrigerator**.

*Refer to package insert for specific instructions on each vaccine. If you have questions about the condition of the vaccines at the time of delivery, first store them properly, then notify the supplier and get instructions.

3. Does diluent need refrigeration?

Protect MMR from light at all times and keep it cold. Don't get the vial from the refrigerator until time to reconstitute and administer. **Diluent does not need refrigeration if MMR is administered right after diluent is added.**

4. How can you avoid outdating of your vaccine?

Rotate vaccine stock to avoid outdating. Note the expiration dates on vials or cartons and use short-dated vaccines first. Keep vials in their cartons. Don't use outdated vaccine. Don't over-order.

5. What type of special electrical plug should your vaccine refrigerator have?

Safeguard the refrigerator. Make sure it stays plugged in**. It should have a safety lock-type plug.**

6. What is another measure you can take to avoid having the vaccine refrigerator inadvertently unplugged?

Post a warning sign so electricians or janitors don't accidentally unplug the refrigerator or turn off the circuit or electricity.

7. What are the proper temperatures to maintain in the vaccine refrigerator? In the freezer?

Maintain proper temperatures in the refrigerator (2°C to 8°C or 35°F to 46°F) and in the freezer (15°C or 5°F or lower). If space allows, help keep temperatures stable by placing big plastic containers of water in the refrigerator, cold packs (blue ice) in the freezer.

8. How often should the vaccine refrigerator and freezer be checked?

Check refrigerator and freezer twice a day, first thing in the morning and last thing at night:

- AM: See if temperatures are correct. (Keep thermometers in both refrigerator and freezer.)
- PM: Make sure the doors are shut tightly and the unit is plugged in.

One of the most common mistakes that practices make is not having a plan for protecting their vaccine supply during a disaster or emergency. Included in this chapter on page IV-17 is a good example of an emergency response worksheet developed by the Vaccines for Children Program.

Another common mistake is for the refrigerator or freezer door to be left open over the weekend. That is why it is so important to not only check the temperature ranges but to check the doors and plugs before leaving at night or closing the practice for the weekend.

If you have storage and/or handling questions or notice your refrigerator temperatures are out of acceptable range, you should call your vaccine representative, VFC contact (303-692-2798) or the Colorado Department of Public Health and Environment (303-692-2363).

PROTECT VACCINE

Handle with Care!

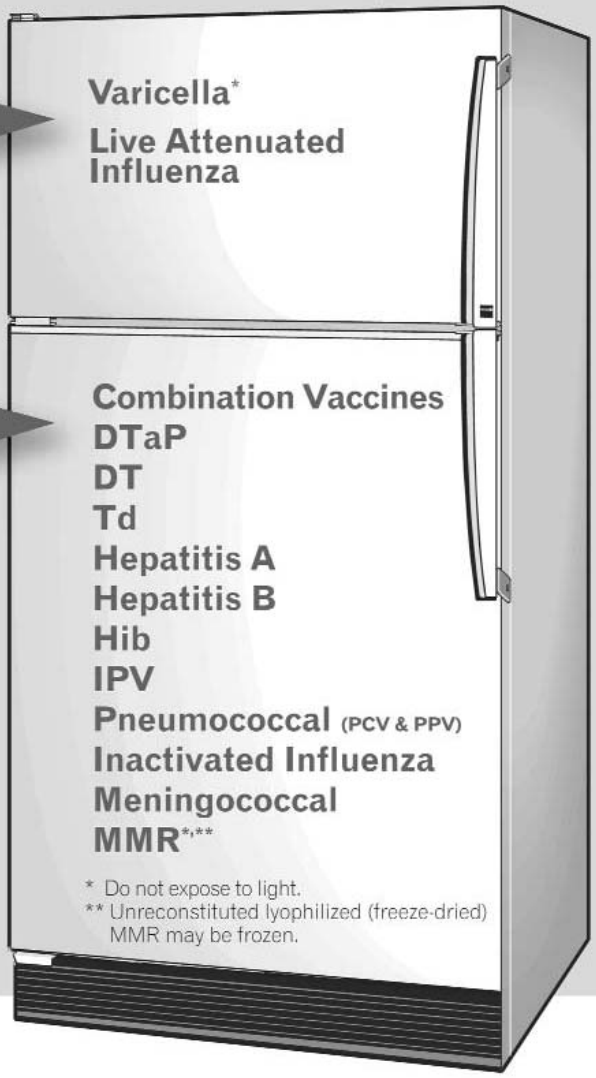
Store in Freezer
≤ 5°F (≤ -15°C)

Varicella*
Live Attenuated Influenza

Store in Refrigerator
35°–46°F (2°–8°C)

Combination Vaccines
DTaP
DT
Td
Hepatitis A
Hepatitis B
Hib
IPV
Pneumococcal (PCV & PPV)
Inactivated Influenza
Meningococcal
MMR*,**

* Do not expose to light.
** Unreconstituted lyophilized (freeze-dried) MMR may be frozen.



Vaccine Storage Rules

- Keep your refrigerator and freezer within the proper temperature ranges.
- Keep your vaccine within the proper temperature ranges.
  - Measure and record refrigerator and freezer temperatures twice daily.
  - Take *immediate action* if temperatures are out of range.
- Keep MMR vaccine cold and protected from light.
- Keep varicella vaccine frozen and protected from light.
- Keep live attenuated influenza vaccine (LAIV) frozen.
- Rotate your vaccine stocks.

PROTECT PATIENTS

VACCINE STORAGE AND HANDLING

It is vitally important to follow proper vaccine storage and handling procedures. Outdated or improperly handled vaccines will not protect patients! The guidelines below will help you ensure that the vaccines you administer are potent, pure, and effective and will help you avoid any unnecessary loss of vaccine.

1. Never use outdated vaccines. Check expiration dates weekly and rotate stock so that the shortest dated vaccine is used first.
2. Check and log temperatures in both the refrigerator and the freezer each morning and each evening. If storing varicella vaccine, check the temperature in the refrigerator frequently to assure that the vaccines stored in the refrigerator are maintained at proper temperatures. Post "Do Not Unplug" signs at the wall outlet and circuit breaker. Develop an emergency plan and keep a cooler nearby if you need to move the vaccines.
3. Never store vaccines in refrigerator door or drawers. Never store food with the vaccines.
4. When transporting vaccines, use insulated containers and ice packs. Vaccine should not touch ice packs. Transporting varicella vaccine is not recommended. Contact the manufacturer, the local health department, or the Michigan Department of Community Health for further guidance.

VACCINE	ARRIVAL CONDITION	STORAGE REQUIREMENTS
DTaP, DTaP-Hib*, DTaP-Hep B-IPV, DT, Td, Hep B-Hib, Hib*, IPV, Hepatitis A & B, Influenza, 23-Valent Pneumococcal Polysaccharide, and 7-Valent Conjugate Pneumococcal	Packed with refrigerant. Vaccine should NOT have been frozen.**	Refrigerate immediately upon arrival at 35º to 46ºF (2º to 8ºC). **DO NOT FREEZE.**
Measles, Mumps, and Rubella (MMR)*	Packed with refrigerant. During shipment vaccine must be maintained at 50ºF (10ºC) or less. May be frozen.**	**Vaccine:** Refrigerate or freeze immediately upon arrival at 35º to 46ºF (2º to 8ºC) or less. **Diluent:** Store separately at room temperature or in the refrigerator. **PROTECT VACCINE FROM LIGHT AT ALL TIMES.**
Live Attenuated Influenza Vaccine (LAIV)	Packed with dry ice. When the vaccine arrives, immediately check the Warm Mark indicator to verify the correct temperature was maintained during shipment.	LAIV must be maintained in a continuously frozen state of 5º (-15º) or colder. It must be stored in a manual-defrost freezer or using a manufacturer supplied FreezeBox in a frost-free freezer.
Varicella*	Packed with dry ice. During shipment vaccine must be maintained at -4ºF (-20ºC) or colder. There must be evidence of dry ice in the package.**	**Vaccine:** Maintain continuously in the frozen state at an average temperature of 5ºF (-15ºC) or colder. **Diluent:** Store separately at room temperature or in the refrigerator. **PROTECT FROM LIGHT BEFORE RECONSTITUTION.**

* Use only the diluent supplied to reconstitute the vaccine.

** If you have questions about the condition of the vaccine at the time of delivery, immediately place the vaccine in recommended storage and contact your local health department if you received the vaccine from the local health department. If you received the vaccine directly from the manufacturer, call the manufacturer for assistance.

PLEASE NOTE: These recommendations are not a substitute for the package insert included with each biologic.

POST IN A VISIBLE LOCATION NEAR THE REFRIGERATOR

VACCINE PREPARATION AND ADMINISTRATION

VACCINE	INSTRUCTIONS FOR RECONSTITUTION OR USE	SHELF LIFE AFTER RECONSTITUTION, THAWING, OR OPENING
DTaP, DTaP-Hib, DTaP-Hep B-IPV, DT, Td, Hib, Hep B-Hib, Hepatitis A & B, Influenza (TIV) and Pneumococcal Polysaccharide (PPV23)	**SHAKE VIAL VIGOROUSLY** to obtain a uniform suspension prior to withdrawing each dose. The vaccine should not be used if it cannot be re-suspended.* **ADMINISTER INTRAMUSCULARLY.** (Pneumococcal Polysaccharide may be administered subcutaneously.)	Use until outdated, unless contaminated.
Measles, Mumps and Rubella (MMR)	**RECONSTITUTE JUST BEFORE USING**. Use ONLY the diluent supplied. Inject the entire volume of the diluent into the vial of lyophilized vaccine and agitate to mix thoroughly. Withdraw entire contents and inject the total volume of vaccine (about 0.5 ml).* **ADMINISTER SUBCUTANEOUSLY**.	After reconstitution, use immediately or store in vaccine vial in a dark place at 35º to 46ºF (2º to 8ºC). Do not freeze reconstituted vaccine. **PROTECT VACCINE FROM LIGHT AT ALL TIMES** since exposure may inactivate the vaccine. **DISCARD IF NOT USED WITHIN 8 HOURS AFTER RECONSTITUTION.**
Inactivated Poliovirus Vaccine (IPV)	**ADMINISTER SUBCUTANEOUSLY OR INTRAMUSCULARLY**.*	Use until outdated, unless contaminated.
Live Attenuated Influenza Vaccine (LAIV)	**THAW JUST BEFORE USING** by holding the sprayer in the palm of the hand, and supporting the plunger rod with the thumb. Do not roll the sprayer or depress the plunger. **ADMINISTER INTRANASALLY.**	Thawed vaccine may be stored in the refrigerator at 35º to 46ºF (2º to 8ºC) for no more than 24 hours. **DISCARD AFTER 24 HOURS**. **DO NOT REFREEZE AFTER THAWING.**
Pneumococcal Conjugate (PCV7)	**SHAKE VIGOROUSLY** immediately prior to use to obtain a uniform suspension in the vaccine container. The vaccine should not be used if it cannot be re-suspended. After shaking, the vaccine is a homogenous white suspension. Visually inspect for particulate matter and discoloration prior to administration. Do not use if particulate matter or discoloration is found. **ADMINISTER INTRAMUSCULARLY**.	Use until outdated, unless contaminated.
Varicella (Var)	**RECONSTITUTE JUST BEFORE USING**. Use ONLY the diluent supplied. Inject 0.7 mL of diluent into the vial of lyophilized vaccine and gently agitate to mix thoroughly. Withdraw the entire contents into a syringe and inject the total volume (about 0.5 mL).* **ADMINISTER SUBCUTANEOUSLY.**	Administer vaccine immediately after reconstitution. Do not freeze reconstituted vaccine. **DISCARD IF NOT USED WITHIN 30 MINUTES AFTER RECONSTITUTION.**

* Visually inspect parenteral drug products before administration. If particulate matter and/or discoloration is noted, do not administer. Refer to the Michigan Department of Community Health (MDCH) *Vaccine Storage and Handling* table for more information.

PLEASE NOTE: These recommendations are not a substitute for the manufacturer's package insert included with each biologic.

Michigan Department of Community Health
MDCH
Jennifer M. Granholm, Governor
Janet Olszewski, Director

POST IN A VISIBLE LOCATION NEAR REFRIGERATOR

Vaccine Responsibility Chart

The following charts list tasks that have been identified as important components to a successful immunization program. Assigning vaccine responsibilities to specific team members is an effective way to assure tasks related to immunizations are completed. Assigning the following tasks to specific staff members will help your practice achieve its immunization goals.

Vaccine Storage and Handling		
Task	**Responsible Person**	**Back-up Person**
Checking and recording refrigerator and freezer temperatures twice daily		
Assuring that vaccine about to expire is used first		
Ordering vaccines monthly		
Picking up *Vaccine Information Statements (VIS)* and vaccine from the health department		
Transporting the vaccine to another refrigerator/freezer in the event of an emergency		

Vaccine Administration		
Task	**Responsible Person**	**Back-up Person**
Assessing each client's immunization status at EVERY visit		
Educating the client and reviewing the *Vaccine Information Statements (VIS)*		
Administering all needed vaccines(s)		
Recording the required documentation on the vaccine administration record and the client's immunization record card		
Sending reminder postcards or making telephone calls		
Entering immunization data in the CIIS or sending immunization data to the regional CIIS office		

Temperature Log for Vaccines (Fahrenheit)

Month/Year:_____ **Days 1–15**

***Instructions:** Place an "X" in the box that corresponds with the temperature. The hatched zones represent unacceptable temperature ranges. If the temperature recorded is in the hatched zone: 1. **Store the vaccine** under proper conditions as quickly as possible, 2. **Call the vaccine manufacturer(s)** to determine whether the potency of the vaccine(s) has been affected, 3. **Call the immunization program at your local health department** for further assistance: (_____) _____, and 4. **Document the action taken** on the reverse side of this log.

