

Dated: August 22, 2008.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Consolidated Vaccine Information Materials for Multiple Infant Vaccines; Revised Instructions for Use of Vaccine Information Statements

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: Under the National Childhood Vaccine Injury Act (NCVIA) (42 U.S.C. § 300aa-26), the CDC must develop vaccine information materials that all health care providers are required to give to patients/parents prior to administration of specific vaccines. CDC seeks written comment on a proposed new vaccine information statement that consolidates the six vaccine information statements for the following childhood vaccines: DTaP, *Haemophilus influenzae* type b, inactivated polio vaccine, pneumococcal conjugate vaccine, hepatitis B, and rotavirus. This consolidated Vaccine Information Statement would be available to be used by vaccination providers as an alternative to providing the six individual Vaccine Information Statements for the same vaccines. On October 4, 2007, CDC published a notice in the **Federal Register** (72 FR 56765) seeking public comments on the proposed consolidated vaccine information materials. The 60 day comment period ended on December 3, 2007. Following review of the comments submitted and consultation as required under the law, CDC has finalized these vaccine information materials. The final materials, and revised instructions for their use and for use of materials for other covered vaccines, are contained in this notice.

DATES: Beginning August 28, 2008, each health care provider who administers vaccine that contains diphtheria, tetanus, pertussis, hepatitis B, pneumococcal conjugate, inactivated polio, *Haemophilus influenzae* type b, or rotavirus vaccines may, prior to administration of each dose of these vaccines, provide a copy of the vaccine

information materials contained in this notice, dated January 30, 2008, to the parent or legal representative of any child to whom such provider intends to administer the vaccines, in lieu of providing vaccine information materials for each individual vaccine.

FOR FURTHER INFORMATION CONTACT:

Anne Schuchat, M.D., Director, National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention, Mailstop E-05, 1600 Clifton Road, NE., Atlanta, Georgia 30333, telephone (404) 639-8200.

SUPPLEMENTARY INFORMATION: The National Childhood Vaccine Injury Act of 1986 (Pub. L. 99-660), as amended by section 708 of Public Law 103-183, added section 2126 to the Public Health Service Act. Section 2126, codified at 42 U.S.C. 300aa-26, requires the Secretary of Health and Human Services to develop and disseminate vaccine information materials for distribution by all health care providers in the United States to any patient (or to the parent or legal representative in the case of a child) receiving vaccines covered under the National Vaccine Injury Compensation Program.

Development and revision of the vaccine information materials, also known as Vaccine Information Statements (VIS), have been delegated by the Secretary to the Centers for Disease Control and Prevention (CDC). Section 2126 requires that the materials be developed, or revised, after notice to the public, with a 60-day comment period, and in consultation with the Advisory Committee on Childhood Vaccines, appropriate health care provider and parent organizations, and the Food and Drug Administration. The law also requires that the information contained in the materials be based on available data and information, be presented in understandable terms, and include:

- (1) A concise description of the benefits of the vaccine,
- (2) a concise description of the risks associated with the vaccine,
- (3) a statement of the availability of the National Vaccine Injury Compensation Program, and
- (4) such other relevant information as may be determined by the Secretary.

The vaccines initially covered under the National Vaccine Injury Compensation Program were diphtheria, tetanus, pertussis, measles, mumps, rubella and poliomyelitis vaccines. Since April 15, 1992, any health care provider in the United States who intends to administer one of these covered vaccines is required to provide

copies of the relevant vaccine information materials prior to administration of any of these vaccines. Hepatitis B, *Haemophilus influenzae* type b (Hib), varicella (chickenpox), pneumococcal conjugate, hepatitis A, meningococcal conjugate and polysaccharide, rotavirus, human papillomavirus (HPV), and trivalent influenza vaccines have subsequently been added to the National Vaccine Injury Compensation Program. Use of the Vaccine Information Statements applicable to all of these vaccines, [except meningococcal, rotavirus and HPV,] is also required. [(Interim versions of Vaccine Information Statements for meningococcal, rotavirus and HPV vaccines are available for discretionary use pending completion of the statutory process for finalizing VISs applicable to those vaccines.)] Instructions for use of the vaccine information materials and copies of the materials can be found on the CDC Web site at: <http://www.cdc.gov/vaccines/pubs/vis>. In addition, single camera-ready copies are available from State health departments. A list of State health department contacts for obtaining copies of these materials is included in a December 17, 1999 **Federal Register** notice (64 FR 70914).

