

Poliovirus Vaccine Options

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► See related patient information handout on *poliomyelitis* (<https://www.aafp.org/aafp/1999/0101/p125.html>), adapted from CDC materials.

As a result of the success of immunization, indigenous wild poliomyelitis has disappeared from the United States. Of 142 confirmed cases of paralytic poliomyelitis reported in the United States from 1980 to 1996, 134 were classified as vaccine-associated paralytic poliomyelitis (VAPP). Persons with VAPP have a disabling illness, and this has caught the attention of the lay media. The risk of VAPP is one case per 750,000 doses distributed for the first dose of oral poliovirus vaccine (OPV) and one case per 2.4 million doses of OPV distributed overall. Because of this risk, most parents prefer a vaccine schedule that starts with inactivated poliovirus vaccine (IPV), even though extra injections are required. IPV does not cause VAPP. New studies show that high immunization rates can be achieved in disadvantaged populations with a schedule starting with IPV. The American Academy of Family Physicians now recommends that the first two doses of poliovirus vaccine should be IPV; that is, either an all-IPV schedule or a sequential schedule of two doses of IPV followed by two doses of OPV. OPV is no longer recommended for the first two doses and is acceptable only under special circumstances, such as when parents do not accept the recommended number of injections.

Dramatic progress has been made in the prevention of poliomyelitis; in 1994, North and South America were declared free of indigenous poliomyelitis (the last such case occurred in Peru in 1991).^{1,2} There have been no cases of wild poliomyelitis contracted indigenously in the United States since 1979. Furthermore, by 1996, most infants (81 percent worldwide) had received three doses of poliovirus vaccine.²

Polioviruses are highly contagious and although most infections are subclinical, paralysis can occur. Poliovirus, an enterovirus, occurs in three serotypes. Transmission of the infection to susceptible household contacts occurs in 73 to 96 percent of cases, depending on the person's age. The virus spreads primarily by the fecal-oral route, although oral-oral transmission is also possible. Entering the body through the mouth, the virus multiplies in the pharynx and gastrointestinal tract before invading the blood stream and, potentially, the central nervous system. The incubation period ranges from three to 35 days.³

Poliovirus infection manifests as (in decreasing order of frequency): subclinical infection (in up to 95 percent of cases); non-specific viral illnesses with complete recovery (about 5 percent of cases); nonparalytic aseptic meningitis (1 to 2 percent of cases); and paralytic poliomyelitis (less than 2 percent of cases).³ The ratio of subclinical to paralytic illness is about 200:1, ranging from 50:1 to 1,000:1; that is, for every person with paralytic illness, about 200 people have subclinical illness.³ The case-fatality rate for paralytic poliomyelitis ranges from 2 to 5 percent in children and from 15 to 30 percent in adults; in other words, 15 to 30 percent of adults who acquire paralytic poliomyelitis die from it.³

Indigenously acquired poliomyelitis last occurred in the United States in 1979. From 1980 to 1996, 142 confirmed cases of paralytic poliomyelitis were reported, for an average of eight cases per year.³ Of these, six cases were imported from outside the United States; the last known importation of poliomyelitis infecting a U.S. citizen occurred in 1986. Two cases were classified as indeterminant in origin, and the remaining 134 cases were classified as vaccine-associated, either through administration of oral poliovirus vaccine (OPV) or through contact with a person who had received this form of vaccine.³ One child came to the United States from Nigeria in 1993 for treatment of paralytic poliomyelitis acquired in Nigeria.⁴ Widespread circulation of indigenous wild polioviruses has not occurred in the United States since the 1960s.⁴ Thus, the risk for exposure to wild poliovirus in the United States is now minimal. It should be noted, however, that wild poliovirus was isolated from stool samples in Canada in 1993 and again in 1996; however, no cases of paralytic poliomyelitis occurred there.^{4,5} The 1993 strain of poliomyelitis infected a group of persons that objected to vaccination and was found to have epidemiologic and genetic links to a 1992 poliomyelitis outbreak in the Netherlands.^{4,5}

Vaccines

Two vaccines are currently available in the United States for the prevention of poliomyelitis: inactivated poliovirus vaccine (IPV) and OPV.

