CHAPTER V

REPORTING AND INVESTIGATION OF CASES IN THE STUDY POPULATION

The second phase of the study concerned the detecting of poliomyelitis cases among members of the study population, the identifying of the patients, the establishing of uniformity and objectivity in diagnoses by the integration of clinical, epidemiological, and laboratory data, and the subsequent classifying of the patients according to vaccination status. It should again be emphasized that all stages of the operation were conducted without knowledge of the vaccination status of a patient in placebo areas and without reference to the status in observed areas.

The patient was identified only by registration sheet and line number, and no record of poliomyelitis vaccination was included. Only after the final diagnosis of all cases was established at VEC was a classification of patients made with reference to vaccination status.

The Evaluation Center was completely dependent upon the ability, willingness, and collaboration at the local level in the 211 study areas from which reports of cases of poliomyelitis would be received. With the number of professional personnel involved in so widespread a study, variability in understanding and performance could be expected. In the hope that variations could be reduced to a minimum, strenuous effort was made to establish uniformity of procedure by detailed instructions and outlines of standardized procedures.

It was recognized that there are uncertainties in the clinical diagnosis of poliomyelitis during the early acute phase, but to encourage early and complete reporting and uniformity of procedure, a prescribed plan was instituted for the investigation of all cases in the entire study population. VEC Memorandum No. 8, included in the Appendix, presented the plan in detail. An Addendum accompanying this memo provided a chronological listing of the necessary steps in the detecting, investigating, and reporting of Case data. The recommended steps were as follows:

1. Patient is reported to health department with diagnosis of paralytic or nonparalytic poliomyelitis.

2. The majority of all patients (paralytic or nonparalytic) from many test areas are admitted to regional hospitals with special poliomyelitis units.

3. Collection of specimens (blood, stool) for virus studies.

4. Epidemiological confirmation as soon as possible with standard forms filled out and notification of physical therapist.

5. Examination by physical therapist in 10-20 day period after onset. Physician's interpretation on same record.

6. Obtain convalescent blood specimen 3-4 weeks after onset.

7. Examination by physical therapist 50-70 days after onset. Physician's interpretation.

8. If the patient is admitted and remains in poliomyelitis hospital center, the evaluation of patient's status by attending physician on the physical therapist's examination form fulfills the clinical requirement.

9. If patient has remained at home or returned from hospital to home or to other

location during the 10-20 day period, provision for the physical therapist to examine the patient there must be made. The consulting specialist should arrange to see the patient at this time and record his interpretation.

REPORTING OF CASES

Every case, paralytic, nonparalytic, suspect or doubtful, was to be reported in any child who was a member of the first, second, or third grade during the spring of 1954, no matter whether he had been inoculated or not or whether participation had been requested or not. The intention was to make certain that no study case would escape investigation because of local uncertainty as to the requirements for reporting. Each reported case in a study member was to be subjected to the same intensive study. Cases in other members of a family containing children belonging to the study population were to be reported to VEC but subjected to limited investigation unless special studies were undertaken.

There is commonly a distinct interval between the onset of illness and diagnosis of poliomyelitis in a patient. To reduce further delay in the reporting of cases to VEC, the health department or program director was urged to impress upon local physicians the need to report each case as soon as the initial diagnosis was made.

As a means of following the occurrence of poliomyelitis as closely as possible in both the study population and among the families of study children of each study area, a weekly reporting system was established as of May 1, 1954, whereby all reported cases of poliomyelitis in all ages were submitted weekly to the Vaccine Evaluation Center on Form VEC-11 which called for the name, age, date of onset as given, city of residence, grade if enrolled in school, and type of case. In addition, each area was asked to report weekly on these same forms all deaths from all causes occurring in the study population.

This plan proved to be too slow, however, and local health officers were subsequently requested to report to the Center by collect telegram immediately upon notification of a case. Thus, it was possible for VEC to send schedules promptly to the health officer listing the additional information to be obtained in the investigation of the case and the date on which that information was due.

