

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Disease Control and Prevention****Interim Polio Vaccine Information Materials**

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

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention has modified its recommendation for use of the two polio vaccines to discourage use of oral poliovirus vaccine (OPV) for the first two doses administered, except in limited circumstances. This revised recommendation necessitates a revision of the vaccine information statement entitled, "Polio Vaccines: What You Need to Know" (dated February 6, 1997), which was developed by the CDC as required by the National Childhood Vaccine Injury Act of 1986 (NCVIA). To ensure that up-to-date information is available regarding this revised recommendation, CDC is distributing the following interim polio vaccine information statement for use pending completion of the formal revision process mandated by the NCVIA.

DATES: Effective February 23, 1999. Beginning as soon as practicable, each health care provider who administers any polio vaccine, prior to administration of each dose of the vaccine, in lieu of providing the February 6, 1997 version of the polio vaccine information materials, should provide a copy of the interim polio vaccine information materials contained in this notice (which are dated February 1, 1999) 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, 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 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.

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 these covered vaccines is required to provide copies of the relevant vaccine information materials prior to administration of the vaccine. Effective June 1, 1999, health care providers will also be 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.

The materials currently in use for Td tetanus diphtheria vaccine were published in a **Federal Register** notice on June 20, 1994 (59 FR 31888). The current materials for diphtheria, tetanus, and pertussis containing vaccines, other than Td vaccine, were published in a **Federal Register** notice on January 9, 1998 (63 FR 1730). Elsewhere in this issue of the **Federal Register**, we have published vaccine information materials for the newly covered vaccines (i.e., hepatitis B, *Haemophilus influenzae* type b (Hib), and varicella (chickenpox) vaccines). In addition, that same notice contains revised vaccine information materials for measles, mumps and rubella vaccines.

The polio vaccine information materials currently in use were published in a **Federal Register** notice on February 6, 1997 (62 FR 5696). The materials contained in that notice included the CDC and Advisory Committee on Immunization Practices (ACIP) recommendations of that time recommending a sequential polio vaccination schedule of two doses of inactivated poliovirus vaccine (IPV), followed by two doses of oral poliovirus vaccine (OPV) as the preferred polio vaccination schedule for routine childhood immunization. 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 the February 6, 1997 **Federal Register** notice 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."

Further Revised Recommendations for Use of Polio Vaccines

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. Specifically, the ACIP approved the following statement:

"Two poliovirus vaccines are currently licensed in the United States: inactivated poliovirus vaccine (IPV) and oral poliovirus vaccine (OPV).

The ACIP, the American Academy of Pediatrics (AAP) and the American Academy of Family Practice (AAFP) now recommend that the first two doses of poliovirus vaccine should be IPV. The ACIP continues to recommend a sequential schedule of two doses of IPV administered at ages 2 and 4 months, followed by two doses of OPV at 12–18 months and 4–6 years. Use of IPV for all doses also is acceptable and is recommended for immunocompromised persons and their household contacts.

OPV is no longer recommended for the first two doses of the schedule and is acceptable only for special circumstances, such as: children of parents who do not accept the recommended number of injections, late initiation of immunization which would require an unacceptable number of injections, and imminent travel to polio-endemic areas.

OPV remains the vaccine of choice for mass immunization campaigns to control outbreaks due to wild poliovirus."

As noted above, this revised ACIP recommendation is in harmony with recently revised policy recommendations of the AAP and AAFP. The CDC has also adopted the ACIP revised polio vaccination recommendation.

At its October 22, 1998 meeting, the ACIP also expressed its intention to consider the timing for the transition to an all-IPV schedule.

Interim Polio Vaccine Information Materials

CDC intends to initiate formal revision of the polio vaccine information materials of February 6, 1997 in the near future when the potential for further revision of the recommended polio immunization schedule becomes more clear. Pending completion of the formal revision process and to ensure that up-to-date information is available in the interim to patients/parents regarding the current CDC recommended polio immunization schedule, CDC is publishing the following interim polio vaccine information materials, dated February 1, 1999.

The previously mentioned notice published elsewhere in this issue of the **Federal Register** that contains the vaccine information materials for newly covered vaccines includes instructions for use of all vaccine information materials, including these interim polio vaccine information materials. That

notice also includes a list of contact telephone numbers for obtaining copies of all of the vaccine information materials.