Day of Month		1		2		3		4		5		6		7		8		9		10		11		12		13		14		15	
Exact Time																															
°F Temp		am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm
	≥49°																														
	48°																														
	47°																														
	46°																														
	45°																														
	44°																														
Refrigerator temperature	43°																														
	42°																														
	41°																														
	40°																														
	39°																														
	38°																														
	37°																														
	36°																														
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	33°																														
	32°																														
	31°																														
	30°																														
	29°																														
	≤28°																														
	≥8°																														
Freezer temp	7°																														
	6°																														
	5°																														
	4°																														
	≤3°																														
Room temp																															
Staff Initials																															

Adapted by the Immunization Action Coalition courtesy of the Michigan Department of Community Health

www.immunize.org/catg.d/p3039.pdf • Item #P3039 (8/04)

Vaccine Storage Troubleshooting Record

Date	Time	Storage Unit Temp	Room Temp	Problem	Action Taken	Results	Initials

Temperature Log for Vaccines (Fahrenheit)

Month/Year:_____ **Days 16–31**

***Instructions:** Place an "X" in the box that corresponds with the temperature. The hatched zones represent unacceptable temperature ranges. If the temperature recorded is in the hatched zone: 1. **Store the vaccine** under proper conditions as quickly as possible, 2. **Call the vaccine manufacturer(s)** to determine whether the potency of the vaccine(s) has been affected, 3. **Call the immunization program at your local health department** for further assistance: (_____) _____, and 4. **Document the action taken** on the reverse side of this log.

Day of Month		16		17		18		19		20		21		22		23		24		25		26		27		28		29		30		31	
Exact Time																																	
°F Temp		am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm
	≥49°																																
	48°																																
	47°																																
	46°																																
	45°																																
	44°																																
Refrigerator temperature	43°																																
	42°																																
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	40°																																
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	37°																																
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	33°																																
	32°																																
	31°																																
	30°																																
	29°																																
	≤28°																																
Freezer temp	≥8°																																
	7°																																
	6°																																
	5°																																
	4°																																
	≤3°																																
Room temp																																	
Staff Initials																																	

Take immediate action if temperature is in shaded section*

Vaccine Storage Troubleshooting Record

Date	Time	Storage Unit Temp	Room Temp	Problem	Action Taken	Results	Initials

Checklist for Safe Vaccine Handling and Storage

Here are the 20 most important things you can do to safeguard your vaccine supply. Are you doing them all? Reviewing this list can help you improve your clinic's vaccine management practices.

Yes	No		
____	____	1.	We have a designated person in charge of the handling and storage of our vaccines.
____	____	2.	We have a back-up person in charge of the handling and storage of our vaccines.
____	____	3.	A vaccine inventory log is maintained that documents: ____ Vaccine name and number of doses received ____ Date the vaccine was received ____ Arrival condition of vaccine ____ Vaccine manufacturer and lot number ____ Vaccine expiration date
____	____	4.	Our refrigerator for vaccines is either household-style or commercial-style, NOT dormitory-style. The freezer compartment has a separate exterior door.
____	____	5.	We do NOT store any food or drink in the refrigerator or freezer.
____	____	6.	We store vaccines in the middle of the refrigerator or freezer, and NOT in the door.
____	____	7.	We stock and rotate our vaccine supply so that the newest vaccine of each type (with the longest expiration date) is placed behind the vaccine with the shortest expiration date.
____	____	8.	We check vaccine expiration dates and we first use those that will expire soonest.
____	____	9.	We post a sign on the refrigerator door showing which vaccines should be stored in the refrigerator and which should be stored in the freezer.
____	____	10.	We always keep a thermometer in the refrigerator.
____	____	11.	The temperature in the refrigerator is maintained at 35–46°F (2–8°C).
____	____	12.	We keep extra containers of water in the refrigerator to help maintain cold temperatures.
____	____	13.	We always keep a thermometer in the freezer.
____	____	14.	The temperature in the freezer is maintained at +5°F (-15°C) or colder.
____	____	15.	We keep ice packs and other ice-filled containers in the freezer to help maintain cold temperatures.
____	____	16.	We post a temperature log on the refrigerator door on which we record the refrigerator and freezer temperatures twice a day—first thing in the morning and at clinic closing time—and we know whom to call if the temperature goes out of range.
____	____	17.	We have a "Do Not Unplug" sign next to the refrigerator's electrical outlet.
____	____	18.	In the event of a refrigerator failure, we take the following steps: ____ We assure that the vaccines are placed in a location with adequate refrigeration. ____ We mark exposed vaccines and separate them from undamaged vaccines. ____ We note the refrigerator or freezer temperature and contact the vaccine manufacturer or state health department to determine how to handle the affected vaccines. ____ We follow the vaccine manufacturer's or health department's instructions as to whether the affected vaccines can be used, and, if so, we mark the vials with the revised expiration date provided by the manufacturer or health department.
____	____	19.	We have obtained a detailed written policy for general and emergency vaccine management from our local or state health department.
____	____	20.	If all above answers are "yes," we are patting ourselves on the back. If not, we have assigned someone to implement needed changes!

www.immunize.org/catg.d/p3035chk.pdf • Item #P3035 (8/04)

EMERGENCY RESPONSE WORKSHEET

(What to do if a power failure occurs, the refrigerator door was left open, the temperature was too cold, or the refrigerator plug was pulled.)

1. Close the door and/or plug in the refrigerator/freezer.
2. Record the current temperature of the refrigerator/freezer.
3. Store the vaccines at appropriate temperatures. (**Make sure that the refrigerator/freezer is working properly or move the vaccines to a unit that is. Do not automatically throw out the affected vaccine. Mark the vaccine so that the potentially compromised vaccines can be easily identified.**)
4. Collect essential data listed below, call the manufacturers and notify the local health department.

DATA COLLECTION*

1. Current temperature of refrigerator: _____ Max/min temperature reached: _____
2. Current temperature of freezer: _____ Max/min temperature reached: _____
3. Amount of time temperature was outside normal range: refrigerator: _____ freezer: _____
4. Vaccines in refrigerator/freezer during the event:

Refrigerator

Vaccine and Lot #	Expiration Date	Amount of Vaccine	# of Opened Vials

Freezer

Vaccine and Lot #	Expiration Date	Amount of Vaccine	# of Opened Vials

OTHER CONDITIONS:

1. Vaccine exposed to prior temperature variations outside recommended range: Y N
2. Water bottles in refrigerator/ice packs in freezer: Y N
3. Temperatures below the recommended range for a vaccine: Y N
4. Other _____

_____

_____

_____

CALL ALL MANUFACTURER(S) OF AFFECTED VACCINE(S):

Vaccine	Manufacturer	Telephone Number
IPV (polio), Tripedia (DTaP), TriHIBit (DTaP-HIB), DT, Td, ActHIB, Fluzone (flu)	Aventis Pasteur	1-800-822-2463
DT	BioPort	1-517-327-1500
Recombivax (Hep B), MMR, Varivax (Varicella), Pedvax-HIB, COMVAX (HIB-Hep B), Pneumovax (pneumonia), VAQTA (Hep A)	Merck	1-800-672-6372
Infanrix (DTaP), Engerix B (Hep B), Havrix (Hep A)	Glaxo-SmithKline	1-800-366-8900 ext. 5231
HibTITER (Hib), Pnu-Immune (23-Valent Pneumococcal Polysaccharide, Prevnar (PCV7)	Wyeth-Ayerst	1-800-572-8221
H-BIG (Hep B Immune Globulin)	Bayer	1-800-288-8371
H-B (Hep B Immune Globulin)	North American Biologics, Inc.	1-800-458-4244

OTHER RESOURCES:

Local Health Department: _____

* Using a recording thermometer is the most effective method of tracking the refrigerator/freezer temperature over time. Visually checking a thermometer twice a day is another effective method to identify inconsistent or fluctuating temperatures in a refrigerator/freezer.

V. Immunization Strategies

Colorado Children's Immunization Coalition

Immunization Strategies

♦ Introduction: Rates need to be raised and maintained.

1. Why are proven immunization strategies important to implement in your practice?

Compared to other states, immunization rates in Colorado remain low. For July 2003 through June 2004, the National Immunization Survey ranked Colorado 50th in the nation for getting our two year-old children immunized.
Proven strategies are important to implement because they have been shown through research and actual use in practices to improve rates.

Better immunization practices achieved through specifically selected strategies is the topic of this chapter. Getting kids fully immunized, raising immunization rates and fully protecting Colorado children from vaccine preventable diseases is the goal.

2. What is an important consideration in selecting one of these proven immunization strategies to use in your office?

Following are several well-documented means of affecting change in your office or practice setting. We offer varied platforms for change because **when selecting an immunization strategy, it is important to carefully consider and then match an identified problem with a likely solution.**

3. What two factors must exist within a practice to successfully implement an immunization strategy?

It is equally important that the change or changes that are implemented be embraced by all levels of staff (e.g. clerical and medical records staff, mid-level providers, physicians, RNs and LPNs as well as medical assistants). **A consensus for change and a commitment to the chosen strategy must exist.**

How to: Strategies to raise and sustain immunization rates

A key concept in adopting strategies is the idea of a group of people "choosing to change." When changes are selected from identified immunization practice problems and solutions chosen by the very people charged with implementing change, the likelihood of sustaining the necessary motivation and, thus, achieving real change is greatly increased.

Presented here are various proven strategies from which to choose. Review them. Choose from them. Brainstorm with other immunization providers and devise your own plan based on proven strategies. It is important to agree on which staff members will be accountable for implementing specific strategic tasks. When the solution matches the identified problem *and* staff agree to accept responsibility for implementing their assigned parts of the plan, you are much more likely to achieve measurable improvement in practice rates.

4. Where can you call to get more information than what is offered here on how to improve immunization rates in your practice?

Please note that this list is not intended to be a complete description of possible solutions to immunization practices. **For more information on how to improve immunization rates in your practice, you can call the Colorado Children's Immunization Coalition (CCIC) at 303-864-5340, The Colorado Immunization Information System at 303-724-1074 and Vaccines for Children (VFC) contact persons at 303-692-2798, as well as the representatives of your local and state health departments.**

5. What should be done as soon as possible with old immunization records that are received by your office?

- **Colorado Immunization Information System.**

Colorado Immunization Information System
(CIIS)
System Overview and Status Update
June 2005

System Description

The Colorado Immunization Information System (CIIS) is a confidential, population-based, computerized information system that collects and disseminates consolidated immunization information for Colorado children. The system is operated by the University of Colorado Health Sciences Center under the Colorado Immunization Act. The Colorado Immunization Information System enables any immunization provider in Colorado to electronically track the shots a child has received, thereby maintaining an ongoing and complete record to ensure that the child receives all recommended shots in a timely manner and is not over-immunized.

An immunization information system is an important tool to increase and sustain high immunization coverage by consolidating immunization records of children from multiple providers, allowing providers to generate reminder and recall notices, and providing official school forms. The Centers for Disease Control and Prevention has guidelines for immunization information system functionality. These guidelines were used to develop the Colorado Immunization Information System.

Core Functions of the Colorado Immunization Information System

- Web-enabled data base for data entry and access
- Interoperable with electronic health records
- Consolidation of all childhood vaccinations and the provider delivering them into one easily accessible record
- Provides a print out to parents of the shot record for school, daycare and camp
- Provides decision support to providers to allow them to track what immunizations are needed under current guidelines
- Enables providers to easily screen for immunizations at each visit
- Enables providers to notify parents if a child has missed an immunization
- Enables parents to opt out of the immunization system or recall activities
- Allows state and local public health officials to make assessments of who is un- or under-immunized and where those children are located to target interventions
- Saves 3-4 minutes of time for every immunization visit compared to paper records

The Colorado Immunization Information System is central to a strategy to immunize Colorado children, ensure the prevention of vaccine-preventable disease and reduce health care costs to individuals and the State. CIIS is endorsed by the Colorado Children's Immunization Coalition and the Colorado Chapter of the American Academy of Pediatrics as the foundation for a statewide information system in Colorado.

Status of Participation

Since its inception in 1996, CIIS has systematically rolled out operations across the state. By 2006, CIIS plans to have 1) regular reporting from all public health sites and community health center sites, 2) regular reporting from 80% of all pediatricians, 3) regular reporting from 60% of all family practice physicians, and 4) complete immunization records for 95% of all children under the age of six in Colorado.

CIIS receives information from Colorado electronic birth certificates every two weeks. CIIS currently has immunization records for 50% of all children under the age of six in Colorado. These records are not, in all cases, complete because CIIS has not had sufficient funding to implement in all provider offices. Currently, 60% of public and community health center clinics and 35% of private providers participate in CIIS. In addition, CIIS receives immunization data from Kaiser Permanente, Rocky Mountain Health Plans, Anthem BC/BS and United Health Plans.

