Chapter 3

Polio: Minnesota's Crucial Role

"It was not until the late 19th century and early 20th century that epidemic poliomyelitis was defined. Few diseases were more feared than polio because it attacked healthy children, killed a few of them, confined some for life to a respirator (iron lung), and left many with permanent physical disabilities. These victims of polio never let you forget the terrible visitation. This was the driving force in the conquest of polio. The terror of the summer months has met its conqueror! A single dose of live oral polio virus vaccine containing the three types 1, 2 and 3, will protect the recipient from infection.

"The Minnesota State Department of Health Laboratories developed the use of a single oral dose of polio vaccine containing the three types, 1, 2 and 3; of the live attenuated Cox strains of polio virus. It is important, for the mass public health immunization programs, that the three types of virus be combined in a single oral dose. More than 100,000 Minnesotans volunteered to receive the Cox oral vaccine, which in this and other carefully designed testing programs, proved the oral vaccine to be safe and efficacious. The use of a single oral dose of the Cox vaccine provided for the uniform immune status of all persons getting the vaccine, which neither the Salk killed virus nor the Sabin live oral vaccine provided in the 1950s.

"The Sabin live oral vaccine, after it was licensed, is being produced with all three types of virus in a single dose as recommended. The Cox vaccine and the Sabin vaccine were arbitrated, and the conclusion favored the Sabin strains of polio viruses because the arbitrators felt the Sabin strains were more stable. The Salk vaccine was dropped because of the cost of needle injections and the difficulty in getting vaccinated individuals to return at set intervals for the second and third dose."

Henry Bauer, Ph.D.
Director of Public Health Laboratories, 1951 to 1976
Deputy Executive Secretary, 1960 to 1966
Minnesota Department of Health, 1938 to 1976

In the 1940s and 1950s polio terrified Minnesotans, as well as the rest of the nation. The disease struck suddenly and without warning, leaving visible reminders: paralysis, wheel chairs, and leg braces. One of the outcomes especially feared was confinement to an iron lung. Without sufficient muscles to breathe, the iron lung sustained life, but the patient was imprisoned with only his or her head exposed. A mirror was placed in such a position so that the patient could look in it. Nursing staff arranged books and other reading materials, but the patient often had little to occupy his or her time.

Even if a child of the 1940s and 1950s didn't suffer from polio or didn't know anyone who did, it affected his or her life. During the summer, fearful for their health, many

parents kept their children confined to the home and yard. Fairs and other mass gatherings were closed, as were swimming pools and even schools.

Thanks to the vigilance of public health workers, those days are memories. Minnesota played a very important role in the eradication of polio, not only statewide but nationally.

Polio became a reportable disease on October 20, 1908²³⁸. During the next four decades, the Board of Health received reports of polio cases and polio deaths every year. The highest death rate during this period occurred in 1946 with 9.8 deaths per 100,000 people.²³⁹ The death rate in 1910 was almost as high: 9.7 per 100,000.²⁴⁰

By 1949, substantial strides had been made in the treatment of polio, but the knowledge and means to prevent it did not exist. There was a growing alarm in June 1949 when an increasing number of polio cases were reported to the board. Most of these were in the Twin Cities area, with a few cases in Freeborn and Fillmore counties. The population feared another epidemic similar to the one in 1946 that affected 2,881 people and resulted in 226 deaths. There were nearly 2,000 cases of polio and 110 deaths from polio in 1949. While high, the numbers did not reach the magnitude of the epidemic three years earlier. In 1950 the number of cases dropped to slightly more than 500. Unfortunately, the downward trend was only temporary. Annual cases and deaths in the early 1950s would top the 1946 epidemic.

Making Public Health Advisories with Limited Information

Throughout this period, and particularly when a polio epidemic threatened, the board was called upon to advise the public as to what they could do to prevent the spread of the disease. This was a difficult responsibility, as the transmission route for polio was still not definitively identified in 1955.²⁴¹ The board had less than perfect information on which to make its recommendations.

Various factors, such as mosquitoes, were suggested as causing polio. In 1949 Dr. Thomas Magath, state board of health president, was asked to support a campaign to fight polio by reducing the number of flies. Dr. Magath responded that killing flies would be good for other public health reasons, but he felt emphasizing it as the solution to polio would hinder the movement rather than help it.²⁴²

Some people noted that polio seemed to occur more frequently following tonsillectomies. Board members were uncertain of the role, if any, this surgery played

²³⁸ BOH, *Minutes*, January 12, 1954, MHC, page 27.

