

COMMUNICABLE DISEASE CENTER

# POLIOMYELITIS

## SURVEILLANCE

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#### SUPPLEMENT TO PSU 268

Surgeon General's Technical Report to the  
Medical Profession Concerning Oral Vaccine  
Usage



# PREFACE

Summarized in this report is information received from State Health Departments, university investigators, virology laboratories and other pertinent sources, domestic and foreign. Much of the information is preliminary. It is intended primarily for the use of those with responsibility for disease control activities. Anyone desiring to quote this report should contact the original investigator for confirmation and interpretation.

Contributions to the Surveillance Report are most welcome. Please address to:  
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**SUMMARY**

The 59 cases, 46 paralytic reported for the two-week period which ended September 15, 1962, are in marked contrast to the 163 cases, 100 paralytic, reported during the comparable two weeks in 1961.

During the two-week period 22 States reported cases. There were no new epidemic concentrations. In Section 2, a further description is provided of the poliovirus outbreak noted in Pasadena (Los Angeles County), California, (see PSU No. 267, September 7, 1962). Also included is a report of cases of poliomyelitis among oral polio vaccinees in Nebraska.

Sections 3 and 4 contain summaries of paralytic cases occurring during 1962 submitted on individual case forms and cases occurring within 30 days of vaccination.

Appended is a special report by the Surgeon General to the Medical Profession on "The Association of Cases of Poliomyelitis with the Use of Type III Oral Poliomyelitis Vaccines."

**1. CURRENT POLIOMYELITIS MORBIDITY TRENDS**

Fifty-nine cases of poliomyelitis, 46 paralytic, were reported during the two-week period ending September 15. The current week ending September 15 accounted for 29 cases, 21 paralytic, compared with 30 cases including 25 paralytic for the previous week. A total of 163 cases, 100 paralytic, was reported for the same two-week period in 1961.

Twenty-two States reported poliomyelitis during the current two-week period. Texas accounted for the largest number with 10 cases, 7 of which were paralytic. California reported 7 paralytic cases. A special report concerning the case concentration in this State is presented in Section 2. Of the remaining 20 States, four reported 4 cases each.

The following tables, which give the total cumulative and six-week incidence through the 37th week for 1962 and for the preceding 4 years, show that this year's totals are much reduced from the 1961 figures.

**Polio (Cumulated Weekly) Through the 37th Week for Past Five Years**

	<u>1962</u>	<u>1961</u>	<u>1960</u>	<u>1959</u>	<u>1958</u>
Paralytic	414	517	1312	3455	1461
Total	529	780	1908	5474	3000

Six-Week Totals (32nd thru 37th Week) for Past Five Years

	<u>1962</u>	<u>1961</u>	<u>1960</u>	<u>1959</u>	<u>1958</u>
Paralytic	159	278	632	1855	839
Total	195	418	960	3023	1746

2. STATE REPORTS

A. California

Of the 7 cases of poliomyelitis reported by Dr. Henry Renteln, Chief of the Surveillance Section, California State Health Department during the past two weeks, 6 were from Los Angeles County, with 3 from the City of Pasadena which is within the county. Type I oral polio vaccine was administered in a mass campaign as an epidemic deterrent in the epidemiologically relevant area in Pasadena on September 9 and the days following. (See PSU #267, September 7, 1962). All of the cases reported during the past two weeks from Pasadena occurred before vaccine administration.

A total of 8 cases has occurred in Pasadena in 1962. Six of the 8 had onsets of illness in August. Six type I poliovirus isolates have been recovered from these. All of the poliomyelitis reported from this city occurred in a lower socio-economic area of Pasadena, and the patients involved have all been Negro. All but two were in the pre-school age group. None had received adequate inactivated polio vaccine immunizations.

To study polio and enterovirus prevalence and the subsequent effect of the vaccine virus, a sampling of 208 rectal swabs was obtained from children in individual households in that area prior to vaccination. Samples from these children will be obtained on two further occasions in a longitudinal study.

B. Nebraska

Dr. E.A. Rogers, Director, Communicable Disease Control, has reported that four cases of poliomyelitis have been observed in this State in 1962. All 4 patients had participated in mass oral polio vaccine immunization campaigns in the State. Epidemiological and clinical data were available on the first 3 of the 4 cases on September 15, 1962, and were included in the group considered by the Surgeon General's special advisory committee (See Appended Report).

A line listing of the 4 cases appears below; they will be listed again in Section 4 at a later date.



Case #	Age	Race	Sex	Doses IPV	Onset	Interval from OPV (days)			Paralytic Status	Isolates	
						Type I	Type II	Type III			
Nebr-1	18	W	F	5	7/1	34	0	-	7	Spinal	III
Nebr-2	51	W	M	0	7/16	51	0	-	22	Spinal	0
Nebr-3	37	W	M	0	7/23	43	0	-	15	Spinal	Not done
Nebr-4	48	W	F	0	8/18	63	0	-	21	Spinal	In progress

### 3. 1962 PARALYTIC CASES REPORTED TO PSU

Of the 414 cases of paralytic poliomyelitis reported through the week ending September 15, 393 had onset in 1962. The Poliomyelitis Surveillance Unit has received individual case forms on 318 of the 393 paralytic cases. The vaccination status of the 318 paralytic cases by age group is shown below.

