CHAPTER III

CONDUCT OF THE FIELD TRIAL

REGISTRATION OF THE STUDY POPULATION

It is essential in a study of a phenomenon occurring in a limited, select population that members of that population be clearly recorded and their status with respect to the study be established. They constitute the denominator against which all effects are to be measured. Furthermore, specific identification of every child is required since he may subsequently be reported to have poliomyelitis. Therefore, each of the series of records which was prepared to cover the different steps of procedure contained the same essential information identifying the person.

While the services of local and state health officers, superintendents, principals and teachers of schools, physicians, nurses, and volunteer workers were all essential to the operation of a successful Field Trial, the accuracy and completeness of records of the study population was mainly the responsibility of the local classroom teachers where clinics were conducted. This phase entailed the filling out of two forms, the Registration Schedule and the Vaccination Record, and the obtaining of a response to a "Parental Request for Participation of Child."

REGISTRATION SCHEDULE

The basic record for identifying the study population was a Registration Schedule (Form FT-3) on which were entered the names of all children in a classroom of the first, second, and third grades of each participating school. Since each sheet and line of Form FT-3 was numbered uniquely, a child could thus be permanently identified. Address, date of birth, sex, color, previous history of poliomyelitis or disability were recorded. Subsequently, data with respect to participation and inoculation were entered as a cross check with data on other forms. The same procedure applied to both the placebo and observed areas. It was necessary in some of the observed areas to emphasize repeatedly that these records were required for the first and third graders, although they were not inoculated, since they constituted the control segment of the population. The registration thus obtained listed the total study population.

PARTICIPATION REQUEST

The parents of each child were to receive a form (FT-1 in observed areas, FT-2 in placebo areas) briefly stating the nature of the study, and providing space to make written request for the child to participate in the study, regardless of whether he was to be inoculated or to be an observed control. In placebo areas it meant that the child would receive an injection of either placebo or vaccine on a concealed basis. The request also gave permission for the collection of specimens of blood, if needed. When a specifically signed request was returned, a "yes" indicating this fact was entered in the proper space on the Registration Schedule. Specific refusals, forms not returned, and forms returned unsigned, were recorded as "no." Certain irregularities were encountered in the observed areas since only one grade, the second, was subject to vaccination; for example, request forms for children of the first and third grades were sometimes used only in those schools where children were to give samples of blood, so that "yeses" and "noes" could not be fully defined for all control children.

VACCINATION RECORD

Form FT-4, Vaccination Record, was filled out for each person who received an inoculation or from whom blood was taken. It duplicated the identification contained in the Registration Schedule and the name of the parent who signed the request form. Three injections of 1 cc. each were to be given intramuscularly at 0, 1, and 5 weeks. The date of each inoculation, the lot or code number of the material given, the name of the physician, and the date blood was drawn were recorded. Space was provided for recording any evidence of reaction. When the vaccination series was not completed, the reason was to be stated. The dates of inoculation and of blood specimens were also entered on the Registration Schedule.

ADEQUACY OF REGISTRATION

These essential records (Forms FT-3 and FT-4) were prepared in triplicate. When vaccinations were completed and the blood specimens collected, the records were to be edited locally and the first two copies sent to the State Health Department which, after review, would send the original copy to the Evaluation Center. The extensive work involved in editing, completing, and processing these records is detailed in Chapter IV.

Although the establishment of a study population would appear to be a relatively simple task within each trial area, misinterpretations of the instructions by the local school and health officials and faulty information received by them made it difficult in some instances for the Evaluation Center to obtain a complete registration of the defined study population.

Early in the program the local health officers were requested to furnish the Center with an alphabetical list of all the eligible schools in a trial area, showing the mailing address of each school and the total enrollment in the first three grades (see VEC Memorandum No. 6 in the Appendix). These lists were ultimately obtained for all study areas and proved to be extremely valuable in checking the completeness of the registrations as they were received from each school. A comparison of the number of children listed in the vaccination report for each school with the total enrollment in the first three grades previously reported on Form VEC-6 quickly indicated any potential shortage in the Field Trial registration; differences of 10 percent or more were investigated before the registrations were accepted as satisfactory. This check also brought to light numerous instances in the observed areas where local officials had failed to report any first or third grade population and instances when only those children whose parents had agreed to participate were listed. These deficiencies were pointed out to the state health offices by correspondence, and either the missing data or a satisfactory explanation was sought.

By mid-summer, when it became apparent that some areas would encounter extreme difficulty in providing the missing registration data, staff members of the Evaluation Center were sent out to assist in completing the reports in states where this procedure had the approval of the state health office. In this manner assistance was provided for more than 30 areas in seven states, and in each instance the registration forms were successfully obtained or completed. At times it required opening schools to obtain the files or class records of first and third grades which had not been properly registered. Complete registration was obtained for all 5,123 schools in placebo areas, except for six where the children whose parents refused participation were not listed; all but 916 children in 26 out of 7,925 schools of observed areas were registered.

Similar assistance was provided later in the fall of 1954 when strenuous efforts were exerted to have the last few delinquent states complete their review of the registration of the study population.

Tables 18 and 19 show the registration of the study population by participation status for each of the placebo control and observed control Field Trial areas.

Table 18

PARTICIPATION STATUS AND VACCINATION STATUS BY FIELD TRIAL AREA
PLACEBO AREAS

State and Area	Total Study Population	Participation Status as Percent of Total Study Population				
		Requested Participation			Did Not Request Participation	Parental Request Unknown
		Total	Inoculated**	Not Inoculated		
Placebo Areas - Total	749,236	60.8	55.9	4.9	37.5	1.7
Alabama						
Montgomery	10,671	93.1	77.9	15.2	6.9	*
California						
Alameda	15,409	51.6	48.0	3.6	44.0	4.4
Illinois						
DuPage	14,582	60.1	57.9	2.1	38.8	1.1
Peoria	10,055	55.5	53.8	1.7	44.1	0.4
Iowa						
Linn	6,255	78.7	76.4	2.4	19.7	1.5
Scott	6,423	57.6	55.3	2.4	41.5	0.9
Woodbury	6,355	73.0	70.7	2.3	26.3	0.7
Massachusetts						
Berkshire:						
Pittsfield	3,209	78.1	75.4	2.7	20.4	1.4
Essex:						
Marblehead	945	64.6	61.8	2.8	35.0	0.4
Salem	2,169	54.9	52.1	2.8	45.1	*
Saugus	1,129	55.1	53.0	2.1	44.7	0.2
Swampscott	742	49.3	44.6	4.7	50.7	-
Franklin:						
Greenfield	933	79.0	76.6	2.4	21.0	-
Middlesex:						
Arlington	2,290	62.9	60.7	2.2	35.2	1.8
Everett	2,542	52.4	49.5	3.0	47.3	0.2
Framingham	1,619	65.3	62.9	2.3	34.3	0.4
Malden	3,356	61.4	58.1	3.3	38.4	0.2
Marlboro	950	66.6	64.8	1.8	33.1	0.3
Medford	3,585	62.4	59.9	2.5	37.6	-
Melrose	1,547	70.7	69.2	1.5	28.7	0.6
Natick	1,823	64.5	62.4	2.0	35.2	0.3

* Less than one-tenth of 1 percent.
** Vaccine or placebo.

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Table 18 Continued

State and Area	Total Study Population	Participation Status as Percent of Total Study Population				
		Requested Participation			Did Not Request Participation	Parental Request Unknown
		Total	Inoculated**	Not Inoculated		
Reading	1,077	64.2	61.1	3.1	8.8	27.0
Waltham	2,525	65.1	63.2	1.9	34.5	0.4
Watertown	1,812	62.0	60.3	1.7	35.2	2.8
Norfolk:						
Milton	1,251	71.0	67.9	3.0	29.0	-
Norwood	1,193	70.5	67.7	2.8	29.5	-
Quincy	4,889	73.1	70.3	2.8	26.7	0.2
Plymouth:						
Hingham	891	69.5	65.0	4.5	30.3	0.2
Plymouth	811	63.5	61.7	1.8	36.5	-
Suffolk:						
Revere	2,344	52.9	50.3	2.6	47.1	-
Winthrop	1,093	61.7	58.2	3.5	36.6	1.7
Worcester:						
Leominster	1,555	66.0	65.1	0.9	34.0	-
Michigan						
Bay	6,249	40.2	36.5	3.7	57.0	2.8
Calhoun	7,574	54.2	47.0	7.2	45.1	0.7
Kent	19,448	62.3	59.7	2.6	37.4	0.3
Lenawee	4,901	52.5	42.9	9.6	45.2	2.3
Macomb	18,150	41.9	39.2	2.7	56.8	1.4
Monroe	5,830	40.5	35.4	5.0	58.5	1.0
Muskegon	9,574	49.9	45.3	4.5	46.6	3.6
Oakland	35,987	50.0	47.1	2.9	47.8	2.2
Ottawa	5,648	38.8	33.9	4.9	60.7	0.5
St. Clair	6,410	38.9	35.2	3.7	60.2	0.9
Montana						
Mineral	194	56.2	54.1	2.1	43.3	0.5
Missoula	2,229	69.3	66.3	3.0	30.4	0.3
Park	776	77.6	77.2	0.4	22.4	-
Gallatin	1,303	77.4	76.1	1.3	21.4	1.2
New York						
Broome	11,741	47.2	42.4	5.0	52.6	0.2
Cattaraugus	4,798	72.5	66.0	6.5	27.1	0.4
Cayuga	3,917	70.2	64.9	5.3	29.5	0.3
Clinton	3,670	41.5	37.6	4.0	53.5	5.0
Dutchess	7,309	58.3	52.7	5.7	41.1	0.6

* Less than one-tenth of 1 percent.
** Vaccine or placebo.