In addition, arrangements were made to obtain from the National Foundation for Infantile Paralysis photostat copies of all NFIP medical care, hospital admission, and discharge records for children in the five-through-nine age group in each of the trial areas. These records were cross-checked with the VEC-11 reports received from local health officers as a means of identifying any eligible cases which had not been reported. In each instance, if notification of a case had not been forwarded by the local health officer, correspondence was initiated by the Center to determine if the case was in the study population.

The total cases reported from each trial area each week were also compared with the standard reports issued by the United States Public Health Service (USPHS) to estimate the adequacy of the reporting obtained at VEC. The need to report cases in study members who migrated to any other communities was strongly emphasized, and a number of cases which would otherwise have been lost to the study were thus recovered.

Through these overlapping methods, the Center had a high degree of assurance that information would be received concerning all poliomyelitis cases in the study population that were reported to local authorities or hospitalized even though delays in notification and investigation occurred. Only two cases, both migrant children, were disclosed through channels other than the established procedures for identification. It is realized, however, that cases not seen by a physician, or not reported if seen, could escape detection. This possibility seems unlikely among the requested participants but might have occurred in that segment of the population which had specifically refused to participate in the vac-

cination program.

The use of all the above sources resulted in the accumulation at VEC of a sizeable number of reports pertaining to persons who were not in the registered first, second, or third grade study population. Records of cases who because of reported age might be in the study population but were not identified in the local report as such were carefully checked with Registration Schedules of the area, and an exhaustive search of school files and Vaccination Records was made. Only if the methods failed to identify the person as a study member was the case listed as "not in the study population."

Where doubt existed as to the identity of the person, correspondence was initiated with the local officials in order to effect clarification. Many of the reports pertained to adults or to children not in school in the spring of 1954, who were in families of registered study children; these clearly did not belong among cases in study children. Most of the cases that were reported to VEC through regular reporting channels were also included in other source lists. The merging of all lists into one log book served to remove duplications and also provided the most complete file of cases for investigation.

INVESTIGATION OF REPORTED CASES

Promptly upon report of a case of poliomyelitis, the health department was to arrange for the successive steps of investigation. Since a high percentage (88.9 percent in placebo, 85.9 percent in observed areas) of patients was admitted to hospitals some of which were outside the county of registration, various means of fulfilling the investigative requirements were necessary. The responsibility remained with the local director of the study, although in a number of instances the state or district authorities assumed all responsibility.

Through the assistance of Dr. Alexander D. Langmuir, Chief, Epidemiology Branch of the Communicable Disease Center of the United States Public Health Service, 22 epidemic intelligence officers were assigned to state health departments or to laboratories participating in the study. Some of these officers accepted a major responsibility for the investigation of cases in the field; others worked closely with or in the laboratories and maintained field observations, as well, in appropriate study areas; others participated as their services were needed by the regional authorities. Their aid and interest were of great value to the Evaluation Center as well as to the local areas.

CLINICAL-EPIDEMIOLOGICAL INVESTIGATION

Every case which was reported to the local health authority was, in turn, to be reported promptly to VEC by means of an FT-6 form. This record included a summary of the clinical history, the results of the physical examination, and a report of findings in the spinal fluid.

The clinical diagnosis (paralytic, suspect, etc.) and an indication of whether the patient was at home or in the hospital were recorded on the form. Information concerning concurrent illness or previous poliomyelitis in members of the family, administration of gamma globulin or recent vaccinations were to be recorded on the same form. The report also provided additional information as to the collection of laboratory specimens. Form FT-6 usually constituted the first official record of a case received at VEC; therefore, the diagnosis reported was accepted as tentative. The responsibility for obtaining the detailed information from family, from physician, and from hospital records was usually assumed by physicians or nurses of the local health department. No case was accepted as a valid admission to the study unless the clinical-epidemiological form was submitted, and it is important to note that an FT-6 record was obtained for every study case that was disclosed through any means of reporting. The evidence contained therein provided the basis for proceeding with the subsequent detailed investigation required for all cases of poliomyelitis. If the FT-6 spe-

cifically stated that a diagnosis other than poliomyelitis had been clearly established in the period since it was first reported, the case was dismissed from further consideration as one of poliomyelitis.