Funding
The primary sources of funding for the development and operation of CIIS are federal (the annual immunization grant from the Centers for Disease Control, through a contract with the Colorado Department of Public Health and Environment), a grant from the Colorado Trust (through a contract with the Colorado Children's Immunization Coalition), in-kind contributions from the University of Colorado Health Sciences Center, integrated health plans and health care providers. In 2005, the Colorado legislature appropriated up to $250,000 for CIIS operations. The costs to an office to implement CIIS range from zero to $5000 for computer hardware, if necessary, and to put existing immunization information into CIIS.

Community Partner Model
CIIS has adopted a very innovative approach to linking practices and clinics with the system that fulfills two very important functions:

1. Ensuring local control of the existing operations and linkage process; and
2. Leveraging local resources, both monetary and in-kind, to initiate and maintain the linkage process.

Under the Community Partner Model, community organizations with existing relationships with the health providers in their area implement and provide technical support for CIIS. Community Partners can include non-profit organizations, service organizations, integrated health care delivery systems, community health organizations and others.

Confidentiality of System
Information in the Colorado Immunization Information System can be released only to:
- The child's parent
- The child's physician
- A school or day care where the child is enrolled
- A managed care organization or health insurer where the child is enrolled
- Hospitals
- Persons or entities who have an agreement with the State of Colorado under the Colorado Immunization Act
- The Department of Health Care Policy and Financing for children enrolled in Medicaid.

Under Colorado law, anyone who releases information in the Colorado Immunization Information System to anyone who is not permitted to have the information commits a crime and can be punished. A parent can choose at any time to have his/her child's shots excluded from the Colorado Immunization Information System.

Security of System
The CIIS security policy and procedures meet current industry standards. Security measures include: user authentication, individual passwords changed every 90 days, and extensive audit trail records. The security policy and procedures are revised as the industry standards are updated.

Colorado Immunization Information System: Tool to Raise Immunization Rates
Identification of who is un- or under-immunized and where these children are located is difficult without a single consolidated record from all immunization providers. The Colorado Immunization Information System will allow state and local public health officials to identify these pockets of need and develop targeted cost-effective interventions. The Colorado Immunization Information System provides a convenient way for providers to generate recall notices for children that are overdue for immunizations. The information in CIIS was used to perform a recall for children at high risk for influenza in five large pediatric offices. The immunization rate for children who were recalled was 42% compared to 25% for the control group.

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Colorado Immunization Information System
University of Colorado Health Sciences Center
P.O. Box 6508, F456
Aurora, Colorado 80045-0508
1-888-611-9918 or 303-724-1072

Immunization Registries: Helping Children Stay Healthy A Guide for Providers

Colorado Immunization Information System

What is the Colorado Immunization Information System?
The Colorado Immunization Information System (CIIS) is a computerized information system that collects vaccination histories to ensure correct and timely immunizations for children. The CIIS is operated by the University of Colorado Health Sciences Center on behalf of the Colorado Department of Public Health and Environment (CDPHE) under the Colorado Immunization Act (24-5-1701, C.R.S.). States and communities throughout the country have developed confidential immunization information systems with assistance from federal, state and local partners. Immunization information systems are endorsed by professional organizations, including the American Academy of Pediatrics, the American Medical Association and the National Medical Association.

How does the CIIS work?
The database is web enabled and accessed using Internet Explorer. Participating immunization providers can retrieve and input immunizations 24 hours a day, 7 days a week. Immunizations for a child are kept in a single record, even if the child is seen by more than one provider.

The CIIS allows a provider to review a patient's immunization history at each visit and quickly determine what immunizations are due based on recommendations by the Advisory Committee on Immunization Practices (ACIP). Participation in the CIIS is voluntary for both providers and parents. Parents have the right to have their child's immunization data excluded. The CIIS provides forms necessary for the provider to inform a parent of the right to exclude the information and of the benefits of having the child's information in the system.

Why should my practice participate in the CIIS?

To provide quality patient care

- CIIS displays recommended immunizations at each visit based on current ACIP standards
- CIIS highlights reactions and contraindications
- CIIS provides a way to identify and recall children who are overdue for immunizations
- CIIS can immediately identify patients for vaccine recalls

To save time

- Retrieve immunizations entered by other offices for your new patients
- Print immunization forms for school, day care and camp without pulling charts
- Track vaccine usage
- Record all data required by the National Childhood Vaccine Injury Act

To ensure more complete immunization records

- For quality improvement in your practice
- For HMO and other payor chart reviews

To save money

- Some malpractice insurers offer discounts on premiums for participation in the CIIS

How do I access the CIIS?

You must sign a User Agreement with the CIIS that states your practice will keep the information confidential and not share it with any unauthorized person. The CIIS provides each individual with his or her own ID and password to ensure confidentiality of the information in the system. To use the CIIS you will need to have one or more computers with Internet Explorer 6.0, Internet access and printing capabilities.

What information is included in the CIIS?

Information in the CIIS includes the immunization delivery information, who administered the immunization, information to ensure accurate records and avoid duplicate records (mother's maiden name, child's gender) and the child's address to allow recall or reminder notices to be sent.

Who has access to information in the CIIS?

The Immunization Act allows the CIIS to gather immunization information from the child's immunization provider, clinics, schools, the child's parent, the child, any HMO where the child is enrolled, hospitals, or entities that have contracted with the CDPHE under the Immunization Act. Information in the CIIS can only be released to the same entities that provide information, plus the Colorado Department of Health Care Policy and Financing for children enrolled in Medicaid. Under the Immunization Act, anyone who releases information in the CIIS to anyone who is not permitted to have the information commits a crime and can be punished.

How much will it cost my practice to participate?
There is no fee for access or use of the CIIS but unlimited Internet access at appropriate locations in your office is necessary. The CIIS will work with you to utilize the equipment you already have. The CIIS will provide training for your staff at no cost to you.

How will HIPAA regulations affect my participation in the CIIS?
HIPAA regulations state that a covered entity can release immunization information without prior authorization to an immunization information system authorized by a state law such as the Immunization Act. The covered entity must keep track of all releases of protected health information. The CIIS keeps a complete record of all information needed to comply with the tracking requirements of HIPAA and will furnish a report to a participating provider at no cost.

Who is participating in the CIIS?
- Public Health Offices
- Private Provider Offices
- Community Health Centers
- Health Maintenance Organizations

A full listing of participating sites is available at: www.coloradoimmunizations.info

How can I find out more about the CIIS?
Contact: Colorado Immunization Information System
University of Colorado Health Sciences Center
P.O. Box 6508, F456
Aurora, CO 80045-0508
(888) 611-9918
(303) 724-1074

Additional information available at www.coloradoimmunizations.info

CIIS was developed in collaboration with:
- Colorado Department of Public Health and Environment
- Colorado Children's Immunization Coalition
- Colorado Chapter of the American Academy of Pediatrics
- Public and Private Healthcare Providers

- **Administrative Methods**
  Record maintenance is critical; accurate, easily interpreted records must be kept. Another option for maintaining a complete immunciation record for a child is to implement the Colorado Immunization System (CIIS) in your office. Each child has a consolidated record in CIIS with information from all offices where they have received immunizations. Immunization charts should be in the same place for every office file *and should be impeccably maintained and complete.* Files should be identified as “active” or “inactive.” **When old records for your patients are received, the information they contain must be incorporated into the vaccine administration sheet.**

This will reduce the provider's time to determine whether a child is up-to-date on his immunizations and make sure all immunizations are given at the appropriate time. To assist in having easily interpreted records, it is a good idea to use a special presentation, perhaps brightly-colored paper, for the vaccine administration sheet and keep it in the front of every chart.

6. What is one way a nurse or office assistant can remind the provider that a child needs shots?

- For Offices that use the CIIS they can print the child's immunization record to place on the front of the chart. Needed immunization series are marked with a red R. ***Or***

- Request that charts be pulled before appointments. When appointments involve children, have the charts available prior to their scheduled time so as to review the immunization history and assess needed immunizations at this visit.
  Some practices place a sticky-note or highlight immunization information to alert the provider of the shots that are due on that day.

7. List two ways practices can track kids that are behind on their shots.

- Offices that use the CIIS can access the recall module to generate lists of children in a specific age group who are not UTD, to create labels for mailing recalls. ***Or***

- Flag the charts of late or catch-up kids. This can be as simple as a *Post-It* flag or a sticky-note. **Some practices use a tickler box or spiral notebook to track kids that are behind on their shots** (see a simple *shoe box* example at the end of this section on page V-15). The assessment portion of AFIX (see the end of this section) enlists various tools such as CASA, which can produce a list of children whose charts were pulled and who are late or due for immunizations. Similarly, children who have received immunizations at a visit but who are still catching up should have their charts "flagged" for follow up.

8. What has been shown to be the most successful way to improve immunization rates?

- **Reminder/Recall Systems—the "best" way to improve rates**
  - Reminder/recall to parents
    - Offices that use the CIIS can access the recall module to generate lists of children in a specific age group who are not UTD to create labels for mailing recalls.
    - Postcards mailed in advance of upcoming appointment: a simple "shoebox system" ordered by month can be easily established and maintained.
      At the time of a current visit, a postcard addressed to the child's parent is completed and filed under the month it should be mailed.

- Postcards after missed appointment: some means of generating a missed appointment postcard (log the children and have staff send a post card or call out following day)
- Phone calls to identified "late" children (lists generated from CASA reports)

- Reminder/recall to providers (doctor reports)
  - For offices that use CIIS whenever a child's immunization record is accessed it is evaluated using the current ACIP recoomendations. Any series for which the child is not UTD a "Red" R appears next to the series.
  - From CASA reports

Please note: During periods of vaccine shortage, log the names of children who still need any immunizations that were missed. When vaccine supplies allow, follow up with phone calls and reminder cards.

9. List two ways an office can make sure there are no missed opportunities to immunize.

- **Delivery/Professional Methods**
- Reduce missed opportunities to immunize including simultaneous administration of vaccines when indicated.
  Make sure that the office follows only the true contraindications to immunization and realize that all childhood vaccines can be given simultaneously.
- Recommendation and reinforcement to parents. Remember that the health care providers opinion is a powerful motivator and recommend parents vaccinate whenever possible. Tolerate and educate parents that object to immunization.

10. What records should a parent keep which will ensure that their child receives all their necessary shots?

- **Encourage parents to maintain their own immunization records for their children. Make sure you update their copy of the immunization record at each visit. Offices that use CIIS should print an official school/day care form for the parent at each visit.**

11. What is a simple way your office can increase the chance that a child returns for his next immunizations on time?

- Reduce barriers within the practice such as:
- Hours… consider whether they meet the needs of the clientele
- Cost *(Become knowledgeable about sources of free vaccines/VFC/501(C) entities.)*
- Scheduling…**schedule the next immunization appointment when child is in the office and always write the date the next shot is due on the parent's immunization record.**

- Coordinate immunization appointments with an office visit for another procedure, such as when a child comes in to have a cast removed (see Standards of Pediatric Practice, Appendix page IX-1).
- Invalid contraindications…don't miss an opportunity to vaccinate due to a lack of understanding…follow up on your "red flags" and ask an immunization expert!
- Cultural competency…review your office routines and protocols with a keen eye for differences in cultural practices. Remember cultural differences, when not acknowledged and accounted, for, can represent barriers to full immunization. See, Tips for Improving Your Clinic's Immunization Rates included in this section.

- **Alternative practice settings:**
  - Mobile vaccine clinics
  - ER/Inpatient settings
  - Subspecialty clinics
  - School-based clinics
  - Special immunization events such as special, easily accessible settings during National Infant Immunization Week

Identify the practice problem that needs addressing: The AFIX method

Standard 14 of the Standards of Pediatric Immunization Practices issued by the National Vaccine Advisory Committee (NVAC) calls upon providers to do semi-annual assessments of coverage levels. There are several means of providing an assessment; the most common is the selection of 60 – 200 randomly chosen charts from which immunization records are extracted and an analysis of practice immunization levels deduced. The AFIX process is discussed below.

AFIX

Assessment—Why assess? Assessment provides an identifiable baseline of immunization rates specific to the practice. It gives a basis of choosing and measuring improvement strategies. (An assessment can be made through a variety of ways including an audit of the practice records by staff, a CASA assessment or Vaccine For Children assessment. CASA software can be downloaded from the National Immunization Program (NIP) website: www.cdc.gov/nip/ For offices that use CIIS they may generate a file from CIIS that contains the information for children seen in their office for import into CASA to create CASA reports without having to do manual data entry into CASA.

Feedback—What's it good for? Delivering feedback produced by the assessments pinpoints practice areas that may need changing and assists staff in selecting the strategies that are best suited to their particular problem area.

Incentives and Recognition—What will best motivate any particular group of people? Incentives must be paired with the people for whom they are meant to affect. Staff should be closely involved in both the selection of improvement strategies *and* any incentive or recognition tied to the outcomes of such changes. Incentives are sometimes as simple rewarding staff with a pizza lunch when subsequent assessments demonstrate measurable improvement in practice rates.

E**X**change—Why share information? The exchange of information among all levels of immunization professionals helps to raise awareness, educate between and across practice levels, and provide motivation for continued effort. It is a critical piece of the improvement process.