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Table 18 Continued

State and Area	Total Study Population	Participation Status as Percent of Total Study Population				
		Requested Participation			Did Not Request Participation	Parental Request Unknown
		Total	Inoculated**	Not Inoculated		
Erie	55,272	59.4	53.7	5.7	38.8	1.8
Jefferson	5,326	68.2	64.8	3.4	31.8	0.1
Monroe	29,843	78.6	73.0	5.6	21.1	0.2
Nassau	70,120	68.1	63.1	5.0	30.0	1.9
Oneida	13,996	55.8	52.0	3.8	43.9	0.3
Onondaga	21,157	69.5	65.3	4.2	29.8	0.7
Orange	8,538	63.0	56.1	6.9	35.9	1.1
Oswego	5,366	70.8	66.8	4.0	27.7	1.5
Otsego	3,039	67.5	63.1	4.3	32.4	0.1
Saratoga	4,846	53.7	50.1	3.6	43.3	3.0
Schenectady	8,273	70.0	65.3	4.7	29.6	0.5
Suffolk	23,382	57.8	52.5	5.3	41.0	1.2
Tompkins	3,319	81.9	78.2	3.7	18.1	-
Ulster	5,175	58.0	54.6	3.4	40.6	1.4
Westchester	37,491	65.9	60.5	5.4	33.0	1.1
New York City:						
Corona-Flushing	32,737	62.5	56.7	5.7	36.8	0.7
Gravesend	14,474	62.7	54.6	8.0	35.0	2.3
Lower East Side	13,852	43.9	37.2	6.7	49.8	6.3
Richmond	10,370	40.0	36.6	3.4	57.5	2.5
Tremont	13,912	61.2	53.5	7.6	36.4	2.4
Ohio						
Montgomery	27,776	53.8	50.5	3.3	39.1	7.1
Richland	6,533	47.0	38.1	8.9	50.1	2.9
Utah						
Cache	2,033	82.0	76.6	5.4	17.7	0.3
Box Elder	1,458	76.7	71.4	5.3	22.6	0.7
Carbon	1,787	68.2	62.0	6.2	31.0	0.8
Davis	3,362	69.6	49.9	19.7	19.7	10.7
Emery	441	83.7	78.9	4.8	16.3	-
Salt Lake	20,936	61.1	55.8	5.4	37.9	1.0
Utah	6,061	65.2	57.9	7.3	34.5	0.3
Weber	6,688	72.2	65.7	6.5	26.8	1.0
Washington						
Kitsap	5,732	58.6	54.2	4.4	39.4	2.0
Whatcom	4,201	55.5	51.7	3.9	43.9	0.5
Yakima	10,002	66.0	60.1	5.9	31.5	2.5

Table 19

PARTICIPATION STATUS AND VACCINATION STATUS BY FIELD TRIAL AREA
OBSERVED AREAS

State and Area	Participation Status as Percent of Total Study Population									
	Population of the 2nd Grade						Population of 1st and 3rd Grade			
	Total Study Population	Requested Participation			Did Not Request Participation	Parental Request Unknown	Total Study Population	Requested Participation	Did Not Request Participation	Parental Request Unknown
		Total	Vaccinated	Not Vaccinated						
Observed Areas - Total	355,507	69.2	65.2	3.9	29.6	1.2	725,173	44.3	31.4	24.3
Arkansas										
Craighead	1,194	52.4	44.6	7.8	46.7	0.8	2,441	45.5	51.5	3.0
Jefferson	1,699	64.1	55.6	8.5	35.5	0.4	3,493	67.0	32.2	0.8
Mississippi	1,915	51.9	46.1	5.7	46.5	1.6	4,016	48.5	43.3	8.2
Pulaski	4,300	56.8	53.8	3.0	43.1	0.1	8,566	34.9	32.7	32.4
Sebastian	1,487	47.5	43.7	3.8	51.9	0.6	2,884	45.1	52.5	2.4
Colorado										
Adams	1,323	75.4	72.0	3.4	23.8	0.8	2,747	6.3	4.0	89.7
Arapahoe	1,813	78.1	75.2	2.8	20.8	1.2	3,590	-	*	100.0
Denver	8,295	82.4	79.0	3.5	17.3	0.3	15,864	5.2	1.1	93.7
El Paso	1,514	89.0	86.7	2.3	10.9	0.1	3,188	4.7	0.3	95.0
Jefferson	1,609	77.0	73.6	3.4	23.0	-	3,334	2.3	-	97.7
Pueblo	2,375	72.0	68.6	3.5	27.8	0.2	4,740	50.0	32.6	17.4
Weld	1,532	71.7	68.0	3.7	27.9	0.3	3,296	3.2	1.5	95.3
Connecticut										
Fairfield:										
Bridgeport	3,477	72.5	69.0	3.5	27.0	0.5	6,512	61.1	36.2	2.7
Danbury	1,059	78.0	72.1	5.9	21.4	0.6	2,205	58.1	20.8	21.1
Fairfield	896	81.8	80.0	1.8	17.6	0.6	1,683	58.1	24.3	17.6
Greenwich	898	76.1	72.6	3.5	23.3	0.6	1,705	61.4	27.0	11.6
Norwalk	1,641	75.9	71.7	4.3	21.9	2.2	3,099	52.7	41.1	6.2
Stamford	2,181	80.3	76.8	3.5	19.2	0.5	4,110	69.0	26.2	4.8
Stratford	1,068	73.6	69.9	3.7	25.6	0.8	2,090	43.5	25.9	30.5
Hartford:										
Bristol	1,058	74.0	71.3	2.7	25.8	0.2	2,037	69.3	29.8	0.9
Hartford	4,415	78.2	73.1	5.1	21.1	0.7	9,008	66.4	26.3	7.3
Manchester	2,684	71.1	66.7	4.3	27.9	1.0	5,158	42.0	28.3	29.8
New Britain	1,924	77.1	73.0	4.1	22.9	0.1	3,797	71.5	28.4	0.2
West Hartford	1,339	86.4	83.9	2.5	13.2	0.4	2,658	71.5	17.8	10.7
Litchfield:										
New Milford	320	83.4	80.0	3.4	16.3	0.3	635	78.9	18.9	2.2
Sharon	174	82.2	81.6	0.6	17.8	-	359	78.3	21.7	-
Torrington	1,280	81.3	79.0	2.3	18.5	0.2	2,522	72.8	24.4	2.8
Winchester	337	85.5	83.1	2.4	14.5	-	746	83.1	15.3	1.6
Delaware										
New Castle	5,008	56.1	50.4	5.7	43.3	0.7	10,196	45.4	53.0	1.6
Florida										
Broward	2,781	69.0	59.3	9.7	29.1	1.9	5,756	58.9	38.3	2.8
Palm Beach	2,904	72.1	64.2	8.0	27.9	*	5,778	63.0	35.5	1.5

* Less than one-tenth of 1 percent.

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Table 19 (Continued)

State and Area	Participation Status as Percent of Total Study Population									
	Population of the 2nd Grade						Population of 1st and 3rd Grade			
	Total Study Population	Requested Participation			Did Not Request Participation	Parental Request Unknown	Total Study Population	Requested Participation	Did Not Request Participation	Parental Request Unknown
		Total	Vaccinated	Not Vaccinated						
Idaho										
Ada	1,638	80.4	78.8	1.6	18.7	0.9	3,446	63.9	35.6	0.5
Bannock	884	83.0	80.3	2.7	16.0	1.0	2,182	77.4	21.5	1.1
Bingham	597	84.1	80.9	3.2	15.9	-	1,280	78.9	20.8	0.3
Nez Perce	449	74.8	70.8	4.0	25.2	-	977	67.2	26.1	6.7
Indiana										
Allen	4,170	81.2	78.8	2.4	16.4	2.3	8,442	39.5	13.7	46.9
Delaware	1,994	73.0	70.2	2.8	25.9	1.1	4,171	40.8	26.0	33.2
Elkhart	2,021	86.1	84.2	1.9	13.0	0.9	4,091	76.5	17.9	5.5
Howard	1,180	81.7	78.7	3.0	17.4	0.9	2,673	62.7	21.9	15.3
Madison	2,313	67.8	64.9	2.9	26.6	5.6	4,969	39.6	24.6	35.8
St. Joseph	4,461	81.1	78.5	2.6	18.6	0.3	9,080	73.6	23.6	2.8
Tippecanoe	1,374	80.0	76.3	3.6	19.5	0.5	2,763	70.6	29.2	0.1
Vanderburgh	3,403	71.5	68.4	3.1	24.9	3.6	6,620	54.7	28.3	17.0
Kansas										
Johnson	2,443	76.8	72.9	3.9	23.0	0.2	4,774	39.0	23.9	37.1
Sedgwick	6,473	74.0	70.9	3.1	24.3	1.8	13,056	29.5	34.3	36.2
Shawnee	2,260	75.4	72.5	2.9	22.8	1.8	4,401	71.8	23.5	4.7
Kentucky										
Fayette	1,988	66.9	63.7	3.2	33.1	0.1	3,797	60.8	38.3	0.9
Jefferson	11,470	59.3	55.0	4.3	39.7	1.0	21,289	52.2	41.4	6.4
Louisiana										
Bossier	1,109	51.3	47.5	3.8	48.7	-	2,219	36.9	36.4	26.7
Caddo	4,619	59.5	54.4	5.1	38.8	1.8	9,148	34.0	49.0	17.0
Rapides	2,216	36.4	33.2	3.2	58.0	5.7	4,401	24.7	67.8	7.4
Maine										
Bangor Area	931	59.2	55.3	3.9	40.7	0.1	2,122	50.3	49.4	0.2
Portland	1,936	65.9	62.3	3.6	32.4	1.7	4,481	10.9	7.5	81.6
Mississippi										
Hinds	3,521	74.6	66.8	7.8	17.5	7.8	7,454	53.7	13.9	32.4
Jones	1,288	70.1	54.5	15.6	23.1	6.8	3,236	66.7	18.4	14.9
Warren	839	71.6	65.2	6.4	26.0	2.4	2,112	58.0	37.9	4.1
Missouri										
Boone	692	77.9	76.6	1.3	21.8	0.3	1,287	57.3	41.2	1.6
Clay	1,212	62.9	60.6	2.3	37.0	0.2	2,760	60.3	39.4	0.3
Greene	2,011	64.5	62.6	1.9	35.1	0.3	4,046	38.1	59.1	2.7
Jackson	2,544	60.1	55.5	4.7	38.8	1.0	4,994	50.7	43.0	6.3
Kansas City	7,432	68.3	65.3	3.0	31.5	0.2	15,055	58.6	38.7	2.7
Pemiscot	1,221	64.1	59.2	4.9	35.9	-	2,599	35.6	58.2	6.2
Nebraska										
Douglas	5,148	81.7	80.5	1.2	18.2	0.1	10,951	1.9	-	98.1
Lancaster	1,994	78.7	75.1	3.6	21.1	0.2	3,952	70.0	29.9	0.2

