

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Centers for Disease Control and Prevention****Proposed Revised Vaccine Information Materials for Polio Vaccines; Proposed Instructions for Use of Vaccine Information Materials**

**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 (42 U.S.C. 300aa-26), the Centers for Disease Control and Prevention must develop vaccine information materials that all health care providers, both public and private, are required to give to patients/parents prior to administration of specific vaccines. CDC seeks written comment on proposed revised vaccine information materials for polio vaccines. These materials are being revised so that they will conform with the CDC's revised recommendation for use of polio vaccines effective January 1, 2000 when the recommendation will be to use only inactivated poliovirus vaccine (IPV), except in very limited circumstances.

In addition, the CDC seeks written comment on proposed instructions for use of these vaccine information materials and the other vaccine information materials mandated under 42 U.S.C. 300aa-26.

**DATES:** Written comments are invited and must be received on or before November 1, 1999.

**ADDRESSES:** Written comments should be addressed to Walter A. Orenstein, M.D., Director, National Immunization Program, Centers for Disease Control and Prevention, Mailstop E-05, 1600 Clifton Road, N.E., Atlanta, Georgia 30333.

**FOR FURTHER INFORMATION CONTACT:** Walter A. Orenstein, M.D., Director, National Immunization Program, Centers for Disease Control and Prevention, 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 Pub. L. 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, both public and private, 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 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 who intends to administer one of the covered vaccines is required to provide copies of the relevant vaccine information materials prior to administration of any of these vaccines. Effective June 1, 1999, health care providers were also required to provide copies of vaccine information materials for the following vaccines that have recently been added to the National Vaccine Injury Compensation Program: hepatitis B, *Haemophilus influenzae* type b (Hib), and varicella (chickenpox) vaccines.

**Revised Recommendations for Use of Polio Vaccines**

Progress continues toward the goal of world-wide eradication of poliomyelitis by the year 2000. As the risk of polio infection has diminished, recommendations for use of polio vaccines in the United States have changed significantly during the last few years to move away from exclusive use of oral poliovirus vaccine (OPV) toward exclusive use of inactivated poliovirus vaccine (IPV) and toward an ultimate goal of being able to cease polio vaccination.

In February 1997, the CDC, in accepting the advice of its Advisory Committee on Immunization Practices

(ACIP), revised its recommendation from a schedule of all OPV to a recommended sequential schedule of two doses of inactivated IPV followed by two doses of OPV as the preferred polio vaccination schedule for routine childhood immunization. At that time schedules using either all IPV or all OPV were also considered to be acceptable and preferred for some children in certain circumstances.

The CDC noted in a February 6, 1997 **Federal Register** notice (62 FR 5696) that the recommended schedules for polio immunization were expected to change further over time:

"The ACIP based their revised recommendations on a determination that the risk-benefit ratio associated with the exclusive use of OPV for routine immunization has changed because of rapid progress in global polio eradication efforts. In particular, the relative benefits of OPV to the United States population have diminished because of the elimination of wild-virus-associated poliomyelitis in the Western Hemisphere and the reduced threat of poliovirus importation into the United States. The risk for vaccine-associated poliomyelitis caused by OPV is now judged less acceptable because of the diminished risk for wild-virus-associated disease. Consequently, the ACIP recommended a transition policy that will increase use of IPV and decrease use of OPV during the next 3-5 years. Implementation of these recommendations should reduce the risk for vaccine-associated paralytic poliomyelitis and facilitate a transition to exclusive use of IPV following further progress in global polio eradication."

Noting further progress toward global eradication of wild poliovirus and ongoing concern regarding the vaccine-associated paralytic poliomyelitis risks associated with administration of OPV vaccine prior to receipt of doses of IPV, the ACIP at its meeting on October 22, 1998, voted to further revise its recommendation for administration of the two polio vaccines to discourage use of OPV vaccine for the first two doses, except in limited circumstances. Interim polio vaccine information materials reflecting this revised recommendation were published by the CDC in the **Federal Register** on February 23, 1999 (64 FR 9040).

At its meeting on June 16, 1999, the ACIP voted to recommend an all IPV schedule as of January 1, 2000, stating: "An all IPV schedule is recommended for routine childhood polio immunization as of January 1, 2000. All children will need to receive four doses of IPV at 2, 4, 6-18 months and 4-6 years of age."

"OPV is acceptable only for the following special circumstances:

(1) Mass immunization campaigns to control outbreaks due to wild-type poliovirus;

(2) Unimmunized children where travel to polio-endemic areas is imminent (i.e. in less than four weeks) may receive OPV for the first dose;

(3) Children of parents who do not accept the recommended number of vaccine injections may receive OPV only for dose 3 or 4 or both. (OPV should be administered only after discussion of the risks of VAPP.)