²³⁹ Ibid.

²⁴⁰ lbid.

²⁴¹ Harold K. Faber, *The Pathogenesis of Poliomyelitis*, (Springfield, Illinois: Charles C. Thomas, 1955) pp. 14-28. ²⁴² BOH, *Minutes*, July 14, 1949, MHC, p. 240.

in the transmission of polio. If asked, they recommended that tonsillectomies be delayed if there was no immediate need. 243

In attempting to reduce the risk of contracting polio, the State Fair was closed during the polio epidemic of 1946. In 1950, when the number of cases indicated another epidemic, the board considered closing the county fairs. They discussed the value of reducing interaction among people:

Magath:"....When you don't know what to do, you just play it about as safe as you can. That is about all you can do. We have got that problem down in Rochester now and the City Health Board doesn't know just what to do. We have a good swimming pool and the local merchants have sponsored bringing groups of children from surrounding villages in to swim. They have some polio at Lanesboro and the other day sixty youngsters from Lanesboro were swimming in the Rochester pool along with the Rochester people. The City Board of Health wrote a letter to the Park Board and asked that they stop that. Nobody can shut down on intercourse of people in communities, but you can do no good by importing youngsters from neighboring cities when there is a polio epidemic. I hope nobody asks the Board of Health for a statement of opinion, and I hope we don't have to go on record. It is very difficult to take a position. We will just have to say, 'Do everything you can within reason.' You can't close up everything, but I do think you can stop deliberately bringing 50 or 60 kids into a community where they are rubbing shoulder to shoulder....You have got to have the cooperation of the public in pubic health matters. If you deliberately buck them and try to hold them to something, you get into trouble. Up to yesterday we had no polio in Olmsted County, and this week we had one case."

One board member likened the board's responses to the population of Minnesota to the relationship between patient and doctor:

Lester Webb, D.D.S.: "We should treat the public as we treat the patient. Satisfy the public by doing something." 245

Privacy Issues and Dealing with Public Fear

Newspaper photos of polio patients confined to iron lungs made deep impressions. Preventive solutions were not known or available. Fear of the disease intensified. Public health workers were left to deal with this aspect, as discussed by Dr. Gaylord Anderson, director of the University of Minnesota School of Public Health and Dr. Albert Chesley, executive officer of the board, at a board meeting in 1950:

Anderson: "You really have two epidemics, an epidemic of polio and an epidemic of hysteria." 246

Chesley (Executive Officer): "...trying to satisfy the people and take care of the cases. It is a big mental problem. People who are normally perfectly stable go completely off the beam when anyone says 'polio." 247

²⁴³ BOH, *Minutes*, July 14, 1949, MHC, p. 238.

²⁴⁴ Ibid.

²⁴⁵ BOH, *Minutes*, July 14, 1949, MHC, p. 240.

²⁴⁶ BOH, *Minutes*, February 14, 1950, MHC, p. 65. lbid., p. 67.

Anderson: "There is panic with polio. You don't want a member of your family to go into a room occupied by a person who has just died of polio, although you know darn well there is no danger." 248

Public fear increased as the statistics indicated an increase in cases and deaths from polio. At a board meeting in October 1952 the board struggled with ways to calm the public, as well as how to deal with privacy issues in releasing information to the media:

H.Z. Giffin, M.D.: "Is it possible to publicize the small proportion of patients that develop paralysis? I see these reports come out in the paper every day and the radio announcer talks about them, and it seems to me that it would do an awful lot of good if people were told that a high percentage have no paralysis."

Dean Fleming, M.D. (Director of Preventable Disease): "We will try to do that, Dr. Giffin."

Giffin: "It wouldn't have to be an accurate statement. The people are all stirred up about them."

Jerome Brower (Chief of Administration): "Mr. President, we are receiving a little more pressure than we have had in the past from newspaper reporters. Yesterday Mr. Martin from the St Paul Dispatch and Pioneer Press called and wanted to know why we couldn't give out the names of those dying from polio. We had a long unsatisfactory conversation about it and I had just a few minutes to talk to Dr. Fleming this morning. I think we could discuss this particular point. It seems the fact of a death is not covered anywhere as a confidential item. Information comes to us that somebody dies from polio. We are perfectly happy to give them the count, but they want to know who dies. I haven't got a satisfactory reply for them."

