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Evaluation of Canadian Poliomyelitis Vaccination Program, 1955

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AT a meeting of Provincial Epidemiologists and Communicable Disease Control Directors held in Ottawa in May, 1955, a plan for evaluating the use of poliomyelitis vaccine in 1955 in Canada was outlined. Since it was recognized that any attempt at conducting a study involving the administration of a placebo substance to a control group was impossible for a number of reasons, a more simplified approach was necessary. It was, therefore, decided that information would be collected which would allow a simple comparison of attack rates in vaccinated children and unvaccinated children, as similar as possible in age and risk of exposure. Because this information would be collected in all 10 provinces, it was recognized that the method of collection would vary but it was agreed that as far as possible certain basic data would be accumulated, which it was hoped, would make an evaluation possible on a nationwide basis. Owing to difficulties in differential diagnosis which would occur if cases of non-paralytic poliomyelitis were included in the study and since opportunity for laboratory confirmation of these cases would be limited, it was decided that for the purposes of this study only cases of paralytic poliomyelitis would be taken into account. It was agreed that the diagnosis of paralytic poliomyelitis would be restricted to cases exhibiting clinical manifestations of poliomyelitis in which muscular weakness was present for more than 24 hours, as determined by two successive examinations. Any attempt to measure the possible modifying effect of the vaccine on paralytic complications by means of muscle grading and scoring was felt to be impractical on a national basis.

It was felt desirable to substantiate the clinical diagnosis of poliomyelitis by laboratory confirmation wherever possible, but it was realized that the limiting factor would be laboratory facilities available. It was, therefore, decided that the objective would be the collection of stool specimens for virus isolation and typing from all paralytic cases in both the vaccinated and unvaccinated groups of ages 2-12 years, and wherever possible, the collection of acute and convalescent blood sera (3-4 weeks later) for antibody estimations in paralytic cases occurring in the vaccinated group only. However, reported paralytic poliomyelitis, as defined in the preceding paragraph, has been used as the basis for evaluation in this study.

It was agreed that the observation period of the study would be from July 1st to November 30th. In deciding on July 1st as the beginning of the period of

observation and November 30th as its termination, it was felt that July 1st would represent a date by which immunity might be expected to be established in vaccinated children, while November 30th was chosen as an arbitrary termination of the study since by then the incidence drops to insignificant levels.

Vaccinations were given during April, May, and June of 1955 and were completed by July 1st. The number of vaccinations given during the summer months and after the re-opening of schools in September to the close of the observation period on November 30th was negligible and can be disregarded for the purposes of this study. The vaccine used was produced by the Connaught Medical Research Laboratories, University of Toronto. Although the ages selected for vaccination varied to some extent in various provinces, the maximum use of the vaccine was made in ages 5, 6, 7 and 8 years. Two doses of vaccine were given approximately 4 weeks apart in all provinces except 2, where 3 doses were used. Reactions to the vaccine were infrequent and mild, the few cases reported being of an urticarial type of skin reaction which was attributed to antibiotic sensitivity. The vaccine was given intramuscularly in two provinces and subcutaneously in the other provinces. The quantity of commercially produced vaccine available in Canada during 1955 is considered to be so small that no significant effects on the evaluation of the vaccination program would be expected. It has not been possible to determine the exact amounts used or the ages to which this commercial vaccine was given.

It is an understatement to say that considerable concern has been felt and expressed about the safety of the vaccine in Canada and elsewhere. If the vaccine contained live virus, it would be reasonable to expect that either clinically recognizable poliomyelitis would be observed among vaccinated children, or if live virus were introduced resulting in a subclinical infection or a "carrier" state in the vaccinated child, clinically recognizable poliomyelitis might be expected to occur in the family contacts of these vaccinated children, within a double incubation period following vaccination. No case of poliomyelitis has been reported in vaccinated children, where the date of onset was within one month of vaccination. Similarly, enquiries have revealed no significant occurrence of recognizable poliomyelitis in contacts of asymptomatic vaccinated children within 30 days of vaccination. It can, therefore, be concluded that the vaccine used in Canada in 1955 was safe.