IPV

IPV, also known as the Salk vaccine, was licensed in 1955, and an enhanced-potency IPV (e-IPV) formulation became available in 1988; e-IPV is used in the United States today. IPV is inactivated and cannot cause poliomyelitis and thus is safe for use in immunocompromised persons and their contacts (*Table 1*).⁴ The disadvantages of IPV include administration by injection only, less gastrointestinal immunity and unknown duration of immunity in populations without indigenous poliomyelitis or OPV use (the duration of immunity from IPV is thought to be long). One result of reduced gastrointestinal immunity is the possibility of infection of the gastrointestinal tract with wild poliovirus; the person receiving the IPV vaccine would be protected from paralytic poliomyelitis but could transmit wild poliovirus to other persons. This happened in Finland in 1984: scattered cases of paralytic poliomyelitis related to wild serotype 3 poliovirus occurred after almost two decades of freedom from the disease.⁶ The IPV vaccine that was being administered in Finland at the time appeared to be inferior to that of other manufacturers in conferring immunity for serotype 3 poliovirus.⁷ All-IPV schedules have been used successfully in other countries.

TABLE 1
Options for Poliovirus Vaccination: Advantages and Disadvantages

FACTOR	OPV	IPV	IPV/OPV
Occurrence of VAPP	Eight to nine cases per year	None	Two to five cases per year*
Other serious adverse events	None known	None known	None known
Systemic immunity	High	High	High
Immunity of gastrointestinal mucosa	High	Lower	High
Secondary transmission of vaccine virus	Yes	No	Some
Extra injections or office visits needed	No	Yes	Yes
Future combination vaccines	Unlikely	Likely	Likely (IPV)

OPV = oral poliovirus vaccine; IPV = inactivated poliovirus vaccine; IPV/OPV = sequential vaccination of IPV followed by OPV; VAPP = vaccine-associated paralytic poliomyelitis.

*—Estimated.

Adapted from Centers for Disease Control and Prevention. 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). *MMWR Morb Mortal Wkly Rep* 1997;46(RR-3):12 [Published erratum in *MMWR Morb Mortal Wkly Rep* 1997;46:183].

Based on the IPV price in 1995, the estimated cost per case of vaccine-associated paralytic poliomyelitis (VAPP) was \$3 million. Cost prevented use of an all-IPV vaccine schedule instead of an OPV schedule.⁸ Now, the costs for IPV and OPV schedules are similar in the private sector.

According to the Recommended Childhood Immunization Schedule for 1999, the third dose of any poliovirus vaccine can be administered to children as young as six months of age.⁹ Previously, the third dose of IPV was approved by the U.S. Food and Drug Administration for use in children beginning at 12 months of age.

OPV

The benefits of an all-OPV vaccination schedule include oral rather than injected administration, protection from poliovirus (probably for a lifetime) for more than 95 percent of recipients after the primary three-dose series and early intestinal immunity (*Table 1*).⁴ OPV is recommended by the World Health Organization for global eradication efforts.

In one study of inner-city children in Detroit and Houston, seropositivity for poliovirus types 1 and 3 ranged from about 80 percent among 12- to 23-month-old children to more than 90 percent in children from 36 to 47 months of age.¹⁰ In children who were unlikely to have been vaccinated, seropositivity rates ranged from 9 to 18 percent for poliovirus types 1 and 3, and from 29 to 42 percent for poliovirus type 2; thus, the secondary spread of vaccine virus plays a modest role in strengthening polio immunity in inner-city populations.¹⁰

The main disadvantage of OPV is the slight risk of infection with VAPP, which can occur when oral polioviruses revert to a more virulent form. Of the 125 cases of VAPP reported between 1980 and 1994, the affected persons were, in descending order, healthy vaccine recipients (49 persons), healthy persons in contact with vaccine recipients (40 persons), vaccine recipients who had immunodeficiency (23 persons), immunodeficient persons in contact with vaccine recipients (7 persons) and persons with community-acquired infection (6 persons).³

VAPP occurs more frequently after administration of the first dose of OPV in the all-OPV series than after subsequent doses; 40 of the 49 healthy vaccine recipients who acquired VAPP did so after the first dose of OPV. VAPP also occurs more commonly in persons vaccinated with OPV as adults and in immunodeficient persons. However, the overall risk of acquiring VAPP is quite small: one case per 2.4 million doses of OPV distributed (125 cases for the 303 million doses of OPV distributed).³ The overall risk for healthy people who receive OPV vaccine, excluding persons who are in contact with these vaccine recipients, was one case per 6.2 million OPV doses distributed.³ The risk of acquiring VAPP after receiving the first dose of OPV is one case per 750,000 first-doses distributed.

