

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Instructions for Use of Vaccine Information Materials (Vaccine Information Statements); Revised Polio Vaccine Information Materials

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

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 2, 1999, CDC published a notice in the **Federal Register** (64 FR 48238) seeking public comments on proposed revised vaccine information materials for polio vaccines. The polio materials are being revised so that they will conform with the CDC's revised recommendations for use of polio vaccines in the United States effective January 1, 2000, when the recommendation will be to use only inactivated poliovirus vaccine (IPV), except in very limited circumstances. The September 2 notice also sought public comments on proposed instructions for use of vaccine information materials. On September 29, 1999, CDC published an additional notice (64 FR 52596) seeking public comments on supplemental vaccine information materials for use when oral poliovirus vaccine (OPV) is proposed to be administered instead of inactivated poliovirus vaccine (IPV). The 60-day comment periods for the two notices ended on November 1, 1999 and November 29, 1999, respectively. Following review of the comments submitted and consultation as required under the law, CDC has finalized these vaccine information materials and instructions for use of vaccine information materials. The final materials and instructions are contained in this notice.

DATES: In order to conform with the revised CDC recommendations for use of polio vaccines effective January 1, 2000, the Instructions for Use of Vaccine Information Materials (Vaccine Information Statements) and revised polio vaccine information materials contained in this notice are effective January 1, 2000.

FOR FURTHER INFORMATION CONTACT:

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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, 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 in 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 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 (VAPP) 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** at 64 FR 9040, February 23, 1999.)

And then, 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.

Therefore, the vaccine information materials covering polio vaccines must be revised to conform with CDC's revised recommendations for use of polio vaccines in the United States effective January 1, 2000.

Development of Revised Polio Vaccine Information Materials and Instructions for Use of Vaccine Information Materials

The CDC has revised the vaccine information materials covering polio vaccines in accordance with the procedures mandated under 42 U.S.C. 300aa–26. On September 2, 1999, CDC published a notice in the **Federal Register** (64 FR 48238) seeking public comments on proposed revised vaccine information materials for use when administering polio vaccines. The September 2 notice also sought public comments on proposed instructions for use of vaccine information materials. On September 29, 1999, CDC published an additional notice (64 FR 52596) seeking

public comments on supplemental vaccine information materials for use when oral poliovirus vaccine (OPV) is proposed to be administered instead of inactivated poliovirus vaccine (IPV). The 60-day comment periods for the two notices ended on November 1, 1999 and November 29, 1999, respectively. Few comments were received on the proposed revised polio vaccine information materials. No comments were received on the proposed instructions for use of vaccine information materials.

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 Pediatrics, American Medical Association, American Pharmaceutical Association, Every Child by Two, Immunization Action Coalition, Infectious Disease Society of America, Informed Parents against VAPP, National Association of Pediatric Nurse Associates and Practitioners, National Coalition for Adult Immunization, National Coalition of Hispanic Health and Human Services Organizations (COSSMHO), National Vaccine Advisory Committee, and the National Vaccine Injury Compensation Program. Also, CDC provided copies of the draft materials to other organizations and sought their consultation; however, those organizations did not provide comments. Comments provided by the consultants, along with the comments submitted in response to the September 2 and 29 **Federal Register** notices, were fully considered in revising the polio vaccine information materials.

Following consultation and review of comments submitted, the revised polio vaccine information materials, including OPV supplemental materials, have been finalized and are contained in this notice. They are entitled "Polio Vaccine: What You Need to Know" and "Oral Polio Vaccine: What You Need to Know."

In addition, the "Instructions for Use of Vaccine Information Materials (Vaccine Information Statements)" have been finalized and are contained in this notice. The instructions are identical to those proposed in the September 2 **Federal Register** notice, except that the final instructions have been revised (1) to note the initial date use of each vaccine's materials was required, (2) to clarify that patients/parents must be given copies of the materials to keep, and (3) to clarify use of the polio and supplemental OPV vaccine information materials. The 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, specify recordkeeping requirements, and include other related information.

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 to keep 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, a health care provider prior to administering any polio vaccine (whether inactivated poliovirus vaccine (IPV) or oral poliovirus vaccine (OPV)) shall give the patient (or in the case of a child, the parent or legal representative) a copy of the vaccine information materials dated January 1, 2000, titled "Polio Vaccine: What You Need to Know" in place of the February 1, 1999 and February 6, 1997 versions of the polio materials. In addition, if the health care provider intends to administer OPV, such person shall also be given a copy of the OPV supplemental vaccine information materials dated January 1, 2000, titled

* Effective 4/15/92.

† Effective 6/1/99.

“Oral Polio Vaccine: What You Need to Know.”

