

Supply, Distribution, and Use of Poliomyelitis Vaccine

By JACK C. HALDEMAN, M.D.

WITH THE ANNOUNCEMENT of the successful results of the 1954 field trials of Salk poliomyelitis vaccine, the way was opened to prevention and control of one more communicable disease.

The extraordinary progress achieved in this past year and a half in providing at least partial immunization to the most susceptible population is a tribute to the working partnership of the medical and pharmaceutical professions, local, State, and Federal governmental agencies, voluntary agencies, the drug manufacturers, and individual citizens. Together, they have labored diligently to insure the most equitable possible distribution and use of the limited amount of vaccine available.

The purpose of this article is to review the results of this cooperative effort and to outline the course that lies ahead for provision of maximum protection against poliomyelitis for the total population.

Supply and Distribution

We are no longer faced with the problem of short supply of vaccine. The voluntary system of Federal allocation of vaccine, which was

adopted as the most equitable method for distribution of a scarce product, was terminated on August 1, 1956. Decontrol of vaccine was made possible by the following sequence of events.

Vaccine production had built up slowly through 1955 and the early months of 1956, but releases during April, May, and June brought the supply up to the demand level in a number of States. By July 27, 1956, more than 85 million cubic centimeters of vaccine had been released. Since there are approximately 65 million persons in the group most susceptible to poliomyelitis in this country (persons 0 through 19 years of age and expectant mothers), enough vaccine was now available to provide two injections for 70 percent of those eligible to receive it.

Because of State variations in immunization programs and the more plentiful supply of vaccine, a number of States did not request their shares of vaccine released during late June and July 1956. This necessitated reallocation of their shares to those areas of the country where demand still exceeded available supply. For these reasons, it was decided that the needs of all areas could best be met by releasing vaccine through normal distribution channels rather than through the Federal system of allocation to the States.

Since Federal decontrol of vaccine, an additional supply of more than 28¾ million cubic centimeters has been released. All parts of the country now appear to be able to get as much vaccine as they need.

Termination of the allocation system does not affect the allotment of Federal funds avail-

Dr. Haldeman is chief, Division of General Health Services, Bureau of State Services, Public Health Service, Washington, D. C. His paper is based on a talk he gave before the 25th annual meeting of the American Academy of Pediatrics, New York City, October 11, 1956. Figures have been revised as of November 15, 1956.

able to the States for the purchase of poliomyelitis vaccine and the administration of public vaccination programs for children under 20 and expectant mothers. These funds, made possible by the Poliomyelitis Vaccination Assistance Act and amounting to \$53,600,000, will be available until June 1957. As of November 15, 1956, \$34,649,454 had been paid to the States and Territories.

Safety and Effectiveness

The early confidence we had with respect to safety and effectiveness of the vaccine has been reinforced by experience in its use to date.

Since May 1955, when vaccine was first released under revised safety standards, there has been no epidemiological evidence that any case of poliomyelitis has been causally related to the use of poliomyelitis vaccine. This reassuring conclusion is drawn from the study of data in which each reported case of poliomyelitis is related to the lot number of vaccine used, date and site of injection, site of first paralysis, and dates of onset of the disease and of paralysis.

Epidemiological studies conducted by 22 States and New York City during the 1955 poliomyelitis season showed that the paralytic attack rate among the unvaccinated children was consistently higher than among the vaccinated. Further studies in 1955 revealed that only among 7- and 8-year-old children, those for whom the vaccine had been used almost exclusively that year, was there a sharp lowering of paralytic attack rates. Thus, the 1955 experience reaffirmed the confidence in poliomyelitis vaccine established by the 1954 field trials.

Because of a continuing higher rate of vaccination throughout the current poliomyelitis season, completely comparable studies, yielding quantitative estimates of vaccine effectiveness, will not be possible. Therefore, characteristics of the current incidence are being studied to determine any changes attributable to the vaccine. Preliminary reports from a number of States in 1956 revealed that vaccinated cases comprise a low proportion of the total paralytic cases. Furthermore, in every age group the proportion of cases that are paralytic is greater among nonvaccinated cases than among the vaccinated.

The weekly incidence of poliomyelitis for the current year (1956) has been running at a lower level than in any year since 1947. The number of cases reported so far this year is about half the past 5-year average. Except for the severe outbreak in Chicago, only Louisiana and Utah have reported high incidence. California reported moderate incidence. Occurrence in most of the remaining States has been exceedingly low. From the national incidence figures alone, it is not possible to attribute this entire decrease to the vaccine. However, the studies mentioned strongly support the conclusion that the reduction is at least partially due to the vaccine. If we can achieve a high level of vaccination coverage, we should be able to conquer poliomyelitis.

