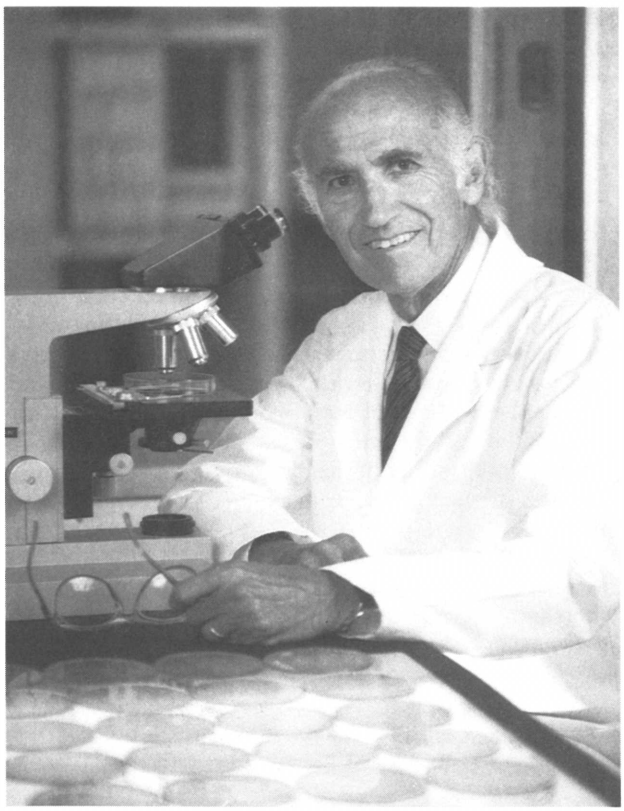
In Memoriam

Jonas E. Salk

1914-1995



Photograph courtesy of the Salk Institute

U.S. Polio Vaccine Policy Under Review

Joan L. Headley

A recent joint meeting of the Vaccine Safety Forum of the Institute of Medicine (IOM) and the Centers for Disease Control and Prevention (CDC) discussed possible changes in polio vaccine policy in the United States. Neither has authority to implement recommendations. Immunization policy for the U.S. is established by the Advisory Committee on Immunization Practices of the U.S. Public Health Service and the Committee on Infectious Diseases of the American Academy of Pediatrics.

✦ ***Why consider changing polio immunization policy now?*** There are several factors which have caused officials to debate the issue. The last naturally occurring case of polio in the U.S. was 1979, and the last naturally occurring case of polio in the Western Hemisphere was in September 1991. With the risk of wild poliovirus in check, the usually 10 or fewer cases of paralytic polio associated each year with the live virus vaccine (OPV) have become a concern for public health officials. Additionally an enhanced potency IPV (inactivated polio vaccine) has been available in the U.S. since 1987. It will not cause vaccine-associated polio (if properly produced) and is recommended for use in immunodeficient individuals and their family members.

✦ ***What new schedule is likely to be implemented?*** Experts at the meeting who support change in policy recommend the use of IPV for the first two or three doses, followed by one dose of live oral polio vaccine (OPV) at 18 months, and another between four and six years of age.

Currently, the United States recommends OPV #1 at two months; OPV #2 at four months; OPV#3 at six months (with OPV #3 at eighteen months as an acceptable alternative). Some recommend OPV #4 between 4-6 years. The IPV is available and is recommended for immunocompromised individuals and their close contacts, as well as for adults who have not had a primary series, or who are at a greater risk of exposure to wild poliovirus because of international travel or an occupation in the health profession.

✦ ***What concerns were expressed about the U.S. introducing IPV into the polio immunization schedule?*** The IPV is administered by injection, whereas OPV is given by mouth. The easier the vaccine is to administer the more likely parents are to have their child vaccinated. There is a substantial difference in price. In the private sector, IPV costs $5.50 more per dose than OPV. The CDC is concerned that the increased cost may reduce funds available for other programs. Some are concerned about reports which indicate that the producers of IPV have been overly active

in the discussion which would change the policy in their favor.

A switch by the U.S. to IPV could affect the worldwide polio eradication program because the U.S. is considered a world leader in public health. Concern was expressed that other nations where polio is still endemic might also switch to IPV from OPV. The use of the OPV is vital to the worldwide effort to eradicate polio because it is easier to administer, it costs less, and is more effective in stopping the spread of wild poliovirus because it stimulates immunity in the intestines and reduces the risk of spread to other children.

According to the World Health Organization, the U.S. now spends about $230,000,000 a year on polio immunization. Once polio is completely eradicated worldwide that $230,000,000 could be spent on other health programs.

✦ *When will a new policy be presented?*

The Advisory Committee on Immunization Practices will review policy options during an October meeting with a goal of reducing cases of vaccine-associated paralytic polio.

✦ *What are the polio immunization policies for selected other countries?*

Australia: The National Health and Medical Research Council recommends OPV at the ages of 2 months, 4 months, 6 months, 5 years, and 15 years.

Canada: The National Advisory Committee on Immunization reports that both the IPV and the OPV are licensed for use in Canada. Both have successfully controlled poliomyelitis in various parts of Canada. Primary vaccination with three doses of IPV will confer immunity in more than 99% of recipients when the first two doses are administered at least six weeks apart and the third dose is given six to 12 months later. A primary course of three doses of OPV, the first two being given at least six weeks apart, and the third given six to 12 months after the second, will give long-lasting immunity to more than 95% of recipients. Some authorities recommend administration of a three-dose course of IPV prior to giving OPV. OPV must never be given to patients who are immunodeficient, those on immunosuppressive therapy, and to persons who will have household or similar close contacts with such individuals in the following four weeks.