Some measurement and feedback activities are currently offered through the Vaccines for Children (VFC) program, CCIC grants and local health departments. Contact the VFC representative for Colorado at 303-692-2798, the Colorado Department of Public Health and Environment at 303-692-2363, or call the CCIC at 303-864-5340.

Let's push our immunization rates up and keep them up!

SELECTED REFERENCES:

Epidemiology and Prevention of Vaccine-Preventable Diseases, 7th edition, Chapter Three (2003)

TIPS FOR IMPROVING YOUR CLINIC'S IMMUNIZATION RATES
Tips for Helping Parents Get Their Children Immunized

1. **Educate Parents** on the immunization schedule and on the diseases that immunizations protect their children from (display posters, provide language appropriate and parent-friendly handouts). Post-immunization care sheets can help decrease calls from parents. Always provide parents with the most recent version of the Vaccine Information Statements (VISs).

2. **Encourage Parents to Maintain their own immunization records** on their children.
   *Remind them verbally to bring the immunization card to all medical visits.
   *Remind them on the phone when they are making an appointment to bring their immunization records to that next appointment.
   *Include a statement in your new patient/parent information about the importance of maintaining an immunization record for their child.
   *Keep track of and remind parents who have failed to provide your office with old records (flag chart, keep a list, etc.).

3. **Take every opportunity to immunize** a child when you have them in your office. Parents may not make a return visit for the shots. (See General Recommendation section, this resource.)
   * Practice Simultaneous Administration
   * Follow only Valid Contraindications
   * Accelerate the Schedule
   * Restart if necessary
   * Immunize at Sick/Recheck visits when possible

4. **Tolerate and educate parents that object to immunizations.**
   * Internet sources of information for parents:
     Immunization Action Coalition: http://www.immunize.org, www.vaccineinformation.org, www.cdc.gov/nip
   * What immunizations will they allow and when?
   * Document refusal for your own medical/legal safety

5. **Return-remind-recall**
   * Place date when next immunization is due on the parental immunization record
   * Have parent make an appointment for the next visit before they leave the office
   * Provide parent with a reminder to place on the refrigerator or calendar (especially for children one year and older)
   * Send reminder or call if parent fails the appointment (especially for the two month and over one year-old visits) **This is one of the most effective ways of improving rates. A simple tickler box can be used if your computer is not capable of performing this function. CCIC, the Colorado Department of Public Health and Environment (CDPHE) and your local health department have reminder cards they can provide your office at no charge.**
   * Send birthday card that contains an immunization and well care visit message

Documentation Tips for Immunization Providers

1. **Meticulously document changes** in demographic data obtained from all sources, including moves discovered through recall letters, request to transfer records to other practices, etc. Have front office verify current address at check-in.

2. **Make your immunization administration sheet a bright color and keep it in the front of the chart.** Recording immunizations in only one place in the chart reduces the chances for transcription errors. It also saves time in the following ways: the nurses have only one place to record immunizations; providers/staff have only one place to search for records to be able to assess immunization status during visits; and the front office will have fewer places to search for records to copy for the schools, daycare, etc. If you use a pediatric database you can bracket the immunization portion and say "see immunization administration sheet."

3. **Immunizations can be included in the vital signs or on your well-child forms.** This will make it easier for staff to remember to assess immunization status at all visits.
   Temp___ Pulse____ Resp._____ BP_____ Wt. _____ Immunizations_____

4. **Document history of varicella disease**

5. **Practice good vaccine record keeping**
   * Document full date vaccine is administered (month, day & year)
   * Document date on the relevant VIS & date VIS is given to parent
   * Document manufacturer and lot number of the vaccine
   * Document name and address of health care provider administering vaccine
   * Document site/dose
   * Remember that VFC recipients must have one eligibility screening on file

TIPS FOR IMMUNIZATION PROVIDERS

1. **Examine and harmonize the immunization schedule in your office.** Try to get as many immunizations as possible completed by the time the child is 12 to 15 months old. Place off-schedule prompts in all work stations. These can be obtained from:
   *Colorado Clinical Care Guidelines from the CDPHE at: 303-692-2363
   *CCIC provides a pocket-sized prompt available at not cost at: 303-864-5340

2. **Designate an immunization "guru" for your staff .** Make sure that all staff are aware of immunization basics and identify key leader/experts.

3. **Hold immunization educational opportunities for your staff yearly**
   CCIC, CDC, CDPHE and local health departments regularly hold immunization education and staff training.

4. **Support access to care.** Participate in plans like: VFC, Child Health Plan+, and Medicaid. Establish a specific protocol for nurses so that appropriate patients can make "nurse only" appointments for immunizations. Offer parent-friendly appointment times.

Immunization Reminder/Recall

A Simple Shoebox Method

Reminder/Recall is a very successful way to improve immunization rates. One easy approach to reminder/recall is to develop a simple tracking system to assist in notifying parents when their child is due for the next immunization. Below is an example of such a system.

The simple shoebox system uses a file box and self-addressed postcards that are filed according to date of a child's next appointment. The card is mailed to the parent prior to the scheduled appointment.

Ask parents to address a postcard when they check in (or out) with the receptionist.

The postcard contains a brief message reminding parents to return on an appointed date for the well-child or immunization visit.
On the day of the current visit, the receptionist attaches the postcard to the patient's chart for the provider's use.
The immunization provider writes on the postcard (or billing sheet) the due date for the next well-child or immunization visit.
At the end of the visit, the receptionist checks for the next recommended appointment date, schedules it, and writes the date on the postcard.
The post card is then filed in the "shoebox" by the month in which the appointment is set. These cards will be pulled two weeks ahead of the scheduled appointment and mailed.

Please note: The postcard is a method of follow-up and serves to augment the verbal instructions from provider and staff to the parent regarding when to return to the clinic for the next appointment.

*Our sincere appreciation to Joyce Weber, RN who provided this outline.

VI. Talking to Families

Colorado Children's Immunization Coalition

Talking to Families

♦ Introduction: The importance of this section is to provide you a limited overview of important immunization information. This material should enhance your abilities to effectively communicate immunization information to patients, parents and patient representatives.

Parents are challenged to absorb a great deal of information in order to make an informed choice regarding immunization; it is important for providers to encourage them. The material that follows will help in your efforts to educate parents. Since some parents will want to conduct their own research, you can help them by sharing printed materials and Internet Web site addresses where they may read in depth on the subject. One exciting new site that may be of particular interest to parents who enjoy technology is www.cdc.gov/nip/scheduler. Here, a new childhood immunization tool is available to help parents know when immunizations are due. Another excellent Web address for parents is www.vaccineinformation.org

Some providers find that when parents receive materials before the office visit, they are more inclined to reflect on the material, share it with those they trust, and perhaps come up with more questions. This process, when guided by the immunization provider, is one that empowers parents to make the best possible decision for their child.

Included in this section is information on vaccine education Web sites, guidance on evaluating information on the Web, important facts regarding the immunization of children, and common questions about vaccine safety, alternatives, and effectiveness. Familiarize yourself with what is here and visit the Internet yourself. In this way, you will be better able to direct parents in their search.

There is yet another element to talking with families that often goes overlooked. It is the element of becoming aware of what we're calling *cultural competency*. American families are diverse. They vary by ethnicity, ancestry, values, beliefs, socioeconomic opportunity, and everyday practices. The immunization provider should be committed to both acknowledging and being sensitive to different cultural behaviors and beliefs. By understanding different cultural points of view, a provider will be better prepared to address those parental objections to immunization that might arise from another cultural perspective.

We as providers must reduce all barriers to full immunization – the barriers of cost, inconvenience, misinformation, office routines, as well as cultural incompetence. It is imperative that each of us evaluate our practices and examine our possible biases, and become more aware. We cannot let a single child go unimmunized or be under-immunized because of any unnecessary barriers.

Evaluating Information on the Web

Are you confused by the amount of information on immunizations on the Internet? Concerned about the rumors linking vaccines and diseases like diabetes and autism? Below are some tips to help you navigate your way through all of the information available and determine its accuracy.

How do I know if the vaccine information I find on the Internet is accurate?

First, consider the **source** of information.

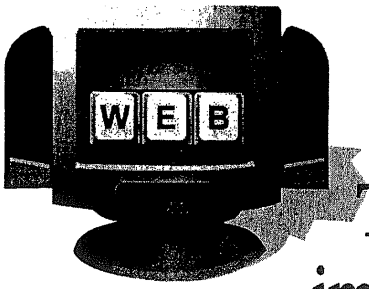
- A good health Web site will display who is responsible for the site. Also, there will be a way to contact the information provider or Webmaster.
- Information should not be slanted in favor of a Web site's sponsor or source of funding. Health information should be accurate and unbiased.

Then, ask the following questions:

- Do scientific experts review the medical information before it is posted on the Web site? What are their credentials?
- Does the information display the date of last revision, and is it kept up to date?
- What is the scientific evidence for claims made? The original source of facts and figures should be shown. For example, the Web site should provide citations of medical articles or other sources of information. You should be able to distinguish facts from opinions. Also, facts are more reliable if they come from a published scientific study on humans rather than from unpublished accounts or from reports of a single person or of animal studies.

Next, consider the **purpose** of the Web site. The purpose should be to provide accurate and unbiased information about that topic. If the purpose is to advertise about a health care product, be skeptical about the information provided.

Finally, discuss with your doctor or health professional the information that you find on the Web. Health information found on the Web should supplement rather than replace the information or advice given by your doctor.



Two-stop shopping for immunization information

www.vaccineinformation.org

At www.vaccineinformation.org you will find a new website from the Immunization Action Coalition. This site presents information about vaccine-preventable diseases and vaccines. Photos, video clips, case histories, journal articles, and resources for parents are available at this site.

www.vaccine.org

The **Allied Vaccine Group** is comprised of websites dedicated to presenting valid scientific information about the sometimes-confusing subject of vaccines. Think of this page as your portal to the ***real*** world of vaccines, a world based on scientific research, followed by honest disclosure of the research results -- pro and con.
At www.vaccine.org you will find links to:

The Vaccine Education Center at The Children's Hospital of Philadelphia

The National Network for Immunization Information

The American Academy of Pediatrics

Parents of Kids with Infectious Diseases

Bill and Melinda Gates Children's Vaccine Program

Be there for your child during shots.

Before shots

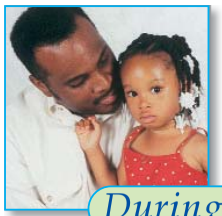
Infants:

- Bring your child's immunization record.

- Read vaccine information statements.
- Ask any questions.
- Bring along a favorite toy or blanket.
- Stay calm–your baby picks up your feelings.

Toddlers–All above, plus:

- Reassure your child honestly, "It might sting but it will only last a few seconds."
- Never threaten your child with shots, "If you are not good, I will have the nurse give you a shot."
- Encourage older siblings to reassure and comfort, not to scare your toddler.



During shots

Infants–Distract and comfort by:

- Touching soothingly and talking softly.
- Making eye contact as you smile at him/her.

Toddlers–Also try:

- Holding your child securely on your lap.
- Talking to or singing with your child.
- Helping your child take deep breaths and slowly blow out the pain.
- Using a hand puppet.
- Pointing out posters or objects around the room.
- Telling your child a story or have him/her tell you one.
- Allowing your child to cry, don't force him/her to be brave.

After shots

Infants–Comfort by:

- Holding, cuddling, caressing, and/or breastfeeding
- Talking lovingly and soothingly.
- Asking your doctor for advice on using a non-aspirin pain reliever when you get home.

Toddlers–Also try:

- Giving praises and hugs or a surprise.
- Reassuring your child that everything is okay.

At home

- Mark your calendar for your next appointment.
- Review vaccine information statements for possible reactions.
- A cool wet cloth can reduce redness, soreness, and/or swelling where the shot was given.
- Observe your child for the next few days. You might see a small rash or notice a fever. If your child has any reaction that concerns you, call your doctor or seek medical attention.
- To reduce pain or fever, your doctor may recommend you give your child a non-aspirin pain reliever.
- Also try giving your child a sponge bath with lukewarm water to reduce fever.
- Give your child plenty of fluids. It is normal if he/she eats less than usual for the next 24 hours.

A parent's love makes all the difference.

IMMUNIZATION TECHNIQUES
Safe • Effective • Caring

IMM-686 E/S (1/01)

Know The Facts About Immunization

- Immunizations are one of the most important ways people can be protected against serious, preventable infectious diseases.

- Immunizations are extremely safe as a result of advances in medical research and ongoing review by doctors, researchers, and public health officials.

- Immunizations are recommended for infants, young children, the elderly, and those with chronic health problems because they are particularly vulnerable to infectious diseases.

- While small risks accompany every immunization, people are far more likely to be seriously harmed by vaccine-preventable diseases than by the recommended immunizations that prevent them.

- Medical advances have resulted in the availability of additional safe and effective vaccines. Now, people can be protected against a greater number of serious preventable diseases.

- Immunization benefits not just the individual, but also the community. Communicable infectious diseases spread among people who have not been immunized, and among the small percentage of people for whom the immunization may not have been fully effective.

- Immunizations work by strengthening the body's own immune system.

- While breastfeeding and vitamins have health benefits, they do not replace the benefits of vaccines in preventing infectious diseases.

