Current Status of Polio Immunization, with Recent Legal Implications

David E. Van Reken, MD, LCDR (MC) USNR*
Portsmouth, Virginia

The administration of live trivalent oral polio vaccine (TOPV) is a daily occurrence in the average family practice. Although the incidence of paralytic poliomyelitis has sharply decreased following the use of the Salk and Sabin vaccines, serious medical and legal problems remain. Physicians should be aware that even the children who have received three doses of TOPV may not be protected against all three types of polio virus. Certain patients have altered immunity and should not be given a live vaccine. Paralytic poliomyelitis can occur in these individuals if another member of their family is given a TOPV, since the live virus is shed in the stool for weeks. Although the incidence of paralytic poliomyelitis associated with the vaccine is extremely low, health-care providers and vaccine manufacturers are currently liable for such untoward side effects in some states. Improved legislation is clearly necessary.

The impact of the poliovirus on family practice has decreased considerably since the advent of the Salk and Sabin polio vaccines. Instead of nearly 5,500 newly diagnosed cases of paralytic polio in 1959, physicians in the United States saw only 22 cases in 1972[1] and only three in the first nine months of 1975.[2] In the average daily practice of medicine, paralysis secondary to poliovirus is nonexistent. Every day, however, the family physician is involved with the administration of live trivalent oral polio vaccine (TOPV) and should, therefore, be aware of the following issues: (1) How effective is the vaccine? (2) Who should receive the vaccine and when? (3) Who should *not* receive the vaccine? (4) What are the side effects of the vaccine? and (5) What are the legal implications of the above? These issues will be reviewed in this article.

*The opinions or assertions contained herein are those of the author and are not to be construed as official or as reflecting the views of the Department of the Navy or the Department of Defense.

Requests for reprints should be addressed to Department of Pediatrics, Naval Regional Medical Center, Portsmouth, Va 23708.

How Effective is the Vaccine?

TOPV is a live attenuated poliovirus preparation containing all three polio viruses, Type 1, Type 2, and Type 3. Since it is a live virus vaccine, if a subclinical infection ensues following the vaccination procedure, the host will interact with the virus in such a way as to become immune. Definite serologic evidence of poliovirus immunity is a serum neutralization titer greater than 8:1, but possibly *any* detectable level of neutralizing antibody is sufficient to protect the individual from disease.[3] Serological conversion from susceptible to immune occurs in approximately 90 to 99 percent of patients receiving the vaccine.[4]

If TOPV is a live vaccine like measles, why is it recommended that each infant receive TOPV three times in the first year of life instead of just once? Administration of an oral vaccine does not guarantee the host will interact with the virus. There may be a concurrent viral infection present. The human antibodies in breast milk may interfere with the vaccine on occasion. The host may develop immunity to one or two types of poliovirus, but not all three on a single vaccination. Errors in the storage of the vaccine may lead to inactive vaccine. Even careless administration of the vaccine itself has been known to occur when the drops do not enter or do not stay in the infant's mouth. Some of these explanations may be why Rasmussen and colleagues[5] found such low poliovirus immunity levels even among children who had received three TOPV doses. In her study of children from six different Illinois communities, she found that the average percentage of children *without* immunity despite three TOPV doses was 40 percent for Type 1, 10 percent for Type 2, and 53 percent for Type 3.[5]

The extremely low level of immunity to a variety of preventable infectious diseases has led concerned physicians to promote publicity campaigns in recent years to make October an immunization month. This concern is heightened by the findings of studies such as those of Eli Gold et al[6] and George Lamb et al[7] which indicate that approximately half of all children one to four years of age do not have adequate antibody levels to all three types of poliovirus.

Who Should Receive TOPV and When?

All infants should be immunized according to the schedule given in Table 1, unless they have a medical contraindication described in the next paragraph. Older children or adults who were not immunized during infancy should receive immunizations using the sequence listed in Table 2. After the primary series, booster doses of TOPV are not required. Both the diphtheria-pertussis-tetanus (DPT) and the TOPV can be given to children with mild upper respiratory infections such as the common cold *unless* fever is present.

Who Should *Not* Receive TOPV?

Children who have or are suspected of having an immune deficiency state, such as hypogammaglobulinemia,

Table 1. Recommended Schedule for Active Immunization of Normal Infants and Children*

2 months	DTP[1]	TOPV[2]
4 months	DTP	TOPV
6 months	DTP	TOPV
1 year	Measles[3]	Tuberculin test[4]
	Rubella[3]	Mumps[3]
1½ years	DTP	TOPV
4-6 years	DTP	TOPV
14-16 years	Td[5]	and thereafter every 10 years

[1]DTP – diphtheria and tetanus toxoids combined with pertussis vaccine.

[2]TOPV – trivalent oral poliovirus vaccine. This recommendation is suitable for breast-fed as well as bottle-fed infants.

[3]May be given at 1 year as measles-rubella or measles-mumps-rubella combined vaccines.

[4]Frequency of repeated tuberculin tests depends on risk of exposure of the child and on the prevalence of tuberculosis in the population group. The initial test should be at the time of, or preceding, the measles immunization.

[5]Td – combined tetanus and diphtheria toxoids (adult type) for those more than 6 years of age, in contrast to diphtheria and tetanus (DT) which contains a larger amount of diphtheria antigen. *Tetanus toxoid at time of injury:* For clean, minor wounds, no booster dose is needed by a fully immunized child unless more than 10 years have elapsed since the last dose. For contaminated wounds, a booster dose should be given if more than 5 years have elapsed since the last dose.

*Report of the Committee on Infectious Diseases, ed 17. Evanston, Illinois, American Academy of Pediatrics, 1974, p 3.