Denmark: The Danish vaccination plan recommends diphtheria, tetanus, polio (IPV) at five months; diphtheria, tetanus, polio (IPV) at six months; diphtheria, tetanus, polio (IPV) at 15 months; OPV at two years; OPV at three years, and OPV at four years.

France: The vaccine policy for France is first injection (IPV) at two months; second injection at three months; third injection at four months; boosters at 15 months, 5-6 years, 11-12 years, 16-20 years. After 21 years a booster is recommended every 10 years.

Germany: The Permanent Vaccination Commission of the Federal Health Agency (STIKO) recommends OPV #1 during the third month; OPV #2 not earlier than six or eight weeks later (it may be postponed to 10 weeks in case of illness); OPV #3 at 24 months which completes basic immunization (OPV #3 can be given somewhat earlier, but never before 15 months); OPV #4 ten years later, repeated every ten years. IPV used only in special cases or health situations respectively.

New Zealand: The New Zealand Ministry of Health Immunisation Handbook, 1993, recommends OPV #1 at three months; OPV #2 at five months; OPV #3 at 18 months; booster at school entry. Boosters are recommended for travelers to countries where polio is epidemic or endemic. An IPV is recommended for use in an individual with a suppressed immune system or living with someone immune suppressed.

Switzerland: The Federal Department of Health, the Swiss Society for Pediatrics, and other medical groups, recommend OPV #1 at two months; OPV #2 at four months; OPV #3 at six months; OPV #4 at 15-24 months; booster five to seven years; booster 12-15 years; booster every 10 years (if going to endemic regions or contacting persons with poliomyelitis in or of endemic regions). IPV is given under certain circumstances, e.g., a never-vaccinated person after age 20, persons with suppressed immunological status, persons with AIDS, etc.

United Kingdom: The Department of Health recommends OPV #1 at two months; OPV #2 at three months; OPV #3 at four months; booster at 3-5 years; booster at 15-19 years.

✦ What recourse does one have in the U.S. if polio is vaccine-associated? The National Childhood Vaccine Injury Act of 1986 (PL-99-660) created a no-fault compensation alternative to suing vaccine manufacturers and providers when injured or killed by the DPT (diphtheria-pertussis-tetanus), MMR (measles-mumps-rubella), or polio vaccines.

The compensation was divided into two parts. One part dealt with injuries or death prior to October 1, 1988 no matter how long ago the injury occurred. The deadline for filing these claims was January 31, 1991. The National Vaccine Information Center, who supplied information for this article, knows of no claims admitted since that deadline date. A total of 4,095 pre-88 claims were filed. One thousand and twenty eight (1,028) cases were dismissed and awards have been paid to 1,241. Because of the large number of claims filed, there are many which have not yet been reviewed by the Claims Court, and many continue to receive extensions.

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The other part, for injuries or deaths occurring after October 1, 1988, requires a citizen to apply for federal compensation prior to pursuing a law suit. Further provisions include: the system will offer to pay up to $250,000 for a vaccine-associated death; the system will offer to pay for all past and future unreimbursed medical expenses, custodial and nursing care; up to $250,000 for pain and suffering; and loss of future earned income; if a citizen rejects the award, or is turned down, a law suit may be filed (restrictions apply to law suits); claims must be filed within 24 months of a death and 36 months of an injury. The system is funded by a sur-charge on each dose of vaccine sold (e.g., polio vaccine — $0.29).

The law also created safety reforms. The law requires physicians to record the date, manufacturer's name and lot number, the signature and professional title of the person administering the vaccine, the address where the vaccine is administered, as well as provide parents with information about childhood diseases and vaccines prior to vaccination. The law requires all physicians who administer vaccinations to report vaccine reactions to federal health authorities. The FDA and the CDC have developed a "Vaccine Adverse Event Reporting System" (VAERS). The national toll free number to receive VAERS forms is 800/822-7967. If a physician or health official does not report the "event," parents are allowed to file their own report. The law further requires physicians to record vaccine reactions in an individual's permanent medical record.

Individuals who want to file a claim for a vaccine injury or death may write to U.S. Claims Court, 717 Madison Place, NW, Washington, DC 20005 (202/219-9657) and ask for a copy of "The Vaccine Rules." This publication gives specific directions for filing a petition for a claim.

The National Vaccine Information Center (NVIC), 512 West Maple Ave., Suite 206, Vienna, VA 22180 (800/909-SHOT) has published a booklet, "The Compensation System and How It Works," which is available for $10.00, as well as other related information and resources.

✦ ***How do adult polio survivors react to the discussion?*** Some feel very strongly that the OPV should continue to be used to wipe out polio worldwide, ultimately sparing the children of the world acute paralytic polio and the late effects of polio.

Other polio survivors feel that if OPV can cause even a few cases of polio (one in 2.5 million doses), it should not be used exclusively and spare individuals from vaccine-associated polio. There is no documented scientific evidence to support any claim that the OPV can cause post-polio syndrome. By current definition, a case of acute paralytic polio must precede any diagnosis, and it is generally accepted that the severity of post-polio syndrome depends to some extent on the severity of the initial paralytic polio. ❐

SOURCES AND CONTRIBUTORS:

Recommended Childhood Immunization Schedule — United States, 1995, *Morbidity and Mortality Weekly Report,* June 16, 1995 (Vol. 44/No. RR-5); World Health Organization Target 2000: A World without Polio; Journal of American Medical Association, July 5, 1995, Vol. 274, No. 1; National Vaccine Information Center; David Hooper, Australia; Sally Aitken, Canada; Susan Hordum Nielsen, Denmark; Nicole Richier, France; Gertrud Weiss, Germany; Denis Hogan, New Zealand; Thomas Chr. Lehmann, Switzerland and Andrew Kemp, United Kingdom.

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