Herbert Bosch: "What harm would it do if you did give it to them?"

Brower: "I don't think any harm would come of it. We do not permit the indiscriminate viewing of birth and death records. We treat those as confidential. They have asked about those matters. What about the reports that are coming in? Why can't we see those and give information from morbidity reports? We point out that reporting on the communicable diseases is an extension of the doctor-patient relationship. Reports are public except where they are made confidential. In only two cases do we have regulations providing for privacy of records—the venereal disease reports and the cancer reports, when that was undertaken, were made confidential. The same is true, of course, with the illegitimate birth records. We are not permitted to disclose any information of that kind. Therefore, since some are made strictly confidential, then the assumption must arise that others are not confidential."

The department didn't release names of patients but sometimes did release the name of the hospital in which the patient died. The media would call the hospital and get the information.

Fleming: "....They usually get it anyway and get annoyed with us because we don't give them the information. Vik Wilson feels quite strongly that it is important to give out every scrap of information about polio, especially deaths.²⁵⁰

The media were not the only ones who wanted information on polio patients.

²⁴⁸ BOH, *Minutes*, February 14, 1950, MHC, p. 63.

²⁴⁹ BOH, *Minutes*, October 2, 1952, MHC, pp. 442-443. lbid., p. 443.

Fleming: "There has been a similar situation in regard to polio insurance policies. We had many requests from the policy holders....We referred them to the physician, saying that we didn't see why the Health Department should get in the middle. We have never given certifications unless occasionally when we have gotten letters from the patient and from the doctor or insurance company saying it was all right to do so." 251

Information on some diseases was not given to the media because of the associated stigma, but this was not the case with polio. Board members were concerned that there may be inaccuracies in the information, particularly when it was given over the telephone. They also wondered where the requests for information would stop:

Robert Barr, M.D. (Deputy Executive Officer): "Accidental deaths will be the next one they will be wanting to know. We are also investigating deaths of women that are pregnant or have been pregnant within three months. That is going to be a rat race if they start in with that." ²⁵²

The board returned to its discussion of whether or not it should release data on polio cases and polio deaths.

Brower (Chief of Administration): "Our arguments here are not down to the real crux of the matter. If a person dies, it is reported to us as such. It might be in error. If there is a correction, they can report it later. That is no concern of ours."

Bosch: "But is it reported to us until we get the death certificate?"

Brower: "No, it is not, but the newspaper can state in some language that it is a tentative or conditional report, or something of that kind."

Charles Netz, PhmD: "It could lead up to the point where they might get a list of people every day."

Brower: "They get them now. Also, they go to the Clerks of Court and health officers."

Barr (Deputy Executive Officer): "That doesn't state the cause."

Brower: "Sure it states the cause."

Netz: "The newspaper account doesn't. I have wondered many times what a younger person dies of."

Brower: "I am looking at the legal justification for withholding that information from them."

Fleming (Director of Preventable Disease): "Dr. Wilson of Rochester might be able to give you some very good information."

Barr: "I think the situation there is different. I think you are endangering the accuracy of your death reports, making them that much less accurate."

Brower: "It doesn't."

²⁵² Ibid., p. 445.

²⁵¹ BOH, *Minutes*, October 2, 1952, MHC, p. 444.

Barr: "If it is generally known that the Health Department can release cause of death in various types of cases, then there is going to be much more reticence in putting down the true cause of death."

Brower: "But everybody knows when a child in his community has polio." 253

Managing the Cases

Children who contracted polio and could be kept at home were isolated for at least two weeks after the first symptoms appeared. A high proportion of polio cases that required hospitalization were sent to the Twin Cities. This placed undue stress on the facilities in St. Paul and Minneapolis, and the Twin Cities felt the brunt of the epidemic. To handle the influx in Minneapolis, the Minneapolis mayor's committee on poliomyelitis was established. Committee Chair Dr. Gaylord Anderson spoke to the board in 1950, appealing for statewide support:

Anderson: "...it has become increasingly evident to us as a committee that this is not the sort of activity that can be done by a city committee in that polio does not respect city lines and our problems too often came down to trying to work out some of the problems that should have been the problems of areas removed from the city of Minneapolis. In other words, we were dealing as a city agency with what was a State problem and it would be presumptuous on our part, we felt, to carry out a great many of the activities that should be carried on in order to assure adequate hospital facilities for the State." 254