- Without immunizations, the diseases we are now protected from could easily return to infect, disable, and even kill, many infants, children and adults.

then . . .

- *your child will be left at great risk of catching the disease*
- *your child will be a threat to others*
- *your child at times must be kept out of school or child care*

- **Without immunizations, your child may have to be excluded at times from school or child care.**

During disease outbreaks, unimmunized children may be excluded from school or child care until the outbreak is over, both for their own protection and for the protection of others. This causes hardship for the child and parent.

what to do. . .

As a parent, you must make a choice, and while we strongly encourage you to immunize your child, ultimately the decision is yours. We hope you discuss your concerns with a trusted health care provider or call the immunization coordinator at your local or state health department. Your final decision affects not only the health of your child, but the health of your child's friends and their families, classmates, neighbors, faith community members, and family members.

For more information about vaccines, go to:

- Immunization Action Coalition: www.vaccineinformation.org and www.immunize.org
- Centers for Disease Control and Prevention: www.cdc.gov/nip
- American Academy of Pediatrics: www.cispimmunize.org
- National Network for Immunization Information: www.immunizationinfo.org
- National Vaccine Program Office: www.cdc.gov/od/nvpo
- Vaccine Education Center at Children's Hosp. of Philadelphia: www.vaccine.chop.edu
- CDC's National Immunization Information Hotline: English (800) 232-2522; Spanish (800) 232-0233

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1573 Selby Avenue, Suite 234
Saint Paul, MN 55104
(651) 647-9009
www.immunize.org • www.vaccineinformation.org

www.immunize.org/catg.d/p4017.pdf • Item #P4017 (1/03)

what if . . . you don't immunize your child?

What if . . .

What if you don't immunize your child? While most state laws provide for religious or personal exemptions to required immunizations, concerned parents should still consider the consequences of not immunizing their children.

Without immunizations, your child is at greater risk of catching one of the vaccine-preventable diseases.

Vaccines were developed to protect individuals from dangerous and sometimes deadly diseases. Vaccines are safe and effective, and such diseases are still a threat.

- Pertussis or "whooping cough" is an extremely dangerous disease for infants. It is not easily treated and can result in permanent brain damage and death. Between 1997-2000, nearly 30,000 cases of pertussis were reported in the U.S., including 62 pertussis-related deaths. Of infected infants younger than age 6 months, two-thirds needed to be hospitalized.

- Measles is dangerous and very contagious. During the 1989-1991 U.S. measles epidemic, approximately 55,000 cases and 132 deaths (mostly children) were reported.

- Diphtheria is an infectious disease of the nose and throat that can lead to serious breathing problems, heart failure, paralysis, and even death. In recent years, there have been few cases of diphtheria in the U.S. However, the disease has not been eliminated from the world. A diphtheria epidemic recently occurred in countries of the former Soviet Union where many children and adults had not been immunized. Their reported cases of diphtheria rose from 839 in 1989 to 47,802 in 1994, when 1,746 persons died. At least 20 infected individuals exported the disease along the way.

- Before the availability of a chickenpox vaccine, almost every child suffered from this disease. Between 1988-1995, up to 10,000 people were hospitalized each year from complications of chickenpox—most of them previously healthy children. An average of 43 children died from chickenpox each year from 1990-1994.

Without immunizations, your child can infect others.

Children who are not immunized can transmit vaccine-preventable diseases throughout the community.

- Unvaccinated people can pass diseases on to babies who are too young to be fully immunized.

- Unvaccinated people pose a threat to children and adults who can't be immunized for medical reasons. This includes people with leukemia and other cancers, HIV/AIDS and other immune system problems, and persons receiving chemotherapy, radiation therapy, or large doses of corticosteroids.

- Unvaccinated people can infect the small percentage of children whose immunizations did not "take."

Common Questions about

Vaccine Safety

Are vaccines safe?

Vaccines are extremely safe and getting safer and more effective all the time as a result of medical research and ongoing review by doctors, researchers, and public health officials. Vaccines must meet the strict safety standards of the Food and Drug Administration (FDA) to ensure that they are safe and effective before they are approved. The FDA and Centers for Disease Control and Prevention (CDC) closely monitor each vaccine's safety as long as it is in use.[1]

- Scientific research and experience have shown that serious adverse effects from vaccines are extremely rare. The chance of serious complications (including death) from the diseases that vaccines prevent is many times higher than the chance of complications related to vaccines.
- As with all medicines, vaccines carry some element of risk. Doctors and public health professionals consider the balance of benefits and risks before recommending any vaccine. This balance is always subject to new information and can change when diseases are controlled or eradicated, or when there is new evidence about a vaccine or a vaccine-preventable disease that calls for a change in recommendations.
    - For example, after 1972 the smallpox vaccine was no longer routinely recommended in the U.S., because no cases of the disease had been seen in this country since 1949. Officials declared that the disease had been eradicated worldwide in 1980. However, because of new concerns about the threat of a smallpox bioterrorism attack, the U.S. government increased its stockpile of smallpox vaccine in 2001 by diluting it to produce additional doses with the same effectiveness. They also ordered the production of a new smallpox vaccine to be available by the end of 2002. The government is also developing new guidelines for use of the smallpox vaccine.[2]
    - In 2000, the polio vaccine recommendation was modified so that doctors in the United States now offer only IPV (inactivated polio vaccine). OPV (oral polio vaccine), the vaccine that is still used in most parts of the world, is no longer available in the U.S. This change was made because the remote risk of OPV causing paralysis (1 case in 2.4 million doses) was no longer considered acceptable,[3] since there have not been any cases of wild polio in the U.S. in over 20 years.

- The RotaShield® rotavirus vaccine is a good example of the effectiveness of the vaccine safety monitoring system. Analysis of Vaccine Adverse Event Reporting System (VAERS) data in 1999, the first year the vaccine was licensed, identified 15 cases of a rare but serious bowel obstruction reported in association with RotaShield® (after approximately 1.5 million doses of the newly licensed vaccine had been given to infants and young children).[4] Based on this finding, the vaccine was voluntarily withdrawn by the manufacturer until further studies could be done to better understand if this observation was true. Subsequent studies found that approximately 1 in 10,000 infants who received this vaccine developed intussusception within one or two weeks after the first dose, a rate about three times higher than in unvaccinated children.[5-8]

How are vaccines tested?

Vaccine development and testing is a lengthy process that may last up to 10 years or more. Vaccines first undergo laboratory studies, then studies in animals, and then in human beings. Vaccines must pass three phases of clinical trials in humans before they are licensed for public use. To establish basic safety, Phase One trials are small, involving only 20-100 volunteers and lasting only a few months. To continue to gather information on the efficacy, safety, and dosage of each vaccine, Phase Two trials are larger (with several hundred volunteers), and last anywhere from a few months to a few years. Phase Three trials have several hundred to several thousand participants and typically last several years. These studies evaluate the effectiveness and safety of a vaccine when used in a large number of people.

Only after the FDA approves the vaccine for use in humans is the manufacturer allowed to release the vaccine for general use. Each batch of vaccine made by the manufacturer is tested for safety, potency, and purity before being put on the market, and a sample from each lot is routinely sent to the FDA. The FDA also regularly inspects the manufacturing facility in an effort to make sure the vaccine is made in a safe and consistent manner.

How is the safety of vaccines monitored?

Sometimes a person will develop adverse signs or symptoms after receiving a vaccine. Healthcare providers are required to report certain health effects that occur after a person is vaccinated. For example, if someone has an allergic reaction, is hospitalized, or dies after receiving a vaccine, this adverse event should be reported. The adverse event may have been caused by something other than the vaccine, such as an infection, a pre-existing illness, or an injury, but there is a small chance that the event was caused by a vaccine. U.S vaccine safety monitoring systems allow scientists to gather enough data to determine which events may be related to vaccines, and which are due to another cause.

Vaccine Adverse Events Reporting System (VAERS)
In 1990, the FDA and CDC established the Vaccine Adverse Events Reporting System (VAERS) so that reports of possible adverse reactions could be collected and analyzed. As many as 12,000 reports have been made in a single year, and about 2,000 of these reports are of serious illnesses and, sometimes, death. All reports are entered into a database; FDA and CDC use the data to monitor vaccine safety and conduct research studies.

To ensure that all relevant data are captured, the VAERS allows anyone to file a report if they suspect that their child or patient has had a vaccine-related reaction. Because all reports are entered in the database, it contains events that are both related and unrelated to vaccines. The FDA and CDC monitor VAERS to determine if any vaccine is associated with adverse events that were not detected during the studies completed before it was licensed, or if reported adverse events are more serious or frequent than expected. However, with further examination, most of these reported events have been found to be unrelated to vaccines. VAERS was designed to identify signals that warrant further investigation, but VAERS data alone cannot establish a cause and effect relationship between a vaccine and an adverse event. Only large studies of the population can show that a certain vaccine caused a particular adverse event.

Vaccine Safety Datalink Project
In 1990, the CDC developed the Vaccine Safety Datalink Project[9-12] to study rare side effects from vaccines. Four large health maintenance organizations provide the CDC with medical information on more than 6 million people. The large number of patients makes this project a powerful tool for examining the relationship between a specific vaccine and serious side effects.

Since its initiation in 1990, the Vaccine Safety Datalink Project has conducted surveillance on about 500,000 children from birth through age six years (2% of the U.S. population in this age group). These data were used, for example, to study the rate of Sudden Infant Death Syndrome (SIDS) after anecdotal evidence suggested a possible link to the DTP vaccine. The risk of SIDS was found to be the same for vaccinated children as for unvaccinated children enrolled in the participating health maintenance organizations. VAERS data have also been used to study questions about possible links between vaccines and diabetes, joint disease, inflammatory bowel disease, and asthma. Such studies are known as "post-marketing" or "Phase Four" clinical studies because the vaccine has been approved by the FDA for marketing.

Clinical Immunization Safety Assessment (CISA) Centers
Since adverse events are rare occurrences, a person entering data into VAERS is likely doing it for the first time. The result is data that are not standard and difficult to interpret. In 2002, Clinical Immunization Safety Assessment (CISA) Centers were established to help standardize, understand, and manage reports of adverse events that follow immunization. The CISA network works with the Centers for Disease Control and Prevention (CDC) to systematically evaluate cases of adverse events reported to VAERS. The network follows up on these specific cases to better understand what led up to the event, and provides its findings, and advice on immunization safety issues, to healthcare providers.

Institute of Medicine (IOM) Reviews and the IOM's Immunization Safety Review Committee
The Institute of Medicine—a prestigious medical research organization that provides objective, timely, authoritative information and advice concerning health to the government, the corporate sector, the professions, and the public—reviews the medical literature on health problems or injuries occurring after vaccination. After these reviews, the IOM presents conclusions and recommendations in comprehensive reports. The following are some of the most relevant reports published by the IOM on adverse events associated with vaccines:

- Institute of Medicine. (1991). *Adverse effects of pertussis and rubella vaccines*. Washington, DC: National Academy Press.
- Institute of Medicine. (1994). *DPT vaccine and chronic nervous system dysfunction: A new analysis*. Washington, DC: National Academy Press. Available online: www.nap.edu/books/NI000680/html
- Institute of Medicine. (1994). *Adverse events associated with childhood vaccines*. Washington, DC: National Academy Press.
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- Institute of Medicine. (2002). *Immunization safety review: Hepatitis B vaccine and demyelinating neurological disorders*. Washington, DC: National Academy Press. Available online: www.iom.edu/IOM/IOMHome.nsf/Pages/Hepatitis+b+report
- Institute of Medicine. (2002). *Immunization safety review: Multiple immunizations and immune dysfunction*. Washington, DC: National Academy Press. Available online: www.iom.edu/IOM/IOMHome.nsf/Pages/multiple+immunizations+report
- Institute of Medicine. (2002). *Immunization safety review: SV40 contamination of polio vaccine and cancer*. Washington, DC: National Academy Press. Available online: www.nap.edu/books/0309086108/html

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2 U.S. Department of Health and Human Services. (2001, November 28). *HHS awards $428 million contract to produce smallpox vaccine* [Press release]. Available online: www.hhs.gov/news/press/2001pres/20011128.html

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8 McPhillips H and Marcuse EK. (2001). Vaccine safety. *Current Problems in Pediatrics, 31*(4), 95-121.

9 DeStefano F, Mullooly JP, Okoro CA, Chen RT, Marcy SM, Ward JI, Vadheim CM, Black SB, Shinefield HR, Davis RL, and Bohlke K. (2001). Childhood vaccinations, vaccination timing, and risk of type 1 diabetes. *Pediatrics, 108*(6), E112.

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Recommended books and Web sites on this topic:

American Academy of Pediatrics (AAP) Web site (www.aap.org)

AAP, Childhood Immunization Support Program Web site (www.cispimmunize.org)

Centers for Disease Control and Prevention (CDC), National Immunization Program Web site (www.cdc.gov/nip)

Department of Health and Human Services, National Vaccine Program Office Web site (www.cdc.gov/od/nvpo)

Food and Drug Administration. (2001). Understanding vaccine safety: Immunization remains our best defense against deadly disease. *FDA Consumer.* Available online: www.fda.gov/fdac/features/2001/401_vacc.html

Humiston SG and Good C. (2000). *Vaccinating your child: Questions and answers for the concerned parent.* Atlanta: Peachtree Publishers.

