April 12, 1961.

Dr. Albert Sabin,
Professor of Research Pediatrics,
University of Cincinnati College of Medicine,
Cincinnati, Ohio.

Dear Doctor Sabin:-

We are enclosing a copy of a highly preliminary summary of our experience with the Sabin type of poliomyelitis vaccine in Rochester and Monroe County, N.Y. There are undoubtedly many additions and corrections that must be made, but we thought that this information, even though preliminary, would be of interest to you.

Very truly yours,

Wendell R. Ames, M.D.,
Director.

WRA:CP
Preliminary Report
(Not For Publication)

EXPERIENCE IN ROCHESTER AND MONROE COUNTY, N. Y. WITH SABIN ORAL POLIOMYELITIS VACCINE, 1960

M. L. Rathbun, M.D., M.P.H.
Wallace Font, M.D.
Samuel Milham, M.D.
W. R. Ames, M.D., M.P.H.

From the Monroe County Health Department,
44 Marshall Street, Rochester 2, N.Y.

April, 1961.
INTRODUCTION

Monroe County, N.Y. is an upstate New York community which includes the third largest city in the State, Rochester, an extensive suburban area and a peripheral rural area. The county itself comprises the City of Rochester, several villages and 19 townships. The population of Monroe County, according to the 1960 preliminary census figures, is 586,387. Of this number 318,611 are in the City of Rochester and, of course, there is a concentration in the first and second ring townships. There were approximately 25,000 non-white people enumerated in the 1960 census, the vast majority in the City of Rochester.

The area has a stable economy, by most standards would be considered generally prosperous, has a high level of interest in medical matters on the part of its population, is the location of a well known medical school and medical center, and has other attributes which can be expected to contribute to a cooperative attitude in reasonably well documented health programs.

OFFICIAL HEALTH ORGANIZATION

The City of Rochester has had a well organized and well staffed Health Department for many years. In 1958 the official public health services of the whole county were brought together to form a County Health Department. The former City Health Department personnel and certain laboratory, sanitation and nursing personnel were consolidated into one organization which facilitates communications and operations for projects such as the one that is the subject of this presentation.
BACKGROUND OF ORAL VACCINATION PROGRAM

In the Spring of 1960 it appeared likely that one or more varieties of living attenuated poliomyelitis immunizing agents would be favorably considered for licensure by the Public Health Service. The State Health Commissioner suggested that several areas in New York State should undertake programs with the agents then under consideration to gain experience in their use. Monroe County was offered the opportunity to use the Sabin type of vaccine which was graciously furnished by Dr. Albert Sabin. Tompkins County was offered the use of the Cox type of vaccine. This discussion will be limited to experience in Monroe County. The definitive request for conduct of the program was made on May 3rd, 1960. The vaccine which was furnished was delivered to the Division of Laboratories and Research of the State Health Department in Albany where the frozen material was suitably diluted and placed in dropper bottles for dispensing.

OBJECTIVES

The objectives of this program were quite simple. The Department wished to gain general experience in the handling, dispensing and administration of one type of oral vaccine. It wished to determine the ease and speed with which the material could be administered and to experiment to a certain extent with methods of administration. It wished to sense the degree of public acceptance of such a material, to determine through short term surveillance whether there were reactions to some component in the vaccine, to determine through intermediate term surveillance whether neuro-paralytic accidents might occur and through long term surveillance
whether there was any measurable effect on incidence of poliomyelitis during the poliomyelitis season that would follow administration of the vaccine.

