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Department of Health, Education, and Welfare
Public Health Service Communicable Disease Center

Poliomyelitis Surveillance Unit 50 Seventh Street, N. E. Atlanta 5, Georgia

PROPOSALS FOR MODIFYING THE NATIONAL POLIONYELITIS SURVEILLANCE PROGRAM

- I. Statement of Objectives of Polio Surveillance
- To Routine Polio Surveillance Procedures
- III. Proposed Vaccine Studies for 1955
 - 1. General Age Distribution Analysas
 - 2. Special Age Group Investigations
 - 3. Epidemic Studies
- IV. Services Available from CDC

Appendix I - Discussion of Changing Concepts of Polio Surveillance

The National Poliomyelitis Surveillance Program was announced on April 28, 1955, and inaugurated on May 1 with the PSU Report No. 1. For more than a year discussions had taken place within the Communicable Disease Center and with State Epidemiologists and others concerned over the desirability of developing such a program. The occurrence of more than the expected number of cases of poliomyelitis in some children vaccinated with some of the products of one manufacturer lead to an acceleration of these plans. The response from the State Health Departments and participating laboratories has been prompt and thorough. A two way flow of information through the PSU Reports has been established so that all technical persons needing the report have been kept currently informed as to the status of the changing and often misunderstood situation.

Now the immediate epidemiologic emergency seems to have passed. is time for a careful reappraisal of the objectives of the National Poliomyelitis Surveillance Program. Future procedures both for field epidemiology and for laboratory confirmation should be planned in relation to future needs and anticipated future problems. The experience of the past two months dictates a number of changes. The routine aspects of the surveil lance procedures should be cut back to a basic minimum. A unique opportunity for additional studies of the effectiveness of the vaccine is afforded by the current short supply and its restriction for a limited period of time to 1st and 2nd grade children. The amended minimum requirements promulgated by the National Institutes of Health for the production of poliomyelitis vaccine have been directed primarily toward increasing the safety of the product. These increases in safety testing should serve effectively to eliminate the possibility of future incidents. The fact that these steps toward insuring safety of the vaccine have been taken further suggest that the poliomyelitis surveillance program should be revised and strengthened in order that the effiacy of the vaccine may be further evaluation.

I. Statement of Objectiveness of Poliomyelitis Surveillance

The Objectives of the Poliomyelitis Surveillance Program can be stated as follows: (See discussion of Changing Concepts of Polio Surveillance in appendix)

- 1. To carry on continuing studies of the incidence of poliomyelitis and polio-like infections in the nation to aid in the most effective application of control procedures.
- 2. To undertake studies of the effectiveness of the poliomyelitis vaccines as used in 1955.

II. Routine Poliomyelitis Surveillance

To attain these objectives a continuing routine surveillance should be maintained in each State and Territory. A history of polio vaccination should be obtained in every case of reported poliomyelitis. If vaccination was given, the following data should be collected: date of onset, date and site of inoculation, manufacturer of vaccine, lot number, and site of 1st paralysis. If two inoculations were given, full data on both should be collected.

If the interval from vaccination to onset is 30 days or less, the question of the safety of the particular lot of vaccine used must be considered, especially if there is correlation between site of inoculation and first paralysis. It is expected that there will be cases in vaccinated children under 30 days as a result of ineffectiveness of vaccine in some children.

In any event the health officer should survey immediately:

- 1. The extent to which the same lot of vaccine has been used.
- 2. The occurrence of additional cases among such vaccinated persons, or among parents and siblings of vaccinated children,
- 3. Incidence of minor illness following vaccinations.

Specimens should be submitted, including stools from cases, and from other vaccinated children when epidemiological investigation warrants. Blood specimens for complement—fixation tests may also be useful for suggesting recent infection.