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Table 19 (Continued)

State and Area	Participation Status as Percent of Total Study Population									
	Population of the 2nd Grade						Population of 1st and 3rd Grades			
	Total Study Population	Requested Participation			Did Not Request Participation	Parental Request Unknown	Total Study Population	Requested Participation	Did Not Request Participation	Parental Request Unknown
		Total	Vaccinated	Not Vaccinated						
Nevada										
Washoe	965	88.0	83.3	4.7	9.8	2.2	2,170	23.3	5.7	71.1
New Hampshire										
Belknap	548	73.4	71.4	2.0	26.5	0.2	1,157	63.0	27.9	9.1
Strafford	1,026	73.2	69.1	4.1	26.1	0.7	2,184	43.1	29.9	27.0
New Jersey										
Bergen	13,227	71.2	67.4	3.8	27.8	1.0	25,367	55.9	32.3	11.8
Cape May	692	47.5	45.5	2.0	51.9	0.6	1,441	42.3	57.5	0.2
Monmouth	4,857	62.0	58.1	3.9	35.3	2.7	9,765	20.2	28.1	51.7
Morris	4,041	75.6	73.2	2.4	24.0	0.3	7,861	44.1	36.4	19.5
Warren	1,162	63.4	58.7	4.7	33.1	3.4	2,316	50.7	38.0	11.4
New Mexico										
Bernalillo	4,469	78.2	73.0	5.2	21.0	0.8	9,144	70.3	24.3	5.4
North Carolina										
Guilford	4,239	71.2	66.7	4.5	28.5	0.2	9,329	62.4	36.4	1.2
North Dakota										
Burleigh	573	80.5	78.7	1.7	19.5	-	1,067	65.1	26.1	8.8
Cass	1,188	81.1	77.3	3.8	18.9	-	2,248	76.7	20.1	3.2
Morton	413	80.9	71.7	9.2	18.9	0.2	849	78.2	21.7	0.1
Oklahoma										
Oklahoma	7,254	74.6	72.6	1.9	23.7	1.7	14,914	67.7	26.5	5.8
Tulsa	6,168	67.0	64.2	2.8	32.8	0.2	12,774	58.6	38.6	2.9
Oregon										
Lane	2,924	68.0	62.8	5.2	30.0	2.0	6,103	54.3	35.0	10.7
Marion	1,883	76.7	71.2	5.5	22.9	0.4	4,148	52.1	25.6	22.3
Multnomah (excl. Portland)	1,844	72.6	65.5	7.1	26.5	0.9	3,700	9.9	5.3	84.8
Pennsylvania										
Centre	1,237	77.8	73.9	3.9	22.2	-	2,314	68.8	30.7	0.5
Clinton	784	75.9	72.4	3.4	24.1	-	1,495	67.1	32.9	-
McKean	1,179	91.5	87.6	3.9	8.4	0.1	2,360	75.2	16.6	8.3
Mercer	2,455	83.4	81.8	1.5	16.5	0.2	4,988	78.8	21.2	*
Rhode Island										
Providence City	4,658	78.5	75.2	3.3	21.1	0.4	8,716	68.1	30.4	1.5
South Carolina										
Charleston	4,762	79.6	73.1	6.4	20.2	0.2	9,967	63.7	24.9	11.5
South Dakota										
Minnehaha	1,493	79.8	77.0	2.8	16.5	3.7	2,905	72.3	19.0	8.7
Tennessee										
Shelby	11,759	74.2	70.6	3.7	24.2	1.6	23,936	52.4	26.5	21.1
Sullivan	2,471	68.4	63.0	5.4	31.6	*	5,446	61.1	38.8	*

* Less than one-tenth of 1 percent.

(Continued on next page.)

Table 19 (Continued)

State and Area	Participation Status as Percent of Total Study Population									
	Population of the 2nd Grade						Population of 1st and 3rd Grades			
	Total Study Population	Requested Participation			Did Not Request Participation	Parental Request Unknown	Total Study Population	Requested Participation	Did Not Request Participation	Parental Request Unknown
		Total	Vaccinated	Not Vaccinated						
Texas										
Bexar	13,021	66.2	61.8	4.4	33.4	0.5	25,136	34.8	49.2	16.0
Dallas	13,835	54.3	51.2	3.1	41.5	4.2	28,875	24.7	50.7	24.6
Harris	20,466	56.3	52.7	3.7	41.3	2.4	42,771	7.0	35.8	57.2
McLennan	2,647	57.8	54.9	2.9	40.5	1.6	5,627	48.3	46.4	5.3
Nueces	5,060	71.1	65.8	5.3	28.7	0.2	11,541	0.2	-	99.8
Orange	1,098	56.4	54.0	2.4	33.3	10.3	2,206	2.7	10.3	87.0
Tarrant	8,718	53.6	47.1	6.5	44.8	1.6	18,492	48.6	47.2	4.2
Taylor	1,227	66.3	63.2	3.1	33.0	0.7	2,971	58.2	38.8	3.0
Tom Green	1,190	52.9	47.9	5.0	44.2	2.9	2,547	40.8	44.7	14.5
Wichita	1,774	73.2	71.5	1.6	25.6	1.2	3,847	53.0	21.2	25.8
Vermont										
Chittenden	1,378	64.9	62.7	2.2	32.7	2.4	2,860	55.5	38.8	5.7
Virginia										
Bristol City	341	78.0	76.5	1.5	22.0	-	775	65.9	28.8	5.3
Chesterfield	1,184	68.8	63.9	4.8	31.3	-	2,581	56.6	43.4	-
Fairfax	3,913	63.5	59.3	4.2	36.5	*	8,124	54.9	44.9	0.3
Henrico	1,406	75.2	70.5	4.8	24.5	0.2	3,303	60.2	39.8	*
Loudoun	535	67.9	63.7	4.1	32.1	-	1,233	56.4	43.6	-
Norfolk (excl. Norfolk and Portsmouth)	3,050	80.5	76.4	4.1	19.5	-	6,724	70.3	29.6	0.1
Richmond City	4,129	72.5	68.6	3.9	27.4	*	8,020	60.6	36.4	3.0
Smyth	683	67.1	63.4	3.7	32.9	-	1,651	55.6	44.3	0.1
Washington	871	67.3	61.8	5.5	32.7	-	2,000	55.4	44.6	0.1
West Virginia										
Cabell	2,115	65.1	61.8	3.2	34.8	0.1	4,105	25.9	22.2	51.9
Kanawha	5,864	59.5	55.9	3.6	39.2	1.3	11,781	52.5	44.5	2.9
McDowell	2,507	72.1	67.2	4.9	27.7	0.2	5,129	61.5	35.7	2.8
Putnam	614	50.7	45.9	4.7	48.7	0.7	1,013	45.4	53.2	1.4
Wayne	862	49.7	44.2	5.5	50.4	-	1,932	38.4	51.8	9.8
Wisconsin										
Dane	3,387	83.6	80.9	2,7	16.2	0.1	6,757	4.6	1.0	94.5
Eau Claire	1,191	79.2	75.6	3.6	20.3	0.5	2,329	70.7	26.5	2.8
Fond du Lac	1,372	86.3	84.1	2.2	13.4	0.3	2,902	7.2	1.8	91.1
Kenosha	1,649	72.8	68.8	3.9	26.4	0.8	3,568	45.2	18.5	36.3
LaCrosse	1,368	63.5	59.9	3.6	36.4	0.1	2,697	61.2	38.6	0.3
Racine	2,347	69.1	66.9	2.2	30.6	0.3	5,080	60.1	38.3	1.6
Rock	1,915	79.2	77.0	2.2	20.2	0.6	3,993	3.3	3.3	93.4
Wood	1,161	74.3	71.2	3.1	24.5	1.2	2,425	65.0	29.3	5.7
Wyoming										
Laramie	977	69.2	62.9	6.2	28.0	2.8	2,090	2.8	-	97.2
Natrona	746	74.0	66.8	7.2	24.5	1.5	1,648	2.6	6.7	90.7
Park	304	83.9	81.3	2.6	16.1	-	744	78.6	20.8	0.5

DEMOGRAPHIC CHARACTERISTICS OF THE STUDY POPULATION

In addition to the extensive efforts to obtain complete records of the study population, certain demographic characteristics were tabulated as a further check on its homogeneity in different areas and to ensure that there were no peculiar distributions by grade, age, sex, or participation status within the trial areas that would reduce the applicability of various comparisons.

