

# AMERICAN ACADEMY OF PEDIATRICS

Committee on Infectious Diseases

## Prevention of Poliomyelitis: Recommendations for Use of Only Inactivated Poliovirus Vaccine for Routine Immunization

**ABSTRACT.** Since 1997, when the American Academy of Pediatrics (AAP) initially recommended expanded use of inactivated poliovirus vaccine (IPV) for routine childhood immunization against poliovirus infection, the occurrence of vaccine-associated paralytic poliomyelitis (VAPP) has decreased in the United States. However, VAPP will not be eliminated until oral poliovirus vaccine (OPV) no longer is given. As a result of continuing progress toward global eradication of poliomyelitis, the risk of imported infection has continued to decrease. Concomitantly, the use of IPV has increased substantially with the corresponding decrease in the use of OPV, indicating widespread acceptance by health care professionals and parents of the sequential or all-IPV immunization schedule previously recommended by the AAP. In addition, availability of OPV will be substantially diminished beginning in early 2000. To eliminate VAPP in the context of decreasing risk of wild-type poliovirus importation, the AAP recommends an all-IPV schedule for routine childhood immunization beginning in early 2000. The AAP further recommends that, effective immediately, OPV no longer should be purchased for routine use. Guidelines are given for utilization of remaining supplies of OPV during the transition in early 2000 to the all-IPV schedule.

ABBREVIATIONS. OPV, oral poliovirus vaccine; IPV, inactivated poliovirus vaccine; AAP, American Academy of Pediatrics; ACIP, Advisory Committee on Immunization Practices; CDC, Centers for Disease Control and Prevention; VAPP, vaccine-associated paralytic poliomyelitis; WHO, World Health Organization; VFC, Vaccines for Children program.

### BACKGROUND

Since 1996, recommendations for routine immunizations of infants and children in the United States against poliomyelitis have evolved from use of oral poliovirus vaccine (OPV) exclusively to increasing use of inactivated poliovirus vaccine (IPV). In 1997, the American Academy of Pediatrics (AAP) issued guidelines for expanded use of IPV<sup>1</sup> and the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) recommended the sequential IPV-OPV schedule.<sup>2</sup> These changes in immunization policy resulted from the occurrence of 8 to 9 cases yearly of vaccine-associated poliomyelitis (VAPP), no reported indigenously acquired cases of poliomyelitis caused by wild-type poliovirus in the United States

since 1979, and the continuing progress of the global eradication program sponsored by the World Health Organization (WHO), targeted for completion by the end of 2000.

### CURRENT CONSIDERATIONS

In late 1998 and 1999, 2 further changes in the recommendations for immunization against poliovirus infection occurred. First, the AAP recommended in January 1999 that the first 2 doses of polio vaccine for routine immunization should be IPV in most circumstances.<sup>3</sup> The AAP further noted that an IPV-only schedule for all doses was acceptable and the only means to eliminate VAPP, and that the IPV-only regimen likely would be recommended for all children in the near future, assuming continued progress in global eradication. Second, the ACIP in June 1999 recommended the IPV-only regimen for routine childhood immunization beginning January 1, 2000.<sup>4</sup> Both of these changes in policy were based on the continuing, albeit rare, occurrence of VAPP, the similar immunogenicity of IPV to that of OPV for primary immunization, the continued progress in global eradication of wild-type poliovirus, and the acceptance of IPV for primary immunization by health care professionals and parents.

Surveillance by the CDC of the purchase of doses of OPV and IPV in the United States demonstrated that whereas 6% of all poliovirus vaccine doses distributed in 1996 were IPV, 29% and 34%, respectively, in 1997 and 1998, were IPV doses (W. Orenstein, CDC, written communication, August 1999). Through August 31, 1999, 69% of doses purchased in 1999 were IPV, indicating further increase in the acceptance of IPV and decreasing utilization of OPV. In a recent AAP study assessing practices for polio immunization, 70% of pediatricians surveyed in mid-1998 reported that they usually recommend the sequential schedule.<sup>5</sup> The increased utilization of IPV in the past several years and the resulting additional injections have not been associated with decreased coverage with polio vaccine or with other childhood vaccines.<sup>6,7</sup>

The use of IPV is likely to increase dramatically in the near future because of the limited availability of OPV. The CDC contract for OPV, which supplies vaccines for the Vaccines for Children (VFC) program, is scheduled to expire in December 1999. As a result of the recent ACIP recommendation, this contract will not be renewed. The VFC program provides approximately 35% of childhood vaccines for infants and children in the United States (D. Mason,

The recommendations in this statement do not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

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written communication, August 1999). In a 1997 assessment, 74% of all children received all or some of their immunizations from a VFC-enrolled provider.<sup>8</sup> Whether OPV will continue to be commercially available from the only US manufacturer after 1999 is uncertain.