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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 can prevent polio. Before polio vaccine, thousands of our children got polio every year. Polio vaccine is helping to rid the world 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

IPV

Inactivated Polio Vaccine

A shot

Both vaccines work well.

OPV

Oral Polio Vaccine

Drops by mouth

3. Which Vaccine(s) Should My Child Get and When?

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

2 months—IPV

4 months—IPV

12–18 months—OPV or IPV (6–18 months when IPV is used)

4–6 years—OPV or IPV

The Centers for Disease Control and Prevention (CDC) recommends IPV for the 1st and 2nd doses, and OPV drops for the 3rd and 4th doses, because this gives the advantages of both vaccines.

Getting OPV drops for the first two doses is not recommended for most people because of higher risks from OPV for those doses, but is acceptable in very limited situations—for instance, when traveling in certain countries or when the parent is willing to accept the risks from OPV to reduce the number of injections the child gets. See risks in item 4 below.

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

4. What Are the Risks and Advantages of Each Vaccine?

Almost all children who get a total of 4 doses of polio vaccine 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.

Most people have no problems from either IPV or OPV.

IPV

Risks

- Mild soreness where the shot is given.

Other Disadvantages

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

Advantages

- Cannot cause polio.
- Safer for immunizing people with immune system problems and people in close contact with them.

OPV

Risks

- OPV has caused several cases of polio each year (about 1 case for every 2.4 million doses of vaccine). 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.
- Protects the community from polio outbreaks better than all IPV.
- Better for people traveling to areas where polio is common.

The CDC-recommended vaccination schedule greatly reduces the risk of children getting polio from the oral vaccine (OPV) by using IPV for the 1st and 2nd doses. Getting 2 shots of IPV first should protect most people from getting polio from the later doses of OPV. By using OPV for the 3rd and 4th doses it also helps to protect the community from polio outbreaks. And, it requires only 2 shots.

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 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 Reporting System (VAERS) form, or call VAERS yourself at 1-800-822-7967.

8. The National Vaccine Injury Compensation Program

In the rare event that you or your child has a serious reaction to a vaccine, a federal program has been created to help you 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.dhhs.gov/bhpr/vicp>.

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'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>

U.S. Department of Health & Human Services

Centers for Disease Control and Prevention

National Immunization Program

Polio (2/1/99) (Interim) Vaccine Information Statement 42 U.S.C. 300aa-26

Dated: February 17, 1999.

Jeffrey P. Koplan,

Director, Centers for Disease Control and Prevention (CDC).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

New Vaccine Information Materials for Hepatitis B, Haemophilus influenzae type b (Hib), and Varicella (Chickenpox) Vaccines, and Revised Vaccine Information Materials for Measles, Mumps, Rubella (MMR) Vaccines

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 all health care providers, whether public or private, are required to distribute to patients/parents prior to administration of each dose of specific vaccines. On September 3, 1998, CDC published a notice in the **Federal Register** (63 FR 47026) seeking public comment on proposed vaccine information materials for the newly covered vaccines hepatitis B, Haemophilus influenzae type b, and varicella vaccines, and also seeking comment on proposed revised vaccine information materials for measles, mumps, rubella (MMR) vaccines. The 60 day comment period ended on November 2, 1998. Following review of the comments submitted and consultation as required under the law, CDC has finalized these vaccine information materials. The final materials are contained in this notice.

DATES: Effective June 1, 1999, each health care provider who administers any vaccine that contains hepatitis B, Haemophilus influenzae type b (Hib), varicella (chickenpox), measles, mumps, or rubella vaccines shall, prior to administration of each dose of the vaccine, provide a copy of the relevant 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.

See Instructions for Use of Vaccine Information Materials (Vaccine Information Statements), in the Supplementary Information section of this notice, for information on required use of previously available vaccine information materials.

FOR FURTHER INFORMATION CONTACT: Walter A. Orenstein, M.D., Director, National Immunization Program,

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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:

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The materials currently in use for measles, mumps, and rubella vaccines and the Td tetanus diphtheria vaccine were published in a **Federal Register** notice on June 20, 1994 (59 FR 31888). The current materials for diphtheria, tetanus, and pertussis containing vaccines, other than Td vaccine, were published in a **Federal Register** notice on January 9, 1998 (63 FR 1730). Elsewhere in this issue of the **Federal Register**, we are publishing revised interim polio vaccine information