A statewide committee was established for locating beds for polio patients. The intention was to find beds in out-state areas, as well as in the metropolitan area. In addition to distributing the load throughout the state, one member of the committee saw another advantage to finding hospital beds in out-state areas: "I think there are some very definite psychological factors involved when a community is encouraged to take care of its own problems." 255

Health officers were relieved when the number of polio cases dropped to 586 in 1950.²⁵⁶ Their greatest problem that summer was rabies, not polio. The following year,1951, was also reasonably light with 617 cases.²⁵⁷

In 1952, the number of cases increased dramatically. By the end of the year, there were 4,131 cases of polio and 220 deaths. Minnesota had more cases of polio than any other state in the nation in 1952. The National Foundation for Infantile Paralysis had to supply 245 nurses from other states to help during the emergency. The foundation featured Minnesota in its annual report, complimenting the state on its response: "Under the challenge of the worst polio outbreak of all time, Minnesota

²⁵³ BOH, *Minutes*, October 2, 1952, MHC, p. 442.

²⁵⁴ BOH, *Minutes*, February 14, 1950, MHC, p. 54.

²⁵⁵ lbid., p. 67.

BOH, *Minutes*, attachment: report from disease prevention and control division, May 21, 1953.

²⁵⁷ Ibid. ²⁵⁸ Ibid.

reacted with calm intelligence. There was little panic and a calm attitude was evident everywhere." ²⁵⁹

Gamma Globulin: A Glimmer of Hope

In addition to killing mosquitoes and avoiding tonsillectomies and mass gatherings of people, gamma globulin was publicized as a potential polio preventive measure. In October 1952 the "Journal of the American Medical Association" reported that immune globulin could effectively provide passive immunity from polio for about five weeks. ²⁶⁰ Limited supplies of gamma globulin became in vital short supply. Executive Officer Dr. Chesley remarked about the situation:

....Very unfortunately the newspapers got hold of this idea and everybody thinks that if you get it you won't get polio and if you get polio you won't get paralyzed, etc. People get into an emotional spasm. Dr. Fleming will have to learn to say 'no' in several different languages. ²⁶¹

In March 1953 the federal defense mobilization office assumed control and allocation of gamma globulin, receiving all the supplies of the American Red Cross. The department was already distributing gamma globulin free for the prevention of measles and hepatitis and was now designated the sole distributor of gamma globulin in the state. The allocation to Minnesota was determined by the office of defense mobilization and was based on the average number of polio cases reported over a five-year period, 1947-1951.

On April 23, 1953, the department announced plans for distributing gamma globulin as a preventive for polio, according to the plan developed by a poliomyelitis planning committee. One dosage represented one pint of human blood, so there was not sufficient supply for widespread use. Distribution was restricted to intimate contacts in members of households in which polio occurred, particularly in children age 15 years and under and pregnant women. Most of the gamma globulin in Minnesota went to three counties – Stearns, Benton and Meeker – due to the seriousness of the polio epidemic in that area. The results, however, were discouraging. The results are contacted by a poliomyelitis planning committee.

Gamma globulin was still being distributed in 1954. It was stocked in 10 or 11 subsidiary stations throughout Minnesota, as well as the Health Department building. Physicians had been told of its availability, and the board approved distribution, but it was reevaluating its effectiveness and usefulness as a prophylaxis of poliomyelitis.

²⁵⁹ MDH, *Minnesota's Health*, Vol. VII, No. 9, October 1953, pp. 1-2.

²⁶⁰ W. Hammon, M.D., etal. "Evaluation of Red Cross Gamma Globulin as a Prophylactic Agent for Poliomyelitis. Preliminary Report of Results Based on Clinical Diagnoses," *JAMA*, 150:757-760, October 25, 1952.

BOH, *Minutes,* December 22, 1952, MHC, Exhibit III.

²⁶² Ibid., Exhibit IV.

²⁶³ BOH, *Minutes,* May 21, 1953, MHC.

²⁶⁴ MDH, *Minnesota's Health*, Vol. VII, No. 9, October 1953, pp. 1-2.

MDH, Minnesota's Health, Vol. 8, No. 7, July-August 1954, p. 4.