#### Paralytic Poliomyelitis by Age Group And Vaccination History Reported on PSU Forms (Through September 21, 1962)

Age Group	Doses of Inactivated Vaccine					Total	Percent
	OV	1-2V	3V	4+V	Unk		
0-4	108	30	6	8	8	160	50.3
5-9	31	8	8	15	3	65	20.4
10-14	15	4	8	4	1	32	10.1
15-19	8	2	4	0	0	14	4.4
20-29	15	5	1	3	3	27	8.5
30-39	6	2	0	2	1	11	3.5
40+	7	1	0	0	1	9	2.8
<b>TOTAL</b>	<b>190</b>	<b>52</b>	<b>27</b>	<b>32</b>	<b>17</b>	<b>318</b>	<b>100.0</b>

#### PERCENT

DOSES	63.1	17.3	9.0	10.6	-	100.0
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Of the 152 cases with known vaccination history in the 0-4 age group, 108 (71.1 percent) had not received any poliomyelitis vaccinations.

To date in 1962, the Poliomyelitis Surveillance Unit has received results of virological studies on 144 of the 318 paralytic cases. Polio-virus isolations have been reported on 119 (82.6 percent) of the 144 cases. Of these, 100 are Type I and 19 are Type III poliovirus. Isolates have been reported from the following States.

Four cases of poliomyelitis, 2 paralytic, occurring within 30 days following oral vaccine feeding were reported to the Poliomyelitis Surveillance Unit.

State	Poliovirus			Total
	I	II	III	
Alabama	2	0	0	2
Arizona	2	0	0	2
California	4	0	2	6
Colorado	1	0	0	1
Georgia	1	0	1	2
Illinois	8	0	2	10
Kentucky	8	0	1	9
Louisiana	3	0	0	3
Massachusetts	2	0	0	2
Michigan	0	0	1	1
Minnesota	4	0	0	4
Mississippi	0	0	1	1
Montana	1	0	0	1
New York	4	0	2	6
Ohio	4	0	4	8
Oregon	0	0	3	3
Pennsylvania	3	0	0	3
Tennessee	1	0	0	1
Texas	49	0	2	51
Utah	1	0	0	1
West Virginia	1	0	0	1
Wyoming	1	0	0	1
<b>TOTAL</b>	<b>100</b>	<b>0</b>	<b>19</b>	<b>119</b>

4. ROUTINE POLIOMYELITIS SURVEILLANCE - 1962

A. Cases with Onset Within 30 Days of Vaccine (Inactivated)

During the two-week period ending September 15, there have been no cases of poliomyelitis within 30 days following vaccination with inactivated vaccine reported to the Poliomyelitis Surveillance Unit.

The total remains at 11 under-30-day cases reported, including 8 paralytic. Eight of the cases have occurred in Texas; Alabama reported two cases, and Pennsylvania one case. None of the sites of inoculations correlated with the sites of first paralysis.

B. Cases with Onset Within 30 Days of Vaccine (Oral)

Four cases of poliomyelitis, 2 paralytic, occurring within 30 days following oral vaccine feeding were reported to the Poliomyelitis Surveillance



Unit during the past two weeks. Pennsylvania and Tennessee reported one case each and Texas accounted for two cases. All four cases had been fed Type I oral polio vaccine. The cases from Texas and Pennsylvania received the vaccine in communities where the oral polio vaccine was used as an epidemic deterrent. A detailed listing of these cases is presented below.

<u>State</u>	<u>County</u>	<u>Age</u>	<u>Sex</u>	<u>Onset</u>	<u>Date Fed</u>	<u>Type Fed</u>	<u>Onset Interval</u>	<u>Paralytic Status</u>
Penna.	Cambria	8	F	8-22	8-18	I	4 days	NP
Tenn.	Gibson	25	M	8-30	8-20	I	10 days	P
Texas	Harris	50	M	7-26	7-22	I	4 days	NP
Texas	Harris	45	M	8-16	7-22	I	25 days	P