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.
December 17, 1999

42 U.S.C. 300aa-26

List of Contact Telephone Numbers for Copies of Vaccine Information Materials

Single camera-ready copies of the vaccine information materials, and copies of the instructions for their use, are available by calling the telephone number listed below for your location:
Alabama—(334) 206-5023

Alaska—(907) 269-8000
American Samoa—011-684-633-4606
Arizona—(602) 230-5855
Arkansas—(501) 661-2962
California—(510) 540-2065
Los Angeles—(213) 580-9800
Colorado—(303) 692-2669
Connecticut—(860) 509-7929
Delaware—(302) 739-4746
Florida—(850) 245-4342
Georgia—(404) 657-3158
Guam—011-671-735-7143
Hawaii—(808) 586-8330
Idaho—(208) 334-5931
Illinois—(217) 785-1455
Chicago—(312) 746-6050
Indian Health Service—(505) 248-4226
Indiana—(317) 233-7704
Iowa—(515) 281-4917
Kansas—(785) 296-5591
Kentucky—(502) 564-4478
Louisiana—(504) 483-1900
Maine—(207) 287-3746
Mariana Islands—011-670-234-8950, ext. 2001
Marshall Islands—011-692-625-3480
Maryland—(410) 767-6030
Massachusetts—(617) 983-6800
Michigan—(517) 335-8159
Detroit—(313) 876-4606
Micronesia—011-691-320-2619
Minnesota—(612) 676-5100
Mississippi—(601) 576-7751
Missouri—(573) 751-6133
Montana—(406) 444-0065
Nebraska—(402) 471-6423
Nevada—(775) 684-5900
New Hampshire—(603) 271-4482
New Jersey—(609) 588-7512
New Mexico—(505) 827-2369
New York State—(518) 473-4437
New York City—(212) 676-2293
North Carolina—(919) 733-7752
North Dakota—(701) 328-2378
Ohio—(614) 466-4643
Oklahoma—(405) 271-4073
Oregon—(503) 731-4020
Palau—011-160-680-1757
Pennsylvania—(717) 787-5681
Philadelphia—(215) 685-6749
Puerto Rico—(787) 274-5612
Rhode Island—(401) 222-4603
South Carolina—(803) 898-0460
South Dakota—(605) 773-3737
Tennessee—(615) 741-7343
Texas—(512) 458-7284
Houston—(713) 794-9267
San Antonio—(210) 207-8794
Utah—(801) 538-9450
Vermont—(802) 863-7638
Virgin Islands—(340) 776-8311, ext. 2151
Virginia—(804) 786-6246 or 6247
Washington, D.C.—(202) 576-7130
Washington—(360) 664-8688
West Virginia—(304) 558-2188
Wisconsin—(608) 266-2346
Wyoming—(307) 777-6001
Copies of the vaccine information materials and instructions for their use

also can be downloaded from the CDC website at: <http://www.cdc.gov/nip/publications/VIS/>.

Polio Vaccine: What You Need to Know

1. What Is Polio?

Polio is a disease caused by a virus. It enters a child's (or adult's) body through the mouth. Sometimes it does not cause serious illness. But sometimes it causes paralysis (can't move arm or leg). It can kill people who get it, usually by paralyzing the muscles that help them breathe. Polio used to be very common in the United States. It paralyzed and killed thousands of people a year before we had a vaccine for it.

2. Why Get Vaccinated?

Inactivated Polio Vaccine (IPV) 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 vaccination was begun in 1955. By 1960, the number of cases had dropped to about 3,000, and by 1979 there were only about 10. The success of polio vaccination in the U.S. and other countries sparked a world-wide effort to eliminate polio.

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. If the effort to eliminate the disease from the world is successful, some day we won't need polio vaccine.

Until then, we need to keep getting our children vaccinated.

Oral Polio Vaccine: No Longer Recommended

There are two kinds of polio vaccine: IPV, which is the shot recommended in the United States today, and a live, oral polio vaccine (OPV), which is drops that are swallowed.

Until recently OPV was recommended for most children in the United States. OPV helped us rid the country of polio, and it is still used in many parts of the world.

Both vaccines give immunity to polio, but OPV is better at keeping the disease from spreading to other people. However, for a few people (about one in 2.4 million), OPV actually causes polio. Since the risk of getting polio in the United States is now extremely low, experts believe that using oral polio

vaccine is no longer worth the slight risk, except in limited circumstances which your doctor can describe. The polio shot (IPV) does not cause polio.

If you or your child will be getting OPV, ask for a copy of the OPV supplemental Vaccine Information Statement.

3. Who Should Get Polio Vaccine and When?

IPV is a shot, given in the leg or arm, depending on age. Polio vaccine may be given at the same time as other vaccines.

Children

Most people should get polio vaccine when they are children. Children get 4 doses of IPV, 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

Adults

Most adults do not need polio vaccine because they were already vaccinated as children. But three groups of adults are at higher risk and should consider polio vaccination: (1) People traveling to areas of the world where polio is common, (2) laboratory workers who might handle polio virus, and (3) health care workers treating patients who could have polio.

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

- ✓ 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 three 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 three groups who have had 3 or more doses of polio vaccine (either IPV or OPV) in the past may get a booster dose of IPV. Ask your health care provider for more information.