²⁶⁶ BOH, *Minutes,* June 1, 1954, MHC, p. 137.

Harold Habein, M.D.: "The thing that interests me is that gamma globulin has no effect. Why are we bothering with it at all and spending any money on it?"

Fleming (Director of Preventable Disease): "That is one of the things that made us think we shouldn't do any more work than we had to in distributing it. If a doctor wants it, we will send it to him but will keep no detailed records of the sort we kept last year. The National Foundation has put many hundred dollars into globuli purchase. It is not available commercially. The only means of distributing it is through health departments. We are the only agency in the state that could distribute it. A number of states have requested that gamma globulin be returned to commercial channels just as it always was. This year, at least, it is coming only through state health departments."

Ruth Boynton, M.D: "I think it is hardly fair to say hat there were no beneficial effects. I know that Dr. Hammond who did the original large-scale inoculations disagrees with that categorical statement because in their experience, while the effect was not too pronounced, still there was a difference. I don't think we are justified in saying it is no good and therefore we should not distribute it."

Fleming: "If it is used like the National Foundation for Infantile Paralysis says it should be used. From a practical standpoint, the way it was used last year was pretty good. You could tell you were at the peak only after the whole thing had subsided. That report has been published in the Journal of the A.M.A. this spring." ²⁶⁷

The First Difficult Decision: Evaluating the Risk Involved

About the same time that gamma globulin provided a ray of hope in the prevention of polio, a second promising – but possibly risky – opportunity came. In 1953 the special advisory committee on active immunization of the National Foundation for Infantile Paralysis (NFIP) recommended that the foundation proceed with large trials to test the vaccine developed by Dr. Jonas E. Salk of the University of Pittsburgh. The NFIP developed a plan to begin active immunization, and wrote all state health departments, including Minnesota, asking if they wanted to participate.

The board was very uncertain as to what to do. There were risks involved, but there was also the potential to save lives. At its meeting on December 18, 1953, board members struggled with the decision and asked Dr. Gaylord Anderson, director of the School of Public Health at the University of Minnesota, to speak on the matter.²⁶⁸

We have had vaccines for a long while, very effective vaccines. It is the simplest thing in the world to immunize an experimental animal against polio. We have been able to do that for the last 25 years – if it survives. The problem is to find something that is effective and safe. The last splurge we have had on vaccines was in 1933 or 34 when Dr. Brodie came out with a vaccine which was...treated by formalin after a certain period of incubation. It was endorsed by the late Dr Park, who was at this time one of the most eminent in his field of biological products. Park endorsed it bag and baggage. At the same time another vaccine came out, namely the Kolmer vaccine. Bacteriologist at Temple, well known for the Kolmer test in syphilis. Both vaccines came out with very good scientific endorsement. There was quite a squabble at the time about them. The forerunner of the Foundation gave a strong endorsement in the Ladies' Home Journal, a long article about polio vaccine, how everybody should have their children given this

²⁶⁷ BOH, *Minutes*, June 1, 1954, MHC, p. 138.

²⁶⁸ BOH, *Minutes*, December 18, 1953, MHC, pp. 107-109.

vaccine in the field trials. Paul De Kruif, in typical fashion, left himself a loop-hole and when it was all over he said....About 10,000 doses of the Brodie vaccine were given down south and about 10,000 of the Kolmer vaccine in the middle of the United States. There were no adequate controls. Studies of the Brodie vaccine came up with the conclusion that it probably wasn't effective. Brodie's own argument was that if he incubated it too long with formalin it wasn't effective and if he incubated it not long enough it wasn't safe. He made it safe but not effective. The Kolmer vaccine was just the opposite. Of the 10,000 children inoculated nine developed paralytic polio in the second week after the inoculation. Twenty cases per 100,000 is a bad outbreak. The upshot was that the Kolmer vaccine was withdrawn very quickly. Five of the nine died. It was felt it was just plain too hot.

I mention this background because at that time a great many of us in positions you are in today took a beating for not using the vaccine. We refused to let the vaccine come into the State moral persuasion. One doctor was going to get me fired because we weren't doing anything about it. But in retrospect we knew it was right. The next two or three years we had the same thing over again with nasal sprays for polio and again a statement that it was to be used widespread, and if you didn't do it you were dead wrong, and again we dropped it and found that those who opposed it were right. It was dangerous. But there was a lot of pressure. But not to begin to compare with what you have to take in 1953 and 1954.