If the interval from inoculation to enset is more than 30 days, the question of the effiacy of the particular lot of vaccine must be considered, especially if a group of such cases is reported. Each situation will require careful epidemiological appraisal comparing the general incidence of paralytic polio in the community with the incidence rate among vaccinated persons. Specimens for laboratory examination should be submitted for virus isolation and typing. It is conceivable that vaccines may vary in the degree of type specific immunity conferred. Also careful clinical and laboratory appraisal is essential to establish diagnosis.

The following Revised Procedures for reporting to PSU in Atlanta recommended to become effective immediately:

- 1. Telegraphis report giving minimum essential data for each case of poliomyelitis in a vaccinated person with interval 30 days or less from vaccination to onset. PSU case form to be sent by air mail when data are complete.
- 2» PSI case form by air mail for each case in a vaccinated person when interval between inoculation and onset is over 30 days.
- that 3. Brief natrative accounts by air mail of any unusual situations may relate to possible safety or effectiveness of vaccine.
- sporadic cases of polio-like illnesses such as encephalitis, Coxsackie tirus infections, leptospirosis, etc. These reports should also be sent simultaneously to NOVS.

Proposed Vaccine Studies for 1955

Program several types of study can be visualized. These may be grouped three broad categories:

1. General Age Distribution Analyses

2. Specific Age Group Investigations

3. Epidemic Studies

The first of these, General Age Distribution Analyses, are relatively simple extensions of the Routine Surveillance procedures. Data on the age incidence of polio can be accumulated for comparison with the abundant data of previous years. Since immunization this year will probably be limited largely to 1st and 2nd grade children or at least to 5-5 year olds, a reduction in incidence in these immunized age groups should become clearly apparent and serve as a rough measure of the effectiveness of the vaccine. This type of study should not be considered as a controlled study but rather as an organized collection of descriptive data that is applicable on a broad national scale. It is hoped that most states will elect to participate with the Polio Surveillance Unit in this phase of the study.

The procedures to be followed by participating states will be the submission of a weekly report to PSU on each Friday of all new verified cases of polio reported in the state. A special form, copy attached, will be available on request. Cases are to be listed only when they have been accepted by the State Polio Reporting Officer with paralytic status, date of onset and age established to his satisfaction. The number of such cases reported to PSU each week will not correspond with the current provisional incidence data reported each week to NOVS because some delay will be required to establish the facts. Indeed the cumulative totals reported to PSU will tend to be lower because some cases reported to NOVS will be later withdrawn as not confirmed polio.

This type of study has been purposefully planned on assimple a basis as possible. No data are requested on laboratory examination, history of vaccination or extent of paralysis. Such details should be reserved for the special investigations and epidemic studies.

It is proposed that these General Age Distribution Analyses cover the period from April 12 to October 31, inclusive. Many case records have already been reported to PSU. A listing of these cases by date of onset from April 12 to June 30 on the new form will be submitted to any participating state on request as a starting point for checking records and making listings complete. Subsequent reports from States should be prepared in duplicate with one copy being retained in the state for further reference.

As reports accumulate at PSU they will be consolidated and published at regular intervals in the PSU reports as nearly weekly as possible.

The Special Age Group Investigations are visualized as more intensive research studies, that certain states may develop in relation to particular opportunities or special local circumstances. The expected limitation of vaccination to a narrow age span will permit special studies which will be comparable in some respects to the observed control studies of the 1954 vaccine Evaluation. Either a whole state or any specified area within a state might be included. The study areas of the 1954 evaluation, both the placebo control and observed control groups, will be most interesting to follow.

In those states where it is possible to make reasonable approximations of the number of children in specified age groups that have received vaccinations, attack rates may be determined for vaccinated children and

unvaccinated children of the same age or of reasonably comparable age groups immediately younger and older than the vaccinated group. In states where groups that received one and two doses this year can be defined, and in areas where 1954 evaluations were carried out and where booster inoculations were given this year, even more detailed investigations can be undertaken.

