

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Revised Polio Vaccine Information Materials

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

**ACTION:** Notice.

**SUMMARY:** Under the National Childhood Vaccine Injury Act (42 U.S.C. 300aa-26), the CDC must develop vaccine information materials that health care providers are required to distribute to patients/parents prior to administration of specific vaccines. On August 16, 1996, CDC published a notice in the Federal Register (61 FR 42770) seeking public comment on proposed revision of the polio vaccine information materials to provide information regarding revised recommendations for use of inactivated poliovirus vaccine (IPV) and oral poliovirus vaccine (OPV). The 60 day comment period ended on October 15, 1996. Following review of the comments submitted and consultation as required under the law, CDC has finalized the revised polio vaccine information materials. Those final materials are contained in this notice.

**DATES:** Effective February 6, 1997. Beginning as soon as practicable, each health care provider who administers any polio vaccine shall, prior to administration of each dose of the vaccine, provide a copy of the vaccine information materials contained in this notice to the parent or legal representative of any child to whom such provider intends to administer the vaccine and to any adult to whom such provider intends to administer the vaccine.

**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, (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 health care providers 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.

The vaccines currently covered under this program are 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 vaccine information materials prior to administration of any of these vaccines. The materials currently in use were published in a Federal Register notice on June 20, 1994 (59 FR 31888). (Interim vaccine information materials pertaining to acellular pertussis vaccine combined with diphtheria and tetanus toxoids (DTaP) were published in the Federal Register on September 13, 1996 (61 FR 48596).)

Development and revision of the vaccine information materials have been delegated by the Secretary to the Centers for Disease Control and Prevention. 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 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.

#### Revised Polio Vaccine Information Materials

During the past two years, the Advisory Committee on Immunization Practices (ACIP) has been considering changing the recommended schedule for polio vaccination from four doses of oral poliovirus vaccine (OPV) to a sequential schedule of two doses of inactivated poliovirus vaccine (IPV), followed by two doses of OPV for routine childhood immunization. At its meeting in June 1996, the committee voted to approve this new sequential schedule as the preferred polio vaccination schedule, while considering schedules using either all IPV or all OPV as also acceptable and preferred for some children in certain situations. Following review of these recommendations, the Director of the Centers for Disease

Control and Prevention adopted the ACIP recommendations on September 18, 1996.

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.

Details regarding these recommendations can be found in "poliomyelitis Prevention in the United States: Introduction of a Sequential Vaccination Schedule of Inactivated Poliovirus Vaccine Followed by Oral Poliovirus Vaccine: Recommendations of the Advisory Committee on Immunization Practices (ACIP)," which was published in the Recommendations and Reports series of the Morbidity and Mortality weekly report on January 24, 1997 (MMWR 1997;46 (No. RR-3) :1-25).

Pending completion of the CDC Director's review and in order to assure timely availability of revised vaccine information materials should the Director adopt the ACIP recommendations, on August 16, 1996, CDC published a notice in the Federal Register (61 FR 42770) seeking public comment on proposed revised polio vaccine information materials.

The 60 day comment period ended on October 15, 1996. Comments were submitted by few individuals and organizations in response to the August 16, 1996 notice. As required by the statute, CDC has also consulted with various groups, including the Advisory Commission on Childhood Vaccines, Food and Drug Administration, American Academy of Family Practitioners, American Academy of Pediatrics, American College of Osteopathic Pediatricians, American Nurses Association, Association of Maternal and Child Health Programs,

Association of State and Territorial Health Officials, Council of State and Territorial Epidemiologists, Dissatisfied Parents Together, Immunization Education and Action Committee: Healthy Mothers/Healthy Babies Coalition, Interamerican College of Physicians and Surgeons, National Association of County Health Officials, National Association of Hispanic Nurses, National Black Nurses' Association, National Coalition of Hispanic Health and Human Services Organizations (COSSMHO), National Council of La Raza, National Medical Association, and Ohio Parents for Vaccine Safety. Comments from the consultants, along with the comments submitted in response to the Federal Register notice, were fully considered in revising the vaccine information materials.

Following consultation and review of comments submitted, revised polio vaccine information materials that comply with the provisions of the National Childhood Vaccine Injury Act have been finalized and are contained in this notice. They are entitled "Polio Vaccines: What You Need to Know."

