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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Proposed Consolidated Vaccine Information Materials for Multiple Infant Vaccines

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

ACTION: Notice with comment period.

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.

DATES: Written comments are invited and must be received on or before December 3, 2007.

ADDRESSES: Written comments should be addressed to Anne Schuchat, M.D., Director, National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention, Mailstop E-05, 1600 Clifton Road, N.E., Atlanta, Georgia 30333.

FOR FURTHER INFORMATION CONTACT: Anne Schuchat, M.D., Director, National Center for Immunization and Respiratory Diseases, Mailstop E-05, 1600 Clifton Road, N.E., 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 Commission 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).

Proposed 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 is proposing 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.

Development of Vaccine Information Materials

The vaccine information materials referenced in this notice are being developed in consultation with the Advisory Commission on Childhood Vaccines, the Food and Drug Administration, and parent and health care provider groups.

In addition, we invite written comment on the proposed vaccine information materials that follow, entitled "Your Baby's First Vaccines: What You Need to Know." Comments submitted will be considered in finalizing these materials. When the final consolidated VIS is published in the **Federal Register**, the instructions for use of vaccine information materials will be revised to note that this alternative consolidated VIS can be used in lieu of the individual vaccine VISs.

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Proposed Multi-vaccine Vaccine Information Statement

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

Babies are scheduled for six vaccines at 2, 4, and 6 months of age. One of these (hepatitis B) is usually given at birth.

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

Your baby will be getting these vaccines today (check):

- DTaP
- Hib
- Polio
- Pneumococcal
- Hepatitis B
- Rotavirus

Some of these vaccines might be given in the same shot (for example, Hepatitis B and Hib, or 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 does not increase the risk to your baby.

This “Vaccine Information Statement” tells you about the benefits and risks of these 6 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 statement 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.

Department of Health and Human Services, Centers for Disease Control and Prevention, Vaccine Information Statement, 42 U.S.C. 300aa-26, X/X/2007.

Vaccine Benefits: Why get vaccinated?

Your baby’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. Most of these diseases are not very common in the U.S. today. But if we stopped vaccinating, they would come back. This has happened in other parts of the world.

8 Serious Diseases

Diphtheria Bacteria

You can get it from contact with an infected person, mainly through the air.

Signs and symptoms include a thick covering in the back of the throat.

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 cannot open his mouth or swallow. It leads to death in about 1 case out of 10.

Pertussis (Whooping Cough) Bacteria

You can get it from contact with an infected person, mainly through the air.

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, mainly through the air.

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, mainly through the air.

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 children a year), and death.

How Vaccines Work

A child who gets sick with one of these diseases becomes immune to that disease, and won’t get it again. But getting the disease the first time can be dangerous. That’s why vaccines are a better way to create immunity.

Vaccines are made with the same bacteria or viruses that cause the disease, but they have been weakened or killed to make them safe. Vaccines fool the immune system into thinking a child has the disease. The child becomes immune without having to get sick first.

Routine Childhood Vaccines

These 6 vaccines are routinely given to children under 6 months of age. 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 vaccine.
- 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 chronic 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

Like any medicine, vaccines can cause side effects. Most of these are mild “local reactions” such as tenderness, redness or swelling where

the shot is given, or a mild fever. These reactions are part of the body's natural immune response. They can occur 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. These do not occur with rotavirus vaccine, since it is not injected.

More severe side effects can occur, but much less often. Some of them occur so rarely 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 are very rare—less than one in a million shots. Usually they occur 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 cause harm than getting a vaccine.

The following conditions (in addition to local reactions and mild fever) have been associated with routine childhood vaccines. By "associated" we mean that they are reported after vaccinations more often than would be expected to occur by chance. This does not "prove" that the vaccine causes the reaction, but suggests that it is likely.

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 it is not possible to tell if they are caused by the vaccine.

Polio Vaccine/Hepatitis B Vaccine/Hib Vaccine

These vaccines have not been associated 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 are slightly (1–3%) more likely to have mild,

temporary diarrhea or vomiting within a week after getting a dose of rotavirus vaccine than children who have not gotten the vaccine. No moderate or severe problems have been associated with the vaccine.

Check With Your Doctor * * *

Most children can get all childhood vaccines, but some children should not. Sometimes a child should wait until after the recommended age before getting vaccinated.

If your child is sick on the date vaccinations are scheduled, ask your doctor about delaying them. A child with a mild cold or other illness, or a low fever, can usually be vaccinated. But with more serious illnesses, the doctor might want to wait until the child recovers.

The doctor might recommend that some children not get a specific vaccine. This includes any child who had a life-threatening reaction to a previous dose of the vaccine, or has a life-threatening allergy to any vaccine component. Other reasons not to get a specific vaccine include if the child has/had:

DTaP Vaccine

—A brain or nervous system disease within 7 days after a previous dose of DTaP.

—A seizure or collapse after a previous dose of DTaP.

—Non-stop crying for 3 hours or more after a previous dose of DTaP.

—A fever over 105°F after a previous dose of DTaP.

Polio Vaccine

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

Hepatitis B Vaccine

—A life-threatening allergy to baker's yeast (the kind used for making bread).

Rotavirus Vaccine

—A child who has had intussusception (an uncommon type of bowel obstruction) should usually not be given rotavirus vaccine. (This is simply a precaution. An older type of rotavirus vaccine, which is no longer used, was associated with several cases of intussusception. Today's vaccine has not been. But children who have had this condition are at increased risk of getting it again.)

What if there is a moderate or severe reaction?

What should I look for?

Look for any unusual condition, such as a serious allergic reaction, high fever, 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 doctor, nurse, or health department to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form. Or you can file this report through the VAERS website at <http://www.vaers.org>, or by calling 1-800-822-7967.

VAERS does not provide medical advice.

The National Vaccine Injury Compensation Program

In the unlikely event that your child has a serious reaction to a vaccine, a federal program exists to help pay for the care of those who have been harmed. For information about the National Vaccine Injury Compensation Program, call 1-800-338-2382 or visit their website at <http://www.hrsa.gov/vaccinecompensation>.

For More Information

Ask your doctor or nurse. 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: September 26, 2007.

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