Johns Hopkins' Institute for Vaccine Safety Web site (www.vaccinesafety.edu)

Offit PA and Bell LM. (1999). *Vaccines: What every parent should know* (Rev. ed.). New York: IDG Books.

Vaccine Education Center at the Children's Hospital of Philadelphia Web site (www.vaccine.chop.edu)

Common Questions about

Vaccine Effectiveness

How do we know that vaccines work?

Vaccination is one of the greatest achievements of medicine and has spared millions of people the effects of devastating diseases.

Before vaccines became widely used, infectious diseases killed thousands of children and adults each year in the United States:

- Before 1985, *Haemophilus Influenzae* type b (Hib) caused serious infections in 20,000 children each year, including meningitis (12,000 cases) and pneumonia (7,500 cases).[1] In 1998, there were 54 cases of Hib disease.[2]
- In the 1964-1965 epidemic, there were 12.5 million cases of rubella (German measles).[3] Of the 20,000 infants born with congenital rubella syndrome, 11,600 were deaf, 3,580 were blind, and 1,800 were mentally retarded as a result of the infection.[3] In 1999, there were 238 cases of rubella and 8 cases of congenital rubella.[3]
- Before 1963, more than 3 million cases of measles and 500 deaths from measles were reported each year.[3] More than 90% of children had measles by age 15.[3] In 1999, there were 86 cases of measles.
- In 1952, polio paralyzed more than 21,000 people.[3] In 1998, there were no cases of polio.
- In the early 1940s, there was an average of 175,000 cases of pertussis (whooping cough) per year, resulting in the deaths of 8,000 children annually.[3] In 1999, 6,031 cases of pertussis were reported.[9]
- In the 1920s, there were 100,000 to 200,000 cases of diphtheria each year and 13,000 people died from the disease.[3] In 1998, there was only one case of diphtheria in the United States.

As a result of the high level of immunization in the United States these diseases have declined to near zero.

Is it better to be naturally infected rather than vaccinated?

No. Diseases cause suffering and, in some cases, permanent disability or death. Vaccines protect from the disease without risking the serious adverse effects of that illness.

- It is much better to gain immunity from a vaccine. Vaccine-preventable diseases can kill; they can cause permanent disabilities such as paralysis from polio, liver damage or liver cancer from hepatitis B infection, and deafness from meningitis caused by several bacteria (Hib, pneumococci, and meningococci). In addition, brain damage can result from measles, Hib meningitis, or pertussis. If a woman gets rubella while pregnant, her baby could have serious birth defects.
- Immunity from a vaccine offers protection against future disease that is similar to immunity acquired from a natural infection. Several doses of a vaccine may be needed for a child to have a full immune response.
- For some vaccines (e.g. tetanus and Hib) the vaccine is better at creating immunity than a natural infection would be.[3]

Vaccine Effectiveness (continued)

Because of better hygiene and sanitation, hadn't diseases already begun to disappear before vaccines were introduced?

No, they had not begun to disappear. In the 20th century, infectious diseases began to be better controlled because of improvements in hygiene and sanitation (clean water and pest control). However, the incidence of vaccine-preventable diseases only began to drop dramatically after the vaccines for those diseases were licensed and began to be used in large numbers of children. For example:

- There were about 500,000 reported cases and 500 deaths from measles each year before the measles vaccine was licensed in 1963.[2] In 1998, only 100 cases were reported in the United States.[5]
- Before the development and use of the Hib vaccine in 1985, approximately 20,000 infants and young children developed life-threatening forms of this infection (meningitis, pneumonia and epiglottitis). Since the introduction of the initial Hib vaccine and the development of the more effective Hib conjugate vaccine, Hib disease has nearly been eliminated in the United States. In 1998 there were only 54 cases of Hib diseases in the United States.[2-4]

During an outbreak, aren't the majority of people who catch a disease those who have been vaccinated?

Although vaccines have very high effectiveness rates, they are not completely effective for 100% of the people who receive them. For example, a full series of measles vaccine will protect 99 of 100 children from measles, and polio vaccine will protect 99 of 100 children from polio.[2] This means that when there is a disease outbreak, the very small number of people for whom the vaccine was not fully effective may still be able to catch the disease. Because almost all children are immunized, and only few are not, during an outbreak a *greater number* of cases of a given disease may occur among those who were immunized, but a *greater proportion* of unimmunized children will develop the disease. The fact remains that those who have not received the vaccine are much more likely to catch the disease.

- By way of example, consider an actual measles outbreak in Colorado in December 1994.[6] Out of 625 children exposed to the disease, 17 got measles. Of the 625 children, 609 had been vaccinated against measles and 16 had not been vaccinated. Of those 609 who had previously been vaccinated, only 10 (or 1.6%) developed measles. Of the 16 children who were not vaccinated, 7 (or 44%) developed measles. In this outbreak, unimmunized children had a risk of measles 25 times larger than immunized children.

If vaccine-preventable diseases have been virtually eliminated from the United States, why do American children need to be vaccinated?

Although many of these diseases have the potential to be eliminated, outbreaks of diphtheria, measles, and other vaccine-preventable diseases still occur.

- Children who are not vaccinated against measles are up to 35 times more likely than immunized children to catch the disease.[7] Ten years ago during a 3 year measles epidemic from 1989 to 1991, state health departments in the United States reported 55,622 measles cases, 11,251 hospitalizations, and 125 deaths.[3,8] An investigation has shown that where this epidemic occurred, as few as 50% of preschool-aged children had received the measles vaccine.[3]

Vaccine Effectiveness (continued)

- Without protection from vaccines, the vaccine-preventable diseases that have nearly been eliminated are likely to return. Thousands of children and adults will become sick, some will have long-lasting health problems, and some will die.
- Many other countries do not have the same levels of immunization that we have achieved in the United States and they continue to have disease outbreaks. Therefore, we must all remain protected with vaccines because dangerous diseases largely under control in the United States are only a plane ride away.

Sources:

1 Bisgard KM, Kao A, Leake J, et al. *Haemophilus influenzae* invasive disease in the United States, 1994-1995: Near disappearance of a vaccine-preventable childhood disease. Emerg Infect Dis 1999;4:229-237.

2 Achievements in Public Health. 1900-1999 Impact of Vaccines Universally Recommended for Children. MMWR Morb Mortal Wkly Rep April, 1999; 48(12); 243-248.

3 Atkinson W, Wolfe C, Humiston S, Nelson R, eds. Epidemiology and Prevention of Vaccine-Preventable Diseases. (The Pink Book.) 6th ed. Atlanta: Centers for Disease Control and Prevention; 2000.

4 Centers for Disease Control and Prevention. Progress toward eliminating *Haemophilus influenzae* type b disease among infants and children — United States, 1987-1997. MMWR Morb Mortal Wkly Rep 1998;47:993-998.

5 Centers for Disease Control and Prevention. Epidemiology of measles—United States, 1998. MMWR Morb Mortal Wkly Rep 1999;48:749-753.

6 Vitek CR, Aduddell M, Brinton MJ, Hoffman RE, Redd SC. Increased protections during a measles outbreak of children previously vaccinated with a second dose of measles-mumps-rubella vaccine. Pediatr Infect Dis J 1999;18:620-623.

7 Salmon DA, Haber M, Gangarosa E, Phillips L, Smith NJ, and Chen RT. Health consequences of religious and philosophical exemptions from immunization laws. JAMA 1999;282: 47-53.

8 Centers for Disease Control and Prevention. Public-sector vaccination efforts in response to the resurgence of measles among preschool-aged children—United States, 1989-1991. MMWR Morb Mortal Wkly Rep 1992;41:522-525.

Recommended books and Web sites on this topic:

American Academy of Pediatrics Web site (www.aap.org)

Centers for Disease Control and Prevention Web site (www.cdc.gov/nip)

Humiston SG and Good C. Vaccinating your child: Questions & answers for the concerned parent. Atlanta: Peachtree Publishers; 2000.

Offit PA and Bell LM. Vaccines: What every parent should know, revised edition. New York: IDG Books; 1999.

Common Questions about

Alternatives to Vaccines

Doesn't breastfeeding offer babies natural protection?

Breastfeeding offers protection against some infections, such as colds, ear infections and diarrhea, by providing infants with immune proteins from the mother's milk. These immune proteins fight infection as they are passing from the infants' mouth into the stomach and gastrointestinal tract. Vaccines stimulate the infant's own immune system to produce immune proteins to fight infection against very specific diseases. Despite it's many benefits, breastfeeding is not effective in preventing contagious, vaccine-preventable diseases.[1] There are no effective alternatives to immunization for protection against serious and sometimes deadly infectious diseases.

- Vaccine-preventable diseases have been around for thousands of years. Even when breastfeeding was more consistently done than it is today, many infants died from these diseases.
- The vaccines recommended for use in infants do not interfere with the beneficial immunity gained from breastfeeding. Likewise, breastfeeding does not interfere with the infant's ability to be effectively vaccinated.

Are there natural remedies (e.g., herbs, vitamins) or approaches (e.g., homeopathy) that can be used in lieu of manufactured vaccines?

No. While many feel that herbs and vitamins have beneficial effects, there are no herbs, vitamins, or approaches to health care that can replace the benefits of vaccines.

- To be protected from preventable infectious diseases, a person must have been naturally infected or vaccinated.
- Boosting the immune system in general through herbs or vitamins does not offer specific protection from the viruses and bacteria that cause vaccine-preventable diseases.

Source:

1 Hanson LA. Breastfeeding provides passive and likely long-lasting active immunity. Ann Allergy Asthma Immunol 1998;81:523-533.

Recommended books and Web sites on this topic:

Humiston SG and Good C. Vaccinating your child: Questions & answers for the concerned parent. Atlanta: Peachtree Publishers; 2000.

Offit PA and Bell LM. Vaccines: What every parent should know, revised edition. New York: IDG Books; 1999.

The American Academy of Pediatrics (www.aap.org).

The National Immunization Program (www.cdc.gov/nip).

Ask Dr. Weil (www.pathfinder.com/drweil).

VII. Tests

Colorado Children's Immunization Coalition

Comprehensive Test and Skills Checklist

♦ Introduction: Following are two tests with which you can examine your immunization knowledge and skill.

One test is a comprehensive test taken directly from this resource. The comprehensive test follows *A Guide to Immunization for the Beginning Immunization Provider,* section-by-section and presents the questions in the same way as they are presented in their respective chapters. The comprehensive test is designed to be either self-administered or given by a preceptor. The advantage of having someone administer the test is that you build in the opportunity for discussion which can advance your understanding of the topic matter. Test answers are included in the Appendix.

The second test is entitled, *Skills Checklist for Pediatric Immunization,* and was developed by the Immunization Branch of the California Department of Health Services. The *Checklist* is designed as both a tool for self-review and as a means for supervisors to observe staff immunization knowledge and skill of application. It is particularly useful in that it encourages continued learning and growth by prompting both staff and supervisors to follow up with a *plan of action.* The *plan of action* is tailored to an individual staff member, and evolves directly from observation and the implied discussion that follows.

Best of luck as you pursue your understanding of immunization. Remember, there are immense resources in both print and electronic formats from many immunization experts who are willing to share their knowledge with you. We encourage you to reach out with your questions; find someone who is willing to help you grow in your understanding and your immunization abilities. We encourage you to keep recognizing the red flags of immunization and defer to the experts when uncertainty persists.

A Guide to Immunization for the Beginning Immunization Provider

COMPREHENSIVE TEST

Basic Principles of Vaccination: Immunity

1) **What is active immunity?**

2) **What is artificial active immunity?**

3) **What is passive immunity?**

4) **What are live attenuated vaccines?**

5) **What are inactivated vaccines?**

6) **What are recombinant vaccines?**

7) **What are inactive and active ingredients in vaccines?**

Basic Principles of Vaccination: General Recommendations on Immunizations

1) **Which type of vaccines are generally not affected by circulating antibodies and can be administered before, after or at the same time as other vaccines and antibody products?**

2) **Which vaccines cannot be administered together?**

3) **If an MMR and Varicella vaccine are not administered together, how long should one wait to give the second vaccine?**

4) **If a child has received one hepatitis B at birth and one at two months of age, and is now presenting at three years of age, to complete the series is it necessary to restart the hepatitis B series? Why?**

5) **Which vaccines require multiple doses and possible periodic boosting to maintain immunity?**

6) **Which is the most common type of adverse reaction?**

7) **How are generalized reactions like fever, malaise and headache classified?**

8) **How can the risk of an allergic reaction be minimized?**

9) **What is the difference between a contraindication and a precaution to immunization?**

10) **What are the conditions generally considered to be permanent contraindications?**

11) What conditions are considered permanent precautions to further doses of pertussis-containing vaccine?

12) What are the temporary contraindications to vaccination with live vaccine?

13) Which type of vaccines can always be given to an immunosuppressed person?

14) Which two live vaccines should susceptible household contacts of persons with HIV infection receive?

15) If a child has mild acute illness such as a low-grade fever and upper respiratory infection, can he be immunized?

16) If a child is presently taking an antibiotic such as Amoxicillin for an ear infection can he receive his vaccines today?

17) What vaccines are contraindicated for breast-fed infants?

18) What vaccine cannot be administered at the same time as a TB skin test?