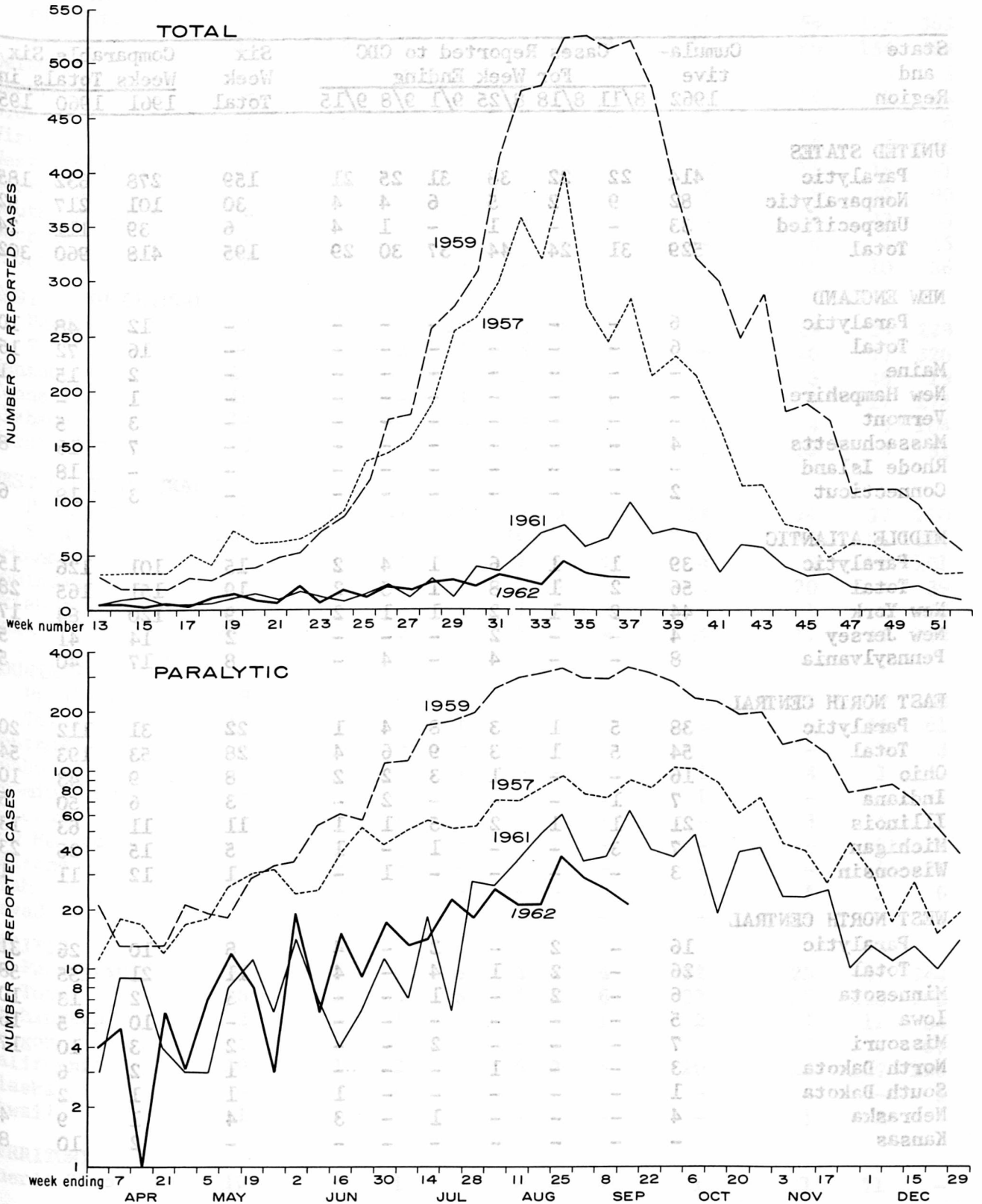




Figure 1

## CURRENT U.S. POLIO INCIDENCE COMPARED WITH YEARS 1957, 1959 and 1961 April - December, by week

DATA PROVIDED BY NATIONAL OFFICE OF VITAL STATISTICS AND COMMUNICABLE DISEASE CENTER



CURRENT U.S. POLIO INCIDENCE  
 COMPARED WITH YEARS 1957, 1958 AND 1959  
 (per 100,000 population per week)

**Table 1**

**TREND OF 1962 POLIOMYELITIS INCIDENCE**

State and Region	Cumulative 1962	Cases Reported to CDC For Week Ending						Six Week Total	Comparable Six Weeks Totals in		
		8/11	8/18	8/25	9/1	9/8	9/15		1961	1960	1959
<b>UNITED STATES</b>											
Paralytic	414	22	22	38	31	25	21	159	278	632	1855
Nonparalytic	82	9	2	5	6	4	4	30	101	217	927
Unspecified	33	-	-	1	-	1	4	6	39	111	241
<b>Total</b>	<b>529</b>	<b>31</b>	<b>24</b>	<b>44</b>	<b>37</b>	<b>30</b>	<b>29</b>	<b>195</b>	<b>418</b>	<b>960</b>	<b>3023</b>
<b>NEW ENGLAND</b>											
Paralytic	6	-	-	-	-	-	-	-	12	48	109
<b>Total</b>	<b>6</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>16</b>	<b>72</b>	<b>159</b>
Maine	-	-	-	-	-	-	-	-	2	15	13
New Hampshire	-	-	-	-	-	-	-	-	1	-	3
Vermont	-	-	-	-	-	-	-	-	3	5	1
Massachusetts	4	-	-	-	-	-	-	-	7	16	80
Rhode Island	-	-	-	-	-	-	-	-	-	18	2
Connecticut	2	-	-	-	-	-	-	-	3	18	60
<b>MIDDLE ATLANTIC</b>											
Paralytic	39	1	1	6	1	4	2	15	101	126	156
<b>Total</b>	<b>56</b>	<b>2</b>	<b>1</b>	<b>8</b>	<b>1</b>	<b>5</b>	<b>2</b>	<b>19</b>	<b>151</b>	<b>165</b>	<b>286</b>
New York	44	2	1	2	1	1	2	9	120	84	171
New Jersey	4	-	-	2	-	-	-	2	14	41	59
Pennsylvania	8	-	-	4	-	4	-	8	17	40	56
<b>EAST NORTH CENTRAL</b>											
Paralytic	38	5	1	3	8	4	1	22	31	112	202
<b>Total</b>	<b>54</b>	<b>5</b>	<b>1</b>	<b>3</b>	<b>9</b>	<b>6</b>	<b>4</b>	<b>28</b>	<b>53</b>	<b>193</b>	<b>543</b>
Ohio	16	-	-	1	3	2	2	8	9	43	104
Indiana	7	1	-	-	-	2	-	3	6	50	56
Illinois	21	1	1	2	5	1	1	11	11	63	136
Michigan	7	3	-	-	1	-	1	5	15	26	231
Wisconsin	3	-	-	-	-	1	-	1	12	11	16
<b>WEST NORTH CENTRAL</b>											
Paralytic	16	-	2	-	2	-	4	8	10	26	310
<b>Total</b>	<b>26</b>	<b>-</b>	<b>2</b>	<b>1</b>	<b>4</b>	<b>-</b>	<b>4</b>	<b>11</b>	<b>21</b>	<b>55</b>	<b>588</b>
Minnesota	6	-	2	-	1	-	-	3	2	13	106
Iowa	5	-	-	-	-	-	-	-	10	5	160
Missouri	7	-	-	-	2	-	-	2	3	10	175
North Dakota	3	-	-	1	-	-	-	1	2	6	9
South Dakota	1	-	-	-	-	-	1	1	1	2	7
Nebraska	4	-	-	-	1	-	3	4	1	9	43
Kansas	-	-	-	-	-	-	-	-	2	10	88