LABORATORY SPECIMENS

Promptly after onset a specimen of stool (or two) and a specimen of blood were collected from the patient and sent immediately to the appropriate laboratory, accompanied by Form FT-9 on which were recorded the identity of the patient and the dates of collection. A copy of this form was sent to the Evaluation Center. If it did not arrive soon after receipt of the FT-6 form, the Center assumed the specimens had not been collected and notified the health officer of the deficiency.

Arrangements were frequently made with hospital staffs to obtain the specimens, but the responsibility for their collection and delivery remained with the local health personnel even though the patient was in a hospital some distance away. If the specimens were obtained before or at the time of the clinical-epidemiological investigation, the information was also recorded on the FT-6 form. Great emphasis was given to the need for efficient arrangements so that omissions or loss of specimens would be minimized. The importance of collecting specimens as soon as possible after onset of illness was also stressed. After three to four weeks, a second specimen of blood was obtained which, together with the first sample, was titrated for diagnosis of poliomyelitis. The stool was tested for the presence of poliomyelitis or other virus. In some areas studies of familial associates were also carried out by the laboratory and the local health authorities.

Frequently, the laboratories played an additionally important part in the collection of specimens and in pointing the attention of health and hospital personnel to the continued need for proper specimens and their prompt delivery. The complete laboratory report was made directly to the Center on Form FT-10, although preliminary reports were sometimes made by letter.

EXAMINATION BY PHYSICAL THERAPIST

On the recommendation of clinical consultants, it was decided that an expert examination of the patient's muscular status should be made within ten to twenty days after onset of illness, when the febrile stage of the disease is commonly past and further progression of paralysis is unlikely. Moreover, spasm and tenderness are generally diminished during that period, and a reasonable measure of disability can be obtained.

The physical therapists who agreed to participate received a two-weeks course of orientation in the use of an abridged system of muscle examination and in grading of muscles or muscle groups. Thus, a uniform system of recording disability was obtained which provided a score of involvement based on muscle mass and severity of dysfunction. This system had been devised by Dr. Jessie Wright and Miss Miriam Jacobs at the D. T. Watson Home in Pittsburgh, Pennsylvania. It had been used by many of the same physical therapists in the field study of gamma globulin carried out by the Communicable Disease Center, USPHS, in 1953. The study areas were apportioned to 67 physical therapists by Miss Lucy Blair of the American Physical Therapist Association, who had enlisted their aid.

At the same time other patient-study procedures were instituted, the local health officer notified the designated therapist of the identity and location of the patient with a request that the examination be made at the proper time. The therapist was not informed of the patient's vaccination status and conducted the examination on all cases reported to be poliomyelitis whether considered to be paralytic or not. Provision was made for a review and interpretation of the case by a physician especially skilled in the clinical aspects of poliomyelitis. This was to be recorded in a space provided on the Muscle Evaluation form (FT-7) and became the established clinical diagnosis. The securing of this specialist's report was left to local authorities and was done under a variety of arrange-

ments, often through the local medical society. In many of the hospitals to which the patients were admitted, the specialist's report was readily obtained. When completed, the original of the examination record was returned to the local health department and forwarded through the state health department to the Evaluation Center. A carbon copy of the report was retained by the state health department.

It had been further agreed that a second examination should take place 50 to 70 days after onset. By this time the patient would have experienced the major degree of his muscular recovery, but, on the other hand, defects not clearly localized earlier may have become more apparent as activity or use of the muscles increased. The other interferences of the acute stage would be absent so that residual injury could be more accurately measured. By this time a patient had frequently returned home or to another location. It required added attention on the part of the physical therapist to arrange for the second examination.