Consolidated Vaccine Information Materials

With six vaccines recommended for infants from birth through 6 months of age—all covered by the National Vaccine Injury Compensation Program—CDC, as required under 42 U.S.C. 300aa-26, developed Vaccine Information Statements for each of those vaccines. CDC proposed an alternative consolidated Vaccine Information Statement covering those six vaccines in one document, which providers could choose to use instead of the existing individual Vaccine Information Statements for the same vaccines.

Following consultation as required under the law and review of comments submitted, these vaccine information materials have been finalized and are contained in this notice. They are entitled *Your Baby's First Vaccines: What You Need to Know*, and are dated January 30, 2008. CDC has also revised the Instructions for the Use of Vaccine Information Statements. The revised instructions, dated May 12, 2008, are included in this notice. These instructions and copies of the materials for all covered vaccines can also be found on the CDC Web site at: <http://www.cdc.gov/vaccines/pubs/VIS>.

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Instructions for the Use of Vaccine Information Statements

Required Use

1. Provide Vaccine Information Statement (VIS) when vaccination is given. As required under the National Childhood Vaccine Injury Act (42 U.S.C. § 300aa-26), all health care providers in the United States who administer, to any child or adult, any vaccine containing diphtheria, tetanus, pertussis, measles, mumps, rubella, polio, hepatitis A, hepatitis B, *Haemophilus influenzae* type b (Hib), trivalent influenza, pneumococcal conjugate, or varicella (chickenpox) vaccine shall, prior to administration of each dose of the vaccine, provide a copy to keep of the relevant current edition vaccine information materials that have been produced by the Centers for Disease Control and Prevention (CDC):

—to the parent or legal representative* of any child to whom the provider intends to administer such vaccine, and
 (* “Legal representative” is defined as a parent or other individual who is qualified under State law to consent to the immunization of a minor or incompetent adult)

—to any adult to whom the provider intends to administer such vaccine. (In the case of an incompetent adult, relevant VISs shall be provided to the individual’s legal representative.* If the incompetent adult is living in a long-term care facility, all relevant VISs may be provided at the time of admission, or at the time of consent if later than admission, rather than prior to each immunization.)

If there is not a single VIS for a combination vaccine, use the VISs for all component vaccines.

The materials shall be supplemented with visual presentations or oral explanations, as appropriate.

2. Record information for each VIS provided.

Health care providers shall make a notation in each patient’s permanent medical record at the time vaccine information materials are provided indicating:

(1) The edition date of the Vaccine Information Statement distributed, and
 (2) the date the VIS was provided.

This recordkeeping requirement supplements the requirement of 42 U.S.C. 300aa-25 that all health care providers administering these vaccines must record in the patient’s permanent medical record (or in a permanent office log):

(3) the name, address and title of the individual who administers the vaccine,

(4) the date of administration, and
 (5) the vaccine manufacturer and lot number of the vaccine used.

Applicability of State Law

Health care providers should consult their legal counsel to determine additional State requirements pertaining to immunization. The Federal requirement to provide the vaccine information materials supplements any applicable State laws.

Availability of Copies

Single camera-ready copies of the vaccine information materials are available from State health departments. Copies are also available on the Centers for Disease Control and Prevention’s Web site at <http://www.cdc.gov/vaccines/pubs/vis>. Copies are available in English and in other languages.

Current VIS Editions

Diphtheria, Tetanus, Pertussis (DTaP or DT): 5/17/07.

Haemophilus influenzae type b: 12/16/98.

Hepatitis A: 3/21/06.

Hepatitis B: 7/18/07.

Human Papillomavirus (HPV): 2/2/07**.

Inactivated Influenza: 7/24/08.

Live, Intranasal Influenza: 10/4/07.

Measles, Mumps, Rubella (MMR): 3/13/08.

Meningococcal: 1/28/08**.

Pneumococcal conjugate: 9/30/02.

Polio: 1/1/00.

Rotavirus: 4/12/06**.

Tetanus Diphtheria (Td): 6/10/94.

Tetanus, Diphtheria, Pertussis (Tdap): 7/12/06.

Varicella (chickenpox): 3/13/08.

Multi-Vaccine: 1/30/08***.