Vaccine Administration

1) **What two factors should be considered when preparing a patient for vaccination?**

2) **List two issues that have contributed to the concerns and anxiety that patients/parents associate with vaccination?**

3) **When considering patient position and restraint, what must the health care provider accommodate for?**

4) **Why do diversionary techniques used for vaccine administration pain control work?**

5) **What is the single, most effective disease prevention activity?**

6) **How should empty vaccine vials be handled?**

7) **When selecting a needle for vaccine administration, what should the needle size be based on?**

8) **What is the rule of thumb about vaccine expiration dates?**

9) **Why is prefilling a syringe discouraged?**

10) Is it important to label each vaccine that you draw up? How can this be accomplished?

11) How can one avoid reaching the muscle when administering a subcutaneous (SC) injection?

12) Which intramuscular (IM) muscle site should never be used to administer vaccines?

13) When administering an intramuscular immunization, how can injection into subcutaneous tissue be avoided?

14) If more than one vaccine is administered in the same limb, how far apart must the two injections be placed?

15) What is the most important step to take when preparing an immunization injection for an individual with a bleeding disorder?

16) If a patient has a history of rare severe latex allergy, what should the immunization provider do first in considering the vaccine administration?

17) What should every facility have in place to prepare for an anaphylaxis after vaccine administration?

Legal and Documentation Issues

1) **What is the National Vaccine Injury Compensation Program (NVICP) and what are the vaccines that the Program covers?**

2) **What is the process involved in filing a NVICP claim?**

3) **What is a Vaccine Information Statement (VIS)?**

4) **When are VISs required?**

5) **What information must the health care provider administering a vaccine document in every patient's permanent medical record?**

6) **Where can providers find a list of the vaccine adverse reactions that must be reported? What form is required?**

7) **How are new vaccines added for coverage under the NVICP?**

8) **Who may file a claim?**

9) **To whom should you direct your call for more information about the NVICP?**

Vaccine Storage and Handling

1) Why is it so important to store vaccine properly?

2) Where should vaccines not be stored in the refrigerator?

3) Does diluent need refrigeration?

4) How can you avoid outdating of your vaccine?

5) What type of special electrical plug should your vaccine refrigerator have?

6) What is another measure you can take to avoid having the vaccine refrigerator inadvertently unplugged?

7) What are the proper temperatures to maintain in the vaccine refrigerator? In the freezer?

8) How often should the vaccine refrigerator and freezer be checked?

Immunization Strategies

1) **Why are proven immunization strategies important to implement in your practice?**

2) **What is an important consideration in selecting one of these proven immunization strategies to use in your office?**

3) **What two factors must exist within a practice to successfully implement an immunization strategy?**

4) **Where can you call to get more information than what is offered here, on how to improve immunization rates in your practice?**

5) **What should be done as soon as possible with old immunization records for your patients that are received by your office?**

6) **What is one way a nurse or office assistant can remind the provider that a child needs shots?**

7) **List two ways practices can track kids that are behind on their shots.**

8) **What has been shown to be the most successful way to improve immunization rates?**

9) List two ways an office can make sure there are no missed opportunities to immunize.

10) What records should a parent keep that will ensure their child receives all the necessary shots?

11) What is a simple way your office can increase the chance that a child returns for his next immunizations on time?

Skills Checklist for Immunization

The Skills Checklist is a self-assessment tool for health care staff who administer immunizations. To complete it, review the competency areas below and the clinical skills, techniques and procedures outlined for each of them. Score yourself in the Self-Assessment column. If you check **Need to Improve** you indicate further study, practice or change is needed. When you check **Meets or Exceeds** you indicate you believe you are performing at the expected level of competence, or higher.

Supervisors: Use the Skills Checklist to clarify responsibilities and expectations for staff who administer vaccines. When you use it for performance reviews, give staff the opportunity to score themselves in advance. Next observe their performance as they provide immunizations to several patients and score in the Supervisor Review columns. If improvement is needed, meet with them to develop a Plan of Action (over) that will help them achieve the level of competence you expect; circle desired actions or write in others. In 30 days, observe their performance again. When all competency areas meet expectations, file the Skills Checklist in their personnel folder. At the end of the probationary period and annually thereafter, observe them again and complete the Skills Checklist.

		Self-Assessment		Supervisor Review		
Competency	**Clinical Skills, Techniques, and Procedures**	**Need to Improve**	**Meets or Exceeds**	**Need to Improve**	**Meets or Exceeds**	**Plan of Action***
A. Patient/Parent Education	1. Welcomes patient/family, establishes rapport, and answers any questions.					
	2. Explains what vaccines will be given and which type(s) of injection will be done.					
	3. Accommodates language or literacy barriers and special needs of patient/parents to help make them feel comfortable and informed about the procedure.					
	4. Verifies patient/parents received the Vaccine Information Statements for indicated vaccines and had time to read them and ask questions.					
	5. Screens for contraindications. (MA: score NA–not applicable–if this is MD function.)					
	6. Reviews comfort measures and after care instructions with patient/parents, inviting questions.					
B. Medical Protocols	1. Identifies the location of the medical protocols (i.e. immunization protocol, emergency protocol, reference material).					
	2. Identifies the location of the epinephrine, its administration technique, and clinical situations where its use would be indicated.					
	3. Maintains up-to-date CPR certification.					
	4. Understands the need to report any needlestick injury and to maintain a sharps injury log.					
C. Vaccine Handling	1. Checks vial expiration date. Double-checks vial label and contents prior to drawing up.					
	2. Maintains aseptic technique throughout.					
	3. Selects the correct needle size. 1"-1 1/2" for IM (DTaP, Td, Hib, HepA, HepB, Pneumo Conj., Flu); 5/8" for SC (MMR, Var); IPV and Pneumo Poly depends on route to be used.					
	4. Shakes vaccine vial and/or reconstitutes and mixes using the diluent supplied. Inverts vial and draws up correct dose of vaccine. Rechecks vial label.					
	5. Labels each filled syringe or uses labeled tray to keep them identified.					
	6. Demonstrates knowledge of proper vaccine handling, e.g. protects MMR from light, logs refrigerator temperature.					

		Self-Assessment		Supervisor Review		
Competency	**Clinical Skills, Techniques, and Procedures**	**Need to Improve**	**Meets or Exceeds**	**Need to Improve**	**Meets or Exceeds**	**Plan of Action***
D. Administering Immunizations	1. Rechecks the physician's order or instructions against prepared syringes.					
	2. Washes hands and if office policy puts on disposable gloves.					
	3. Demonstrates knowledge of the appropriate route for each vaccine. (IM for DTaP, Td, Hib, HepA, HepB, Pneumo Conj, Flu; SC for MMR, Var; Either SC or IM for IPV and Pneumo Poly).					
	4. Positions patient and/or restrains the child with parent's help; locates anatomic landmarks specific for IM or SC					
	5. Preps the site with an alcohol wipe using a circular motion from the center to a 2" to 3" circle. Allows alcohol to dry.					
	6. Controls the limb with the non-dominant hand; holds the needle an inch from the skin and inserts it quickly at the appropriate angle (45° for SC or 90° for IM).					
	7. Injects vaccine using steady pressure; withdraws needle at angle of insertion.					
	8. Applies gentle pressure to injection site for several seconds with a dry cotton ball.					
	9. Properly disposes of needle and syringe in sharps container. Properly disposes of live vaccine vial.					
	10. Encourages comfort measures before, during and after the procedure.					
E. Records Procedures	1. Fully documents each immunization in patient's chart: date, lot number, manufacturer, site, VIS date, name/initials.					
	2. If applicable, demonstrates ability to use IZ registry or computer to call up patient record, assess what is due today, and update computer immunization history.					
	3. Asks for and updates patient's record of immunizations and reminds them to bring it to each visit.					

Plan of Action:

Circle desired next steps and write in the agreed deadline and date for the follow-up performance review. **a.** Watch video on immunization techniques. **b.** Review office protocols. **c.** Review manuals, textbooks, wall charts or other guides. **d.** Review package inserts. **e.** Review vaccine handling guidelines or video. **f.** Observe other staff with patients. **g.** Practice injections. **h.** Read Vaccine Information Statements. **i.** Be mentored by someone who has these skills. **j.** Role play with other staff interactions with parents and patients, including age-appropriate comfort measures. **k.** Attend a skills training or other courses or training. **l.** Attend health care customer satisfaction or cultural competency training. **m.** Renew CPR certification. **Other:**_____

Employee Signature _____ Date _____

Supervisor Signature _____ Date _____

Plan of Action Deadline _____

Date of Next Performance Review _____

IMMUNIZATION TECHNIQUES
Safe • Effective • Caring

California Department of Health Services • Immunization Branch • 2151 Berkeley Way • Berkeley, CA 94704

IMM-694B (9/01)

VIII. Resources

Additional Immunization Resources and Ordering Information

- The California Department of Health Services' Immunization Branch has developed a complete package of resources on vaccine administration, including a training video entitled, *Immunization Techniques: Safe, Effective, Caring.*

  The cost is $15.00. Ordering information is available on the Immunization Action Coalition (IAC) Web site at www.immunize.org/iztech Or, you may call the IAC at 651-647-9009 for ordering assistance.

- *Epidemiology and Prevention of Vaccine-Preventable Diseases, 7th edition,* (January 2003) (The Pink Book) can be purchased from the Public Health Foundation. The cost is $29.00 plus shipping and handling. Order at www.phf.org or

  Mail: Send your order with check, money order, purchase order or credit card information to:

  Public Health Foundation, Publications Sales
  P.O. Box 753
  Waldorf, Maryland 20604

  Phone: Telephone orders accepted with Visa or MasterCard. Call toll free: 877-252-1200 or 800-418-7246, and a Customer Service Representative will assist you between 9:00 a.m. and 5:00 p.m. (ET), Monday through Friday. For international orders, call 301-645-7773.

  Fax: Purchase orders and credit card orders may be faxed to 301-843-0159.

  Email: Send your email order with payment information to phf@tasco1.com

- The Colorado Immunization program has a comprehensive Immunization Resource Manual. Call 303-692-2363 for additional information.

- Teaching Immunization Delivery and Evaluation (TIDE) is an on-line, interactive curriculum to further your immunization knowledge and skills. The training tool uses scenarios to trigger problem solving and discussion. It is organized into three modules, with each covering a different aspect of immunization delivery. For more information visit the TIDE web site at www2.edserv.musc.edu/tide

- Other immunization web sites:
  From the Immunization Action Coalition, www.vaccineinformation.org
  Information for both the general public and health professionals with many topics including vaccine safety, vaccine-preventable diseases and links to various other immunization sites.

Allied Vaccine Group, www.vaccine.org
This site's Home page states, that the Group is "…comprised of Web sites dedicated to presenting valid scientific information about the sometimes confusing subject of vaccines."

IX. Appendix

Standards for Pediatric Immunization Practices

Availability of Vaccines

1. Vaccination services are readily available.
2. Vaccinations are coordinated with other healthcare services and provided in a medical home when possible.
3. Barriers to vaccination are identified and minimized.
4. Patient costs are minimized.

Assessment of Vaccination Status

5. Healthcare professionals review the vaccination and health status of patients at every encounter to determine which vaccines are indicated.
6. Healthcare professionals assess for and follow only medically indicated contraindications.

Effective Communication about Vaccine Benefits and Risks

7. Parents/guardians and patients are educated about the benefits and risks of vaccination in a culturally appropriate manner and in easy-to-understand language.

Proper Storage and Administration of Vaccines and Documentation of Vaccinations

8. Healthcare professionals follow appropriate procedures for vaccine storage and handling.
9. Up-to-date, written vaccination protocols are accessible at all locations where vaccines are administered.
10. Persons who administer vaccines and staff who manage or support vaccine administration are knowledgeable and receive ongoing education.
11. Healthcare professionals simultaneously administer as many indicated vaccine doses as possible.
12. Vaccination records for patients are accurate, complete, and easily accessible.
13. Healthcare professionals report adverse events following vaccination promptly and accurately to the Vaccine Adverse Events Reporting System (VAERS) and are aware of a separate program, the National Vaccine Injury Compensation Program (NVICP).
14. All personnel who have contact with patients are appropriately vaccinated.

Implementation of Strategies to Improve Vaccination Coverage

15. Systems are used to remind parents/guardians, patients, and healthcare professionals when vaccinations are due and to recall those who are overdue.
16. Office- or clinic-based patient record reviews and vaccination coverage assessments are performed annually.
17. Healthcare professionals practice community-based approaches.

source: http://www.cdc.gov/nip/recs/rev-immz-stds.htm

COMPREHENSIVE TEST
ANSWER SHEET

Basic Principles of Vaccination: Immunity

1) What is active immunity?
Active immunity is what occurs when the body is exposed to a "wild-type" or naturally occurring viral or bacterial strain. The exposure generally leads to illness. The body then responds by producing protective antibodies.

2) What is artificial active immunity?
Artificial active immunity results from a person being vaccinated. Vaccines spur the body to produce an immune response similar to a wild-type viral or bacterial strain-produced response. However, vaccines do not expose the body to the wild disease and its potential complications. Thus, this is a safer and more predictable way for a person to develop active immunity.

3) What is passive immunity?
Passive immunity occurs when a specific antibody is introduced into the body from an outside source. The body is not stimulated to produce its own antibodies, but absorbs them from an external source.