The specialist's interpretation of the entire character and course of the case was expected at the time of the second examination; this form (FT-8) transmitted to the Center by way of the state health department was the last of the field investigations which provided the basis for clinical classification of the patient.

Although most of the physical therapists engaged in the program were carrying out that work in addition to regular full-time duties, the diligence and competence with which they sought to meet the requirements was outstanding. The intricate patterns of communication and collaboration often resulted in delays in examination and in the receipt of reports by VEC even when completed expeditiously by the physical therapist. The consultant's comments and diagnosis were often difficult to obtain, requiring special communications and insistence by VEC.

The following abstract from a report of the American Physical Therapist Association relates the development of the plan used in the 1954 Field Trial:

Contact was made with state health officers requesting the use of the resident physical therapist who had aided in the 1953 gamma globulin study. Also letters were sent to the administrators of the facilities requesting their permission to make use of the physical therapist's services in the 1954 Field Trial.

Contact was made with state health officers for information regarding the physical therapists in state services who could be made available and oriented to the abridged muscle grading system. State Services for Crippled Children also were contacted regarding the availability of physical therapists for the vaccine program.

Where personnel from state health services were not obtainable, schools of physical therapy and local chapters of the American Physical Therapy Association were contacted for suggestions regarding qualified physical therapists for participation in the program.

There were physical therapists, in residence, provided for all states participating in the study with the exception of Maine, Rhode Island, Louisiana, Mississippi, Nebraska, North Dakota, and South Dakota. The physical therapist covering Massachusetts was able to include Maine and Rhode Island in her schedule. For the remaining five states, it was deemed advisable to employ a physical therapist on a full-time basis from June 1 through December 31, 1954, with headquarters at the National Office.

It was necessary to arrange for the orientation of 35 supplementary physical therapists to cover the study areas. When the selection of each had been made, a letter confirming his or her participation was sent to the state health officer. The orientation session for these additional therapists was held at the D. T. Watson School in April, 1954.

The syllabus entitled Testing of the Patient With Early Poliomyelitis was accepted

as standard reference with changes in context only where there was reference to the gamma globulin study of 1953.

Individual conferences were held with each physical therapist, or with a group from each state, the consultants being from the American Physical Therapy Association, pertaining to local plans and the establishing of areas of responsibilities in accepting patients for muscle tests.

A prospectus used as a working manual and compiled by the Association, with the assistance of the Evaluation Center and the National Foundation for Infantile Paralysis, was given to all physical therapists participating in the program. In addition, each was provided with a supply of forms to be used for recording and reporting.

All physical therapists who had attended the orientation sessions in 1953, whether their participation in 1954 was assured or not, were sent the various directives and forms which were used. In this way, all physical therapists familiar with the abridged system of muscle grading were informed regarding the 1954 vaccine study and were ready to assist if patients from the study areas moved into their territory before the muscle tests were completed.

Following the orientation session, a memorandum listing the name and address of the physical therapist serving the area was sent to respective state health officers for transmittal to the local health officers in each participating county or city.

It then became the responsibility of the individual physical therapist to establish contact with local health departments.

In August the decision was made to include areas in the Canadian provinces of Alberta, Manitoba, and Nova Scotia, in the Poliomyelitis Vaccine Field Trial. In cooperation with the Canadian Physiotherapy Association and local ministries of health, one physical therapist for each province was selected to be responsible for the muscle tests in her respective area. The three physical therapists reported to the D. T. Watson School in Pennsylvania for the prescribed orientation session in August, 1954. The same type of supportive and complementary service from the American Physical Therapy Association was provided in coordinating their activities and paying for services rendered as was given the physical therapists in the United States.

All physical therapists prepared in the abridged muscle grading system were ready to accept the referral of patients at the completion of the poliomyelitis vaccination clinics.

There were many local variations used in referring patients for muscle tests to the selected physical therapist. Lack of understanding was evident in a few instances early in the follow-up phase of the program. One characteristic oversight which persisted in many areas was the delay in referring patients to the physical therapists in time for the 10-20 day muscle test.

