

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Proposed Vaccine Information Materials for Use With Oral Poliovirus Vaccine (OPV)

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

ACTION: Notice with comment period.

SUMMARY: On September 2, 1999, the Centers for Disease Control and Prevention (CDC) published a **Federal Register** notice seeking comment on proposed revised vaccine information materials for use effective January 1, 2000, when the routine polio immunization schedule changes to an all inactivated poliovirus vaccine (IPV) schedule. With this notice, CDC seeks written comment on proposed supplemental vaccine information materials for use in those limited circumstances where oral poliovirus vaccine (OPV) will still be acceptable.

DATES: Written comments are invited and must be received on or before November 29, 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: Under the National Childhood Vaccine Injury Act of 1986 (42 U.S.C. 300aa-26), the Centers for Disease Control and Prevention (CDC) develops and revises vaccine information materials for those vaccines covered under the National Vaccine Injury Compensation Program. As provided under that law, all health care providers in the United States, whether public or private, must distribute copies of these materials to any patient (or to the parent or legal representative in the case of a minor) prior to administering any of the covered vaccines.

On September 2, 1999, CDC published a **Federal Register** notice (64 FR 48238) seeking comment on proposed revised vaccine information materials for use effective January 1, 2000, when the routine polio immunization schedule

changes to an all inactivated poliovirus vaccine (IPV) schedule. (See the September 2 notice for a description of the statutory requirements for development and use of the vaccine information materials. Also, see that notice for an explanation of the revisions in the CDC-recommended schedule for use of polio vaccines.)

As listed in the September 2 **Federal Register** notice, as of January 1, 2000, use of OPV will only be acceptable in 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 OPV vaccine-associated poliomyelitis.); and

(4) OPV may be administered when the vaccinee has had a life-threatening allergic reaction to any component of IPV.

With this notice, CDC seeks written comment on proposed supplemental vaccine information materials for use in these limited circumstances where oral poliovirus vaccine (OPV) will still be acceptable.

Proposed Supplemental Polio Vaccine Information Materials—OPV

We invite written comment on the proposed supplemental vaccine information materials that follow, entitled "Oral Polio Vaccine: What You Need to Know." Comments submitted will be considered in finalizing these supplemental materials. As required under the National Childhood Vaccine Injury Act, prior to finalizing these materials CDC also will consult with the Advisory Commission on Childhood Vaccines, appropriate health care provider and parent organizations, and the Food and Drug Administration.

Oral Polio Vaccine: 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 each 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.

3. Two Types of Polio Vaccine

There are two types of polio vaccine: IPV (Inactivated Polio Vaccine): A shot.

IPV is recommended for almost all people. It works very well to protect people from paralytic polio.

OPV (Oral Polio Vaccine): Drops, by mouth.

OPV works very well, especially in preventing polio outbreaks. It is due to OPV that there is no polio in the United States today. But it can also actually cause polio. This is rare, but with the risk of polio extremely low in the U.S., OPV is no longer recommended except in special situations.

This statement is about Oral Polio Vaccine. You can also request a copy of the Vaccine Information Statement that describes the routine all-IPV schedule.

4. Who Should Use Oral Polio Vaccine (OPV) and When?

OPV is no longer recommended for routine use in the United States. It may be used only in certain limited circumstances:

(1) Mass immunization campaigns to control polio outbreaks;

(2) Unimmunized people who plan to travel within 4 weeks to countries where polio is common. These people may get OPV for the first dose;

(3) Children whose parents want them to get fewer injections. These children should get IPV for the first two doses of the polio vaccine series, but may get OPV for the 3rd or 4th dose, or both;

(4) People with a life-threatening allergy to a component of IPV. These people may get OPV instead.

If you, or your child, are one of the few people who should get OPV, your doctor or nurse will tell you when the

vaccine should be given. Speak to your doctor or nurse about the risks of vaccine-associated polio before getting OPV.

OPV may be given at the same time as other vaccines.

5. *Some People Should Not Get Oral Polio Vaccine (OPV) or Should Wait*

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.

Anyone who has had a severe allergic reaction to a dose of OPV should not get another dose.

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

6. *What Are the Risks From Oral Polio Vaccine (OPV)?*

OPV can, in rare circumstances, actually cause polio. This is why it is not recommended for routine use any more. It caused several cases of polio each year (about 1 case for every 2.4 million doses of vaccine) during the years it was used. The oral vaccine can cause polio in children who get OPV or in people who are in close contact with

them. The risk of polio is higher with the first dose than with later doses.

7. *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, behavior changes, or signs of paralysis.

If a serious allergic reaction occurred, it would happen within a few minutes to a few hours after the vaccination. Signs of a serious allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

If paralysis were to occur, symptoms might include severe muscle aches and spasms, or loss of movement in an arm or leg. This could happen from about a week to about a month after the vaccination.

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,

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>.

9. *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>

U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Immunization Program Vaccine Information Statement, Polio—OPV Supplement (1/1/2000) (Proposed), 42 U.S.C. 300aa-26

Dated: September 23, 1999.

Thena M. Durham,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

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