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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, or polio vaccine shall, prior to administration of *each dose* of the vaccine, provide a copy of the relevant 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, in appropriate cases.

"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

Beginning as soon as practicable after February 6, 1997, health care providers shall distribute copies of the February 6, 1997 version of the polio vaccine information materials in place of the June 10, 1994 version of the polio materials.

##### Recordkeeping

Health care providers shall make a notation in each patient's permanent medical record at the time vaccine information materials are provided indicating the edition (date of publication) of the materials distributed and 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 available in English and in other languages.

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##### Polio Vaccines

###### *What You Need To Know*

#### 1. Why Get Vaccinated?

Polio is a disease. It can paralyze (make arms and legs unable to move) or even cause death.

Polio vaccine prevents polio. Before polio vaccine, thousands of our children got polio every year. Polio vaccine is helping to rid the whole of polio. When that happens, no one will ever get polio again, and we will not need polio vaccine.

#### 2. There Are 2 Kinds of Polio Vaccine

##### Inactivated Polio Vaccine

A shot

OPV

Oral Polio Vaccine

Drops by mouth

Both vaccines work well.

#### 3. Which Vaccines Should My Child Get and When?

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

- 2 months.
- 4 months.
- 12-18 months.
- 4-6 years.

You can choose to get any of these 3 acceptable schedules:

- 2 shots of IPV, then 2 doses of OPV drops.
- or
- 4 shots of IPV.
- or
- 4 doses of OPV drops (the 3rd dose can be given as early as 6 months of age).

The Centers for Disease Control and Prevention (CDC) recommends 2 shots of IPV, then 2 doses of OPV drops for most children because this has the advantage of both vaccines.

#### 4. What Are the Risks and Advantages of Each Choice?

Almost all children who complete any of the 3 schedules will be protected from polio.

As with any medicine, vaccines carry a small risk of serious harm, such as a severe allergic reaction (hives, difficulty breathing, shock) or even death.

On rare occasions, OPV can cause polio because it contains live, but weakened, virus. IPV cannot cause polio because it does not contain live virus.

Most people have no problems from either IPV or OPV.

#### 2 Shots/2 Drops (2 IPV, Then 2 OPV)

##### Risks and Advantages

For most children, the choice using both shots and drops gives the benefits of both vaccines:

- Less risk of getting polio than from all OPV.
- Only 2 shots.
- Protects the community from polio outbreaks better than all IPV.

#### All Shots (4 IPV)

##### Risks

- Mild soreness of arm or leg.

##### Other Disadvantages

- Not as good as OPV for protecting the community from polio outbreaks.

##### Advantages

- Does not cause polio.

## All Drops (4 OPV)

## Risks

- Causes about 8 cases of polio each year. (At least 15 million doses have been given each year in the U.S.) This can happen to children who get OPV or people who are in close contact with them. The risk of polio is higher with the first dose than with later doses.

## Advantages

- No shots.
- Can best protect the community from polio outbreaks.

## 5. Some Children Should Get Only Shots. And Some Should Get Only Drops

Do NOT use OPV drops, if your child, you, or anyone who takes care of your child

- Can't fight infections.
- Is taking long term steroids.
- Has cancer.
- Has AIDS or HIV infection.

Do NOT use OPV drops, if you or anyone who takes care of your child never had polio vaccine.

Do NOT use IPV shots, if your child is allergic to the drugs neomycin, streptomycin, or polymyxin B.

## 6. Some Children Should Not Get These Vaccines or Should Wait

Tell your doctor or nurse if your child:

- Ever had a serious reaction after getting polio vaccine.
- Now has a moderate or severe illness.

## 7. What If There Is a Serious Reaction?

What should I look for?

- See item 4, on the other side, for some possible risks.

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 Report (VAERS) form, or call VAERS yourself at: 1-800-822-7967.

## 8. The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program is a federal program that gives payment for serious vaccine injuries.

For details call 1-800-338-2382.

## 9. How Can I Learn More?

- Ask your doctor or nurse. She/he 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 1-800-232-7468 (English).

or

Call 1-800-232-0233 (Spanish).

or

Visit the CDC website at <http://www.cdc.gov/nip>.

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

Polio (2/6/97)

Vaccine Information Statement

42 U.S.C. 300aa-26

Dated: January 31, 1997.

Joseph R. Carter,

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