After receipt of referral, it was the responsibility of the physical therapist to perform the muscle tests within the prescribed period of time. Following the completion of each muscle evaluation report, three copies were returned to the local health department, one for filing and two for transmittal to the state health department and the Vaccine Evaluation Center. In addition, many attending physicians of the patients requested a copy of the muscle test data.

Monthly reports from the participating physical therapists were sent to the National Office of the American Physical Therapy Association. These reports included the names and addresses of patients on whom muscle tests had been completed, as well as dates and mileage required. The American Physical Therapy Association then compiled a monthly list of all patients tested in all states and forwarded copies to the Vaccine Evaluation Center and the National Foundation for Infantile Paralysis.

Monthly memoranda were sent to each participating physical therapist communicating

specific directions from the Vaccine Evaluation Center regarding the conduct of the program and sharing the experiences of others as a means of solving individual problems.

It is appreciated that the number of muscle tests performed does not give a true picture of the time factor required in making the Field Trial study an effective one. It has been estimated that each muscle test required an average of $5\frac{1}{2}$ hours of work including not only the actual muscle test but time in making appointment, travel, professional contacts, records, and reports.

Following is a time breakdown recorded by a physical therapist in a state agency for crippled children who was permitted to include the muscle testing program as part of her assigned responsibilities. Thirty-three percent of her total duty time was spent on the vaccine study. Analysis of distribution of vaccine study time, April 26 through December 31, 1954, is listed below.

26 percent required for travel
30 percent required for records
44 percent required for

1. Attending orientation course in Pennsylvania
2. Touring participating counties for pre-planning and interpretation
3. Contacting attending physicians
4. Contacting patients for appointments
5. Contacting allied professional personnel
6. Performing muscle test

When the terminal phase of the field program was reached, each physical therapist submitted, as a final check, a recapitulation of all the muscle tests performed including the name of each person tested plus the dates of the first and second muscle examination; if either of these tests was not made, an explanation was shown on the report.

A total of 2,101 muscle tests were completed by 66 physical therapists who covered 130,000 miles in the selected areas of 44 states and 3 Canadian provinces included in the Poliomyelitis Vaccine Field Trial of 1954.

FATAL CASES

It was requested that any fatality in the study population be reported to the Evaluation Center by telephone, and every effort was made to obtain a complete autopsy, central nervous system tissue, and other specimens for laboratory study. VEC Memo No. 8, sent to all study areas early in May, contained a special message asking that any fatal cases among inoculated children, occurring within four weeks after last injection, be given particular attention. The Center and the regional laboratory were to be notified immediately, and a request made for a complete post-mortem examination to be done by a well-qualified pathologist. Clinical and epidemiological reviews were requested. The Center offered to assist in obtaining the desired personnel if necessary and to meet expenses incurred in fulfilling the requirements.

STEPS TAKEN TO ENSURE COMPLETENESS OF INVESTIGATION

The substantial amount of correspondence required early in the Trial concerning proper follow-up and collection of specimens indicated that clarification beyond printed instructions was necessary. As previously stated, meetings were held in May and June in study areas with state and local health officials and NFIP representatives and cooperating hospital personnel in 32 of the 44 states in the Field Trial. At these meetings, staff members of the Evaluation Center discussed in detail the requirements for follow-up of cases and sought to aid in formulation of local plans for this phase of the operation. It was strongly suggested that one person from the staff, usually a public health nurse, be designated to oversee the scheduling and performance of the indicated steps in the study of a patient.

By July the pattern of deficiencies in re-

ports of case studies had become quite apparent, and steps were taken to correct them. Physicians' interpretations and signatures as required on Forms FT-7 and 8 were frequently lacking; hence, a form letter was developed which provided a convenient means for requesting the missing information promptly. An additional circular letter restating in detail the plan of procedure was distributed to all areas on July 12.