Although poliomyelitis vaccine is now being used throughout the country, there has been considerable discussion about the use of vaccine during the season of high incidence, particularly in areas where epidemic conditions prevail. This discussion centers around the balance between the benefits of vaccination and the quantitative importance of the provoking effect of vaccinations under such conditions. The ability of immunizing injections of diphtheria, pertussis, and tetanus antigens, and of therapeutic injections such as penicillin, to provoke paralytic poliomyelitis has been reported by several authors. Consequently, before it was tried, there was some concern that poliomyelitis vaccine used during an outbreak of disease might show a similar ability to provoke paralysis.

Poliomyelitis vaccine was first used in an epidemic situation at a naval base in Hawaii in the fall of 1955. Although analysis of this program did not firmly establish the effectiveness of the vaccine in controlling an epidemic, incidence was lower in the vaccinated population. Moreover, a thorough evaluation failed to demonstrate any evidence of a provoking effect of the vaccine. During the first month after initiation of the mass vaccination program, incidence rates were identical in the vaccinated and unvaccinated populations. In the highly exposed family contacts of demonstrated cases, incidence was again similar in the vaccinated and unvaccinated contacts. However, examination of the clinical character of the vaccinated

Prompt Use of Poliomyelitis Vaccine

Secretary Folsom's report on the Salk poliomyelitis vaccine deserves the attention of every young adult, of every parent, in America.

The supply of vaccine is now plentiful.

I join with Secretary Folsom, the Surgeon General of the Public Health Service, and the National Foundation for Infantile Paralysis in urging that the vaccine be used promptly before the next poliomyelitis season arrives.

DWIGHT D. EISENHOWER

President of the United States

November 28, 1956

Opportunity Ahead

Knowing of your interest in the poliomyelitis vaccination program I am making this report on developments to date and on a great opportunity which lies ahead.

Millions of children who have so far received only 1 or 2 injections should, before next summer, be given the additional protection provided by the recommended 3 doses. The full benefit of the vaccine is achieved only with 3 injections.

Millions of young adults, as well as children who have had no vaccine at all so far, should now begin their vaccinations in order to receive the full three doses before next summer's peak of poliomyelitis incidence. All States have now made commercial supplies of the vaccine available to adults.

Prompt use of the vaccine—this is our problem and opportunity now. And this will require the earnest and vigorous cooperation of parents, physicians, schools, officials at all levels of government, and public and private health agencies.

Through prompt use of increasing supplies of vaccine, the Nation can go a long way, next year, toward elimination of this dread disease.

The National Foundation for Infantile Paralysis has recognized the need for prompt action and is presently engaged in a vigorous campaign to urge that all unite in this cause—the cause of preventing needless illness.

Since the vaccine was approved for public use—some 18 months ago—about 115 million cc's, or doses, have been released by the Public Health Service. More than \$53 million in Federal funds have been made available to help pay for vaccine for children and expectant mothers.

The results have been extremely encouraging.

Surveys show that among children vaccinated with only one or two doses, the incidence of paralytic poliomyelitis has been reduced about 75 percent. We can expect an even greater reduction as more and more persons receive three injections.

I know you share my gratification at the great progress that has been made, and my hope that the people of the Nation will take full advantage of this opportunity to protect their children and themselves against the ravages of poliomyelitis.

—*From a report to the President,*
by MARION B. FOLSOM, *Secretary*
of Health, Education, and Welfare.

cases showed no predominance of paralytic disease, no concentration of cases 4 to 14 days after vaccination, nor any cases with first paralysis in the inoculated limb. In brief, the characteristics of provoked poliomyelitis were not present. Further, considering the extent of final paralysis in the paralytic cases which occurred within a month following vaccination, it was demonstrated that prior inoculation in an extremity did not increase the frequency of paralytic involvement of the extremity.

Thus, this report is reassuring because no measurable provoking effect could be found. But the study was based on only small numbers of cases.

The Chicago experience will provide an opportunity for further study of the use of vaccine during a serious outbreak—and on a larger population base. More than 1,000 cases of poliomyelitis occurred in Chicago in 1956, comprising more than 10 percent of the national incidence. Soon after the outbreak, a mass vaccination program was undertaken; more than a million doses of vaccine were given. The local health authorities, in cooperation with the Public Health Service, are intensively studying this outbreak. Particular emphasis is being given to evaluation of any evidence of a provoking effect. Although final conclusions cannot be drawn at this time, preliminary analyses have failed to reveal any such evidence so far.