Table 1 (Continued)

State and Region	Cumulative 1962	Cases Reported to CDC For Week Ending						Six Week Total	Comparable Six Weeks Totals in		
		8/11	8/18	8/25	9/1	9/8	9/15		1961	1960	1959
<b>SOUTH ATLANTIC</b>											
Paralytic	31	4	3	3	3	2	1	16	54	115	362
Total	35	5	3	3	3	2	1	17	69	154	464
Delaware	-	-	-	-	-	-	-	-	-	-	3
Maryland	-	-	-	-	-	-	-	-	14	32	14
D.C.	2	-	-	-	-	-	1	1	-	-	6
Virginia	8	3	-	1	1	-	-	5	7	12	126
West Virginia	5	-	-	-	1	1	-	2	11	16	91
North Carolina	4	-	-	1	-	1	-	2	6	32	90
South Carolina	4	-	2	-	1	-	-	3	8	43	33
Georgia	6	2	1	1	-	-	-	4	8	9	65
Florida	6	-	-	-	-	-	-	-	15	10	36
<b>EAST SOUTH CENTRAL</b>											
Paralytic	34	1	1	10	5	4	1	22	19	24	229
Total	44	1	1	11	5	4	4	26	26	77	326
Kentucky	17	-	-	6	1	1	-	8	3	48	19
Tennessee	10	1	-	1	-	1	3	6	7	17	172
Alabama	14	-	-	4	4	2	1	11	4	3	104
Mississippi	3	-	1	-	-	-	-	1	12	9	31
<b>WEST SOUTH CENTRAL</b>											
Paralytic	188	10	11	11	7	9	6	54	24	37	210
Total	238	17	13	12	10	11	7	70	47	61	314
Arkansas	6	1	1	-	1	-	1	4	9	10	101
Louisiana	14	-	1	-	-	3	-	4	20	2	39
Oklahoma	11	-	2	1	1	2	2	8	1	4	46
Texas	207	16	9	11	8	6	4	54	17	45	128
<b>MOUNTAIN</b>											
Paralytic	8	-	-	-	-	-	-	-	4	7	33
Total	12	-	-	1	-	-	1	2	8	25	61
Montana	3	-	-	-	-	-	-	-	-	1	3
Idaho	2	-	-	1	-	-	-	1	4	1	-
Wyoming	2	-	-	-	-	-	1	1	-	14	-
Colorado	1	-	-	-	-	-	-	-	3	5	11
New Mexico	-	-	-	-	-	-	-	-	-	2	12
Arizona	3	-	-	-	-	-	-	-	-	1	27
Utah	1	-	-	-	-	-	-	-	1	1	6
Nevada	-	-	-	-	-	-	-	-	-	-	2
<b>PACIFIC</b>											
Paralytic	54	1	3	5	5	2	6	22	23	137	244
Total	58	1	3	5	5	2	6	22	27	158	282
Washington	2	-	1	-	-	-	1	2	7	12	84
Oregon	5	-	-	-	-	-	-	-	4	7	67
California	50	1	2	5	5	2	5	20	15	137	126
Alaska	-	-	-	-	-	-	-	-	-	-	5
Hawaii	1	-	-	-	-	-	-	-	1	2	-
<b>TERRITORY</b>											
Puerto Rico	10	-	1	-	-	-	-	1	1	71	-



On September 15, 1962, the Surgeon General's Oral Poliomyelitis  
**The Association of Cases of Poliomyelitis**  
 Vaccine Advisory Committee met in Washington, D. C. and reviewed the  
**With the Use of Type III Oral Poliomyelitis Vaccines**  
 data concerning the occurrence of cases of poliomyelitis after the  
**A Technical Report**<sup>1</sup>

administration of oral poliomyelitis vaccines during the current  
 by  
**Luther L. Terry, M. D.**  
 Surgeon General, Public Health Service  
 U. S. Department of Health, Education, and Welfare  
 September 20, 1962