Before attempting to evaluate the results of the vaccination program, it is necessary to consider the reported incidence of poliomyelitis in 1955 in relation to previous years. From Table I it is seen that the cumulative total of reported cases all forms for all ages from January 1st to the week ending December 3rd for all Canada was 995 as compared with 3,791 or 26% of the 5 year average. It is necessary to go back to the year 1950 to find a lower cumulative total of reported cases to this date. When individual provincial totals are considered separately, it is seen that in all provinces except one (Nova Scotia), this year's totals to December 3rd, are substantially less than the 5 year average for the same period. When paralytic cases only are considered (Table II) a similar picture is seen, as the 1955 cumulative total to December 3rd was 522 or 27% of the 5 year average of 1,893 reported paralytic cases for the same period. The 1955 provincial totals to December 3rd similarly

TABLE I
POLIOMYELITIS (ALL FORMS)
Reported cases during period January 1st to December 3rd.
5 Year average (1950-54) and Year 1955.

| | 5 Year average (1950-54) | 1955 | % of 5 Year average |
|----------------------|-----------------------------|------|------------------------|
| Canada | 3,791 | 995 | 26 |
| Newfoundland | 52 | 11 | 21 |
| Prince Edward Island | 46 | 11 | 24 |
| Nova Scotia | 91 | 108 | 119 |
| New Brunswick | 127 | 39 | 31 |
| Quebec | 338 | 122 | 36 |
| Ontario | 1,053 | 175 | 17 |
| Manitoba | 655 | 28 | 4 |
| Saskatchewan | 533 | 71 | 13 |
| Alberta | 556 | 212 | 38 |
| British Columbia | 346 | 218 | 63 |

were well below the 5 year average in all provinces except British Columbia where the 1955 incidence of paralytic poliomyelitis was 101% of the 5 year average, and in Prince Edward Island and Nova Scotia where this percentage was 92 and 81, respectively. It should be noted that although the 5 year average (1950-1954) includes the year 1953, when the incidence of poliomyelitis greatly exceeded all previous years, the number of reported cases for all Canada in 1955 was substantially less than any year since 1945 with the exception of the year 1950, while on the basis of rates, the 1955 incidence of poliomyelitis, all forms, was the lowest in the past 10 years. This low incidence in 1955 has a direct bearing on the attempt to evaluate the results of the vaccination program, since we are dealing with unusually small numbers of reported cases, as compared with recent years, in both the vaccinated and unvaccinated groups.

The tendency to attribute the low incidence of poliomyelitis in 1955 to the effects of the vaccination program must be accepted with caution. The complex factors which determine the wide annual variations in this unpredictable disease are largely unknown and it would seem impossible to assess the exact part the vaccination program played in reducing the total incidence to the low level experienced in 1955.

TABLE II
PARALYTIC POLIOMYELITIS
Reported cases during period January 1st to December 3rd.
5 Year average (1950-54) and Year 1955.

| | 5 Year average (1950-54) | 1955 | % of 5 year average |
|----------------------|-----------------------------|------|------------------------|
| Canada | 1,893 | 522 | 27 |
| Newfoundland | 36 | 8 | 22 |
| Prince Edward Island | 12 | 11 | 92 |
| Nova Scotia | 68 | 55 | 81 |
| New Brunswick | 22 | 6 | 27 |
| Quebec | 196 | 75 | 38 |
| Ontario | 415 | 77 | 18 |
| Manitoba | 390 | 12 | 3 |
| Saskatchewan | 171 | 19 | 11 |
| Alberta | 450 | 123 | 27 |
| British Columbia | 134 | 136 | 101 |

