EVALUATION OF THE 1954 FIELD TRIAL OF POLIOMYELITIS VACCINE

FINAL REPORT

POLIOMYELITIS VACCINE EVALUATION CENTER
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"In the placebo control package, the three vaccine vials will be labeled with an identical lot number. Similarly, all three vials of control material will bear an identical lot number differing, however, from the vaccine number. Thus, each package of six vials will have three vials with one number and three with a different number.

"Each package bears a label on the end where two lot numbers should be recorded - one for the vaccine and one for the control solution. (The administering physician will not know which is which.) In addition, this label has space for recording the school name, class, and Registration Schedule sheet number for the group of twenty children receiving material from this package.

"Space is also provided to indicate if additional material will be needed before the second or third clinic to ensure the twenty children given material from the first two vials receive similar material at succeeding inoculations.

"It is advisable to refrigerate vaccine continuously, but exposure to room temperature for a few hours will not have a deleterious effect. Care should be taken not to place the vaccine on a radiator or expose it to intense sunlight. Thus, vaccine should be refrigerated until shortly before clinic time and returned to the refrigerator after the clinic is ended. Vaccine must not be frozen."

Before each vaccination clinic, packages of inoculum were delivered to clinics, vaccine and placebo in the placebo control areas, and only vaccine in the observed areas. Seven days after the first inoculation the second was administered; and 35 days after V-Day, the third injection was made. The coding system used on labels and packages of inoculum assured accuracy in giving children the materials called for on their individual records without revealing the identity of the vaccine or placebo. Make-up clinics were scheduled for children who had been absent.

Approximately 2 percent of the children participating gave blood samples, the first of which were taken on V-Day before inoculations were administered. The same children from whom the original blood specimens were collected were called upon for a second specimen two weeks after the third inoculation. The third series of blood specimens from these same children were collected in the fall of 1954 after the poliomyelitis season was over. All samples were sent directly to a specified laboratory by the county health officer.

Administrators of the local vaccine program were urged to record and report any unfavorable reaction coincidental with or related to the inoculations.

While the Manual of Suggested Procedures provided by the National Foundation was a comprehensive plan for the conduct of the vaccine Field Trial at the time the activities began, it became evident that supplemental directions would be necessary to the adequate collecting and reporting of data. Therefore, the Vaccine Evaluation Center made use of a series of VEC Memoranda, Nos. 1 through 11, which were dispatched to all state and local health officers (see Appendix). The Center also found it advisable to send members of its own staff to visit clinics in many areas to verify accuracy of procedures and to advise on preparation of the needed records.

VACCINE-PLACEBO CODE SCHEME

The previously discussed principle of the placebo plan of study was to match equal populations one of which received inoculations of vaccine and the other placebo on a concealed basis. The plan adopted, therefore, was to prepare a solution (placebo) which in general appearance and consistency resembled quite closely that of the vaccine. For this purpose "199" solution was employed; its pH was adjusted so that its color after addition of phenol red was the same as the vaccine. Antibiotics were added in the same concentration as that used in the vaccine. The material was treated with formalin, and the formalin was then neutralized as was done in the vaccine. The placebo material served its purpose well.