The increasing use of IPV has led to a decrease in the reported number of cases of VAPP. Whereas an average of 8 cases were reported annually between 1980 and 1994 in the United States, the CDC has confirmed 5 cases in 1997 and only 1 case in 1998.<sup>9</sup> All cases occurred in children or contacts of children immunized with only OPV; 4 were recipients and 1 was a contact. Several additional cases associated with OPV in 1998 are under investigation by the CDC (W. Orenstein CDC, written communication, September 1999). This decrease indicates the success of the sequential schedule in reducing VAPP. However, as long as OPV is given for any doses of polio immunization, the potential for VAPP in nonimmunized contacts and in the community will continue to exist.

The adoption by the ACIP and endorsement by the AAP of the sequential schedule in 1997 was based, in part, on the need to maintain optimal intestinal immunity. The administration of 2 doses of OPV would prevent community transmission in a case of inadvertent introduction of wild-type poliovirus, ie, a population-based barrier for overall public health benefit.<sup>1,2</sup> However, the only identified imported case of paralytic poliomyelitis since 1986 in the United States occurred in 1993 in a 2-year-old child from Nigeria who had been transported to the United States for treatment of poliomyelitis.<sup>2</sup> The risk of importation continues to decrease as a result of the considerable progress toward global eradication.<sup>10</sup> Poliovirus transmission in 1998 was confined largely to the remaining major foci in southern Asia, western and central Africa, and the Horn of Africa. The southern Asia reservoir countries reported 80% or more of all global cases of polio in 1998. A plan for accelerating poliovirus eradication has been developed by the WHO in collaboration with its partners to achieve the goal of global eradication by the end of 2000.

### CONCLUSION

The AAP, in its 2 recent policy statements on prevention of poliomyelitis, indicated that the IPV-only regimen likely would be recommended for all children in the near future.<sup>1,3</sup> In view of the continuing, albeit rare, occurrence of VAPP, the decreasing risk of importation into this country, the acceptance of IPV by health care professionals, and the probable lack of availability of OPV in the near future, the AAP recommends an all-IPV schedule for routine immunization of all children in the United States beginning in early 2000. While the ACIP has adopted the date of January 1, 2000,<sup>4</sup> this date may not be feasible for physicians and health care organizations with remaining supplies of OPV. To implement the transition to an all-IPV schedule as rapidly as possible and to eliminate the residual risks of OPV-associated VAPP, supplies of OPV no longer should be

purchased for the routine immunization of infants and children. Because cases of VAPP have not occurred in association with children immunized according to the sequential schedule, remaining supplies of OPV can be used to complete the sequential schedule in children who already have received at least 2 or more doses of IPV and for 4- to 6-year-old children receiving their fourth dose of vaccine, irrespective of the prior vaccines that were given. Priority in this circumstance should be given to children at 4 to 6 years of age; vaccination of these children should be associated with the least risk of VAPP because they are continent of stool and are unlikely at this age to have an unidentified immunodeficiency. Use of IPV for the fourth dose also is acceptable. OPV also may be given to children who previously received 2 or 3 doses of this vaccine.

### RECOMMENDATIONS

1. Effective in early 2000, IPV is routinely recommended for all children at 2 months, 4 months, 6 to 18 months, and 4 to 6 years of age.
2. Transition to the all-IPV schedule should be completed as soon as feasible and no later than the first 6 months of 2000. To effect this change as soon as possible, OPV supplies no longer should be purchased for routine use.
3. OPV should be used only in the following circumstances, unless otherwise contraindicated:
  - a. Mass vaccination campaigns to control outbreaks of paralytic poliomyelitis.
  - b. Unvaccinated children who will be traveling in less than 4 weeks to areas where polio is endemic or epidemic, ie, those for whom time before departure is insufficient for administration of 2 doses of IPV.
  - c. Children of parents who do not accept the recommended number of vaccine injections to fulfill the current childhood immunization schedule may receive OPV for the third or fourth dose. However, OPV should not be given for the first or second dose of the schedule.
  - d. During the transition to an all-IPV schedule in early 2000, remaining supplies of OPV should be preferentially used for 4- to 6-year-old children who have previously received 3 doses of any poliovirus vaccine to fulfill requirements for school entry. Administration of OPV to children who have previously received 2 doses of IPV or OPV also is acceptable for depletion of existing OPV supplies.
4. Whenever OPV is administered, the risk of VAPP in recipients and contacts should be discussed with the parents or caregivers.
5. For children who have previously received only OPV and are scheduled to receive their fourth dose for school entry, IPV may be given to complete the routine schedule. Four doses of any combination of IPV or OPV by age 4 to 6 years of age are considered immunologically equivalent to a complete poliovirus immunization series of all-IPV, all-OPV, or the sequential IPV-OPV schedule when administered according to the recommendations for minimum ages and intervals.<sup>11</sup>

6. Precautions or contraindications in administration of IPV and OPV remain unchanged from those in the current edition of the *Red Book*.<sup>11,12</sup>
7. If an outbreak of wild-type poliovirus infection occurs in the United States, OPV is the vaccine of choice to control most effectively the spread of infection. The AAP supports the need for sufficient federal resources to ensure an adequate supply of OPV for outbreak control in such a public health emergency.
8. The AAP supports the WHO recommendation for use of OPV to achieve global eradication of poliomyelitis, especially in geographic areas with continued or recent circulation of wild-type poliovirus.

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