"Limited availability of OPV is expected in the near future in the U.S."

The CDC has adopted these recommendations. In addition, CDC accepts use of OPV when the vaccinee has a life-threatening allergy to any component of IPV.

With this notice, CDC proposes revised vaccine information materials to incorporate these revisions. CDC also intends to publish in a separate **Federal Register** notice proposed revised materials for use when OPV is being considered.

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#### **Proposed Instructions for Use of Vaccine Information Materials**

As noted above, under section 2126 of the Public Health Service Act (42 U.S.C. 300aa-26), all health care providers are required to distribute CDC-developed vaccine information materials to patients/parents prior to administering any covered vaccine. This notice includes proposed instructions for implementing the statutory requirement. The proposed instructions specify the effective date for mandated use of each vaccine's information materials, note when the materials must be provided, delineate the edition dates of the current materials, delineate recordkeeping requirements, and include other related information. Under the proposed instructions, a health care provider would be required to note in the patient's medical record the date the vaccine information materials were provided and the edition date of the materials. The CDC considered various alternatives for documenting compliance with this statute, including requiring a patient/parent signature to acknowledge receipt of the materials. We concluded that a contemporaneous notation in the patient's medical record would be less burdensome than requiring a signature and would provide comparable evidence for purposes of establishing that the statutory mandate had been met, and as such should also meet the medico-legal needs of health care providers.

We invite written comment on the proposed instructions that follow which delineate required use of the vaccine information materials and recordkeeping to verify compliance.

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#### **Instructions for Use of Vaccine Information Materials (Vaccine Information Statements)**

##### *Required Use*

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 any vaccine containing diphtheria, tetanus, pertussis, measles, mumps, rubella, polio, hepatitis B, Haemophilus influenzae type b (Hib), or varicella (chickenpox) vaccine shall, prior to administration of each dose of the vaccine, provide a copy of the relevant current edition vaccine information materials that have been produced by the Centers for Disease Control and Prevention (CDC):

(a) to the parent or legal representative of any child to whom the provider intends to administer such vaccine, and

(b) to any adult to whom the provider intends to administer such vaccine.

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

"Legal representative" is defined as a parent or other individual who is qualified under State law to consent to the immunization of a minor.

##### *Additional Recommended Use of Materials*

Health care providers may also want to give parents copies of all vaccine information materials prior to the first visit for immunization, such as at the first well baby visit.

#### **Use of Revised Polio Vaccine Information Materials**

Effective January 1, 2000, health care providers shall distribute copies of the IPV polio vaccine information materials, dated [insert edition date], and/or OPV polio vaccine information materials, dated [insert edition date], in place of the February 1, 1999 and February 6, 1997 versions of the polio materials.

#### **Current Editions of Other Vaccine Information Materials**

Diphtheria, Tetanus, Pertussis (DTP/DTaP/DT) Vaccine Information Materials, dated August 15, 1997  
Tetanus, Diphtheria (Td) Vaccine Information Materials, dated June 10, 1994

Measles, Mumps, Rubella Vaccine Information Materials, dated December 16, 1998

Hepatitis B Vaccine Information Materials, dated December 16, 1998

Haemophilus influenzae type b (Hib) Vaccine Information Materials, dated December 16, 1998

Varicella (chickenpox) Vaccine Information Materials, dated December 16, 1998

#### **Recordkeeping**

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 materials distributed and (2) the date these materials were 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) the name, address and title of the individual who administers the vaccine, the date of administration and 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 law.

#### **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 website at: <http://www.cdc.gov/nip/publications/VIS/>. Copies are available in English and in other languages. 00/00/00 (Proposed) 42 U.S.C. 300aa-26

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#### **Proposed Revised Polio Vaccine Information Materials**

We invite written comment on the proposed revised vaccine information materials that follow, entitled "Polio Vaccines: What You Need to Know." During the 60-day comment period, CDC also will consult with the Advisory Commission on Childhood Vaccines, appropriate health care provider and parent organizations, and the Food and Drug Administration. Comments submitted will be considered in finalizing these materials. We anticipate that the final version will be published

this November, with an effective date of January 1, 2000.

Proposed OPV polio vaccine information materials, for use when OPV is being considered, will be published in a separate **Federal Register** notice.

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## Polio Vaccines: What You Need to Know

### 1. What is polio?

Polio is a disease caused by a virus. It can get into a child's (or adult's) body, usually through the mouth. Sometimes it does not cause serious problems. But sometimes it causes paralysis (can't move arm or leg), and sometimes it kills its victims.