It must be mentioned that no attempt was made to conduct a controlled type of study. Monroe County participated in the 1954 poliomyelitis vaccination field trials. Substantially satisfactory immunization levels have been achieved since that date. The poliomyelitis immunization status of several segments of the population in Rochester was estimated in 1959 and again in 1960 using the quota sampling technique developed by Serfling, Sherman and Cornell of the Communicable Disease Center. Rochester was stratified into three socioeconomic levels, using median family income and median school years completed by heads of households as indices. One-quarter of the census tracts were allocated to the high socioeconomic grouping, one-half to the middle and one-quarter to the low. The low socioeconomic grouping was further subdivided into low negro and a housing project, Hanover Houses, which is approximately 80 percent negro, but presents a special situation with regard to availability of preventive health services. The 1960 sample showed an extremely favorable immunization status with from 82 to essentially 100 percent of the groups sampled in the age group 5 through 19 giving a history of having had three or more injections of conventional vaccine. The highest figure was in the upper socioeconomic area and the lowest, 82 percent, was in the low negro area. In the age group under 5, the range was from 48 percent in the low negro group to 69 percent in the upper socioeconomic group. Under these circumstances it is considered unlikely that any differential attack rates can be detected by doing a controlled study.
PROCEDURE

There was little time for slow and meticulous organization. As was previously mentioned, the definitive request to conduct the program was received May 3rd. When one considers that current recommendations require that Type I material be fed first, that there be a lapse of several weeks and then that Type III material be fed, followed later by Type II, it is obvious that only Types I and III could be administered before the end of the school year. This resulted in the establishment of an intensive schedule of feedings during the week of May 16th in school children and the week of May 23rd for preschool children. The second dose (Type III) was scheduled in the same manner for June 10th in the schools and June 20th for preschool children. Type II was not given until November of 1960.

Because of the shortness of time, discussions were held with the Monroe County Board of Health, with the Child Welfare Committee and the Executive Committee of the Medical Society of the County of Monroe, printing of the necessary informational material and permission slips went forward, we ordered certain materials and supplies, including plastic squeeze bottles and spoons, the vaccine was prepared for administration, and a number of other matters went on almost simultaneously rather than in tandem.

There was excellent cooperation from the press, radio and television. It was necessary to rely largely on these mass media of communication, again because of the short time available. Special credit should go to the Rochester public schools, the parochial school system, and the numerous school districts in the area outside of Rochester because of their support in what was, after all, a somewhat experimental program.
In order to estimate the prevalent character of the intestinal viral flora, approximately 100 rectal swabs were obtained from children attending clinics in the central part of Rochester. This area was chosen because it was thought that the highest frequency of viral infection in the gut would be detected in this area. The examinations were performed by Dr. Paul Fiset in the virus laboratory at the University of Rochester's School of Medicine and Dentistry. This laboratory is supported by a contract with the Health Department. No cytopathogenic agents were detected in the specimens collected.

We were advised by representatives of the Division of Laboratories and Research of the State Health Department that the vaccine furnished to us was diluted so that there were approximately \(5.0 \times 10^6\) PFU of virus present in 0.1 ml. of suspension. The suspension, when the original material had been thawed and diluted, was dispensed in approximately 45 ml. quantities in dropper bottles. The droppers were calibrated to deliver roughly 0.1 ml. for each 2 drops. The original plan was to prepare a simple syrup in plastic squeeze bottles similar to ketchup dispensers, to dispense this simple syrup in plastic teaspoons, to place two drops of vaccine in the syrup and then to feed the syrup and vaccine mixture to the children by the spoons. This plan was generally followed. It was soon discovered, however, that the vaccine had no unpleasant taste and the two drops could easily be placed on the tongues of cooperative children directly from the dropper. This was found to be inadvisable with the very young children who frequently attempted to lick the dropper and thus possibly contaminate the whole bottle of vaccine.
Supplies of vaccine were offered to private practitioners who felt that they would have substantial numbers of children to do in their own offices. The opportunity thus offered was used only seldom. The burden of the program fell almost entirely on the Health Department personnel. In summary, the following numbers of persons were fed the indicated types at the specified ages.