People with immunodeficiencies are at higher risk for VAPP, particularly those with B-cell disorders such as agammaglobulinemia.³ In a series of 20 cases of VAPP occurring in immunodeficient persons, 15 cases occurred in persons with hypogammaglobulinemia or agammaglobulinemia.

SEQUENTIAL IPV/OPV SCHEDULE

The combined IPV/OPV schedule for routine immunization against poliomyelitis includes two doses of IPV administered at two and four months of age followed by two doses of OPV administered at six to 18 or 12 to 18 months of age and at four to six years of age (*Table 2*). In 1988, options for immunization against polioviruses in the United States were reviewed at the Institute of Medicine, and a sequential IPV/OPV schedule was recommended if a combination vaccine containing diphtheria and tetanus toxoids and pertussis vaccine and IPV were licensed.¹¹ This has not occurred yet.

TABLE 2
Poliovirus Vaccination Schedule, United States, 1999

<i>SCHEDULE</i>	<i>TWO MONTHS</i>	<i>FOUR MONTHS</i>	<i>SIX TO 18 MONTHS</i>	<i>FOUR TO SIX YEARS</i>
Sequential	IPV	IPV	OPV*	OPV
IPV only	IPV	IPV	IPV	IPV
OPV only†	OPV	OPV	OPV	OPV

IPV = inactivated poliovirus vaccine; OPV = oral poliovirus vaccine.

*—The AAFP and AAP recommend giving the third dose of the sequential schedule at six to 18 months of age. The ACIP recommends giving the third dose of the sequential schedule at 12 to 18 months of age.

†—No longer recommended and acceptable only in special circumstances.

Adapted from Centers for Disease Control and Prevention. 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). MMWR Morb Mortal Wkly Rep 1997;46(RR-3):12 [Published erratum in MMWR Morb Mortal Wkly Rep 1997;46:183].

Most studies have shown that two doses of IPV induce protective levels of antibodies in 90 percent or more of recipients.⁴ Thus, when OPV is administered as part of the sequential schedule, most recipients already have humoral seroprotection due to IPV, which should greatly reduce the incidence of VAPP occurring after the first dose of OPV. A 1984 review of poliomyelitis in Denmark,¹² which has used a six-dose sequential schedule since 1968, reported only one case of VAPP. This occurred in a child who previously had received only one dose of IPV. The Advisory Committee on Immunization Practices (ACIP) concluded that the use of a four-dose sequential IPV/OPV schedule theoretically reduces the cumulative number of cases of VAPP by 50 percent or more.⁴ The use of a sequential schedule should reduce the risk of VAPP in individual recipients by 95 percent.³ In addition to risk reduction, other advantages of the sequential schedule include fewer injections compared with the all-IPV schedule, the development of eventual mucosal immunity and, possibly, postponement of OPV administration until 12 to 18 months of age, at which time many congenital immunodeficiencies in children have already been diagnosed (*Table 1*).⁴

The sequential immunization schedule provides better intestinal immunity than the all-IPV schedule. The percentage of children who shed poliovirus in their stools after being given a challenge dose of OPV is 85 percent after the administration of three doses of IPV; 66 percent after the administration of two doses of IPV and one previous dose of OPV; 25 percent after the administration of two doses of IPV and two previous doses of OPV; and 24 percent after the administration of two doses of IPV and three previous doses of OPV.¹³ Based on this data, the ACIP concluded that two doses of OPV were necessary in the sequential schedule.⁴ Priming with IPV in the sequential schedule does not reduce reversion of attenuated OPV viruses to virulent forms; thus, unvaccinated persons in contact with persons being immunized on the IPV/OPV sequential schedule still have a very small risk for VAPP; however, shedding of serotype 3 poliovirus may be reduced in vaccine recipients.^{14,15}