The basic procedures necessary for such studies are a field investigation by a trained worker to verify the clinical data, to determine the exact dates of onset, history of vaccination and dates of inoculation, manufacturer and lot number, and to collect specimens for laboratory confirmation of diagnosis. A 50 to 70 day muscle grading by a qualified physical therapist along with isolation and typing of virus would add materially to the accuracy and value of the study.

While the detailed plans for these special studies must be developed in relation to the local circumstances and opportunities, and while primary responsibility for directing the studies should remain local, the CDC will make a maximum effort to provide collaborative support upon request.

Epidemic Studies will be of special importance this year. In some

epidemic situations local authorities will choose to avoid use of polio vaccine. Here it should be possible to obtain the most accurate evaluation of the effectiveness of the vaccine among children inoculated before the epidemic began. In other areas authorities may well continue vaccination at least in selected age groups, if supplies of vaccine are available. Meticulous field epidemiological studies supported by clinical, laboratory and physical therapist examinations will be most important not only to evaluate the effectiveness of vaccine as a procedure for the control of epidemics but also to determine the extent of the possible provoking effect.

It is believed that the services of CDC may be particularly applicable in such epidemic situations during the present summer. All assignments of Epidemic Intelligence Service Officers will be contingent upon their availability for such epidemic studies both within the State of their assignment and elsewhere.

IV. Services Available from CDC

Disease Center and will be available to the States on request commensurate with maintaining a national balance in the program:

- 1. Forms
 - a. Polio Surveillance Form

A case investigation form for field use for routine surveillance or for special studies or epidemics

b. Age Distribution Analysis Form

A simple roster for weekly reports to PSU by States participating in this phase of surveillance

c. Laboratory Specimen Forms

Two forms are available, one for submission of specimens to the laboratory and the other for the laboratory reports. The upper half of both forms is identical and contains identifying data and description of the specimens submitted. The lower half of the first form is detachable and will be returned upon request to the sender as acknowledgement of receipt of the specimen. The lower half of the second form will be forethe results of the laboratory tests.

2. Consultation and Epidemic Aid.

The full resources of Epidemiology Branch, CDC are alerted for first priority duty on Polio Surveillance during the present summer. Epidemic Intelligence Carvice Officers, (physicians, * rses and statisticians) will be available for epidemic aid and for assistance in locally developed and directed special studies.

3. Physical Therapy

Arrangements for physical therapists to participate in special studies should be worked out directly by the states. Where this is not achieved, CDC stands ready to assist in arranging for PT services.

4. Laboratory Diagnosis

Funds have been made available in May and June 1955 through the NIH to several laboratories to support laboratory references diagnosis services in Polio Surveillance, and beginning in July 1955 funds will become available through CDC. Further information regarding these laboratory services should be obtained through Dr. Ralph Hogan, Chief, Laboratory Branch, CDC

5. Reports

The periodic PSU Reports will continue on the present FOR OFFICIAL USE ONLY basis to avoid possible misinterpretations of the incomplete and often quite fragmentary data that will be included. In addition to publishing data on routine surveillance and general age distribution analyses, progress reports of special studies, epidemic situations, or interesting laboratory findings will be included when submitted by responsible investigators. These also will be limited to OFFICIAL USE ONLY in order to encourage the maximum interchange of information among technical persons participating in the Surveillance Program. However, it is expected that consolidated scientific reports of fully evaluated data will be given at appropriate scientific meetings.

Appendix I

Changing Concepts of Poliomyelitis Surveillance

As originally conceived, Poliomyelitis Surveillance was patterned after other CDC Surveillance Programs such as those for malaria, smallpox and other communicable diseases of national importance. Experience has shown that one of the primary problems with these diseases was faulty diagnosis leading to erroneous reporting. It was anticipated that this problem would also be encountered in Poliomyelitis Surveillance as an increasing number of children became immunized, Furthermore it was expected that a substantial number of the children in the country would be immunized before the 1955 polio season and the major problem during the coming season Would be the occurrence of outbreaks and sporadic cases of a variety of infections that simulate polio but that actually were other diseases. not correctly diagnosed such cases might lead to considerable worry, if not community alarm and if frequent in occurence would lead to discrediting of the vaccine erroneously. It was also recognized that the contemplated Surveillance Program would provide useful data on any defects either in the efficacy or safety of specific lots of vaccine, although this was felt to be a rather remote possibility.