- The present report summarizes the information which was reviewed by the Committee and upon which its recommendations were based. Included are: (1) a brief review of the use of poliomyelitis vaccines in the United States, particularly the use of the recently licensed oral poliomyelitis vaccines; (2) an appraisal of the present poliomyelitis problem; and (3) a listing, in detail, of the cases of poliomyelitis that have occurred in association with the use of oral poliomyelitis vaccines.
- 
1. The data in this report have been compiled by the Poliomyelitis Surveillance Unit, Communicable Disease Center, Public Health Service, U.S. Department of Health, Education, and Welfare. The information is based on routine morbidity and special poliomyelitis surveillance reports, individual case investigations and a wide variety of laboratory and field studies, all of which represent the work of several hundred practicing physicians, local, state and federal health officials, epidemiologists, and laboratory scientists. Their contribution is gratefully acknowledged.

On September 15, 1962, the Surgeon General's Oral Poliomyelitis Vaccine Advisory Committee met in Washington, D. C. and reviewed the data concerning the occurrence of cases of poliomyelitis after the administration of oral poliomyelitis vaccines during the current calendar year. After a full discussion of the problem the Committee unanimously recommended that the use of Type III vaccine be limited to pre-school and school age children and to adults at high risk, i.e. those travelling to hyperendemic areas and those living in areas where Type III epidemics were present or impending. They advised that mass programs using Types I and II oral vaccines be continued for all age groups.\*

The present report summarizes the information which was reviewed by the Committee and upon which its recommendations were based. Included are: 1) a brief review of the use of poliomyelitis vaccines in the United States, particularly the use of the recently licensed oral poliomyelitis vaccines; 2) an appraisal of the present poliomyelitis problem; and 3) a listing, in detail, of the cases of poliomyelitis that have occurred in association with the use of oral poliomyelitis vaccines.

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\* The members of the Special Oral Poliomyelitis Vaccine Advisory Committee who approved the recommendations are: Drs. David Bodian, John P. Fox, Archie L. Gray, William McD. Hammon, Hugh H. Hussey, Alexander D. Langmuir, Roderick Murray, John R. Paul, Edward B. Shaw, Joseph E. Smadel. Dr. Albert B. Sabin, also a member of the Committee, participated in its first two meetings on August 9 and 16, 1962. He was out of the country on September 15 and was thus unable to be present at the meeting on that date. The Surgeon General served as Chairman of the Committee.



This information is being made broadly available to the medical and health professions at this time in order that they may have the opportunity for a full understanding of the basis for the recommendations.

Use of Poliomyelitis Vaccines:

The Type I oral vaccine was licensed for distribution in interstate commerce on August 17, 1961; Type II vaccine on October 10, 1961; and Type III on March 27, 1962. Prior to these dates, experimental lots of the respective vaccines were employed in a number of small scale and some large scale community programs.

Since vaccine licensure, a great many community-wide vaccination programs have been carried out. The programs have ranged in size from those involving single small towns, to those which include metropolitan areas in several contiguous counties, to an essentially state-wide program in Massachusetts. The oral vaccines have also been employed for smaller programs among selected population groups and for routine use in private practice and health department immunization clinics.

In epidemic control, Type I vaccine was used immediately following release in the Syracuse, New York area and, in 1962, in many counties of Texas; in Mobile, Alabama; Pasadena, California; and several rural counties in Kentucky and Pennsylvania to abort existent or impending epidemics. Experimental lots of Type III vaccine were used in 1961 in outbreaks in Atlanta, Georgia, and in Newberry County, South Carolina. Commercial Type III vaccine was used in Washington County, Virginia, in 1962.

The estimated use of oral vaccines in the United States is summarized in Table 1. Utilization of both experimental lots and the licensed product is shown. Since it was recommended that Type I vaccine be fed first and because many programs did not start until late spring, the estimates show a much greater use of this type of vaccine than Types II and III. Estimated use in community programs of the 3 types of vaccine by month is shown in Figure 1.

In most areas the vaccine was offered to persons of all ages and found wide acceptance among adults as well as children. In a few areas, as in Massachusetts, use of the oral vaccines in public programs was largely limited to children.

During the past twelve months, the inactivated (Salk) poliomyelitis vaccines (IPV) have continued to be used although less widely. Since April 1955, a total of 537 million doses of IPV has been distributed. A random sample survey of the population in September 1961 indicated that slightly more than 50,000,000 persons in the population had received 4 or more doses of the inactivated vaccine.

#### Incidence of Poliomyelitis:

The annual incidence of reported cases of poliomyelitis by paralytic status from 1955 through 1961 is shown in Table 2. The marked decline in paralytic cases can be attributed largely to the widespread use of the inactivated polio vaccine. During the first 9 months of 1962, the incidence of poliomyelitis has further declined as shown in Table 3.

Present data indicate that for 1962, the paralytic poliomyelitis rate for those under 20 will be approximately 7.6 per million; for those over 20, about 0.9 per million. These rates will represent a record low for the 52 year period since the reporting began.