Disadvantages of the sequential immunization schedule include the need for two injections and the lack of efficacy data from U.S. studies. Although other countries have used the sequential schedule successfully, these countries use more than the four total doses of poliovirus vaccine recommended in the U.S. schedule. The estimated cost per case of VAPP prevented using the U.S. sequential immunization schedule is \$3.1 million based on 1995 prices.⁸

Recommendations

The American Academy of Family Physicians (AAFP) actively participated in the national debate regarding the revision of the poliovirus vaccine schedule. For 1997, the AAFP recommended that physicians and parents jointly decide on the most appropriate vaccine schedule for routine immunization against poliomyelitis of normal children. Since that decision, several issues have been clarified: first, the price of IPV has dropped in the private sector and is now equivalent to the price of OPV. Second, global eradication of poliovirus has continued, and thus the risk of importation is less. Third, no negative impact on the U.S. decision has been noted in developing countries. Fourth, anti-vaccine media attention has grown, and VAPP has been a major issue. Fifth, health services research has shown that 61 percent of parents would choose an IPV schedule even if more injections were required, and 88 percent of parents would choose IPV if IPV were combined with another vaccine.¹⁶ In public health clinics that recommended the sequential schedule, data indicate that 91 percent of infants started with IPV, and that these infants were up-to-date with other vaccinations, including diphtheria, tetanus toxoids and pertussis vaccine/diphtheria and tetanus toxoids and acellular pertussis vaccine, and *Haemophilus influenzae* type b vaccine.¹⁷

Successful litigation against physicians for VAPP has occurred when the risk of VAPP from OPV and the vaccine options were not presented to the parent or patient. Given the dictum to do no harm, the occurrence of litigation for VAPP, the media attention given to VAPP, and resolution of the aforementioned issues, the poliovirus schedule has been changed. Currently, the AAFP, ACIP and AAP all recommend that the first two doses of poliovirus vaccine should be IPV. In particular, AAFP recommends either an all-IPV schedule or a sequential schedule of two doses of IPV followed by two doses of OPV. OPV is no longer recommended for the first two doses of the poliovirus vaccine schedule and is acceptable only in special circumstances, such as children of parents who do not accept the recommended number of injections and late initiation of the first dose of the immunization schedule if it requires an unacceptable number of injections. A third reason for the all-OPV schedule is imminent travel of an infant to a country where polio is endemic. OPV remains the vaccine of choice for mass campaigns in developing countries to eradicate polio and control outbreaks. The ACIP recommends the use of the sequential immunization schedule of two doses of IPV followed by two doses of OPV.

The United States stopped vaccination for smallpox before most other areas of the world, and many experts expect that the United States will switch to an all-IPV schedule within one to three years. Thus, a few experts suggest that it may be easier to switch to an all-IPV schedule now.

Federal law requires that physicians provide a Vaccine Information Statement (VIS) on poliovirus vaccines to parents before administration of a poliovirus vaccine. The VIS can be downloaded from the Centers for Disease Control and Prevention's Web site at <http://www.cdc.gov/> (<http://www.cdc.gov/>), or it may be obtained from state health departments.

The all-OPV schedule is contraindicated in children with immunodeficiencies. Immunocompromised children, including children with HIV infection, and persons in contact with immunocompromised individuals should receive the all-IPV schedule. The other contraindication to OPV is anaphylaxis after a previous dose. Premature infants who are vaccinated in the hospital generally should not receive OPV because of potential transmission to other high-risk infants in the hospital. Contraindications to IPV include anaphylaxis after a previous dose of IPV or following streptomycin, polymyxin B (Aerosporin) or neomycin (Neosporin) administration. IPV should be used for the primary vaccination of adults 18 years of age and older.⁴

In general, four doses of poliovirus vaccine are recommended before entry into school. One exception is children who receive the third dose late—on or after their fourth birthday—in which case the fourth dose is not required (this exception is not allowed for the sequential schedule).⁴ Any of the three vaccine schedules administered by the time a child is four to six years of age is considered to be a completed series. After one or more doses of OPV, there is little benefit in switching to IPV.

If a child vomits or spits up a dose of OPV, a replacement dose may be given during the same visit. If the child also vomits the replacement dose, neither dose should be counted, and another dose should be given at a subsequent visit.⁴


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