4. Some People Should Not Get IPV or Should Wait

These people should not get IPV:

- Anyone who has ever had a life-threatening allergic reaction to the drugs neomycin, streptomycin or polymyxin B should not get the polio shot.
- Anyone who has a severe allergic reaction to a polio shot should not get another one.

These people should wait:

- Anyone who is moderately or severely ill at the time the shot is scheduled should usually wait until they recover before getting polio vaccine. People with minor illnesses, such as a cold, may be vaccinated.

Ask your health care provider for more information.

5. What Are the Risks From IPV?

Some people who get IPV get a sore spot where the shot was given. The vaccine 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 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 unusual behavior.

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, weakness, hoarseness or wheezing, a fast heart beat, hives, dizziness, paleness, or swelling of the throat.

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 the VAERS toll-free number yourself at 1-800-822-7967. Reporting reactions helps experts learn about possible problems with vaccines.

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 (Espanol)
—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, Vaccine Information Statement, Polio (1/1/2000),

42 U.S.C. 300aa-26

Oral Polio Vaccine: What You Need To Know

1. What Is Polio?

Polio is a disease caused by a virus. It enters a child's (or adult's) body through the mouth. Sometimes it does not cause serious illness. But sometimes it causes paralysis (can't move arm or leg). It can kill people who get it, usually by paralyzing the muscles that help them breathe.

Polio used to be very common in the United States. It paralyzed and killed thousands of people 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 vaccination was begun in 1955. By 1960 the number of cases had dropped to about 3,000, and by 1979 there were only about 10. The success of polio vaccination in the U.S. and other countries sparked a world-wide effort to eliminate polio.

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. If the effort to eliminate the disease from the world is successful, some day we won't need polio vaccine.

Until then, we need to 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 the recommended polio vaccine for almost everyone in the United States.

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

Until recently, OPV was recommended for most children in the United States. But it is no longer recommended, except in limited circumstances. OPV helped us rid the country of polio, and it is still used in many parts of the world.

Both vaccines give immunity to polio, but OPV is better at keeping the disease

from spreading to other people. However, for a few people (about one in 2.4 million), OPV actually causes polio. Since the risk of getting polio in this country is now extremely low, experts believe that using oral vaccine is no longer worth the slight risk. The polio shot we now use (IPV) does not cause polio.

This Vaccine Information Statement supplement is about Oral Polio Vaccine (OPV). Your health care provider should also give you the Vaccine Information Statement for inactivated polio vaccine (IPV).

4. Who Should Get OPV and When?

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

- (1) Mass immunization campaigns to control polio outbreaks;
- (2) Children who have never gotten any polio vaccine who plan to travel within 4 weeks to countries where polio is common. These children may get OPV for the first dose;
- (3) Children whose parents do not accept the recommended number of 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 the antibiotics neomycin, streptomycin, or polymyxin B, or people who have had a life-threatening allergic reaction to a dose of IPV. These people may get OPV instead.

If you or your child is in one of these 4 groups, ask your health care provider when the vaccine should be given. Also, ask 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 OPV or Should Wait

These people should not get OPV:

- Anyone who is taking long-term steroids or any other drug that affects the immune system.
- Anyone who has cancer or is getting chemotherapy.
- Anyone who has AIDS or HIV infection, or another disease that affects the immune system.

- If anyone in these three groups will be changing a child's diapers or be in close contact with a child getting polio vaccine, that child should not get OPV.

- A baby should not get OPV if someone who will be in close contact with the baby (for instance changing diapers) has never had any kind of polio vaccine.

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

These people should wait:

- Anyone who is moderately or severely ill at the time the immunization is scheduled should usually wait until they recover before getting OPV. People with minor illnesses, such as a cold, may be immunized.

Ask your health care provider for more information.

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

OPV can, rarely, actually cause polio. This is why it is no longer recommended for most people. 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. OPV can cause polio in people who get the vaccine or in people who are in close contact with them. Today, with polio under control in the U.S., experts believe IPV can protect children and adults just as well, without the risk.

A vaccine, like any medicine, could cause other serious problems, such as a severe allergic reaction. The risk of OPV causing serious harm, or death, is extremely small.

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, unusual behavior, or signs of weakness or paralysis.

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, weakness, hoarseness or wheezing, a fast heart beat, hives, dizziness, paleness, or swelling of the throat.

If paralysis were to occur, it could happen from about a week to about a

month after the vaccination. Symptoms might include:

- Severe muscle aches and spasms
- Weakness
- Loss of movement in an arm or leg

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 the VAERS toll-free number yourself at 1-800-822-7967. Reporting reactions helps experts learn about possible problems with vaccines.

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>.

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U.S. Department of Health & Human Services, Centers for Disease Control and Prevention, National Immunization Program, Vaccine Information Statement, Polio—OPV Supplement (1/1/2000),

42 U.S.C. 300aa-26.

Jeffrey P. Koplan,

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

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