** Available interim VIS pending completion of statutory process.

*** This VIS is an optional alternative when two or more routine childhood vaccines (i.e., DTaP, hepatitis B, Hib, pneumococcal, polio, or rotavirus) are administered at the same visit.

Reference 42 U.S.C. 300aa-26.

5/12/08.

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Multi-vaccine Vaccine Information Statement:

YOUR BABY’S FIRST VACCINES: WHAT YOU NEED TO KNOW

Babies get six vaccines between birth and 6 months of age.

These vaccines protect your baby from 8 serious diseases (see the next page).

Your baby will get vaccines today that prevent these diseases:

- Hepatitis B
- Polio

- Pneumococcal Disease
- Diphtheria, Tetanus & Pertussis
- Rotavirus
- Hib

(Provider: Check appropriate boxes)

These vaccines may be given separately, or some might be given together in the same shot (for example, Hepatitis B and Hib can be given together, and so can DTaP, Polio and Hepatitis B). These “combination vaccines” are as safe and effective as the individual vaccines, and mean fewer shots for your baby.

These vaccines may all be given at the same visit. Getting several shots at the same time will not harm your baby.

This “Vaccine Information Statement” (VIS) tells you about the benefits and risks of these vaccines. It also contains information about reporting an adverse reaction, the National Vaccine Injury Compensation Program, and how to get more information about childhood diseases and vaccines.

Please read this VIS before your child gets his or her immunizations, and take it home with you afterward. Ask your doctor, nurse, or other healthcare provider if you have questions.

Individual Vaccine Information Statements are also available for these vaccines. Many Vaccine Information Statements are available in Spanish and other languages. See <http://www.immunize.org/vis>.

Department of Health and Human Services

Centers for Disease Control and Prevention

Vaccine Information Statement, 42 U.S.C. 300aa-26, 1/30/2008.

Vaccine Benefits: Why Get Vaccinated?

Your children’s first vaccines protect them from 8 serious diseases, caused by viruses and bacteria. These diseases have injured and killed many children (and adults) over the years. Polio paralyzed about 37,000 people and killed about 1,700 each year in the 1950s before there was a vaccine. In the 1980s, Hib disease was the leading cause of bacterial meningitis in children under 5 years of age. About 15,000 people a year died from diphtheria before there was a vaccine. Most children have had at least one rotavirus infection by their 5th birthday. None of these diseases has completely disappeared. Without vaccination, they will come back. This has happened in other parts of the world.

*8 Diseases Prevented by Childhood Vaccines***Diphtheria: Bacteria**

You can get it from contact with an infected person.

Signs and symptoms include a thick covering in the back of the throat that can make it hard to breathe.

It can lead to breathing problems, heart failure, and death.

Tetanus (Lockjaw): Bacteria

You can get it from a cut or wound. It does not spread from person to person.

Signs and symptoms include painful tightening of the muscles, usually all over the body.

It can lead to stiffness of the jaw, so the victim can't open his mouth or swallow. It leads to death in about 1 case out of 5.

Pertussis (Whooping Cough): Bacteria

You can get it from contact with an infected person.

Signs and symptoms include violent coughing spells that can make it hard for an infant to eat, drink, or breathe. These spells can last for weeks.

It can lead to pneumonia, seizures (jerking and staring spells), brain damage, and death.

Hib (*Haemophilus influenzae* Type b): Bacteria

You can get it from contact with an infected person.

Signs and symptoms. There may be no signs or symptoms in mild cases.

It can lead to meningitis (infection of the brain and spinal cord coverings); pneumonia; infections of the blood, joints, bones, and covering of the heart; brain damage; deafness; and death.

Hepatitis B: Virus

You can get it from contact with blood or body fluids of an infected person. Babies can get it at birth if the mother is infected, or through a cut or wound. Adults can get it from unprotected sex, sharing needles, or other exposures to blood.

Signs and symptoms include tiredness, diarrhea and vomiting, jaundice (yellow skin or eyes), and pain in muscles, joints and stomach.

It can lead to liver damage, liver cancer, and death.

Polio Virus

You can get it from close contact with an infected person. It enters the body through the mouth. Signs and symptoms can include a cold-like illness, or there may be no signs or symptoms at all. It can lead to paralysis (can't move arm or

leg), or death (by paralyzing breathing muscles).