Each participating laboratory was sent a list of all cases on record in its areas and of all reported collections of specimens. On all new cases thereafter, a postcard reporting this information was routinely sent by VEC to the appropriate laboratory so that its staff would have a complete record of cases from whom specimens should be expected.

A system of logging each case by area was also put into effect at the Center. It provided a complete and compact record on which receipt of the various forms required could be posted; at intervals during the latter part of the year, a list was mailed to each state health officer relative to cases in his area on which records were not complete.

In a third attempt to obtain qualified medical reviews and interpretations on Forms FT-7 and 8, a general letter was mailed to all state health officers on August 27, reemphasizing the need for specialists' comments written on the back of the forms and asking that the professional status of the diagnostician be indicated below his signature. In this letter, the states were again reminded to furnish the names and qualifications of the specialists selected for this purpose, if they had not already done so.

In September it became evident that further effort to reduce the waiting period for each of the reports must be made. Form VEC-31, Special Attention note, was developed for this purpose and sent to the local agencies concerning each case, showing the dates on which each report was due in the office of the Evaluation Center. The request for specialists' comments, signature, and status was stressed by a quote from the VEC letter of August 27 on this subject clipped to the VEC-31 form.

Data were still missing after the middle of November, and again lists were prepared and sent to state health officers requesting immediate action. Telephone calls were made to some of the delinquent areas.

As of December 31, a tally showed that, out of a total of 1,103 reported cases, there were approximately 290 study cases on whom the records were still incomplete. An intensive follow-up by telegram, telephone, letter, and field visit was made during January, and the open cases were reduced to 78 as of January 31. The last of the available FT-6, 7, and 8 reports were received from the trial areas on March 9, 1955. Reports on the laboratory investigation of specimens were incomplete for 14, or 3.3 percent, of the 428 placebo study cases and 44, or 7.5 percent, of the 584 observed study cases at the time the summary report was prepared. These missing data have since been received and are incorporated in the detailed report.

FOLLOW-UP OF PERSONS WHO MOVED DURING THE STUDY PERIOD

Follow-up of cases of poliomyelitis in children who moved during the study period was conducted in accordance with directions contained in VEC Memorandum No. 9. State health officers investigated each case in the 5-9 age group and learned the child's grade and school, as well as the county and state in which the school was located. Registration Schedules for his state enabled the health officer to ascertain whether or not the case was a child in the study population; if so, arrangements were made with the local health office, whether in a participating or nonparticipating county, to initiate the follow-up procedure.

If the child had been a resident of a participating county in another state, an inquiry as to the child's status in the program was submitted immediately to the Evaluation Center

where an examination of the central files was made in order to establish whether the child was a member of the study population. The state health officer was then informed if an investigation of the case was to be made and was expected to assist the local health officer if such an investigation were necessary.

Other methods for discovery of migrant cases were also suggested, such as enlisting the aid of hospitals, physicians, parents, and Foundation chapters and asking them to try to determine, for each case which came to their attention, whether or not he was a registered member of the study population.

At the Evaluation Center, the weekly reports of cases of poliomyelitis in the study areas were carefully examined, and all cases in the 5-9 age group for which the prescribed follow-up was not being made were investigated. The hospital admission and discharge records, furnished VEC by NFIP, were instrumental in turning up eight migrant study cases which otherwise might not have been located.

Children in the pre- and post-vaccination blood sample who had moved to another area prior to the drawing of the third blood were located in a similar manner. The local health officials were asked to provide VEC with the name, new address, former address, and registration sheet and line number for each of such children. This information was then relayed by VEC to the appropriate health official with a request that arrangements be made to secure the bloods and to send them to the proper laboratory for testing. In several instances, the child moved to a non-study area which required VEC to supply venules for bleeding and venule labels. In a considerable number of instances, the local health officer made all necessary arrangements without the help of VEC. This was particularly true in those instances of within-state migration.