The further decline in the incidence of poliomyelitis in 1962 may be attributed to the steadily improved immunization status of the population resulting both from the continued use of inactivated polio vaccine and the wide use of oral vaccines.

#### The Occurrence of Cases Following Oral Vaccine:

With the licensing of Type I oral vaccine in August 1961, the poliomyelitis surveillance program of the Communicable Disease Center placed particular stress on the evaluation of reported cases of poliomyelitis developing after vaccine use. It was recognized that when millions of persons participate in an immunization program, any of a variety of subsequent events might occur coincidentally but be attributed erroneously to the vaccine. This could be particularly true of an intercurrent disease such as aseptic meningitis that might simulate poliomyelitis and even poliomyelitis due to infection with wild polioviruses that had been acquired prior to the vaccination. The problem is compounded during the summer and early fall when many enteroviruses are actively circulating.

In epidemic control a number of cases of disease among vaccinees can be expected in the days immediately following an immunization program before there has been opportunity for immunity to develop. In non-epidemic areas, the frequency of coincidental cases should be lower,

although not necessarily zero. If vaccine is related in a causal way to the cases, the intervals between immunization and onset of disease should group within the expected 7 to 30 day incubation period of the disease.

Since August 17, 1961, when Type I oral vaccine became commercially available, there have been 62 cases of poliomyelitis officially reported to the Public Health Service in which oral polio vaccine had been administered within 30 days prior to the onset of symptoms.

During the epidemic in New York State in 1961, a total of 32 "under 30-day vaccinated cases" was reported. Most of these developed soon after administration of the vaccine, in fact, 15 within 6 days. The early appearance of these cases indicates a coincidental rather than a causal relationship to vaccination. Similarly, in South Carolina, Georgia, and Texas, a total of 17 "under 30-day vaccinated cases" was reported. Again, most appeared soon after vaccination, 11 within 6 days, and do not suggest a causal relationship.

In the non-epidemic areas, a total of 16 "under 30-day vaccinated cases" has been reported. These have come from 7 states. Two followed Type I vaccine, one followed Type II vaccine, and 13 followed Type III vaccine. Eleven of the 16 occurred between the 15th and 29th day. This finding warranted further consideration of the possibility of a causal relationship to the vaccine, particularly to the Type III vaccine.

The Advisory Committee directed special attention to these 16 under 30-day cases reported from non-epidemic areas. All available clinical, epidemiological, and laboratory information was reviewed.



Each case was considered individually, and excluded or not excluded by group decision from further consideration as to the possibility of its being vaccine induced. No case was excluded except by unanimous agreement of the committee members. Included for consideration were those cases clinically compatible with poliomyelitis which demonstrated any significant paralysis and in which laboratory findings to date were not inconsistent with a vaccine relationship. Descriptive data regarding these cases are summarized in Table IV.

Of the two cases of poliomyelitis reported following Type I vaccine administration, only one (case 2) was thought by the Committee to be entirely compatible clinically with poliomyelitis. Of recent onset, the virologic studies on this patient are still in process. The clinical history of the other case (case 1) indicated it to be exceedingly mild and atypical. The patient experienced no known febrile illness, he was not hospitalized, and no cerebrospinal fluid studies were performed. He recovered with no residual paralysis.

The single case reported following immunization with Type II vaccine was found to have a Type III virus in his stool. Since Type III vaccine had not been fed, it can be concluded that the infection was due to a wild virus.

Eleven of the thirteen cases following Type III oral polio vaccine were considered by the Committee as possibly vaccine related. Of the two cases excluded, one (case 14) had an illness atypical for poliomyelitis with no functional impairment after 30 days. Both Type I and

Type III polioviruses were recovered from the stool, 55 and 27 days respectively after Types I and III vaccines had been fed to the child. The Type I virus which was recovered was characterized as "wild-like" according to the results obtained by the modified Wecker and McBride tests. These tests are used to demonstrate slight antigenic differences between poliovirus strains of the same type. Since the virus strains may, after a period of intestinal multiplication, show such a shift in the antigenic characteristics of the viruses, no definitive interpretation of this finding was possible. The second case (case 16) which was excluded from further consideration had an insignificant paralytic residual and no detectable Type III antibody in either acute or convalescent serum specimens.

From 6 of the 11 cases, Type III poliovirus was recovered from stool specimens. Four of the six were characterized as "vaccine-like" by the modified Wecker and McBride tests. Although this finding was of interest, it unfortunately provided little help in determining whether the vaccine played a causal role. Each of these considered had been fed oral vaccine and, hence, might be expected to be excreting the Type III vaccine virus which might appear by the modified Wecker and McBride tests to be, as noted above, wither "wild-like" or "vaccine-like". Further, it is possible that the oral vaccine strain may have displaced a "wild" enterovirus which was, in fact, the etiological agent responsible for the paralytic illness. In summary, isolation of a Type III virus from the stool and demonstration of Type III antibodies in the patient's sera served to indicate only that the paralytic disease would not be incompatible with Type III vaccine-induced disease.

The eleven cases considered as possibly related to Type III vaccine feeding are between 16 and 52 years of age, with all but three of the cases over 30. The vaccine administered to this group of cases was from several lots and was not produced by any single manufacturer. Of the 11 cases, 3 occurred in Oregon, 3 in Nebraska, 2 in Michigan, 2 in Ohio, and one in New York State. The clinical illnesses in these patients range from significant to severe. No deaths occurred. Among the eleven cases, the entire spectrum of non-fatal paralytic illness characteristic of poliomyelitis was evident.