The degree of recorded participation by grade appeared to be reasonably uniform for the placebo areas with a very low percentage of unknown parental requests as indicated in Table 20.

The distribution of participants by grade in the observed areas indicates accuracy in recording of the second grade similar to that in the placebo areas. In the first and third grades, however, the proportion with parental request unknown is high, owing to the fact that in many areas consent forms were sent to the parents of only the children in those schools where blood samples were to be drawn. For this reason many parents did not have the opportunity to indicate their willingness to participate. It is of interest, however, that the number of confirmed refusals for first and third graders is in about the same proportion as for second graders, and not too different from the proportion who refused in the placebo areas, suggesting that "unknowns" might have been largely "yeses" had they been fully canvassed.

Although the proportion of unknowns was less than 5 percent of the combined first and third grades in more than 50 of the observed areas, the extreme variations in the proportion of unknowns in the balance of the observed areas would not permit the use of only requested participants in the first and third grades as the control population.

In both placebo and observed areas a slightly higher proportion of the study population attended urban schools than would be expected on the basis of general population distribution by place of residence. This is due, no doubt, to the consolidated school system in many areas where children from rural homes are transported to urban schools. The distribution by community size shown in

Table 20

SCHOOL GRADE BY PARTICIPATION STATUS
PLACEBO AND OBSERVED AREAS

School Grade	Total Study Population	Requested Participation		Did Not Request Participation		Parental Request Unknown	
		Number	Percent	Number	Percent	Number	Percent
Placebo Areas - Total	749,236	455,474	60.8	280,868	37.5	12,894	1.7
1st Grade	288,924	177,104	61.3	106,689	36.9	5,131	1.8
2nd Grade	252,735	154,853	61.3	93,614	37.0	4,268	1.7
3rd Grade	207,577	123,517	59.5	80,565	38.8	3,495	1.7
Observed Areas - Total	1,080,680	567,210	52.5	332,870	30.8	180,600	16.7
2nd Grade	355,507	245,895	69.2	105,211	29.6	4,401	1.2
1st and 3rd Grades	725,173	321,315	44.3	227,659	31.4	176,199	24.3

Table 21

DISTRIBUTION OF STUDY POPULATION
BY COMMUNITY SIZE AND BY COLOR
PLACEBO AND OBSERVED AREAS

Community Size	Total Study Population		White*		Nonwhite	
	Number	Percent	Number	Percent	Number	Percent
Placebo Areas						
Study Population - Total	749,236	100.0	719,387	100.0	29,849	100.0
2,500 - 9,999	91,568	12.2	89,734	12.5	1,834	6.1
10,000 - 49,999	152,864	20.4	147,438	20.5	5,426	18.2
50,000 - 99,999	60,373	8.1	58,041	8.1	2,332	7.8
100,000 - 499,999	109,883	14.7	100,366	14.0	9,517	31.9
500,000 and Over	113,878	15.2	107,200	14.9	6,678	22.4
Rural (Under 2,500)	220,670	29.5	216,608	30.1	4,062	13.6
Observed Areas						
Study Population - Total	1,080,680	100.0	958,231	100.0	122,449	100.0
2,500 - 9,999	78,280	7.2	71,905	7.5	6,375	5.2
10,000 - 49,999	176,703	16.4	163,867	17.1	12,836	10.5
50,000 - 99,999	113,426	10.5	101,260	10.6	12,166	9.9
100,000 - 499,999	353,918	32.7	305,914	31.9	48,004	39.2
500,000 and Over	46,937	4.3	36,750	3.8	10,187	8.3
Rural (Under 2,500)	311,416	28.8	278,535	29.1	32,881	26.9

* Includes unknown race.

Table 21 indicates that the study populations are not confined to any one size group. The study population was drawn from rural areas and urban areas of various sizes so that it represents a wide distribution by size of community.

It can also be determined from these tables that the color distribution of the study population follows the general pattern of the total population of the country, 4 percent non-white in the placebo and 11 percent in the observed, the majority of the placebo areas being located in northern states and the observed areas located in both the north and the south.

ADMINISTRATION OF VACCINE

ORGANIZATION OF VACCINE CLINICS

The first step in the organization of the vaccine clinics was the publishing and distribution of a Manual of Suggested Procedures for the Conduct of the Vaccine Field Trial by the National Foundation for Infantile Paralysis. The book covered basic operating policies and procedures for the preparation of the community for the Field Trial, such as the organization in schools and the setting up of actual vaccination clinics; the use of the essential

printed forms; the cooperation of volunteers from local chapters, and the problems of public education.

Volunteer Field Trial personnel, 300,000 of them, were mustered during the planning period, March 1 to April 25, 1954, for carrying on the work in 211 areas involving 1,829,916 children in the first, second, and third grades. This army of volunteers was composed of teachers, principals and superintendents of schools, classroom mothers, physicians, physical therapists and nurses, clubwomen, government officials, and parents. In addition, there were the many thousands of parents who took part in a special way by requesting that their children participate directly in the inoculation program.

As an aid to the local health, medical, and school authorities, without whose full cooperation the Field Trial as set up could never have been completed, the Manual suggested an operational time schedule hinged on "V-Day." This schedule listed preliminary activities from "Four Weeks Before V-Day," to "V-Day plus 49," and the follow-up for "Spring, Summer, and Fall, 1954." It outlined the steps necessary to make certain that all materials and personnel were on hand at the right moment to administer vaccine or placebo as called for in the study plan, and to secure bloods for testing at the laboratories in order to determine the potency of the several lots of vaccine.

Every school vaccination clinic was headed by a physician-in-charge who either gave the necessary inoculations himself or supervised other physicians in the procedure. The professional services of these hundreds of volunteer physicians who assumed the major responsibility were vital to the safe conduct of the Vaccine Field Trial. Each physician was assigned a nurse to assist him in giving the inoculations, and another nurse was on hand for emergencies which might arise. A reliable recorder was present to assist each physician, and other volunteers helped the teacher maintain order, helped prepare children's left arms for vaccination, and assisted in the "emergency" room, if necessary.

The following general recommendations were made in the Manual:

"Wherever practicable, in observed control areas, clinics should be organized to vaccinate a minimum of 50 children. In the placebo control areas, the minimum number of children per clinic will be 60. This number has been selected to simplify the eventual evaluation procedures. If a school in a test area contributes less than 50 or 60 children to the Field Trial, arrangements should be made, if possible, to transport the children involved to another school where the combined number exceeds the minimum figure.

"The physician-in-charge of each clinic shall be in attendance at all times that children are receiving vaccine or when blood samples are being collected."

The National Foundation supplied state health officers with sufficient vaccine, placebo, syringes, needles, and venules for distribution to the Field Trial areas. It also made available to the local health officers the services of its professional and field staffs in organizing the local field clinics and paid for essential medical supplies not already on hand.

Local health officers were responsible for seeing that all clinic supplies were delivered to the clinic, that vaccine was refrigerated, that sterile syringes and needles were ready for use. Information concerning the packaging of vaccine and instructions for handling it were provided in the Manual:

"In areas using the observed control method of study, vaccine will be supplied in 10 cc. vials, ten to a package.

"In areas using placebo controls, material for injections will be furnished in packages of six 10 cc. vials; three of these will be vaccine and three control solution. Therefore, there will be sufficient material in the placebo control package to provide three inoculations of the same substance to twenty children.

"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.

CONDUCT OF THE FIELD TRIAL

The plan of study established for the placebo control areas required the development of a code scheme for identification of the material injected which would meet the following special objectives:

1. To conceal the identity of the inoculum from all personnel throughout all phases of the program, including vaccination, the processing of records, the review and diagnostic study of reported cases in the study population, and the final phase of applying the diagnostic criteria;

2. To provide identification of the manufacturer and of the particular lot in which the material was produced;

3. To provide a means of detecting errors made in the field in recording the identification code on the Vaccination Records;

4. To be readily adaptable to the various processes of editing and mechanical tabulation;

5. Finally, when required, to provide means of identifying the inoculum, i.e., "vaccine" or "placebo."

In conjunction with the development of the code scheme, it was also necessary to develop a plan for packaging and labeling the vials to assure delivery of equal quantities of vaccine and placebo to each vaccination clinic without identifying the substance to the field and to provide maximum assurance that each child would receive three successive inoculations of the same type of substance and from the same manufacturing lot.

In February, 1954, careful attention was given to the complex problem of devising a code and a plan for labeling and packaging which would meet these specifications. The development of the code patterns was assigned to only one staff member and from the onset strict security measures were observed. As finally adopted, the code scheme used for placebo areas consisted of five digits and a two-letter suffix which provided the identification.

The first two digits of the code in combination with the two-letter suffix denoted the type of inoculum (vaccine versus placebo). The pattern was as follows:

1. If the first two digits and their corresponding letter suffixes were both even characters, i.e., 00...AA, 02...AC, 24...CE, etc., then the materials so labeled was vaccine;

2. If the first two digits and their corresponding letter suffixes were both odd characters, i.e., 11...BB, 13...BD, 37...DH, etc., then the material was placebo;

3. If the first two digits consisted of an odd-even or even-odd combination, i.e., 01, 23, 74, 56, etc., and the two-letter suffix was a combination of letters from A through J, the material was vaccine;

4. If the first two digits consisted of an odd-even or even-odd combination, and the two-letter suffix was a combination of letters from Q through Z, the material was placebo;

5. Letters from A through J were never combined with letters from Q through Z;

   (Many other combinations could have been used to make the code patterns even more complex and difficult to decipher, but the patterns just described were deemed sufficient to satisfy the required objective.)