Now, today we have got the situation of some new vaccines. Four have been developed. Only one is involved in this issue. The Salk vaccine. The Salk vaccine is a repetition of the Brodie vaccine. It has been treated with formalin and you carry the formalin in stock for a certain period at the temperature of melting ice. The only thing that Salk has that Brodie didn't have is that the virus is being grown on tissue culture. It is being grown in the Connaught Laboratories in Toronto and being shipped to this country for inactivation with formalin. It is believed to be effective against all three strains. At the time of the Brodie vaccine only one strain was recognized. Aside from that we have got a repetition of the Brodie vaccine.

The two issues which come up on the use of this sort of this are, (1) Is it safe? And (2) Is it effective? On the question of safety, I think it is fair to say that I represent a maybe somewhat noisy minority and skeptical minority in not being fully convinced that it is safe. 269

Concerned about the magnitude of the decision placed on them, Prof. Bosch wondered if the Minnesota Medical Association had made an official statement on the Salk vaccine.

Barr (Deputy Executive Officer): "Yes. They took definite action that they had confidence in the State Board of Health and that they were standing by any action the State Board of Health and the Health Department would take in relation to this. It was put up to them basically that if anything was done relative to this it had to be done by the entire medical profession. They also indicated that they felt they had nobody on their Council who was competent to render a real opinion as to the relative value, safety, etc."270

Chesley(Executive Officer): "They are perfectly willing for the State Board of Health to take all responsibility. The vaccine will be sent from the National Foundation to the National Foundation, in care of the State Board of Health, and you are responsible the moment you sign that receipt."271

The NFIP planned to begin its trials in the southern United States, moving northward. It estimated it would be in Minnesota the latter part of March or early April. This gave the

²⁶⁹ BOH, *Minutes*, December 18, 1953, MHC, pp. 107-109.

²⁷⁰ Ibid., 114. ²⁷¹ Ibid., 115.

board some time to decide whether it wanted to accept or reject the foundation's plan to immunize second graders in those Minnesota counties where the incidence of polio during the past five years was the highest.

On January 12, 1954, the board appointed a scientific advisory committee on polio vaccine to advise the board about participation in NFIP's poliomyelitis vaccination program of the National Foundation for Infantile Paralysis. Members of this committee were:

- Dr. Gaylord Anderson, Mayo professor and director, University of Minnesota Public Health School, chair
- Dr. Irvine McQuarrie, professor and head, pediatrics department, University of Minnesota
- Dr J. T. Syverton, professor and head, bacteriology and immunology department, University of Minnesota
- Dr. Dennis W. Watson, professor, bacteriology and immunology department, University of Minnesota
- Dr. R. L. J. Kennedy, Rochester, president-elect, American Academy of Pediatrics
- Dr. G. B. Logan, Rochester, chairman, Child Health Commission, State Medical Association
- Dr. L. F. Richdorf, Minneapolis, Child Health Commission, State Medical Association
- Dr. F. G. Hedenstrom, St. Paul, Child Health Commission, State Medical Association
- Dr. C. O. Kohlbry, Duluth, Vaccination and Immunization Commission, State Medical Association

The committee met with Dr. Ruth Boynton, board chairman, on January 20, 1954.²⁷³ Others attending the meeting were: Dr. R. N. Barr, deputy executive officer and director of local health services; Dr. D. S. Fleming, director of disease prevention and control; and Dr. A., J. Chesley, executive officer.

After much discussion, the committee made its recommendation:

That the Board defer final action on the N.F.I.P. program until results of field trials of vaccination of 10,000 children with the commercially produced Salk vaccine are available for review; then provide for a Minnesota control study of poliomyelitis vaccination to meet requirements of the scientific advisory committee, the State Medical Assn., and the State Board of Health. 274

In a March 3, 1954, internal memo to Dr. Chesley, Dr. Fleming reported that former Board President T.B. Magath supported the board's decision. Dr. Magath had spoken with Dr. Culbertson of Eli Lilly and Co., and Dr. Culbertson believed at least a year's work was necessary to evaluate the effectiveness and potency of the vaccine. The committee met again on April 7, 1954.²⁷⁵ It agreed to reaffirm its earlier resolution to defer vaccination.