Discussion Summary:

Of the reported cases to date, one following Type I vaccine and eleven following Type III vaccine were considered by the Committee to be clinically consistent with paralytic poliomyelitis and with laboratory findings which could not exclude a possible relationship to the administration of oral vaccine.

As noted, a single case occurred within 30 days of Type I vaccine administration during a period of almost 9 months when approximately 20,000,000 persons were fed Type I vaccine. This is wholly compatible with coincidental origin.

The 11 cases following Type III vaccine cannot all be assumed to be coincidental. The adult age distribution ranging from 16 to 52 years with 8 of the cases over 30 years of age, and the clustering of the intervals from vaccine feeding to onset in the 2-3 week period suggest a vaccine relationship. For these reasons the Committee concluded that "there is sufficient epidemiological evidence to indicate

that at least some of these cases have been caused by the Type III vaccines."

The incidence, assuming all cases to have been vaccine induced, is but 11 cases among more than 13 million fed. This is less than one case per million doses given. When the risk is related to age it is apparent that adults are exposed to a greater hazard than are children. Inadequate information on the age specific vaccine acceptance rate, however, makes it impossible to calculate a more precise estimate of the risk at this time.

With the incidence of poliomyelitis at a low level in this country, the Committee therefore recommended that the Type III vaccine be restricted to pre-school and school age children and to those adults in high risk groups, such as those travelling to hyperendemic areas or in areas where a Type III epidemic is present or impending.

Since the vast majority of poliomyelitis cases occur among young children and since children are the principal disseminators of the virus, continued intensive immunization programs among this group are clearly indicated. If this group can be adequately immunized, the spread of the poliomyelitis viruses will be sharply restricted, if not essentially eradicated.





**Figure 1**  
**Estimate of the Number of Persons Fed**  
**During Known Mass Community Oral Polio Vaccination Programs**  
**by Month from Date of Licensure, United States**