6. The first digit, by itself, identified the manufacturer;

7. The third digit identified the particular lot of vaccine or placebo produced by the manufacturer;

8. The fourth and fifth digits denoted the set of three vials to be packaged together.

Labeling and Packaging

The manufacturers were provided with the following specifications for the printing, labeling, and packaging of the vaccine and placebo:

CONDUCT OF THE FIELD TRIAL

1. Each substance (vaccine or placebo) will be in 10 cc. vials.

2. Vials will be packaged in sets of six, each set made up of three vials of the vaccine and three of the placebo, with suitable protective dividers between vials.

3. The three vials of vaccine in any package will be from the same lot, and will bear identical labels. The three vials of placebo will bear identical labels differing from the vaccine label.

4. The identifying code for both vaccine and placebo will consist of a five-digit number and a two-letter suffix. The numbers will be applied serially, the same number being used for a set of three vials from the same lot; e.g., the first three vials may bear the number 00001 and the second set of three vials would then bear the number 00002, etc. The letter suffix will consist of two letters, a different letter suffix being associated with each successive sequence of 1000 serial numbers.

5. While any given serial number (but not suffix letters) may be identical for a set of three vials of vaccine and for another set of three vials of placebo, no package will contain vials of vaccine having the same serial number as the vials of placebo.

6. Each package will bear an outside label, per sample (see next page), with spaces for entering the identifying code for each set of vials. This is to permit identification necessary for correct use in the field. The manufacturers will enter the identifying codes for both vaccine and placebo; the side on which vaccine or placebo code is entered will be alternated in a random fashion.

7. When the packages are placed in cartons for shipment to the field areas, each carton will include a variety of two-letter suffix codes:

Number of Packages in Carton	Number of Two-Letter Suffix Combinations to Be Included
Less than 20	At Least 4
20 to 30	At Least 6
30 to 40	At Least 8
40 to 60	At Least 10
Over 60	At Least 12

8. It is suggested that the manufacturer immediately have printed all labels for the vials, in accordance with the following pattern:

   a. Print six series of labels, 100,000 to each series, numbering the series consecutively from 00000 to 99999.

   b. Subdivide each of the six series into groups of 1,000 labels each, as follows:

Group 1	00000 to 00999
Group 2	01000 to 01999
Group 3	02000 to 02999
	etc. to
Group 100	99000 to 99999

   c. For three of the six series, imprint the labels in each group of 1,000 with a different combination of two-letters from the alphabetical sequence A through J, as follows:

Group 1	00000 to 00999, imprint AA
Group 2	01000 to 01999, imprint AB
Group 3	02000 to 02999, imprint AC
	etc. to
Group 11	10000 to 10999, imprint BA
Group 12	11000 to 11999, imprint BB
	etc. to
Group 99	98000 to 98999, imprint JI
Group 100	99000 to 99999, imprint JJ

   d. For the remaining three series, imprint each group of 1,000 with a different se-

quence Q through Z, using the same pattern of letter changes as in "c" above. (Note that for successive groups of 1,000 labels in a given series, the letter combinations will be QQ, QR, QT...QZ, RR, RS, RT...RZ, SS, SR, ST...etc., to ZZ.)

e. Retain each of the six series of labels in numerical order. They will then be grouped according to alphabetical suffix. There will be six series, 100 groups in each series, 1,000 labels in each group. Thus, there will be a total of 600,000 labels, bearing 200,000 different codes, with three labels bearing each of the codes.

9. The manufacturer will provide the Poliomyelitis Vaccine Evaluation Center at the University of Michigan with a listing indicating the manufacturer's lot numbers of each batch of vaccine and placebo as they become ready for bottling and labeling, together with a statement of the volume (number of vials) in each lot.

10. After receiving this list the Evaluation Center, in turn, will provide the manufacturer the code designations to be applied to the vials in each lot of vaccine and placebo. These code designations will be assigned in groupings that can easily be located in the stock of pre-printed labels.

The identifying label on the jacket of the package containing the three vials of vaccine and three vials of placebo, showing directions for use, is shown below.

6 Vials — 10 cc. Size

Material For Use In
POLIOMYELITIS VACCINE FIELD TRIALS
SUFFICIENT FOR 3 INJECTIONS IN EACH OF 20 CHILDREN

PRESERVATIVE: 0.01% Thimerosal, N.F.
DOSE: 1 cc. injected intramuscularly.
CAUTION: New Drug—Limited by Federal Law to Investigational Use.
Exp. Date: Dec. 31, 1954.
Keep at 2° to 10° C. (35.6° to 50° F.)

DIRECTIONS FOR USE

This box contains sufficient material for a series of three (3) injections for twenty (20) children. Take one (1) vial and inject the first ten (10) children. Take another vial of a different lot number and inject the next ten (10) children. Close the box and return to refrigerator. For second and third doses, see that each child receives material from a vial bearing the identical lot number to that used in the same child in the previous injection.

Produced for
THE NATIONAL FOUNDATION FOR INFANTILE PARALYSIS, INC.
NEW YORK, N.Y.

Reproduced below is the label for the individual vials of material:

10 cc. Size — 10 DOSES
MATERIAL FOR USE IN POLIOMYELITIS VACCINE FIELD TRIALS
Exp. Date: Dec. 31, 1954
CAUTION: New Drug—Limited by Federal Law to Investigational Use.
DOSE: 1 cc. intramuscularly
PRODUCED FOR
THE NATIONAL FOUNDATION FOR INFANTILE PARALYSIS, INC.
NEW YORK, N.Y.
LOT NO. 02115-AC

VACCINE CODES IN OBSERVED CONTROL STUDY AREAS

The codes used in the observed areas merely reflected the identity of the manufacturer and the particular lot of vaccine, since it was known which subjects received actual injections of vaccine. A four-digit code was imprinted on the label of each vial; the first digit denoted the manufacturer, and the next three digits, the particular lot number of the the vaccine. These codes were similarly reduced to a two-digit code at the time the records were processed for punching and mechanical tabulation. The first digit denoted manufacturer and the second digit the lot number.

It should be noted that a different series of digits was employed to distinguish the vaccine used in observed areas from that of the placebo areas, as follows:

VACCINE LOTS USED

Placebo Areas	Observed Areas
302	303
304	305
306	307
308	309
503	502
505	506
512	507
513	508
514	

In the observed control study there was a greater number of instances in which more than one lot of vaccine was used in an area; this came about partly as a supply problem

and partly from a decision to use for the third inoculation lots which appeared upon test to be stronger antigenically, in combination with those which appeared to be only moderately so. Consequently, as many as seven or eight different lot combinations were used in some areas.

CLINIC PROCEDURES

The Manual of Suggested Procedures for the Conduct of the Vaccine Field Trial in 1954 provided by the National Foundation for Infantile Paralysis for field clinic personnel included instructions in the use of the vials of inoculum under ideal conditions as well as in complicated situations that might arise. In placebo areas, inoculum was received in packages of six vials each, three containing 10 cc. of vaccine, and three containing the same amount of placebo, the quantity required for the three injections of twenty children. The method of packaging and the code system were devised to ensure that lot and sub-lot numbers (vaccine or control solution) could be identified without revealing the code. This procedure also assured that equal quantities of vaccine and control solution would be used in each inoculation clinic without identification of the substance in the field. It also provided a means of making sure that each subject received three successive injections of the same lot of material.

The classroom groups of the first, second, and third grades of a participating school constituted the basic clinic unit and remained so through the three inoculations. The following plan of procedure was outlined in the Manual:

> "As each class appears at the clinic, the teacher will accompany each child into the clinic room in alphabetical order. (The Vaccination Record forms should also be in alphabetical order, as should the listing of children's names on the Registration Schedule.) In the placebo control areas it will be essential that classrooms attending a given clinic follow each other in the same sequence in succeeding clinics.
>
> "As the child enters the room, the recorder should verify with the teacher the identification of the child, and place that child's Vaccination Record on the table before her. The physician should call out to the recorder the lot number of the vaccine to be given to that child. The recorder should record the lot number on the Vaccination Record. Having done so, she should repeat the lot number so that the physician can verify her recording. The month and day of vaccination should then be recorded on the Registration Schedule.
>
> "...The physician will then give the vaccine in the left triceps muscle. (If for some special reason another site of inoculation is used, notation indicating the actual site should be made under "Remarks" on the Vaccination Record.)
>
> "The dose of material given should be accurately measured as 1 cc. The recommended procedure is to fill each syringe to the 5 cc. mark, using 1 cc. for each of 5 children, changing the needle each time. If blood is drawn into the barrel of the syringe, it should be discarded and a fresh syringe used. Accurate measurement of dosage is essential, since it is planned to inject 10 children from each vial."

A second sterile syringe was used to remove from the vial the remaining 5 cc. which was then administered to five additional children.

The 10 cc. of material from the first of a pair of vials, bearing one lot number, was used to inoculate the first ten children listed on the Registration Schedule of a given class. The second 10 cc. vial bearing the other lot number and containing the other inoculum was used for the next ten children. The remaining four vials in the package were set aside to be used in similar fashion for the second and third injections of the same children. Before returning these vials to the refrigerator, however, the recorder entered the name of the school, the grade, and the Registration Schedule number on the end label on the package.