One of the assumptions that was made at the beginning of the Surveillance Program was that, if associated cases were due to live Virus in certain lots of the vaccine, then the cases developing would result from inoculation of virus into the peripheralnerves, and systemic infection would be unlikely. Such cases would probably not be infectious. Hence special emphasis was placed on examining stool specimens from household contacts with the concept that the virus would be found rarely if at all among contacts of such "inoculation" cases.

Experience showed this assumption to be quite wrong. Stool specimens from household contacts of inoculated cases yielded Type I poliomyelitis virus on numerous occasions. Furthermore the virus was isolated from vaccinated children who had only mild febrile illnesses, sore throats, stomach upsets, or no symptoms at all. These individuals apparently spread their infection to parents and siblings. Thus the laboratory examination of stool specimens from household contacts of vaccinated cases has not proved useful in distinguishing inoculation cases from spontaneous or coincidental cases. This formerly recommended procedure longer needs to be followed.

On the other hand the occurence of numerous mild or inapparent infections following vaccination points to new procedures for the most rapid field detection of unsafe lots of vaccine in the future should any appear. Whenever minor illnesses or febrile reactions occur with increased frequency following vaccination, stool specimens from a group of these vaccinated children should be collected and submitted to a virus laboratory and in priority attention. The isolation of polio virus from even a lot number of such cases would be strong presumptive evidence of an unsafe of vaccine if these were few or no other cases reported in the community. The collection of such laboratory evidence might be initiated well before first associated paralytic cases were reported. Also whenever one or that cases of poliomyelitis occur in vaccinated persons under circumstances suggest the possibility of inoculation poliomyelitis, the most rapid

method to check the possibility would be to collect the specimens from a number of children who had received the same lot of vaccine and submit them to a laboratory. The finding of several carriers would suggest the possibility of unsafe lot of vaccine, but it might not be conclusive.

At the initiation of the Surveillance Program as mentioned previously, it was anticipated that a large proportion of the children in the country would be inoculated by August 1. It was expected that only a moderate number of cases of polio would be reported and that most of these would fail to be confirmed by laboratory study. On these assumptions each State was requested to submit "minimum essential information" on all reported cases and to seek laboratory confirmation whenever possible.

Now it is apparent that the available supplies of vaccine may be so limited that few children outside the first and second grades will receive immunizations before the polio season is well underway. Therefore the incidence of polio this year may be such that daily individual reports on all cases to the PSU could become a severe burden. Revision of procedures is clearly indicated.

Finally the situation is now developing in many ways similar to 1954 at the time when the Vaccine Evaluation Program under Dr. T. Francis, Jr., was initiated. Most 1st and 2nd grade children have received one dose of vaccine and many have been given or will receive a second dose in the near future. Also children who participated in the 1954 evaluation have received booster doses. Large and well identified populations of vaccinated children are available for observation. A unique opportunity is thus afforded to evaluate on a comprehensive and practical scale, the effectiveness of the Polio vaccine as used in 1955. The procedures already developed for Poliomyelitis Surveillance can be readily adapted to certain broad types of study. Several states have indicated their interest in conducting detailed studies.