Table 2. Primary Immunization for Children Not Immunized in Infancy*

1 Through 5 Years of Age	
First visit	DTP, TOPV, Tuberculin test
1 month later	Measles, Rubella, Mumps
2 months later	DTP, TOPV
4 months later	DTP, TOPV
6 to 12 months later or preschool	DTP, TOPV
6 Years of Age and Over	
First visit	Td, TOPV, Tuberculin test
1 months later	Measles, Rubella, Mumps
2 months later	Td, TOPV
6 to 12 months later	Td, TOPV
Age, 14 to 16 years	Td – continue every 10 years

*Report of the Committee on Infectious Diseases, ed 17. Evanston, Illinois, American Academy of Pediatrics, 1974, p 9.

Physicians may choose to alter the sequence of these schedules if specific infections are prevalent at the time. For example, measles vaccine might be given on the first visit if an epidemic is underway in the community.

should not be exposed to a live virus immunization. Wyatt has calculated that the risk of a hypogammaglobulinemic individual developing vaccine associated paralytic poliomyelitis is 10,000 times greater than the risk in normal persons.[8] Similarly, the use of TOPV in patients with severe underlying disease processes, such as leukemia or lymphoma, would be unwise. TOPV is also contraindicated in infants or children who are being treated with immunosuppressive medication, high dose steroids, or radiation.

There is one other situation in which the TOPV should be used with caution. Poliovirus persists in the stools of vaccine recipients for four to six weeks.[9] If a close family member has an immune deficiency disease or is unimmunized against polio, there is a remote chance of that individual acquiring active paralytic disease from the virus shed in the infant's stool. Such a sequence of events has been documented to occur in 40 cases since 1965.[10] In families where a known altered host resides, it would be safer to utilize the killed polio (Salk) vaccine.

What are the Side Effects of the TOPV?

The common reactions to other immunizations, such as fever, rash, or diarrhea, are rare with the TOPV. The current risk for vaccine associated paralysis in recipients of TOPV is 0.063/1,000,000 doses.[10] For contacts of the TOPV recipient, the risk is 0.193/1,000,000 administered doses.[10] These are very low rates and verify the safety of the TOPV.

What are the Legal Implications?

Although the risk for developing paralysis following administration of TOPV is about 1 in 15,000,000 doses, it is this victim who goes to court and receives wide publicity. In the recent case of *Reyes vs Wyeth Laboratories*, a Texas jury awarded the plaintiff $200,000 in damages. This award was

given despite the fact that it was not proven a vaccine strain of poliovirus was involved. The court admitted that the TOPV was as safe as possible, but it remained an "unavoidably unsafe product," and as the manufacturer of such a product, Wyeth had a duty to warn the consumer of the risk, no matter how slight.

The package insert for the TOPV now contains this warning, and some physicians and clinics have required recipients to read and sign an informed consent form prior to immunization. However, even a signed consent form may *not* protect the health-care provider in court. Unless the risk is adequately explained to the patient (or the parent), the patient can deny that full disclosure occurred.

The courts have consistently upheld the right of state legislatures to require compulsory immunizations in children, and all states have such statutes.[11] Most of these statutes require immunization for poliomyelitis, diphtheria, and whooping cough, unless there is a medical contraindication. In some states the physician could conceivably be caught in a difficult situation. In accordance with a state law he may administer a dose of TOPV to a healthy child, and later be held liable for the one patient in 15,000,000 who develops paralytic poliomyelitis.

Obviously, this is an unwieldy situation. R. D. Krugman has called for legislation which characterizes unavoidable reactions, such as with the TOPV, as "dyspractice" in contrast to "malpractice" which implies negligence or ignorance.[12] He has recommended that a trust be established, paid for by a one-cent surcharge on each dose of all vaccines manufactured. In this way, society would pay for these unavoidable occurrences rather than the individual physician who gave the vaccine or the pharmaceutical firm which manufactured it. Physicians should take an active role in encouraging such improvements in the nation's laws.

References

1. Center for Disease Control: Poliomyelitis Surveillance, Annual Summary 1972. Atlanta, Issued October 1974, p 2
2. Total for 1975 so far: 3 paralytic polio cases. JAMA 234:264, 1975
3. Phillips CF: Children out of step with immunization. Pediatrics 55:877-881, 1975
4. Cabasso VJ, Nozell H, Ruegsegger JM, et al: Poliovirus antibody three years after oral trivalent vaccine (Sabin strains). J Pediatr 68:199-203, 1966
5. Rasmussen CM, Thomas CW, Mulrooney RJ, et al: Inadequate poliovirus immunity levels in immunized Illinois children. Am J Dis Child 126:465-469, 1973
6. Gold E, Fenrier A, Hatch MH, et al: Immune status of children one to four years of age as determined by history and antibody measurement. N Engl J Med 289:231-235, 1973
7. Lamb GA, Feldman HA: Rubella vaccine responses and other viral antibodies in Syracuse children. Am J Dis Child 122:117-121, 1971
8. Wyatt HV: Poliomyelitis in hypogammaglobulinemics. J Infect Dis 128:802-806, 1973
9. Horstmann DM, Niederman JC, Paul JR: Attenuated type I poliovirus vaccine. Its capacity to infect and to spread from "vaccinees" within an institutional population. JAMA 170:1-8, 1959
10. Center for Disease Control: Poliomyelitis Surveillance, Annual Summary 1973. Atlanta, Issued February 1975, p 10
11. Holder AR: Compulsory immunization statutes. JAMA 228:1059-1060, 1974
12. Krugman RD: Immunization "dyspractice": The need for "no fault" insurance. Pediatrics 56:159-160, 1975