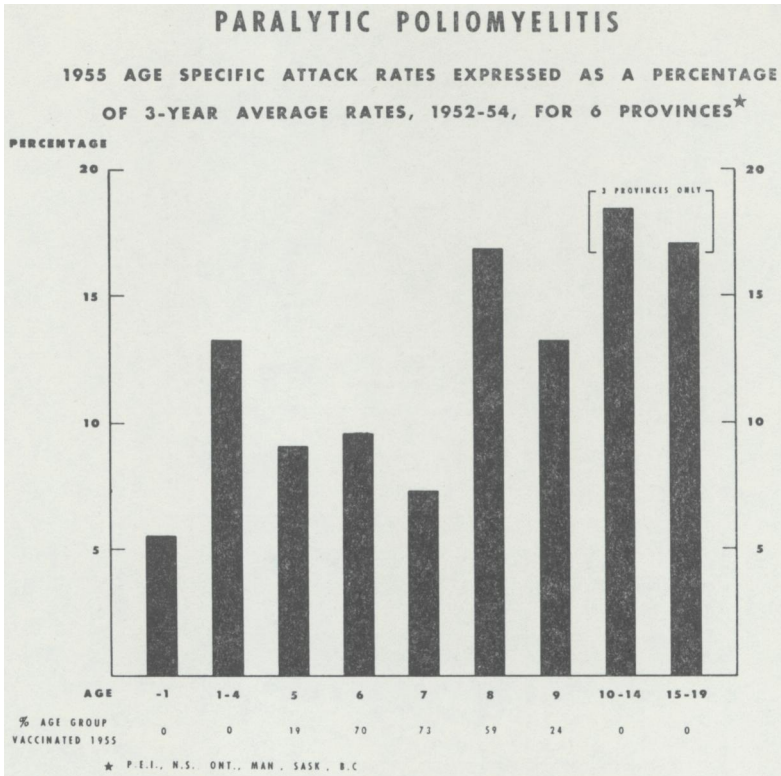


FIGURE 1

It is of interest to compare 1955 age specific paralytic attack rates with comparable figures for the previous three years, because it would seem reasonable to expect that differences between the 1955 and the 3 year average age specific attack rates might reflect the use of the vaccine in vaccinated ages in 1955, so that the greatest differences could be expected to occur in ages which were most completely protected by the vaccine. Unfortunately, it has not been possible to obtain age specific attack rates in past years for all provinces because only 6 provinces (Newfoundland, New Brunswick, Manitoba, Saskatchewan, Alberta, British Columbia) have routinely reported paralytic cases by age, to the Dominion Bureau of Statistics and only since 1949, and even here, the age breakdown is such that a direct comparison by individual years is not possible. However, age specific paralytic attack rates for previous years have been secured from 6 provinces which enable an interesting comparison with 1955 rates for comparable ages to be made. Figure 1 expresses the 1955 age specific paralytic attack rates as a percentage of the 3 year averages for these 6 provinces together. It will be noted that the 1955 paralytic attack rates were substantially lower at all ages, the decline being more apparent in the younger ages where the vaccine was used.

In Table III and Figure 2, a comparison is made of reported paralytic cases and observed attack rates in vaccinated and unvaccinated populations of specified ages by provinces. It will be noted that in all provinces where para-

TABLE III

NUMBER OF CHILDREN OF SPECIFIED AGES AVAILABLE FOR VACCINATION, NUMBER RECEIVING 2 OR MORE DOSES OF VACCINE BY JULY 1ST, 1955, AND NUMBER OF REPORTED PARALYTIC CASES AND ATTACK RATES IN VACCINATED AND UNVACCINATED POPULATION JULY 1ST - NOV. 30, 1955

| Province | Ages ^a considered | Number available for vaccination | Number vaccinated 1954 | Number vaccinated 1955 | | Observed paralytic cases in vaccinated | Rate/100,000 population in vaccinated | Number not vaccinated | Observed paralytic cases in non vaccinated | Rate/100,000 population in non vaccinated |
|---|------------------------------|----------------------------------|------------------------|------------------------|-----------------|--|---------------------------------------|-----------------------|--|---|
| | | | | 1 dose | 2 or more doses | | | | | |
| Newfoundland | 5 | 12,300 ^b | 0 | 183 | 3,412 | 0 | 0.00 | 8,705 | 0 | 0.00 |
| Prince Edward Island | 5-8 | 10,400 ^b | 0 | 94 | 4,855 | 0 | 0.00 | 5,451 | 3 | 55.03 |
| Nova Scotia | 5-8 | 63,300 ^b | 1,111 | e | 15,551 | 0 | 0.00 | 46,638 | 10 | 21.44 |
| New Brunswick | 5-10 | 82,400 ^b | 0 | e | 24,000 | 0 | 0.00 | 58,400 | 1 | 1.71 |
| Quebec | 5-9 | 540,800 ^b | 0 | 1,257 | 62,850 | 1 | 1.59 | 476,693 | 20 | 4.19 |
| Ontario | 5-10 | 513,158 ^c | 0 | 6,783 | 306,311 | 2 | 0.65 | 200,064 | 4 | 1.99 |
| Manitoba | 5-9 | 87,200 ^b | 3,369 | 600 | 51,333 | 0 | 0.00 | 31,898 | 0 | 0.00 |
| Saskatchewan | 5-6 | 39,800 ^b | 0 | 590 | 27,528 | 0 | 0.00 | 11,682 | 0 | 0.00 |
| Alberta | 1-4 | 89,241 ^c | 7,381 | e | 48,809 | 2 | 4.09 | 33,051 | 3 | 9.07 |
| British Columbia | 5-7 | 58,130 ^d | 0 | 575 | 45,067 | 0 | 0.00 | 12,488 | 10 | 80.07 |
| Prince Edward Island and Nova Scotia combined | 5-8 | 1,496,729 | 11,861 | 10,082 | 589,716 | 5 | 0.84 | 885,070 | 51 | 5.76 |
| | | 73,700 | 1,111 | 94 | 20,406 | 0 | 0.00 | 52,089 | 13 | 24.95 |

^aFor purpose of comparison, children of the ages specified only have been included. For example a substantial number of children in the Province of Quebec under 5 years of age who received 2 doses of the vaccine, have not been included.

^bEstimated provincial populations for ages specified, June 1st, 1955 (D.B.S.).

^cElementary school populations for ages (or grades) specified.

^dNumber of children of ages 5, 6 and 7, to whom the vaccination program was available.

