

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Proposed Revision—Vaccine Information Materials

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

**ACTION:** Notice with comment period.

**SUMMARY:** Under section 2126 of the Public Health Service Act, the CDC must develop vaccine information materials which health care providers are required to provide to patients/parents prior to administration of specific vaccines. CDC proposes to revise the vaccine information materials pertaining to polio vaccine for distribution should the recommended schedule for use of particular polio vaccines be revised. CDC seeks written comment on these proposed materials. **DATES:** Written comments are invited and must be received on or before October 15, 1996.

**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, (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 guardian 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).

Development and revision of the vaccine information materials has 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.

#### Proposed Revisions to the 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 polio vaccine (OPV) to a sequential schedule of two doses of inactivated polio 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 fully acceptable and preferred for some children in certain situations. Adoption of this ACIP recommendation is under consideration by the Director of the Centers for Disease Control and Prevention.

Should the Director of the CDC adopt this recommendation, revised polio vaccine information materials will need to be available to provide information on the new recommendation for a sequential schedule on all OPV and IPV schedules prior to any implementation date. Therefore, given the statutory time frame for revising the materials, CDC is initiating revision of the polio vaccine information materials by publishing this notice that seeks comment on proposed materials for all three schedules. This notice will be withdrawn or modified if the Director rejects or modifies the polio vaccination recommendation of the ACIP.

We invite written comment on the proposed polio vaccine information statement included in this notice, entitled "Polio Vaccine: What You Need to Know Before You or Your Child Gets Either Oral or Inactivated Polio Vaccine." CDC also intends to consult with the Advisory Commission on Childhood Vaccines, health care provider and parent organizations, and the Food and Drug Administration, as mandated under section 2126, prior to finalizing these materials.

#### POLIO VACCINE

What you need to know before you or your child gets either oral or inactivated polio vaccine.

##### About the Disease

Polio is a serious disease. It spreads when germs pass from an infected person to the mouths of others. Polio can:

- Paralyze a person (make arms and legs unable to move)
- Cause death

##### About the Vaccines

##### *Benefits of the Vaccines*

Vaccination is the best way to protect against polio. Before we had polio vaccines, there were thousands of cases of polio in the United States. Now most children get the vaccines, and there are very few cases.

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

IPV, or Inactivated Polio Vaccine, is given as a shot in the leg or arm.

OPV, or Oral Polio Vaccine, is given by mouth as drops.

##### *Polio Vaccine Schedule*

Most children should have a total of 4 doses of polio vaccine. The recommended schedule uses both IPV and OPV:

2 months of age—IPV  
4 months of age—IPV  
12-18 months of age—OPV  
4-6 years of age—OPV

##### *Why This Schedule?*

IPV by itself protects against polio, but an all-IPV schedule means getting 4 shots. IPV has no known problems, except mild soreness where the shot was given, but IPV only protects the child who gets the shot. It does not help stop the spread of polio germs from one person to another.

OPV by itself protects against polio and helps stop the spread of polio germs from one person to another. But OPV, very rarely, causes polio in the child who receives it or in a person in close contact with the child who receives it.

With the recommended schedule, using IPV first followed by OPV, your

child gets the benefits of both vaccines: Excellent protection against polio, fewer shots, protection from epidemics, and less risk of polio from OPV. Also, the IPV shots are thought to protect the person getting the vaccine from getting polio from later vaccinations with OPV.

If you prefer, your child may get only OPV or only IPV. Either of these vaccines alone will protect your child against polio. Ask your doctor or nurse about these options.

Other vaccines may be given at the same time as polio vaccine.

#### *Who Should Get Polio Vaccine?*

Most doctors recommend that almost all young children get polio vaccine. But some children should get only one type of polio vaccine, and some should not get any polio vaccine at all:

✓ Tell your doctor or nurse if the person getting the vaccine or anyone in close contact with that person can't fight serious infections because of:

- A disease she/he was born with.
- Treatment with drugs such as long-term steroids.
- Any kind of cancer.
- Cancer treatment with x-rays or drugs.

If so, your doctor or nurse will probably give all IPV doses.

✓ Tell your doctor or nurse if the person getting the vaccine has an allergy to the drugs neomycin or streptomycin. If so, your doctor or nurse will probably give all OPV doses.

✓ Tell your doctor or nurse if the person getting the vaccine:

- Ever had a serious allergic reaction or other problem after getting polio vaccine.

- Has a moderate or severe illness

If you are not sure whether any of these statements apply to you, ask your doctor or nurse.

If you are over 18 years old, you probably do not need polio vaccine unless you are likely to be exposed to polio virus while traveling to countries where polio still occurs.

#### *Travel*

If you are traveling to a country where there is polio, you should get either IPV or OPV. Ask your doctor or nurse which vaccine you should get.

#### *Pregnancy*

If protection is needed during pregnancy, either IPV or OPV can be used.

#### *Child Getting OPV (Unvaccinated Parents or Guardians)*

If you have never gotten polio vaccine and your child is getting vaccinated with OPV, it is important to talk to your doctor or nurse about getting IPV for yourself. There is a very slight chance that a person who has close contact with a person who has received OPV could get polio if that person was never vaccinated against polio. IPV will provide protection against this risk.

#### *What Are the Risks From Polio Vaccine?*

As with any medicine, there is a very small risk that a person getting polio vaccine could have a serious problem, or even die. This risk is much smaller than the risks from the disease would be if people stopped using polio vaccine.

Almost all people who get polio vaccine have no problems from it.

#### *Risks: All-IPV Schedule*

This vaccine is not known to cause problems except mild soreness where the shot is given.

#### *Risks: All-OPV Schedule*

There is a very small chance of getting polio paralysis from the vaccine.

- After the first dose of OPV: About 1 case occurs for every 1½ million doses.

- After later doses of OPV: About 1 case occurs for every 30 million doses.

Also, if you never got polio vaccine yourself, there is a very small chance of getting polio paralysis from having close contact with a child who got OPV in the past 30 days.

- After the first dose of OPV, about 1 case occurs for every 2 million doses.

- After later doses of OPV, about 1 case occurs for every 15 million doses. Examples of close contact include changing diapers or kissing.

#### *Risks: IPV-OPV Schedule*

There is still a very small risk of getting polio disease from OPV after 2 doses of IPV. But the risk is much lower than when OPV alone is given.

There is still a risk of getting polio disease from close contact with a child who got OPV. It may be less when the child gets one or more doses of IPV before a dose of OPV.

What to do if there is a serious reaction:

- ☞ Call a doctor or get the person to a doctor right away.
- ☞ Write down what happened and the date and time it happened, and tell your doctor.
- ☞ Ask your doctor, nurse, or health department to file a Vaccine Adverse Event Report (VAERS) form, or you can call: (800) 822-7967 (toll-free).

The National Vaccine Injury Compensation Program gives payment to persons thought to be injured by vaccines. For details call: (800) 338-2382 (toll-free).

If you want to learn more about polio vaccines, your doctor or nurse can give you the vaccine package inserts or suggest other sources of information.

#### *U.S. Department of Health and Human Services*

#### *Centers for Disease Control and Prevention*

Polio 00/00/00 (Proposed)

Vaccine Information Statement

42 U.S.C. 300aa-26

Dated: August 8, 1996.

Claire V. Broome,

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

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