Pneumococcal: Bacteria

You can get it from contact with an infected person.

Signs and symptoms include fever, chills, cough, and chest pain.

It can lead to meningitis (infection of the brain and spinal cord coverings), blood infections; ear infections, pneumonia, deafness, brain damage, and death.

Rotavirus: Virus

You can get it from contact with other children who are infected.

Signs and symptoms include severe diarrhea, vomiting and fever.

It can lead to dehydration, hospitalization (up to about 70,000 a year), and death.

How Vaccines Work

Immunity from Disease: When a child gets sick with one of these diseases, her immune system produces immunity, which keeps her from getting the same disease again. But getting sick is unpleasant, and can be dangerous.

Immunity from Vaccines: Vaccines are made with the same bacteria or viruses that cause a disease, but they have been weakened or killed to make them safe. A child's immune system responds to a vaccine the same way it would if the child had the disease. This means he will develop immunity without having to get sick first.

Routine Childhood Vaccines

Six vaccines are recommended for children between birth and 6 months of age. They can prevent the 8 diseases described on the previous page.

Children will also get at least one "booster" dose of most of these vaccines when they are older.

- **DTaP (Diphtheria, Tetanus & Pertussis) Vaccine:** 5 doses—2 months, 4 months, 6 months, 15–18 months, 4–6 years. Some children should not get pertussis vaccine. These children can get a vaccine called DT, which does not contain pertussis.

- **Hepatitis B Vaccine:** 3 doses—Birth, 1–2 months, 6–18 months.

- **Polio Vaccine:** 4 doses—2 months, 4 months, 6–18 months, 4–6 years.

- **Hib (*Haemophilus influenzae* type b) Vaccine:** 4 doses—2 months, 4 months, 6 months, 12–15 months. Several Hib vaccines are available. With one type, the 6-month dose is not needed.

- **Pneumococcal Vaccine:** 4 doses—2 months, 4 months, 6 months, 12–15 months. Older children with certain diseases may also need this vaccine.

- **Rotavirus Vaccine:** 3 doses—2 months, 4 months, 6 months. Rotavirus is an oral (swallowed) vaccine, not a shot.

Vaccine Risks

Vaccines can cause side effects, like any other medicine. Mostly these are mild "local reactions" such as tenderness, redness or swelling where the shot is given, or a mild fever. They happen in up to 1 child out of 4 for most childhood vaccines. They appear soon after the shot is given and go away within a day or two.

More severe reactions can also occur, but this happens much less often. Some of these reactions are so uncommon that experts can't tell whether they are caused by vaccines or not. Among the most serious reactions to vaccines are severe allergic reactions to a substance in a vaccine. These reactions happen very rarely—less than once in a million shots. They usually happen very soon after the shot is given. Doctor's office or clinic staff are trained to deal with them.

The risk of any vaccine causing serious harm, or death, is extremely small. Getting a disease is much more likely to harm a child than getting a vaccine.

Other Reactions

The following conditions have been associated with routine childhood vaccines. By "associated" we mean that they appear more often in children who have been recently vaccinated than in those who have not. An association doesn't "prove" that a vaccine caused a reaction, but it does mean it is probable.

DTaP Vaccine

Mild Problems: Fussiness (up to 1 child in 3); tiredness or poor appetite (up to 1 child in 10); vomiting (up to 1 child in 50); swelling of the entire arm or leg for 1–7 days (up to 1 child in 30)—usually after the 4th or 5th dose.

Moderate Problems: Seizure (jerking or staring) (1 child in 14,000); non-stop crying for 3 hours or more (up to 1 child in 1,000); fever over 105°F (1 child in 16,000).

Serious Problems: Long-term seizures, coma, lowered consciousness, and permanent brain damage have been reported very rarely after DTaP vaccine. They are so rare we can't be sure they are caused by the vaccine.

Polio Vaccine/Hepatitis B Vaccine/Hib Vaccine

These vaccines have not been associated with mild problems other than local reactions, or with moderate or serious problems.

Pneumococcal Vaccine

Mild Problems: During studies of the vaccine, some children became fussy or drowsy or lost their appetite.

Rotavirus Vaccine

Mild Problems: Children who get rotavirus vaccine are slightly more likely than other children to have mild, temporary diarrhea or vomiting. This happens within the first week after getting a dose of vaccine. No moderate or serious problems have been associated with the vaccine.