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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

FORM APPROVED BUDGET BUREAU NO. 68-R574

Public Health Service

Communicable Disease Center

POLIOMYELITIS SURVEILLANCE PROGRAM

Age Distribution Analysis Form Weekly Summary of All Poliomyelitis Cases

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INSTRUCTIONS:

- All states participating in the Age Distribution Analysis of the 1955 Poliomyelitis Vaccine Study are requested to submit information weekly on all cases of poliomyelitis occurring in their state. Cases should be listed as soon as they have been accepted by the State Poliomyelitis Reporting Officer and their status (paralytic or nonparalytic) has been determined.
- All cases should be listed regardless of vaccination history. (A
 Poliomyelitis Surveillance Case Form should also be submitted on
 all cases vaccinated in 1955 as part of the Routine Surveillance
 Program.)
- 3. The Age Distribution Analysis Form should be completed in duplicate and the original copy airmailed each Friday to the Poliomyelitis Surveillance Unit, Communicable Disease Center, 50 Seventh Street, N.E., Atlanta 23, Georgia. The carbon copy should be retained by the state for reference.
- 4. Space is provided at the bottom of the form for revisions of previously listed cases. Such cases should be listed in their revised form with the date, sheet number and line number of the original listing indicated.

Use this space for additional remarks:

Public Health Service

Communicable Disease Center

POLIOMYELITIS SURVEILLANCE PROGRAM

Specimen Shipment Form

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6 400.118 (CDC) GA. FORM APPROVED DEPARTMENT OF Public Health Service HEALTH, EDUCATION, AND WELFARE Communicable Disease Center DISTRIBUTION: Copy 1. Person submitting POLIOMYELITIS SURVEILLANCE PROGRAM specimen(s) 2. Polio Surveillance Laboratory Report Form Unit, CDC 50 Seventh St., N.E. Atlanta 23, Georgia To be filled by laboratory: 3. State Health Officer 4. Retain in laboratory Date received _____ Lab. No. of specimen(s): Specimen(s) collected from: Date Date Item 1. Name 2. Sex 3. Age ____ Coll. Sent tal Swab 1 4. State _____ 5. County ____ 6. City ____ oat Swab 7. Street Address 8. Date of first symptoms Convalescent Convalescent 9. Vaccination (check appropriate item): Specimen(s) 1955 1954 None Pecify) 10. Clinical diagnosis (check appropriate item): (b)___Bulbar (c)___Paralytic (a) Fatal (d)___Non-parul,___ (g)Other_____(specify disease) (d)___Non-paralytic (e)___Suspect (f)__Not ill $^{t_{i_{k\in \mathbb{N}}(s)}}$ collected and sent by: 11. Contact of polio case: Yes No 12. Other pertinent information: NOTTAJOS!

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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE COMMUNICABLE DISEASE CENTER

POLIOMYELITIS SURVEILLANCE UNIT

COLLECTION OF SPECIMENS FOR POLIOMYELITIS DIAGNOSIS

Recommendations on the selection of individuals for laboratory study have been outlined in a separate communication.

The following generally accepted methods are recommended for collection of laboratory specimens. Instructions from individual laboratories may be at variance with these recommendations, particularly if designed for special studies, and should be followed when available.

Shipments should be timed so that laboratory specimens arrive on a work-day, and not on weekends or holidays, whenever possible.

FORMS

Two laboratory forms will be used for poliomyelitis reference diagnosis.

Specimen Shipment Form is to be filled out by the field investigator and sent with the specimen to the diagnostic laboratory. A section of this form will be detached and remitted to the field investigator to confirm receipt of specimen by the laboratory. The remainder of the form will be retained by the laboratory.

Laboratory Report Form will be filled out in quadruplicate by the laboratory when laboratory diagnosis has been completed. Four copies will be distributed as follows: Copy 1: Mail to the field investigator submitting specimen; Copy 2: Mail to the PSU; 50 Seventh Street, Atlanta; Copy 3: Mail to the State Health Department; Copy 4: Retained by Laboratory.