4) What are live attenuated vaccines?
Live attenuated vaccines are produced by modifying a "wild type" bacteria or virus in the laboratory, thus creating a weakened version.

5) What are inactivated vaccines?
Inactivated vaccines are produced by growing the bacteria or virus, then inactivating or killing it. It is not alive and cannot replicate.

6) What are recombinant vaccines?
Recombinant vaccines are genetically engineered and can contain either live or killed antigens.

7) What are inactive and active ingredients in vaccines?
Vaccines contain both active and inactive ingredients. Active ingredients, such as adjuvents, are used to help the body to produce a vigorous immune response. Inactive ingredients, like stabilizers and preservatives, are not involved in promoting or enhancing the immune response.

Basic Principles of Vaccination: General Recommendations on Immunizations

1) **Which type of vaccines are generally not affected by circulating antibodies and can be administered before, after or at the same time as other vaccines and antibody products?**
   Inactivated antigens are not substantially affected by circulating antibody, so they can be administered before, after, or at the same time as the antibody.

2) **Which vaccines cannot be administered together?**
   There is no contraindication to the simultaneous administration of any routine childhood vaccines.

3) **If an MMR and Varicella vaccine are not administered together, how long should one wait to give the second vaccine?**
   Live injected vaccines (MMR and varicella) that are not administered simultaneously should be separated by at least four weeks.

4) **If a child has received one hepatitis B at birth and one at two months of age, and is now presenting at three years of age, to complete the series is it necessary to restart the hepatitis B series? Why?**
   It is not necessary to restart the series of any vaccine due to extended intervals between doses because increasing the interval between doses of a multidose vaccine does not diminish the effectiveness of the vaccine.

5) **Which vaccines require multiple doses and possible periodic boosting to maintain immunity?**
   For inactivated vaccines, the first dose usually does not provide protection. A protective immune response may not develop until the second or third dose.

6) **Which is the most common type of adverse reaction?**
   The most common type of adverse reactions are local reactions, such as pain, swelling and redness at the site of injection.

7) **How are generalized reactions like fever, malaise and headache classified?**
   Systemic adverse reactions are more generalized events, and include fever, weakness, myalgia (muscle pain), headache, loss of appetite and others.

8) **How can the risk of an allergic reaction be minimized?**
   The risk of an allergic reaction may be minimized by good screening prior to

vaccination.

9) What is the difference between a contraindication and a precaution to immunization?

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 itself.

A precaution is a condition in a recipient that *may increase* the chance of a serious adverse reaction, or that may 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).

10) What are the conditions generally considered to be permanent contraindications?

Only two of these conditions are generally considered to be permanent: severe allergy to a vaccine component or severe allergic reaction following a prior dose of a vaccine; and encephalopathy within seven days of pertussis vaccination.

11) What conditions are considered permanent precautions to further doses of pertussis-containing vaccine?

Four conditions are considered permanent precautions to further doses of pertussis-containing vaccine: temperature >105° F; collapse or shock-like state (hypotonic hyporesponsive episode); persistent inconsolable crying lasting three or more hours occurring within 48 hours of a dose; or a seizure, with or without fever, occurring within three days of a dose.

12) What are the temporary contraindications to vaccination with live vaccine?

Two conditions are temporary contraindications to vaccination with live vaccines: pregnancy and immunosuppression.

13) Which type of vaccines can always be given to an immunosuppressed person?

Inactivated vaccines are not contraindicated for immunosuppressed persons.

14) Which two live vaccines should susceptible household contacts of persons with HIV infection receive?

Susceptible household contacts (such as an unimmunized child in the home) of persons with HIV infection should receive MMR and varicella vaccines.

15) **If a child has mild acute illness such as a low-grade fever and upper respiratory infection, can he be immunized?**
Children with mild acute illnesses, such as low-grade fever, upper respiratory infection, colds, otitis media, and mild diarrhea, can and should be vaccinated.

16) **If a child is presently taking an antibiotic such as Amoxicillin for an ear infection can he receive his vaccines today?**
Yes, the child can receive immunizations while taking antibiotics such as Amoxicillin.

17) **What vaccines are contraindicated for breast-fed infants?**
All vaccines, including live vaccines (MMR and varicella) can be given to infants or children with pregnant household contacts, as well as to breast-feeding infants.

18) **What vaccine cannot be administered at the same time as a TB skin test?**
All vaccines, including MMR, can be given on the same day as a TB skin test, or any time after a TB skin test is read.

Vaccine Administration

1) **What two factors should be considered when preparing a patient for vaccination?**
Patients should be prepared for vaccination with consideration for their age and stage of development.

2) **List two issues that have contributed to the concerns and anxiety that patients/parents associate with vaccination?**
Vaccine safety issues and the need for multiple injections have increased the concerns and anxiety associated with immunizations.

3) **When considering patient position and restraint, what must the health care provider accommodate for?**
The health care provider must accommodate for the patient's comfort, safety, age, activity level, and the site of administration when considering patient positioning and restraint.

4) **Why do diversionary techniques used for vaccine administration pain control work?**
Age-appropriate, non-pharmacologic techniques may provide distraction from pain associated with injections.

5) **What is the single, most effective disease prevention activity?**
The single, most effective disease prevention activity is good handwashing.

6) **How should empty vaccine vials be handled?**
Empty or expired vaccine vials are considered medical waste and should be disposed of according to state regulations.

7) **When selecting a needle for vaccine administration, what should the needle size be based on?**
Needle selection should be based upon the prescribed route, size of the individual, and viscosity of the vaccine.

8) **What is the rule of thumb about vaccine expiration dates?**
Vaccine can be used through the last day of the month indicated by the expiration date.

9) **Why is prefilling a syringe discouraged?**
Prefilling syringes or loading vaccine into syringes to prepare for patients to be seen later is discouraged by ACIP because of the risks for vaccine contamination, administration errors and vaccine wastage.

10) **Is it important to label each vaccine that you draw up? How can this be accomplished?**
There are a variety of methods for identifying or labeling syringes. These can include keeping syringes with the appropriate vaccine vials, placing the syringes in a label-partitioned tray, or using color-coded labels or preprinted labels. Some providers may choose to include the lot number and date of filling on the identification.

11) **How can one avoid reaching the muscle when administering a subcutaneous (SC) injection?**
To avoid reaching the muscle, the fatty tissue is pinched up, the needle is inserted at a 45 degree angle and the vaccine is injected into the tissue.

12) Which intramuscular (IM) muscle site should never be used to administer vaccines?
The buttock should never be used to administer vaccines.

13) When administering an intramuscular immunization, how can injection into subcutaneous tissue be avoided?
To avoid injection into subcutaneous (SC) tissue when administering an intramuscular (IM) immunization, a 90 degree angle should be used and the skin of the selected vaccine administration site can be spread taut between the thumb and forefinger, isolating the muscle. Another technique, acceptable mostly for pediatric and geriatric patients, is to grasp the tissue and "bunch up" the muscle.

14) If more than one vaccine is administered in the same limb, how far apart must the two injections be placed?
If more than one vaccine must be administered in the same limb, the injection sites should be separated by 1-2 inches so that any local reactions can be differentiated.

15) What is the most important step to take when preparing an immunization injection for an individual with a bleeding disorder?
A physician familiar with the patient's bleeding disorder or therapy should be consulted regarding the safety of administration by this route.

16) If a patient has a history of rare severe latex allergy, what should the immunization provider do first in considering the vaccine administration?
Medical consultation and direction should be sought regarding vaccination.

17) What should every facility have in place to prepare for an anaphylaxis after vaccine administration?
Each facility that administers vaccines should have a protocol, procedures and equipment to provide initial care for suspected anaphylaxis.

Legal and Documentation Issues

1) What is the National Vaccine Injury Compensation Program (NVICP) and what are the vaccines that the Program covers?
The National Vaccine Injury Compensation Program (NVICP) is a no-fault insurance program created by Congress in 1986. The program is funded with a federal excise tax that is paid on each dose of DTaP, DT, OPV, IPV, MMR,

Hib, hepatitis B and varicella vaccine.

2) What is the process involved in filing a NVICP claim?

This process involves filing a claim which is then investigated by the program and judged according to whether the claim meets the requirements of the Vaccine Injury Table (see table this resource), or the claimant can prove that the vaccine caused the injury. If the claim is accepted, the parent is awarded compensation. If the parents accept compensation, they cannot then initiate a civil suit to seek another award.

3) What are Vaccine Information Statements (VISs)?

Vaccine Information Statements (VISs) are documents designed to inform and educate an adult, or the parent or legal representative of a child receiving the vaccine.

4) When are VISs required?

Health care providers who administer any vaccine covered by the NVICP are required to give a copy of the relevant Vaccine Information Statements (VISs) to any adult or to the parent or legal representative of a child receiving the vaccine.

5) What information must the health care provider administering a vaccine document in every patient's permanent medical record?

The following information must be recorded in the permanent medical record.

- The date of administration of the vaccine
- The manufacturer and lot number of the vaccine
- The name and address of the health care provider administering the vaccine
- The version date on the relevant VIS given to the patient or patient representative
- The date the VIS was given to the patient

6) Where can providers find a list of the vaccine adverse reactions that must be reported? What form is required?

These adverse events are listed in the Vaccine Injury Table. Adverse events should be reported on a Vaccine Adverse Event Reporting System (VAERS) form.

7) How are new vaccines added for coverage under the NVICP?

A final rule was published which, in part, provided for the "automatic" addition of future vaccines recommended by the CDC for routine administration to children. However, Congress will still need to set an appropriate excise tax on any new vaccines recommended by the CDC before those vaccines are effectively covered under the Program.

8) Who may file a claim?
The injured individual may file, or a parent, legal guardian, or trustee may file on behalf of a child or an incapacitated person.

9) To whom should you direct your call for more information about the NVICP?
The National Injury Compensation Program Internet Home page can be found at the following address: www.hrsa.gov or call toll-free 1-800-338-2382. For further information write to:

National Vaccine Injury Compensation Program
Parklawn Building, Room 8A-46
5600 Fishers Lane
Rockville, Maryland 20857

Vaccine Storage and Handling

1) Why is it so important to store vaccine properly?
Outdated and improperly handled vaccines will not protect patients.

2) Where should vaccines not be stored in the refrigerator?
Do not store vaccine in the door of the refrigerator.

3) Does diluent need refrigeration?
Diluent does not need refrigeration if MMR is administered right after diluent is added.

4) How can you avoid outdating of your vaccine?
Rotate vaccine stock to avoid outdating.

5) What type of special electrical plug should your vaccine refrigerator have?
The vaccine refrigerator/freezer should have a safety lock-type plug.

6) What is another measure you can take to avoid having the vaccine refrigerator inadvertently unplugged?
Post a warning sign so electricians or janitors don't inadvertently unplug the refrigerator or turn off the circuit or electricity.

7) **What are the proper temperatures to maintain in the vaccine refrigerator? In the freezer?**
Maintain proper temperatures in the refrigerator (2°C to 8°C or 35°F to 46°F) and in the freezer (-14°C or 7°F or lower).

8) **How often should the vaccine refrigerator and freezer be checked?**
Check the refrigerator and freezer twice a day, first thing in the morning and last thing at night.

Immunization Strategies

1) **Why are proven immunization strategies important to implement in your practice?**
Proven strategies are important to implement because they have been shown through research and actual use to improve rates.

2) **What is an important consideration in selecting one of these proven immunization strategies to use in your office?**
When selecting an immunization strategy, it is important to carefully consider and then match an identified problem with a likely solution.

3) **What two factors must exist within a practice to successfully implement an immunization strategy?**
A consensus for change and a commitment to the chosen strategy must exist.

4) **Where can you call to get more information than what is offered here, on how to improve immunization rates in your practice?**
For more information on how to improve immunization rates in your practice, you can call the Colorado Children's Immunization Coalition (CCIC) at 303-864-5340 and Vaccines for Children (VFC) contact persons at 303-692-2798 as well as the representatives of your local and state health departments.

5) **What should be done as soon as possible with old immunization records for your patients that are received by your office?**
When old records for your patients are received, the information they contain must be incorporated into the vaccine administration sheet.

6) **What is one way a nurse or office assistant can remind the provider that a child needs shots?**
Some practices place a sticky-note or highlight immunization sheet information to alert the provider of the shots that are due that day.

7) **List two ways practices can track kids that are behind on their shots.**
Offices that use the Colorado Immunization Information System can print the child's immunization record to place on the front side of the chart. Needed immunization series are marked with a red "R".
Some practices use a tickler box or spiral notebook to track kids that are behind on their shots.

8) **What has been shown to be the most successful way to improve immunization rates?**
Reminder/recall systems are the "best" way to improve immunization coverage rates.

9) **List two ways an office can make sure there are no missed opportunities to immunize.**
Make sure that the office follows only the true contraindications to immunization, and realize that all childhood vaccines can be given simultaneously.

10) **What records should a parent keep that will ensure their child receives all the necessary shots?**
Encourage parents to maintain their own immunization records for their children. Make sure you update their copy of the immunization record at each visit.

11) **What is a simple way your office can increase the chance that a child returns for his next immunizations on time?**
Schedule the next immunization appointment when the child is in the office, and always write the date the next shot is due on the parent's immunization record.