PROCEDURE FOR TABULATION OF CASE DATA

It was necessary to transfer and code the desired information on reported cases of poliomyelitis in the study population to transcription forms in order to facilitate the punching of the data into tabulation cards. The multiple line Forms VEC-32, 33, 35 and 35A, and 36 were designed for this purpose. These forms, together with the specific instructions, are illustrated in the Appendix together with a description of each corresponding tabulation punch card.

There was a minimum of nearly ninety days from date of onset until all follow-up reports on a study case could be received at the Center; it took even longer in the early part of the program when many of the laboratories were unprepared for the required examinations of specimens. Because of these delays, the transcription operations were not begun until late November after a sizeable number of reports had been accumulated.

Separate groups of clerks were specially trained in the transcription of basic registration and clinical and epidemiological data (FT-3 and FT-6), the muscle evaluation data (FT-7 and 8), and the laboratory findings on serological tests and tests for detection of virus (FT-10). Insofar as possible, these transcribing operations were performed on study or family cases for which all the required follow-up records had been received. As in the processing of the basic records, the transcription of the case data was done on a concealed basis with respect to vaccination status. At the close of the reporting period, December 31, 1954, nearly a third of the expected reports on muscle evaluations and laboratory findings were still outstanding so that it became necessary to perform the transcription work on a report-received basis to avoid time losses. Each of the laboratory reports was reviewed for acceptability and completeness by a member of the VEC medical staff before the data were transcribed. If there were unexplained gaps or inconsistencies, they were brought to the attention of the participating laboratory with a request that an explanation or supplementary information be supplied.

At the time the transcription of the muscle evaluation data was done, a preliminary diag-

nostic classification was assigned to each case by the VEC medical staff. The diagnostic classification at the time of the 10-20 day muscle examination was based on the clinical and epidemiological data submitted on Form FT-6 together with the muscle scoring completed by the physical therapist, her comments if any, and the physician's interpretation given on the back of the Form FT-7. A similar diagnostic classification was assigned after the 50-70 day muscle examination, taking into consideration the factors previously noted as well as the extent of muscle impairment remaining at the time of the second muscle examination, any comments given by the physical therapist at this stage, and the physician's interpretation of the complete experience of the case at this chronological point.

The transcription forms were then sent directly to be punched on the tabulation cards and listings of all of the information recorded were prepared mechanically. These listings were then used to perform a complete verification on each case by comparing the mechanical listing with the original reporting document. Any errors or omissions were then corrected on both the transcription form and the punch card, and a new card was punched and verified mechanically. It is believed that this method of verification using independent cross checks reduced the number of errors in the case cards to a minimum.

The case cards punched at this intermediate stage of study were then mechanically collated, and a set of summary cards was reproduced carrying the information from the intermediate cards essential for the Summary Report tabulations. Data from reports received later could be added. The content of the summary card (Form VEC-50) is listed in the Appendix. At the time this summary form was established early in March, 1955, there were still some laboratory reports outstanding. A concentrated telephone round-up was conducted to obtain as much of the missing data as possible, and the results were immediately incorporated in the summary cards with a final cut-off date of March 11.

At this point, a tabular listing of the summary cards was prepared, without the record of the vaccination status of cases, in order that an interpretation of laboratory findings could be assigned to each case as well as the final Evaluation Center diagnostic classification which took into consideration all of the data available for each case. The VEC laboratory interpretation code was devised to indicate the status of virus isolation, the results of the serological findings, and the type of virus isolated or indicated by the serological findings. The final VEC diagnosis assigned to each reported case placed it in one of the following categories: not poliomyelitis, nonparalytic poliomyelitis, paralytic spinal, paralytic bulbar, paralytic bulbospinal, poliomyelitis death, nonpoliomyelitis death, suspect poliomyelitis, and other diseases.

After the VEC interpretation of laboratory findings and the final VEC diagnostic classification had been determined for all reported cases, the summary cards containing all the data including vaccination status were used in the series of tabulations to determine the effectiveness of the vaccine.