^eNot known.

lytic cases were reported in the vaccinated or unvaccinated populations, the attack rates in the unvaccinated were in excess of attack rates in the vaccinated. In British Columbia where the 1955 reported incidence of paralytic poliomyelitis in all ages was substantially the same as the 5 year average, no cases were reported in 45,067 vaccinated children, whereas 10 cases occurred in 12,488 unvaccinated children of comparable ages during the period of observation. The attack rate in the unvaccinated was therefore greatly in excess, the difference being statistically significant. In contrast, in Manitoba, Saskatchewan and Newfoundland where the 1955 incidence of paralytic poliomyelitis was exceptionally low, no cases of paralytic poliomyelitis were reported in either the vaccinated or unvaccinated groups of the ages examined. If figures for the other provinces where the 1955 incidence of paralytic poliomyelitis varied between 18% and 92% of the 5 year average, are considered individually, the observed attack rates in the unvaccinated were in excess of the attack rates in vaccinated children of comparable ages but these differences were not statistically significant. However, if figures for Prince Edward Island and Nova Scotia, which apart from British Columbia, were the only 2 provinces where the incidence of paralytic poliomyelitis in 1955 was comparatively high in relation to the 5 year average (92% and 81%), are considered together, it is observed that no paralytic cases were reported in 20,406 vaccinated children, while 13 cases were recorded in 52,089 unvaccinated children of comparable ages, giving an attack rate in the unvaccinated of 24.9 per 100,000. These figures have statistical significance.

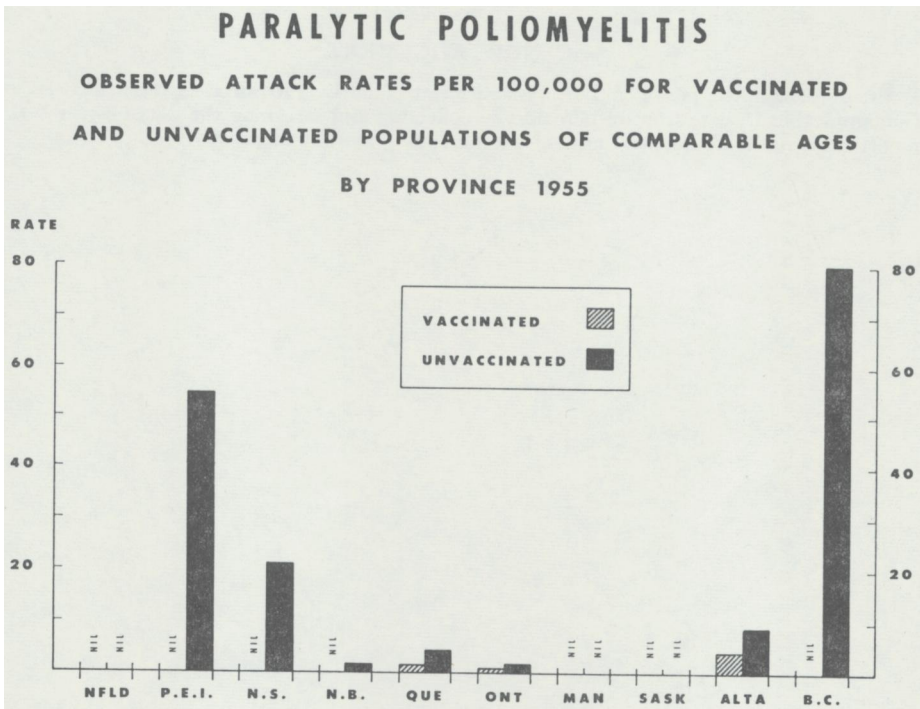


FIGURE 2

CONCLUSIONS

1. It is shown that the incidence of poliomyelitis in Canada in 1955 was exceptionally low. The reported incidence rates of poliomyelitis, all forms, in 1955 was the lowest in ten years, while the incidence of paralytic poliomyelitis in 1955 was lower than any year since 1950. In only three provinces did the 1955 incidence of paralytic poliomyelitis approach the 5 year average.

2. In all provinces where paralytic cases occurred in the vaccinated or unvaccinated groups, the attack rate in the unvaccinated exceeded the attack rate in vaccinated children of comparable ages during the period of observation.

3. In provinces where the 1955 incidence of paralytic poliomyelitis was low in relation to the 5 year average, these differences, although observed, were not statistically significant.

4. However, in the three provinces where the 1955 incidence of paralytic poliomyelitis more nearly approached the 5 year average, these observed differences in the vaccinated and unvaccinated groups have statistical significance, assuming that the vaccinated and unvaccinated populations were similar in other respects.

5. It is concluded, therefore, that a protective effect from the vaccine might be inferred in areas where the 1955 incidence was low, and was demonstrated where the 1955 incidence more nearly approached the 5 year average.

6. Poliomyelitis vaccine as used in Canada in 1955 was safe.

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