Persons Fed Living Poliovirus Vaccine by Age Group and Type Fed, With Available Populations and Percentages Fed
Monroe County, 1960

<table>
<thead>
<tr>
<th>Age Group</th>
<th>1960 Pop.</th>
<th>Type I</th>
<th>No.</th>
<th>%</th>
<th>Type III</th>
<th>No.</th>
<th>%</th>
<th>Type II</th>
<th>No.</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 - 1</td>
<td>13076</td>
<td>837</td>
<td>6.4</td>
<td>775</td>
<td>5.9</td>
<td>566</td>
<td>4.3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 - 5</td>
<td>58061</td>
<td>13011</td>
<td>22.4</td>
<td>13477</td>
<td>23.2</td>
<td>8414</td>
<td>14.5</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5 - 18</td>
<td>134111</td>
<td>95913</td>
<td>71.5</td>
<td>92675</td>
<td>69.1</td>
<td>89867</td>
<td>67.0</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18 plus</td>
<td>-</td>
<td>4122</td>
<td>-</td>
<td>4044</td>
<td>-</td>
<td>3377</td>
<td>-</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Totals</td>
<td>-</td>
<td>113883</td>
<td>-</td>
<td>110971</td>
<td>-</td>
<td>102224</td>
<td>-</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Totals exc.</td>
<td>205248</td>
<td>109761</td>
<td>53.5</td>
<td>106927</td>
<td>52.1</td>
<td>98847</td>
<td>48.2</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Some observations were made on frequency of acceptance of the oral vaccine according to socioeconomic grouping. It is now well known that the lower socioeconomic part of the population in certain cities has been in difficulty with poliomyelitis in recent years, and the evidence points to low immunization rates as a responsible factor. In this program, vaccine was freely available without cost to the recipient, the school children were all given the same opportunity to participate, and yet in Rochester the

(1) Preliminary figures.
(2) 1/2 of population aged 5 allocated to each category because of variable composition of preschool and school groups at that age.
elementary schools showed differences when classified according to socioeconomic area served.

<table>
<thead>
<tr>
<th>Area Served</th>
<th>Upper</th>
<th>Middle</th>
<th>Low</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of schools</td>
<td>24</td>
<td>29</td>
<td>19</td>
</tr>
<tr>
<td>Range-% acceptance</td>
<td>71-100</td>
<td>66.7-96.6</td>
<td>58.3-93.9</td>
</tr>
<tr>
<td>Median-% acceptance</td>
<td>84.3</td>
<td>78.0</td>
<td>73.9</td>
</tr>
</tbody>
</table>

Schools in the county outside of Rochester are not classifiable as above, nor are the secondary schools.

In order to estimate antibody response it was decided to obtain approximately one blood specimen from every 200 receiving the vaccine, preferably from persons who had received little or no formalin inactivated vaccine. About 300 paired specimens were secured. The second specimen to complete the paired serological specimens was not collected until after November, the time of feeding Type II. The results of these antibody determinations are not yet available to us.

The vaccine is apparently quite stable. The Type I vaccine which had been diluted, but then refrozen when a substantial amount was not used, was furnished to Dr. John Paul and his associates for the Middletown, Conn. project. We are informed that this particular material still had an adequate titer of virus after it had been thawed, (3.0 x 10^6 to 3.5 x 10^6 PFU/ml of 1:10 dilution)

SURVEILLANCE

At the time this program was started it was difficult to secure information on reactions that could be attributed to the material. Shortly after the beginning of the second day of feeding, a 16 year old girl with a history of severe penicillin sensitivity developed
generalized and moderately severe urticaria within minutes of receiving vaccine. She was admitted temporarily to a nearby hospital emergency department, but was promptly relieved of her symptoms by appropriate treatment. This was the first of approximately six instances of cutaneous allergic manifestations which developed anywhere between minutes to 48 hours after the vaccine had been fed. Four of these had clear histories of previous manifestations of penicillin sensitivity. The other two were not known to be sensitive to penicillin.