Precautions

If your child is sick on the date vaccinations are scheduled, your provider may want to put them off until she recovers. A child with a mild cold or a low fever can usually be vaccinated that day. But for a more serious illness, it may be better to wait.

Some children should not get certain vaccines. Talk with your provider if your child had a serious reaction after a previous dose of a vaccine, or has any life-threatening allergies. (These reactions and allergies are rare.)

If your child had any of these reactions to a previous dose of DTaP:

- A brain or nervous system disease within 7 days
- Non-stop crying for 3 or more hours
- A seizure or collapse
- A fever over 105°F

Talk to your provider before getting DTaP Vaccine.

If your child has:

- A life-threatening allergy to the antibiotics neomycin, streptomycin, or polymyxin B.

Talk to your provider before getting Polio Vaccine.

If your child has:

- A life-threatening allergy to yeast

Talk to your provider before getting Hepatitis B Vaccine.

If your child has:

- A weakened immune system
- Ongoing digestive problems
- Recently gotten a blood transfusion or other blood product
- Ever had intussusception (an uncommon type of intestinal obstruction)

Talk to your provider before getting Rotavirus Vaccine.

What if my child has a moderate or severe reaction?

What should I look for?

Look for any unusual condition, such as a serious allergic reaction, high fever, weakness, or unusual behavior.

Serious allergic reactions are extremely rare with any vaccine. If one

were to happen, it would most likely come within a few minutes to a few hours after the shot.

Signs of a serious allergic reaction can include:

- difficulty breathing
- weakness
- hives
- hoarseness or wheezing
- dizziness
- paleness
- swelling of the throat
- fast heart beat

What should I do?

Call a doctor, or get the child to a doctor right away.

Tell your doctor what happened, the date and time it happened, and when the shot was given.

Ask your healthcare provider to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form. Or you can file this report through the VAERS Web site at <http://www.vaers.hhs.gov>, or by calling 1-800-822-7967.

VAERS does not provide medical advice.

The National Vaccine Injury Compensation Program

A federal program exists to help pay for the care of anyone who has a serious reaction to a vaccine.

For information about the National Vaccine Injury Compensation Program, call 1-800-338-2382 or visit their Web site at <http://www.hrsa.gov/vaccinecompensation>.

For More Information

Ask your healthcare provider. They can give you the vaccine package insert or suggest other sources of information.

Call your local or state health department.

Contact the Centers for Disease Control and Prevention (CDC) at 1-800-232-4636 (1-800-CDC-INFO).

Visit CDC Web sites at: <http://www.cdc.gov/vaccines> and <http://www.cdc.gov/ncidod/diseases/hepatitis>.

Dated: August 20, 2008.

James D. Seligman,

Chief Information Officer, Centers for Disease Control and Prevention (CDC).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Disease Control and Prevention****Board of Scientific Counselors, National Center for Health Statistics**

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC), National Center for Health Statistics (NCHS) announces the following meeting of the aforementioned committee.

Times and Dates: 11 a.m.–5:30 p.m., September 18, 2008. 8:30 a.m.–2 p.m., September 19, 2008.

Place: NCHS Headquarters, 3311 Toledo Road, Hyattsville, Maryland 20782.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 100 people.

Purpose: This committee is charged with providing advice and making recommendations to the Secretary, Department of Health and Human Services; the Director, CDC; and the Director, NCHS, regarding the scientific and technical program goals and objectives, strategies, and priorities of NCHS.

Matters To Be Discussed: The agenda will include welcome remarks by the Director, NCHS; introduction of members and key NCHS staff; scientific presentations and discussions; the review of the National Health Interview Survey; presentation of the long term care program in the initial stage of review; and an open session for comments from the public.

Requests to make oral presentations should be submitted in writing to the contact person listed below. All requests must contain the name, address, telephone number, and organizational affiliation of the presenter.

Written comments should not exceed five single-spaced typed pages in length and must be received by September 12, 2008.

The agenda items are subject to change as priorities dictate.

Contact Person for More Information: Virginia S. Cain, Ph.D., Director of Extramural Research, NCHS/CDC, 3311 Toledo Road, Room 7211, Hyattsville, Maryland 20782, telephone (301) 458-4500, fax (301) 458-4020.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: August 22, 2008.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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