If the number of eligible children in the class was less than twenty, the remaining material in the first two vials would be used to start the next class. If the initial class included more than twenty, the remaining children were started on a new package of six vials, as explained previously.

At the second series of inoculations (V-Day plus one week), children were arranged in the same sequence within classes and in class order as at the time of the first inoculation. Material from the second pair of vials was used making sure that the number of the lot given to each child matched the code shown on his Vaccination Record to have been used for the previous injection.

The package of material was opened as the designated group of children approached the physician's station, and when the group had received the specified material, the vials were returned to the package which was then removed to prevent use in the wrong group of children and prepared for storage until the next scheduled clinic.

In a number of schools additional methods of safeguarding uniformity during vaccinations were devised. For example, in many clinics a badge was pinned on each child in line bearing the child's name, registration number, and the coded lot number of his inoculum. In other schools master lists showing the exact sequence of classes and children were often used.

Make-up Clinics

Absences from school on specified clinic days were inevitable. If a child whose parents requested vaccination was not present for the first injection, he received no injections at any subsequent time. On the other hand, every effort was made to continue inoculations in those who received the first but were absent at the time of the second or third clinics. To accomplish this, make-up clinics were organized, usually in a central location. The parents or teachers took responsibility for getting the absentees to the clinic. Each of these children had to be specifically identified, and the code number of his inoculum had to be precisely matched. It was recommended that the make-up clinic for the second injection be held not more than four days later than the date originally scheduled; for the third dose, within seven days of the scheduled date. The additional clinics for absentees in observed areas created no significant problem with respect to lot number or recording since all inoculated children received vaccine.

Supplemental Supplies of Vaccine and Placebo

During the interval of four weeks between the second and third series of inoculations, an inventory of all packages was made since loss of vaccine or placebo might have occurred due to breakage or wastage. If supplements were needed, material from the same lot was ordinarily available in adequate quantities in the local area or county. The only proviso was that this material bear in its lot number the same two-letter suffix as shown on the Vaccination Record.

Although all original procedures were based on the expectancy that 10 cc. would be obtained from each vial, in practice only 8 to 9 cc. were actually obtainable. As a result, the number of matched children served by a package was usually less than twenty. Therefore, estimates of the number of packages necessary were increased, and supplementary supplies could be obtained before the scheduled third clinics were to be conducted.

If proper supplement could not be found locally, a list giving suffix letters needed to complete the sets and also a list of the suffixes available in the area were sent to the Poliomyelitis Vaccine Evaluation Center. The Center reported immediately as to what substitutions were to be made in the given area in order to be certain that the proper lot of vaccine or placebo was received by each individual child. In such situations an explanation of the different code numbers recorded was to be given by the physician-in-charge of the clinic on the Vaccination Card under "Remarks."

Atmosphere of Clinics and Awards to Participants

The atmosphere of competence and quiet orderliness which prevailed in the clinics generally was a direct reflection of the care and thought which those who guided the children and staffed the clinics had given to the problem. The mental preparation of the children toward the procedures established a healthy cooperative attitude; the precision with which they were handled eliminated apprehension and excitement. The school authorities used great care in the preparation and handling of the Registration Records, especially in placebo areas, and in the recording of information in the clinic. The physicians and nurses were particularly attentive to their personal relations with the children as well as to the details of technical responsibilities. The volunteers assisted in many ways to make the experience a pleasant one which undoubtedly will influence the reaction of these children to health measures in the future. Any tendency to group excitement or reaction was gently and quietly dispelled. The response of the children themselves, with few exceptions, was one of surprise that the injections did not hurt or otherwise disturb them.

In recognition of their unselfish service as volunteers in the study, a Polio Volunteer button was presented by the National Foundation for Infantile Paralysis to each child who received at least the first inoculation and also in observed areas to those of the uninoculated controls whose parents had filed a Participation Request. In addition, Polio Pioneer Award cards were given to all children who completed the full series of three inoculations. Special recognition was also given to those who participated in the serological studies by donating specimens of blood. The distribution of these awards was ordinarily made at a ceremony at the end of the vaccination program and after the second specimens of blood had been procured.

COMPLETENESS OF VACCINATION AND MATCHING OF CONTROLS

A summary is given of the number of persons who received complete or partial series of vaccine or placebo in Table 22. About 8 percent of those who originally requested participation either did not appear for the first inoculation or withdrew. Only 4 percent of those who received the first injection failed to complete the series, and they were equally divided between recipients of vaccine and placebo. Only the 200,745 who completed the vaccine series were maintained as the experimental population for comparison of incidence with the 201,229 controls who completed the placebo series. The numbers are essentially identical. In only 1.7 percent of the total study population of these areas was the character of the parental request not known; these children were excluded from the experimental population. It is of interest that of those who failed to complete the vaccine series, 80.5 percent received two doses; similarly, of the incomplete placebo group, 80.3 percent received two doses. Only 26 out of 209,229 children involved received vaccine at a later time without having received the first injection.

In general, only one lot of vaccine or placebo was used in a placebo study area or in a school. Because of supply problems this was not completely uniform, and in 14 placebo areas more than one lot was employed. Even then, the uniformity in the 206 schools of those areas was maintained, and the controls for each lot of vaccine were clearly designated on the 22,997 records according to corresponding codes.

In 346 schools with small classes the number of participants was insufficient to complete the use of a 10 cc. vial, as the procedure called for; thus, 1,529 children received only placebo. This was balanced by 1,761 children in 387 other small schools who received only vaccine. It is important to emphasize that the equal distribution of vaccine and placebo held at every level. Moreover, according to the VEC records, out of a total of 1,237,446 injections in 419,035 persons inoculated in placebo areas, only 748 persons received a mixed series of vaccine and placebo.

Table 23 presents the summary of vaccinations in observed areas. It is noted that the proportions of the second grade requesting participation is somewhat higher than in

placebo areas. This may relate to the fact that only vaccine was to be administered in these areas. Similarly, only 5.7 percent of those who originally requested vaccinations either were absent or withdrew at the time of the first clinic. As in placebo areas, only 4.3 percent failed to complete the vaccination series, and 76 percent of these received two injections, mainly the first and second. Only 47 of the 231,902 vaccinated children missed the first injection and later received vaccine. The completely-vaccinated population was the 221,998 children in the second grade who, according to plan, would be studied in comparison with the totally-unvaccinated population of the combined first and third grades.

Table 22

PARTICIPATION STATUS OF STUDY POPULATION BY VACCINATION STATUS PLACEBO AREAS

Participation Status	1st, 2nd, and 3rd Grades	
	Number	Percent
Study Population - Total	749,236	100.0
Requested Participation	455,474	60.8
Did Not Request Participation	280,868	37.5
Parental Request Unknown	12,894	1.7
Requested Participation - Total	455,474	100.0
Absent or Withdrew	36,439	8.0
Complete Series of Vaccinations	200,745	44.1
Incomplete Series of Vaccinations	8,484	1.9
Number Receiving 2 Doses	6,827	1.5
1st and 2nd Vaccinations Only	4,283	0.9
1st and 3rd Vaccinations Only	2,524	0.6
2nd and 3rd Vaccinations Only	20	*
Number Receiving 1 Dose	1,657	0.4
1st Vaccination Only	1,651	0.4
2nd Vaccination Only	4	*
3rd Vaccination Only	2	*
Complete Series of Placebo	201,229	44.2
Incomplete Series of Placebo	8,577	1.9
Number Receiving 2 Doses	6,888	1.5
Number Receiving 1 Dose	1,689	0.4

* Less than one-tenth of 1 percent.

As mentioned earlier, in most of the observed areas more than one lot of vaccine was used. As a result, a variety of lots was sometimes used in a single school. There were 268 schools out of the total 7,925 in observed areas where this occurred involving a study population of 51,157 of whom 11,533 were vaccinated, less than 5 percent of the total complete vaccinations in observed areas. Since it was impossible to allocate the control population to each lot combination in these schools, both the vaccinated and control populations involved have been assigned in the report to "mixed lots within schools."

In 765 other schools in observed areas, there were a few children who received a lot combination different from the major series used in the school. In these schools involving a vaccinated group of 39,914 children where only one, two, or three second graders received a series of lots different from the rest of the vaccinated group, the total first and third grade populations were taken as the control population for the major lot combinations, and specific controls for the 1,144 children receiving odd combinations were not established.

Table 23

PARTICIPATION STATUS OF STUDY POPULATION BY VACCINATION STATUS
OBSERVED AREAS

Participation Status	1st, 2nd, and 3rd Grades		2nd Grade		1st and 3rd Grades	
	Number	Percent	Number	Percent	Number	Percent
Study Population - Total	1,080,680	100.0	355,507	100.0	725,173	100.0
Requested Participation	567,210	52.5	245,895	69.2	321,315	44.3
Did Not Request Participation	332,870	30.8	105,211	29.6	227,659	31.4
Parental Request Unknown	180,600	16.7	4,401	1.2	176,199	24.3
2nd Grade Request - Total	245,895	22.8	245,895	69.2		
Absent or Withdrew	13,993	1.3	13,993	3.9		
Complete Series of Vaccinations	221,998	20.5	221,998	62.4		
Incomplete Series of Vaccinations	9,904	0.9	9,904	2.8		
Number Receiving 2 Doses	7,518	0.7	7,518	2.1		
1st and 2nd Vaccinations Only	7,268	0.7	7,268	2.0		
1st and 3rd Vaccinations Only	227	*	227	0.1		
2nd and 3rd Vaccinations Only	23	*	23	*		
Number Receiving 1 Dose	2,386	0.2	2,386	0.7		
1st Vaccination Only	2,362	0.2	2,362	0.7		
2nd Vaccination Only	13	*	13	*		
3rd Vaccination Only	11	*	11	*		

*Less than one-tenth of 1 percent.