STOOL SPECIMENS

Collection: Obtain a stool specimen as early as possible after onset of illness. Use a receptacle which contains no disinfectant. Transfer to a sterile jar, ointment box, or waxed container. If a regular stool is unobtainable, one of the following methods can be used: 1) tap water enema (do not use soapsuds); 2) specimen collected on a glove by rectal examination; 3) rectal swab which must contain visible fecal material. Rectal swab should be suspended immediately in a screw-cap liquid tight bottle containing 1.0 cc of sterile water.

A second stool specimen should be collected 1 to 3 days after the first specimen has been obtained.

Storage: Refrigerate in deep freeze or freezing compartment of refrigerator.

Shipment: If a specimen will be in transit less than 21 hours it can be shipped without refrigeration. A specimen which will be in transit more than 21 hours should be mailed in a refrigerated container as follows:

Specimen (s) should be packed in dry ice (solid carbon dioxide), in a card-board container or insulated paper bag and this packed inside a larger container, with insulation between the two containers. Shredded paper, saw-dust, wood shavings or other available material may be used for insulation. Reuseable commercial shipping boxes are also available. Note: Glass thermos type containers are too fragile for mailing and should be avoided.

See footnote on page 2.

BLOOD SPECIMENS

Collection: Two specimens must be obtained on every patient studied, serologically. The first specimen should be obtained on the first day of observation, the second specimen two to four weeks later.

Obtain 10 cc of blood in a sterile dry syringe and transfer whole blood to a sterile tube. The tube should be closed with a paraffin-dipped cork stopper and secured with tape. Do not use anticoagulants or preservatives in the test tube. Commercially prepared bleeding tubes in vacuum containers may be used to draw blood conveniently when the number of patients are large or in the field where syringes and needles are not readily available.

Storage: Specimens to be shipped within 21 hours of collection can be sent as whole blood. Such specimens may be kept over night in an ordinary refrigerator. Specimens to be stored for longer periods must be processed as follows: 1) allow several hours after collection for formation of blood clot; 2) centrifuge until clot is packed firmly (usually 15 minutes in an ordinary laboratory centrifuge at about 2000 RPM) and pour off serum; 3) store serum in an ordinary refrigerator.

Shipment: Whole clotted blood or serum specimens may be shipped without refrigeration but should be carefully packed to prevent breakage. Ship regular mail special delivery to laboratory within 100 miles, air mail special delivery to laboratories over 100 miles distant.

POST-MORTEN SPECIMENS

Collection: At the time of autopsy obtain under sterile precations the following samples if possible: 1) a section $\frac{1}{2}$ inch thick from medulla, pons, mid-brain, and cervical and lumbar enlargement of the spinal cord: 2) a specimen of tonsillar tissue; and 3) a 3-inch segment of the descending colon tied off at both ends. (The last is particularly important if no ante-mortem stool specimens have been obtained.) Wherever possible, histologic examination of the Central Nervous System for evidence of poliomyelitis should be requested from the local pathologist.

Blood specimens, if not obtained ante-mortem, can be obtained post-mortem and handled as suggested above.

Storage: Specimens may be transferred to sterile containers or suspended in a sterile solution of half-and-half glycerol and saline. Glycerinized specimens may be stored in an ordinary refrigerator. Untreated specimens should be kept in a deep freeze.

Shipment: Specimens must be carefully packaged to avoid breakage. If suspended in glycerol-saline, refrigeration is not necessary. Otherwise, specimens should be packed in dry ice in a cardboard container or insulated paper bag, and then packed inside a larger container with insulation between the two containers. Shredded paper, sawdust, wood shavings, or other available material may be used for insulation. Reusable commercial shipping boxes are also available. All specimens should be dispatched to the laboratory with the least possible delay.

* Boxes of this type costing about \$17.50 may be obtained from: The Hallinge Corporation, 3834 S. Four-Mile Run Drive, Arlington Virginia. Similar containers produced by other manufacturers would be equally useful. Such boxes will be returned to the sender promptly for subsequent shipments.