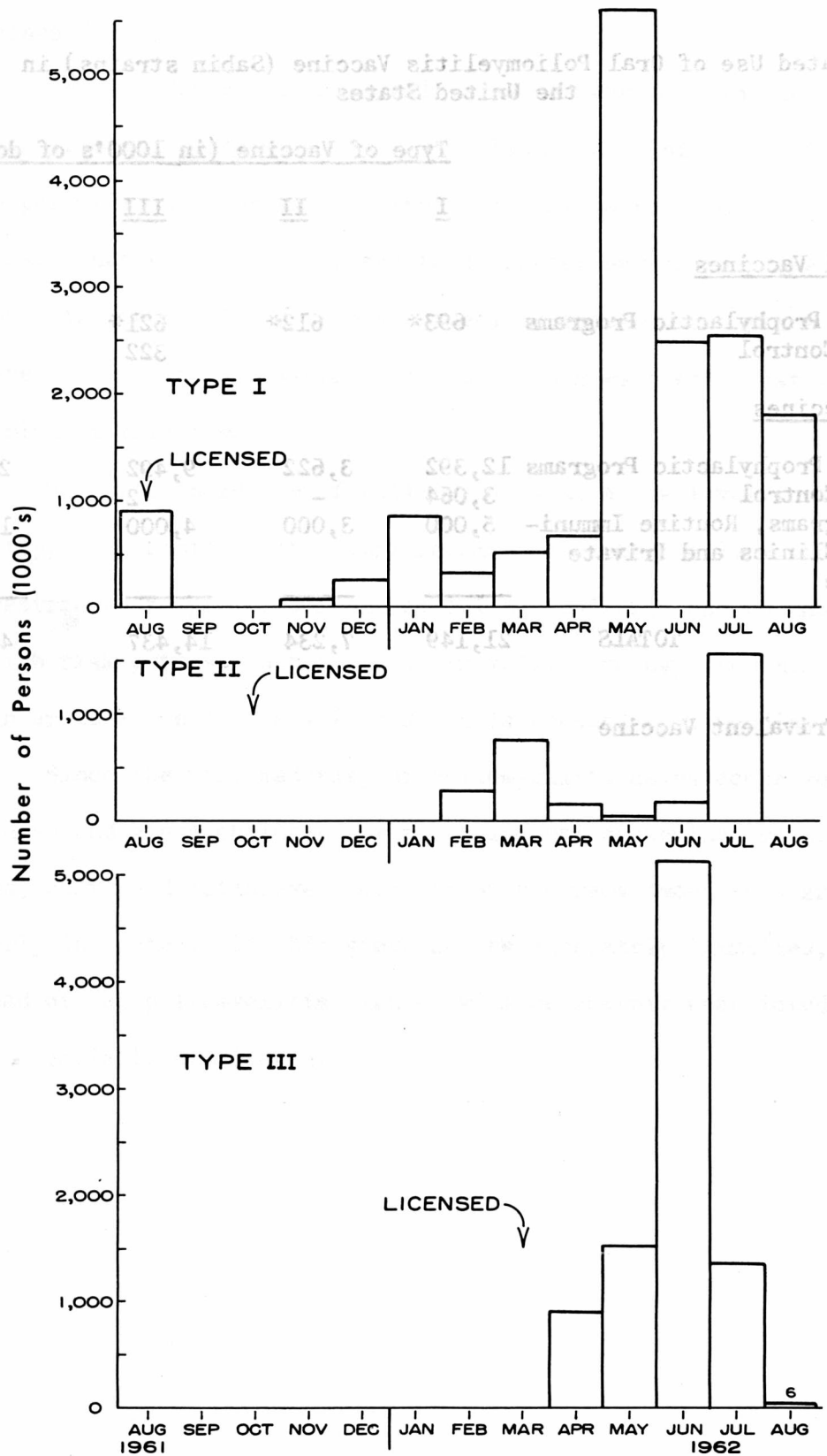


Table II

Annual Incidence of Reported Cases of Poliomyelitis  
by Paralytic Status in the United States  
1955-1961

Year	Paralytic	Non-Paralytic	Unspecified	Total
1955	13,850	12,453	2,682	28,985
1956	7,911	6,555	674	15,140
1957	2,499	2,826	160	5,485
1958	3,697	1,941	149	5,787
1959	6,289	2,045	91	8,425
1960	2,225	626	39	3,190
1961	988	305	19	1,312

Table III

Incidence of Poliomyelitis by Paralytic Status in the United States  
January thru 36th Week - 1962 and Comparable Periods in Previous Years

Paralytic Status	1962	1961	1960	1959
Paralytic	393	454	1,200	3,122
Non-Paralytic	78	151	363	1,394
Unspecified	29	77	167	440
<b>TOTAL</b>	<b>500</b>	<b>682</b>	<b>1,735</b>	<b>4,956</b>

Table IV

## Cases of Reported Paralytic Poliomyelitis Occurring Within 30 Days of the Administration of Oral Poliomyelitis Vaccines in Non-Epidemic Areas

January 1 to September 15, 1962

Case #	Age	Race	Sex	Doses IPV	Onset First Symptom	Clinical Severity	Interval from OPV (days)			Virus Isolates		Antibody Response	Committee <sup>1</sup> Appraisal
							Type I	Type II	Type III	Type	Character		
1	3	W	M	2	5/29	1	23	--	--	I	Wild Like	I	Excluded
2	25	W	M	1	8/30	3	10	--	--	**	**	**	Compatible
<u>Type II Vaccine</u>													
3	2	W	F	2	2/23	3	Over 90	8	--	III	-	-	Excluded
<u>Type III Vaccine</u>													
4	23	W	M	4	7/16	3	76	--	17	III	Wild Like	III	Compatible
5	36	W	F	0	7/20	3	--	--	22	III	Vaccine Like	III	Compatible
6	18	W	F	5	7/1	3	34	--	7	III	**	**	Compatible
7	51	W	M	0	7/16	3	51	--	22	0	-	**	Compatible
8	37	W	M	0	7/23	3	43	--	15	-	-	-	Compatible
9	49	W	M	0	6/18	4	+90	--	26	0	-	II&III	Compatible
10	16	W	M	0	6/8	3	43	--	15	-	-	-	Compatible
11	36	W	M	0	7/15	4	--	--	21	0	-	I & III	Compatible
12	48	W	F	0	5/5	4	34	--	7	III	Vaccine Like	III	Compatible
13	39	W	M	0	5/21	4	50	--	23	III	Vaccine Like	-	Compatible
14	6	W	M	0	5/25	1	54	--	27	I	Wild Like	-	Excluded
15	52	W	M	0	6/26	4	52	--	19	III	Vaccine Like	III	Compatible
16	6	W	M	4	6/12	2	37	--	5	I	**	I	Excluded

(SEE FOLLOWING PAGE FOR FOOTNOTES)



Footnotes for Table IV

Key for Severity: 1 - Complete Recovery, no residual paralysis  
2 - Minor Involvement  
3 - Significant Disability  
4 - Severely Disabled (bed, wheelchair, extensive bracing)

Key for Virus and Antibody Studies: 0 - Negative Test  
- - Test not Done  
\*\* - Test in Progress

Virus character was determined by the modified Wecker and McBride tests.

1 Considered compatible with vaccine-induced disease were those cases clinically indistinguishable from poliomyelitis with some significant residual paralysis and laboratory studies not inconsistent with the possibility of vaccine relationship.

Summary of results of studies on the relationship between the presence of antibody to the antigen and the presence of disease in patients with various types of infectious diseases.

TABLE I  
Summary of results of studies on the relationship between the presence of antibody to the antigen and the presence of disease in patients with various types of infectious diseases.

and laboratory studies not inconsistent with the possibility of vaccine relationship. In studies with some significant results, the relationship between antibody and disease was not inconsistent with the possibility of vaccine relationship.

1. Considered complete with vaccine-induced disease were those cases of influenza

2. Virus cultures was determined by the modified Becker and Webster tests.

\*\* - Test in progress

- - - Test not done

Key for Virus and antibody studies: 0 - Negative test

4 - Slightly impaired (red, wheezing, extensive phlegm)

3 - Slightly impaired

2 - Minor impairment

Key for severity: 1 - Complete recovery, no residual disease