COMPARABILITY OF THE TEST POPULATIONS

The distribution of the vaccinated and control populations by vaccination status, sex, and age or grade is presented in Table 24 and indicates the degree of comparability of the vaccinated and non-vaccinated segments of the study populations. It should be emphasized that the vaccinated and placebo populations are essentially identical and strictly proportionate to the total in each respect. Incidence bases selected from any of these various characteristics should have a high degree of reliability. In the observed areas, the distributions by age and sex also appear normal for the involved grades, and the difference in age distribution between the vaccinated of the second grade and observed controls of the first and third grades is also normal but clearly limits comparisons.

Table 24

VACCINATION STATUS, SEX, AND AGE OF STUDY POPULATION
PLACEBO AND OBSERVED AREAS

Sex by Age As Of May 1, 1954	Placebo Areas						Observed Areas									
	Total Study Population		Complete Vaccine		Complete Placebo		Total Study Population		2nd Grade Total		Complete Vaccine 2nd Grade		Uninoculated Controls			
													1st Grade Total		3rd Grade Total	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
Males and Females - Total	749,236	100.0	200,745	100.0	201,229	100.0	1,080,680	100.0	355,507	100.0	221,998	100.0	428,267	100.0	296,906	100.0
Males	387,949	51.8	104,194	51.9	104,170	51.8	560,373	51.9	182,899	51.4	113,837	51.3	223,687	52.2	153,787	51.8
Females	361,287	48.2	96,551	48.1	97,059	48.2	520,307	48.1	172,608	48.6	108,161	48.7	204,580	47.8	143,119	48.2
Males and Females - Total	749,236	100.0	200,745	100.0	201,229	100.0	1,080,680	100.0	355,507	100.0	221,998	100.0	428,267	100.0	296,906	100.0
Under 6 Years	2,088	0.3	547	0.3	535	0.3	2,677	0.2	201	0.1	106	*	2,363	0.6	113	*
6 Years	156,584	20.9	42,991	21.4	43,056	21.4	222,749	20.6	3,215	0.9	1,963	0.9	219,274	51.2	260	0.1
7 Years	270,246	36.1	73,758	36.7	74,447	37.0	377,913	35.0	202,244	56.9	134,404	60.5	172,489	40.3	3,180	1.1
8 Years	203,810	27.2	54,982	27.4	55,133	27.4	275,255	25.5	122,786	34.5	74,291	33.5	13,500	3.2	138,969	46.8
9 Years	94,431	12.6	24,736	12.3	24,281	12.1	136,833	12.7	18,692	5.3	8,627	3.9	2,333	0.5	115,808	39.0
10 Years and Over	15,609	2.1	3,441	1.7	3,479	1.7	34,687	3.2	5,672	1.6	2,128	1.0	1,240	0.3	27,775	9.4
Age Unknown	6,468	0.9	290	0.1	298	0.1	30,566	2.8	2,697	0.8	479	0.2	17,068	4.0	10,801	3.6
Males - Total	387,949	100.0	104,194	100.0	104,170	100.0	560,373	100.0	182,899	100.0	113,837	100.0	223,687	100.0	153,787	100.0
Under 6 Years	1,011	0.3	259	0.2	257	0.2	1,339	0.2	106	0.1	66	0.1	1,172	0.5	61	*
6 Years	79,511	20.5	21,739	20.9	21,945	21.1	113,165	20.2	1,507	0.8	950	0.8	111,526	49.9	132	0.1
7 Years	138,325	35.7	38,075	36.5	38,008	36.5	192,813	34.4	99,484	54.4	66,385	58.3	91,893	41.1	1,436	0.9
8 Years	104,210	26.9	28,142	27.0	28,209	27.1	140,660	25.1	65,343	35.7	39,539	34.7	7,993	3.6	67,324	43.8
9 Years	51,421	13.3	13,582	13.0	13,315	12.8	74,765	13.3	11,528	6.3	5,368	4.7	1,406	0.6	61,831	40.2
10 Years and Over	10,003	2.6	2,236	2.1	2,270	2.2	21,568	3.8	3,454	1.9	1,267	1.1	749	0.3	17,365	11.3
Age Unknown	3,468	0.9	161	0.2	166	0.2	16,063	2.9	1,477	0.8	262	0.2	8,948	4.0	5,638	3.7
Females - Total	361,287	100.0	96,551	100.0	97,059	100.0	520,307	100.0	172,608	100.0	108,161	100.0	204,580	100.0	143,119	100.0
Under 6 Years	1,077	0.3	288	0.3	278	0.3	1,338	0.3	95	0.1	40	*	1,191	0.6	52	*
6 Years	77,073	21.3	21,252	22.0	21,111	21.8	109,584	21.1	1,708	1.0	1,013	0.9	107,748	52.7	128	0.1
7 Years	131,921	36.5	35,683	37.0	36,439	37.5	185,100	35.6	102,760	59.5	68,019	62.9	80,596	39.4	1,744	1.2
8 Years	99,600	27.6	26,840	27.8	26,924	27.7	134,595	25.9	57,443	33.3	34,752	32.1	5,507	2.7	71,645	50.1
9 Years	43,010	11.9	11,154	11.6	10,966	11.3	62,068	11.9	7,164	4.2	3,259	3.0	927	0.5	53,977	37.7
10 Years and Over	5,606	1.6	1,205	1.2	1,209	1.2	13,119	2.5	2,218	1.3	861	0.8	491	0.2	10,410	7.3
Age Unknown	3,000	0.8	129	0.1	132	0.1	14,504	2.8	1,220	0.7	217	0.2	8,120	4.0	5,163	3.6

* Less than one-tenth of 1 percent.

PROCUREMENT OF BLOOD SAMPLES

Another important responsibility assigned to the clinics was that of obtaining specimens of blood from a proportion of the study population. It had been decided, after careful consideration, that samples of blood should be taken from 2 percent, or a minimum of 100, of the children in each participating study area. The contingent for bleeding would include children who were scheduled to receive injections and also, in observed areas, uninoculated children of the first and third grades. The serum would be subjected to laboratory tests designed to measure antibody titers to the three types of poliomyelitis virus so as to determine the amount of antibody present previous to vaccination, the response to vaccine, and the duration of response. Study of sera from control children would provide information of the natural changes occurring in that segment of the study population as well as a measure of technical variations. The data would also provide a basis for evaluating the changes observed in the vaccinated group.

The first blood specimen was usually taken in the clinic just before the first injections were given. In placebo areas this required the bleeding of equal numbers of children receiving the two coded materials. In observed areas it meant that equal proportions of vaccinated and unvaccinated controls were to be included. Hence, request to participate in the Trial indicated willingness to have blood samples taken. Obviously no specimens were obtained from the nonparticipants.

The second specimen was to be obtained from the same children two weeks after the time of the third injection when antibody would be expected to be at its height. Not infrequently, this required that additional clinics be held after the schools had closed for the summer. There was, as a result, variation in the time the specimen was obtained, and although none was to be obtained less than seven days after the third inoculation, some were taken as late as three weeks after the third clinics. In some instances special arrangements had to be made because children had left for vacations in other areas.

The third specimen was to be taken in November, 1954. The details of these arrangements are referred to elsewhere, but changes in location of the children often required considerable effort and communication to locate them and to arrange for obtaining the blood.

The dates of the first two bloods drawn were to be recorded on the Registration Schedule (FT-3) and on the Vaccination Record (FT-4) before these forms were sent to VEC. The late specimens were recorded on special forms (VEC-38). Because of difficulty with the labels previously supplied, new adhesive taped labels were distributed to be placed on the tube for the third blood specimen.

The bloods or the separated sera were sent by the local health officer directly to the designated laboratory. It was inevitable that losses from breakage, spoilage, shipping, inadequate volume, or defective labeling would occur. Since the specimens were identified by grade and by registration sheet and line number, the laboratory had no knowledge of the nature of the inoculum received in placebo areas; in observed areas it could be ascertained whether the specimen was from a vaccinated child or not, but the laboratories ordinarily tested the sera without seeking that information.

It should be emphasized here that this was not a random 2 percent sample, but a selected group which it was hoped would reflect a range of varied characteristics in this age group of the community. Because of special interests some laboratories arranged with the health officers to obtain a larger collection of blood, 5 to 8 percent rather than the usual 2 percent.

It is apparent that only the advent of tissue culture methods made such an undertaking feasible, involving, as it did, a scope of work which previously had never been possible in the field of poliomyelitis.

The following table shows the number of bloods obtained at the different times of collection.

Table 25

BLOOD SPECIMENS DRAWN (FIRST, SECOND, AND THIRD BLEEDINGS) BY VACCINATION STATUS PLACEBO AND OBSERVED AREAS

	1st Bleeding		2nd Bleeding		3rd Bleeding	
	Number	Percent	Number	Percent	Number	Percent
Placebo Areas - Total	14,475	100.0	12,382	100.0	12,888	100.0
Vaccinated	7,220	49.9	6,210	50.2	6,520	50.6
Placebo	7,255	50.1	6,172	49.8	6,368	49.4
Observed Areas - Total	26,406	100.0	20,046	100.0	20,974	100.0
Vaccinated	9,789	37.1	7,870	39.3	9,166	43.7
Controls	16,617	62.9	12,176	60.7	11,808	56.3

Detailed procedures and explanation of the blood sample were provided by the Manual of Procedures as follows:[27]

"Selection of Children From Whom Blood Samples Will Be Taken

"In each county under study, blood samples must be obtained from 2 percent of all the children taking part in the study. This means that in the observed control areas blood samples must be obtained from children in the first and third grades, who will not be vaccinated, as well as from children in the second grade who will be vaccinated. In the placebo control areas, of course, the blood samples will be taken from a total of 2 percent of the children being inoculated either with vaccine or placebo. In test areas where fewer than 5,000 children are involved, a minimum of at least 100 blood samples must be obtained at each collection.