Polio used to be very common in the United States. It paralyzed and killed thousands of children a year before we had a vaccine for it.

### 2. Why get vaccinated?

Polio vaccine can prevent polio.

History: A 1916 polio epidemic in the United States killed 6,000 people and paralyzed 27,000 more. In the early 1950's there were more than 20,000

cases of polio each year. Polio vaccine was introduced in 1955. By 1960 the number of cases had dropped to about 3,000, and by 1979 there were only about 30. This change would not have been possible without polio vaccine.

Today: No wild polio has been reported in the United States for over 20 years. But the disease is still common in some parts of the world. It would only take one case of polio from another country to bring the disease back if we were not protected by vaccine. Until the disease is gone from the whole world, we should keep getting our children vaccinated.

Inactivated polio vaccine (IPV) is a shot, given in the leg or arm, depending on age.

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

#### Children

Most children should get 4 doses of IPV polio vaccine, at these ages:

- A dose at 2 months
- A dose at 4 months
- A dose at 6–18 months
- A booster dose at 4–6 years

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

#### Adults

Most adults do not need polio vaccine because they are already immune. But some adults should consider polio vaccination. These adults include:

- People traveling to areas of the world where polio is common,
- Laboratory workers who might handle polio virus,
- Health care workers in contact with patients who could have polio.

Adults in these groups who have never been vaccinated against polio should get 3 doses:

- ✓ The first dose at any time,
- ✓ The second dose 1 to 2 months later,
- ✓ The third dose 6 to 12 months after the second.

Adults in these groups who have had 1 or 2 doses of polio vaccine in the past should get the remaining 1 or 2 doses. It doesn't matter how long it has been since the earlier dose(s).

Adults in these groups who have received the complete series of polio vaccinations in the past may get a single dose of polio vaccine to make sure they are protected.

#### Oral Polio Vaccine: No longer recommended

Until recently a live, oral polio vaccine (OPV) (drops that are swallowed) was recommended for most children in the United States. It was this oral vaccine that helped us rid the country of polio, and it is still used in many parts of the world.

The oral vaccine is very good at preventing outbreaks of polio. But sometimes it actually caused polio (about once for every 2.4 million doses).

Since the risk of getting polio in the United States is now extremely low, experts decided that using oral vaccine is no longer worth the slight risk, except in very limited circumstances that can be described by your doctor. The polio shot (IPV) we now use can not cause polio.

If you or your child will be receiving oral polio vaccine (OPV), you should request a copy of the separate OPV vaccine information statement.

### 4. Some People Should Not Get Polio Vaccine or Should Wait

People should not get polio shots (IPV) if they have ever had a life-threatening allergic reaction to the drugs neomycin, streptomycin or polymyxin B. Anyone who has a severe allergic reaction to a polio shot should not get another one. These people can get the oral polio vaccine.

People who are moderately or severely ill at the time the shot is scheduled should usually wait until they recover before getting polio vaccine.

Ask your doctor or nurse for more information.

### 5. What are the risks from IPV polio vaccine?

Some people who get IPV polio vaccine get a sore spot where the shot was given. The type of IPV used today has never been known to cause any serious problems, and most people don't have any problems at all with it.

However, a vaccine, like any medicine could cause serious problems, such as a severe allergic reaction. The risk of a polio shot (IPV) causing serious harm, or death, is extremely small.

### 6. What if there is a serious reaction?

What should I look for?

Look for any unusual condition, such as a serious allergic reaction, high fever, or behavior changes. If a serious allergic reaction occurred, it would happen within a few minutes to a few hours after the shot. 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 file a Vaccine Adverse Event Reporting System (VAERS) form,

or call VAERS yourself at 1-800-822-7967.

### 7. The National Vaccine Injury Compensation Program

In the rare event that you or your child has a serious reaction to a vaccine, there is a federal program that can help pay for the care of those who have been harmed.

For details about the National Vaccine Injury Compensation Program, call 1-800-338-2382 or visit the program's website at <http://www.hrsa.gov/bhpr/vicp>.

### 8. How can I learn more?

- 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's immunization program.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call 1-800-232-2522 (English)
  - Call 1-800-232-0233 (Español)

—Visit the National Immunization  
Program's website at [http://  
www.cdc.gov/nip](http://www.cdc.gov/nip)

U.S. Department of Health & Human  
Services, Centers for Disease Control  
and Prevention, National  
Immunization Program.

Vaccine Information Statement, Polio—  
IPV (1/1/2000) (Proposed), 42 U.S.C.  
§ 300aa–26.

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**Joseph R. Carter,**

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