There were many telephone calls regarding suspected reactions. The majority of these were concerned with reports of headache, stiff neck, backache and similar symptoms, occurring anywhere between 1 and 6 hours after the vaccine had been fed. In these instances simple reassurance was sufficient to allay parental anxiety. More serious symptoms or signs were followed by one of two Health Department physicians. In the course of visiting this latter category of cases, measles, dermatitis venenata, acute glomerulonephritis, acute gastroenteritis, and respiratory infections were found. Only one instance of aseptic meningitis came to the attention of the Health Department subsequent to the initial feedings of the material and within a reasonable period of time. This girl had not been fed vaccine although 75 percent of her classmates in school had. No agent was isolated from stool specimens and paired blood specimens failed to show a rise in antibody against any of the types of poliomyelitis virus. The etiology of this illness, therefore, remains undetermined.
POLIOMYELITIS DURING 1960

Monroe County's experience with poliomyelitis during the so-called poliomyelitis season of 1960 did not differ from recent years.

<table>
<thead>
<tr>
<th>Year</th>
<th>Cases Reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>1960</td>
<td>5</td>
</tr>
<tr>
<td>1959</td>
<td>7</td>
</tr>
<tr>
<td>1958</td>
<td>1</td>
</tr>
<tr>
<td>1957</td>
<td>2 (Rochester only)</td>
</tr>
<tr>
<td>1956</td>
<td>35</td>
</tr>
<tr>
<td>1955</td>
<td>94</td>
</tr>
<tr>
<td>1954</td>
<td>90</td>
</tr>
</tbody>
</table>

During 1960 there were 5 cases of paralytic disease. One in a 37 year old man was fatal, the diagnosis was made on the basis of histopathology, and no satisfactory specimens were available for virus studies. The onset of poliomyelitis in this fatal case was 2 days before his children were fed Type I virus. The 4 other paralytic cases were 27, 20, 10 and 4 years of age, one in a pregnant woman, and in 3 instances Type I virus was isolated from stool specimens. None had been fed the Sabin virus.

As was mentioned earlier, approximately 100 rectal swabs failed to reveal cytopathogenic agents before vaccine was fed. Approximately 75 similar specimens taken after the feeding of the last type (II) have revealed 6 agents. They are in the process of being identified as this report is being written.

SUMMARY AND RECOMMENDATIONS

Between May and November of 1960, between 102,000 and 114,000 doses of the Sabin type of oral attenuated poliomyelitis virus were fed in Monroe County, N.Y. The bulk of the feeding was to children aged 5 through 18. It was done with no evidence of
neuroparalytic accidents. The material was found to be easy to administer. A small number of sensitivity type reactions follows such feeding, probably attributable to some component in the vaccine. So-called wild virus was not eliminated from the community in spite of this rather intensive program.

By way of suggestion, it is recommended that serious consideration should be given to elimination of penicillin from this or similar products. It is also recommended that techniques for combining the three types of virus in the same dose should be developed. The scheduling in sequence of the appropriate types is perhaps reasonable for an intensive community-wide program, but seems clumsy for small volume utilization. Even in intensive programs there is dose-to-dose and therefore type-to-type loss of vaccine. It is further recommended that even though these intensive community-wide programs may temporarily displace wild virus, they will ultimately fall of their own weight and through loss of popular interest. Reliance must eventually be placed on continuing programs with a very high element of participation by private practicing physicians. It is of interest that socioeconomic differentials in acceptance rates for oral vaccine are easily demonstrable, just as with the injected material. The availability of an oral product will not solve the acceptance barrier in a voluntary society.
Acknowledgments. In addition to persons and agencies mentioned in the text, many others gave liberally of their time or special skills in this program. Dr. John Hotchin of the N.Y. State Health Department Laboratory is doing serological determinations and Miss Jessie Hendry of that laboratory prepared the frozen vaccine for administration. Many others, in and out of the Monroe County Health Department, paid and volunteer, worked at high speed for long hours.