

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Proposed Vaccine Information Materials for Rotavirus Vaccine

**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 proposed new vaccine information materials for rotavirus vaccine.

**DATES:** Written comments are invited and must be received on or before October 12, 2010.

**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, NE., Atlanta, Georgia 30333.

**FOR FURTHER INFORMATION CONTACT:** Skip Wolfe, National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention, Mailstop E–52, 1600 Clifton Road, NE., Atlanta, Georgia 30333, telephone (404) 639–8809.

**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. Since then, the following vaccines have been added to the National Vaccine Injury Compensation Program, requiring use of vaccine information materials for them as well: hepatitis B, *haemophilus influenzae* type b (Hib), varicella (chickenpox), pneumococcal conjugate, rotavirus, hepatitis A, meningococcal, human papillomavirus (HPV), and trivalent influenza 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 may be 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 Rotavirus Vaccine Information Materials

With the publication in 2009 of updated Advisory Committee on Immunization Practices (ACIP) recommendations for rotavirus vaccine, incorporating information about both the pentavalent and newer monovalent formulations, CDC, as required under 42 U.S.C. 300aa–26, is proposing vaccine information materials covering rotavirus vaccine, which are included in this notice. Interim materials have been available for use pending completion of the formal development process.

#### 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 “Rotavirus Vaccine: What You Need to Know.” Comments submitted will be considered in finalizing these materials. When the final materials are published in the **Federal Register**, the notice will include an effective date for their mandatory use.

We also propose to revise the June 9, 2010 Instructions for the Use of Vaccine Information Statements to update references to these vaccine information materials.

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#### *Proposed Rotavirus Vaccine Information Statement:*

#### **Rotavirus Vaccine: What You Need To Know**

##### *1. What is rotavirus?*

Rotavirus is a virus that causes severe diarrhea, mostly in babies and young children. It is often accompanied by vomiting and fever. Rotavirus is not the only cause of severe diarrhea, but it is one of the most serious. Before rotavirus vaccine was used, rotavirus was responsible for:

- More than 400,000 doctor visits,
- More than 200,000 emergency room visits,
- 55,000 to 70,000 hospitalizations, and
- 20–60 deaths in the United States each year.

Almost all children in the U.S. are infected with rotavirus before their 5th birthday.

Children are most likely to get rotavirus diarrhea between November and May, depending on the part of the country.

##### *2. Rotavirus Vaccine*

Better hygiene and sanitation have not reduced rotavirus diarrhea very much in the United States. The best way to protect your baby is with rotavirus vaccine.

Rotavirus vaccine is an oral (swallowed) vaccine, not a shot.

Rotavirus vaccine will not prevent diarrhea or vomiting caused by other germs, but it is very good at preventing diarrhea and vomiting caused by rotavirus. Most babies who get the vaccine will not get rotavirus diarrhea at

all, and almost all of them will be protected from severe rotavirus diarrhea.

Babies who get the vaccine are also much less likely to be hospitalized or to see a doctor because of rotavirus diarrhea.

A virus (or parts of the virus) called porcine circovirus is in both rotavirus vaccines. This virus is not known to infect people and there is no known safety risk. For more information, see <http://www.fda.gov>, and search for "porcine circovirus."

### 3. Who should get rotavirus vaccine and when?

There are two brands of rotavirus vaccine. A baby should get either 2 or 3 doses, depending on which brand is used.

The doses are recommended at these ages:

First Dose: 2 months of age

Second Dose: 4 months of age

Third Dose: 6 months of age (if needed)

The first dose may be given as early as 6 weeks of age, and should be given by age 14 weeks 6 days. The last dose should be given by 8 months of age.

Rotavirus vaccine may be given at the same time as other childhood vaccines.

### 4. Some Babies Should Not Get Rotavirus Vaccine or Should Wait

- A baby who has had a severe (life-threatening) allergic reaction to a dose of rotavirus vaccine should not get another dose. A baby who has a severe (life threatening) allergy to any component of rotavirus vaccine should not get the vaccine. Tell your doctor if your baby has any severe allergies that you know of, including a severe allergy to latex.

- Babies with "severe combined immunodeficiency" (SCID) should not get rotavirus vaccine.

- Babies who are moderately or severely ill at the time the vaccination is scheduled should probably wait until they recover. This includes babies who have moderate or severe diarrhea or vomiting. Ask your doctor or nurse. Babies with mild illnesses should usually get the vaccine.

- Check with your doctor if your baby's immune system is weakened because of:

- HIV/AIDS, or any other disease that affects the immune system

- Treatment with drugs such as long-term steroids

- Cancer, or cancer treatment with x-rays or drugs

In the late 1990s a different type of rotavirus vaccine was used. This vaccine was found to be associated with

an uncommon type of bowel obstruction called "intussusception," and it was taken off the market.

The new rotavirus vaccines have not been associated with intussusception.

However, babies who have had intussusception, from any cause, are at higher risk for getting it again. If your baby has ever had intussusception, discuss this with your doctor.

### 5. What are the risks from rotavirus vaccine?

A vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. The risk of any vaccine causing serious harm, or death, is extremely small.

Most babies who get rotavirus vaccine do not have any problems with it.

- Babies might become irritable, or have mild, temporary diarrhea or vomiting after a dose of rotavirus vaccine.

- Rotavirus vaccine does not appear to cause any serious side effects.

### 6. What if there is a moderate or severe reaction?

What should I look for?

- Any unusual condition, such as a high fever or behavior changes. Signs of a serious allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

What should I do?

- Call a doctor, or get the person to a doctor right away.

- Tell your doctor what happened, the date and time it happened, and when the vaccination 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 web site at <http://www.vaers.hhs.gov>, or by calling 1-800-822-7967.

VAERS does not provide medical advice.

### 7. The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) was created in 1986.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling 1-800-338-2382 or visiting the VICP Web site at <http://www.hrsa.gov/vaccinecompensation>.

### 8. How can I learn more?

- Your provider 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):

—Call 1-800-232-4636 (1-800-CDC-INFO) or

—Visit CDC's Web site at <http://www.cdc.gov/vaccines>.

Department of Health and Human Services, Centers for Disease Control and Prevention, Vaccine Information Statement, Rotavirus Vaccine, (00/00/0000) (Proposed), 42 U.S.C. 300aa-26.

Dated: August 3, 2010.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Proposed Vaccine Information Materials for Pneumococcal Conjugate Vaccine and Human Papillomavirus 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 proposed new vaccine information materials for pneumococcal conjugate vaccine and human papillomavirus vaccines.

**DATES:** Written comments are invited and must be received on or before October 12, 2010.

**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, NE., Atlanta, Georgia 30333.

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