"While a random sampling of blood from 1 child in every 50 being vaccinated or observed in the test areas would be desirable, it is practically necessary to confine the taking of samples to children in a limited number of schools. The local health officer, in consultation with the superintendent of schools, will select 'typical schools' where the blood samples will be taken from every child in the study in these schools. The choice of schools should provide a good representation of the child population under study in the county with respect to socio-economic and racial background, urban-rural, and male-female distribution, and other necessary demographic conditions.

"Suggested Procedure for Blood Sampling Program in Selected Schools

"The first blood sample will be taken just before the first inoculation with vaccine or placebo is given. Clinic procedures for school vaccination clinics must be somewhat modified for this purpose, and additional supplies will be needed.

"The National Foundation will supply:

1. Sterile vacuum tubes (Shepard Venules) equipped with sterile 22 gauge needles for taking blood samples.

2. Identifying labels for blood tubes.

"The venules will be supplied 120 to a box and each box will contain 150 labels.

"The local health officer will be responsible for the following additional supplies:

Suitable racks for holding blood samples in vertical position.
Containers for transportation of blood samples to collecting points.
Tourniquets.
Band-aids.
Adhesive tape for fastening labels to tubes.

"Identification of Samples

"Before taking the blood sample, the tube in which it will be taken must be properly labeled with a ball point pen (important to avoid ink blurring from moisture). An identifying label should be filled out by teachers and recorders and securely attached to the tube with adhesive tape before it is given to the physician who will perform the venipuncture. These labels should be attached with adhesive tape in such a manner that they can be transferred to other tubes in the course of laboratory processing of the samples. The information called for on each blood sample label is as follows:

BLOOD LABEL

REG. SCHEDULE SHEET No. _____
LINE No. _____
Name _____
School _____
County _____ State _____
Date of Bleeding _____
THE NATIONAL FOUNDATION
FOR INFANTILE PARALYSIS — FTSA

"Handling of Samples

"After the physician has taken the blood sample, he will place the tube in a suitable rack.

"The local health officer will arrange for the collection of blood samples from the clinic. He will be responsible for the immediate storage and the shipment of blood specimens as soon as possible to a laboratory to be designated by the state health officer. Specimens should not be kept for more than 8 hours without refrigeration. The blood should be stored under refrigeration at normal ice-box temperatures (approximately 37 to 42 degrees F) and should not be allowed to freeze.

"The National Foundation will advise each state health officer of the specific laboratories to which blood samples collected in his state should be shipped. He in turn will notify the county health officer, who will make direct shipment."

Although there had been reservations by some local authorities, because of the work entailed as to the need or desirability of the serological studies planned, it was made a requirement of area participation that blood specimens as recommended would be obtained. Generally, serious effort was made to meet the requirements but variations did occur, especially in rural counties. In only one placebo area were specimens not obtained, and it was not known until too late to rectify the situation. In one borough of New York City, they were omitted by administrative arrangement. In two observed areas with relatively small populations, no bloods were obtained but those areas had received the same lots of vaccine as adjoining areas of the respective states in which specimens were taken.

VEC STAFF SUPERVISION

OBSERVATION OF CLINICS

During the vaccination period, April 26 to June 15, members of the Evaluation Center staff visited clinics in schools of 32 of the 44 participating states to inspect the procedures used and to advise on proper recording and

understanding of the various reports required from the local health offices. Specifically, nineteen first clinics, seventeen second clinics, and twelve third clinics were observed by staff members of the Evaluation Center.

The observations made by the staff were recorded on a standard reporting form (VEC-8) which also served as a check list of the important points to cover. These reports indicated that the listing of data on the basic Registration and Vaccination forms and the correct sequence of inoculations according to lot numbers were reasonably uniform in all of the clinics which were observed. Special emphasis was placed upon registration of the first and third grade control population and the recording of their parental requests in the observed areas where it was found that the instructions had not been at all times correctly interpreted. Detailed instructions were again explained with the hope that complete registration could be obtained.

Although there was some variation as to the site of the injection, probably due to the individual habits of the local volunteer physicians, the standard injection of 1 cc. in the left triceps was achieved with remarkable uniformity. There were some objections concerning the size of the needle provided, but very little difficulty was observed. The recording of the seven digit lot numbers of the vaccine code for each individual child appeared to have been accomplished with a minimum of error in the clinics visited.

The greatest source of difficulty in the clinics was the drawing of the pre-vaccination blood sample with the vacuum tubes provided for this purpose. This difficulty undoubtedly contributed to the failure to obtain the minimum 2 percent quota of bloods in several of the areas. In the clinics observed by members of the staff of the Evaluation Center, the methods for selection of the children from whom bloods were drawn varied all the way from the suggested method to the use of "volunteers" among the participating children or the selection of those with "good" veins as they were examined by the doctors. Although the recommended procedure did not propose completely random sampling, it did call for selection of grades and schools in order to assure some representation from each age class and from each local demographic group. Efforts were made in most areas to meet these requirements.

The general requirements of antiseptic care in the use of the equipment and the materials for inoculation during and between clinics were followed carefully. Although there were some exceptions, the local health offices had arranged for the proper storage and refrigeration of the inoculant promptly so that it was exposed to room temperature for less than 24 hours at each clinic.

MEETINGS WITH STATE AND LOCAL AUTHORITIES

In addition to the observation of 48 separate vaccination clinics, the Evaluation Center staff also met with the state health officers and their staff members who were assigned continuing responsibilities in the vaccine Field Trial program. Representatives from 32 of the 44 participating states and from those provinces of Canada which participated in the Canadian Field Trial attended the conferences.

When arranging for these meetings, the Evaluation Center recommended that the state health officer invite not only the state health personnel, but also the directors of poliomyelitis clinics in hospitals caring for large numbers of patients in the state; as many as possible of the local health officers from trial areas and their public health nurses; heads of the assigned laboratories, if possible; the state NFIP representative, and others with responsibility for carrying on case studies. In some situations it was necessary to hold several meetings in a state because of the distance and large numbers of areas involved. Under these conditions, common understanding could be enhanced, and the activities of the local and state authorities could be further integrated in completion of the vaccination and bleeding program.

The meetings, moreover, provided an opportunity to review and discuss the required procedures essential to the complete follow-up of all reported cases of poliomyelitis in the study population. Concentration on registration and vaccination had left little time to think about the study of cases. At each meeting the Evaluation Center staff members reviewed the procedures established for the reporting and investigation of cases in the total study population, the clinical and epidemiological records to be submitted, the arrangements for prompt collection of specimens, the establishing of relations with the designated laboratory, the notification to the physical therapists associated with the Trial for muscle examinations at the proper time, and prompt submission of reports. It was found advantageous at these meetings to outline the memoranda issued by the Center to the state and local health officers and to point out specifically the requisite information desired and the need for uniformity and completeness of the data to be supplied on cases of poliomyelitis that would occur during the season. The Evaluation Center staff sought to have the responsibilities of each of the state and local officials clearly outlined so that the program would operate smoothly.

Just as the operation of the vaccination clinics in the field required the assistance and integrated activity of many kinds of personnel, so the preparation of records and the follow-up of cases required the assistance and cooperation of thousands of people. In many of the states Epidemiological Intelligence Officers from the U.S. Communicable Disease Center were assigned to assist in the investigation of reported cases.

COMMUNICATION WITH FIELD TRIAL AREAS

Satisfactory operation of the vaccine Field Trial program was keyed to cooperative efforts of the state and local health offices involved in meeting the specific requirements of the Evaluation Center. In order to establish a positive, direct system of communication with the field areas covering these requirements, VEC Memoranda were issued as problems on specific items of procedure developed. They were distributed at the appropriate times to the state and local health offices in sufficient quantity to provide copies for the people immediately concerned with the program. At the same time, copies were sent to the participating laboratories and to NFIP for further distribution to their field staff.

The first of these Memoranda was issued on April 14, 1954, following the distribution of the NFIP Manual of Suggested Procedures for the Conduct of the Vaccine Field Trial which advised the cooperating personnel of the general arrangements for reporting to the Center. This memorandum outlined the basic functions of the Center and its relation to the field activities and provided the specified address and telephone numbers for prompt communication. Additional VEC Memoranda are listed in brief by number, date, and subject matter:

No. 2, April 21, 1954 (Immediately prior to the first vaccination clinic): Procedure to be used in the Field Trial areas for replacement or substitution of the appropriate inoculant when additional supplies were needed to complete the series of three injections.

No. 3, April 24, 1954: Procedure for recording gamma globulin injections given to children in the study population even though the general policy in most states was to avoid its use among Field Trial children.

No. 4, April 28, 1954: Procedure for the investigation of reported cases of poliomyelitis among the children in the study population and family members of households in which there were study children. It suggested ways of ensuring complete follow-up of such cases and emphasized the importance of including those children who moved away from the trial areas during the course of the year, as well as the problems of vacationers temporarily removed from