Use of Vaccine

The amount of vaccine shipped into a State is a gross index of use since shipments are made only on bona fide orders which, for the most part, are promptly used.

In one State (Massachusetts) enough vaccine has been shipped to meet more than 65 percent of the total need for 3 injections for persons 0 through 19 years of age and expectant mothers; and in three more States (Illinois, Connecticut, and Utah) more than 50 percent. At the opposite end of the scale, less than 30 percent of the full amount needed has been shipped to 1 State and 1 Territory. Twenty-eight States and 3 Territories could meet between 40 and 50 percent of the need with the

vaccine already received, and 17 States and 2 Territories could meet between 30 and 40 percent. Of course, since many children and expectant mothers are not yet due for their third injections, these percentages are not indicative of the proportion of the priority group who have received some immunization. The figures do, however, indicate the dimensions of the job that remains to be done before the next poliomyelitis season.

Here, then, is the present challenge to the health profession, particularly to pediatricians, general practitioners, and public health physicians. This is still a new program as events in medical history are counted. Continuing educational efforts are required to impress parents with the importance of having their children immunized.

Several States are using some rather unique and interesting methods for stimulating an increase in the demand for vaccine. For example, the Mississippi State Board of Health employed 54 school teachers as "home visitors" for the summer to determine to what extent children in the families visited had been vaccinated and to inform the parents about the vaccination program and, particularly, where vaccinations could be obtained. This technique resulted in an immediate increase in immunizations both by physicians in private practice and by local health departments.

It is of interest to note that even though local health officials had extensively used radio, television, and newspaper publicity to announce the availability of the vaccine, the home visitors found that failure to take advantage of the program stemmed largely from ignorance of the availability of the vaccine or of the eligible age group.

Studies such as this help to pinpoint "soft spots" in educational campaigns, not only with respect to younger children under the supervision of pediatricians but also with respect to older children. The adolescent group is especially difficult to reach, falling in a sort of "never-never" land, too old to be seen regularly by the pediatrician and usually too young for regular visits to other medical practitioners. Perhaps the older siblings of the pediatrician's patients could be offered immunization

if they are not being reached by other arrangements.

Unquestionably, high school programs will be needed to "step up" vaccination of teen agers. With schools now in session, there will undoubtedly be more active vaccination programs for adolescents.

Pediatricians have an excellent opportunity to urge young parents to seek immunization for themselves as well as for their children. The incidence of poliomyelitis among young parents is also high, and the degree of paralysis severe, often with tragic socioeconomic consequences. As with the adolescent group, very little preventive medicine is being practiced among these young adults since they have not yet reached the age where they are likely to be reporting regularly to a physician for physical checkups or for treatment of a chronic illness or disability.

Laboratory Diagnosis of Poliomyelitis

Relatively recent findings, which indicate that many diseases masquerade as poliomyelitis, have made physicians increasingly aware of the difficulty of diagnosing true poliomyelitis. It is now generally recognized that nonparalytic cases cannot be accurately diagnosed without laboratory tests. There is growing evidence that laboratory tests are equally important in diagnosing some paralytic cases.

The development of the poliomyelitis vaccine intensifies the need for laboratory confirmation of all cases of poliomyelitis and polio-like diseases. With widespread vaccination, the ratio of polio-like diseases to true poliomyelitis can be expected to increase. Also, the vaccine itself may modify the course of the disease, thus making the diagnosis on purely clinical grounds correspondingly more difficult. Furthermore,

if an accurate evaluation is to be made of the total and long-range effect of the vaccine, it is essential to identify, by laboratory testing, the type of poliomyelitis virus involved for all reported cases.

To provide such testing, a network of laboratories, especially equipped to analyze specimens taken from patients with poliomyelitis or polio-like diseases, has been organized by the Communicable Disease Center of the Public Health Service. The network includes a number of academic research laboratories and State health department laboratories.

Physicians are urged to use these facilities by sending specimens to their State health department or to whatever laboratory the department designates. Full cooperation by all physicians will not only aid in obtaining more accurate diagnoses but will also promote research and make possible a continuing evaluation of the effectiveness of the poliomyelitis vaccine.

Conclusion

In conclusion, the job immediately ahead is to continue immunizing as high a proportion of the susceptible population as possible. This will require the unrelenting effort of both physicians in private practice and members of the public health profession. Once a high level of protection has been attained, holding it over the years becomes our mutual objective. Unless this is done, sporadic outbreaks will continue to recur, as has been clearly demonstrated in the history of diphtheria control.

No group has a more important role in achieving full protection against poliomyelitis than the pediatricians of this country. More mothers are taking their children to pediatricians than ever before. Taking full advantage of this opportunity is a real challenge.