The board accepted the recommendation made by the committee, and a report was released to the press on April 13, 1954. Prof. Bosch read the release, which included this excerpt:

²⁷² BOH, *Minutes*, January 12, 1954, MHC, p. 27.

²⁷³ Ibid.

²⁷⁴ Ibid

²⁷⁵ BOH, *Minutes*, April 13, 1954, MHC, p. 29.

"The Board emphasized its sincere concern with the problem of poliomyelitis in Minnesota and its desire to do everything possible to meet this problem. Preliminary planning for a vaccine program in 1954 has already been completed, in the event that such a program will be possible. It should be emphasized that under the most favorable circumstances vaccine would be available only to a small fraction of children in a few locations in Minnesota and that the program would be an experimental one with no established proof of the protective value of the vaccine. The Board's first concern is to avoid any possible harm that might result from premature use of the vaccine in Minnesota children and hopes that as much scientific data as possible will be gathered if and when the vaccine is used."²⁷⁶

Minnesota State Board of Health, April 13, 1954

The First Vaccine is Cautiously Distributed

By 1955, the board's advisory committee decided it could safely recommend the use of Salk vaccine in Minnesota. In trials outside the state the vaccine had proven to be 60 percent to 70 percent effective against Type I polio and better than 90 percent effective against Type II and III. Committee Chair Dr. Gaylord Anderson reflected on Minnesota's decision to not deliver the vaccine in 1954:

There is always going to be an element of risk, but the risks are infinitely less than the risk of polio. That we didn't know last year, and that is the reason we felt we should hold out. Those doubts have been resolved in my own mind. ²⁷⁸

During the planning of a vaccination program, the committee deliberated over the age group which would receive the vaccine and how many doses should be given. It had not yet received recommendations from NFIP. It still was very cautious about use of the vaccine, as seen in its May 13, 1955, recommendations:

Recommendations of the State Advisory Committee on Poliomyelitis

- 1. The vaccine is safe so far as any vaccine is safe.
- 2. The decision as to injections, the time and number, will have to wait until information is received from the National Foundation;
- 3. Instructions should be given regarding using up of all the vaccine and regarding the significance of its change in color, etc.
- 4. In addition to Grades I and II, priority should be given to children five years of age and under and to pregnant women, and then if there is enough vaccine left, move up; and
- 5. That records be kept as per National Foundation of Infantile Paralysis. 279

On May 13, 1955, the committee and the board held a special meeting. At this meeting they definitely agreed to go forward with the vaccination program. Three decisions were made:

²⁷⁶ BOH, *Minutes,* April 13, 1954, MHC, p. 33.

²⁷⁷ BOH, *Minutes,* April 14, 1955, MHC, p. 101.

²⁷⁸ Ibid.

²⁷⁹ Ibid., p. 92.

- 1. Go ahead, at the earliest possible moment when the vaccine is available, but not until adequate vaccine is available (both lots).
- 2. The second dose be given in two to four weeks after the first, depending upon availability of vaccine.
- 3. The Board issue a formal statement at this time covering some of the points brought out in the present meeting and stating that although every possible known test has been made as to the effectiveness of the vaccine, nothing definite can be stated, and there may still be new cases of polio, which may have developed in any case. ²⁸⁰

Later that day Board Vice President Herbert Bosch released the following statement to the press:

"The State Board of Health convened today with its Advisory Committee, and acting on the advice of that Committee, the Board has decided to go ahead when an adequate amount of vaccine becomes available. We should tell you that as of this date we have had official clearance of one batch of vaccine but have not yet had clearance on the other batch of vaccine, the smaller batch. When both batches are approved by the National Institutes of Health, there will be immediate distribution." ²⁸¹

Minnesota State Board of Health May 13, 1955

A lengthier news release, issued May 16, 1955, emphasized that the board did not guarantee that the vaccine would provide complete protection against poliomyelitis. While not 100 percent effective, the board believed it was the first major breakthrough in the fight against polio. The news release ended with large type:

"POLIOMYELITIS VACCINE OFFERS THE FIRST AND ONLY EFFECTIVE MEASURE TO PREVENT THE PARALYTIC EFFECTS OF THIS DISEASE." 282

The board worried about its decision to release polio vaccine. It was concerned that the public would have a false sense of the effectiveness of the vaccine. It worried about the number of polio cases that might be a direct result of the vaccine, as had happened in other parts of the country. After belaboring these issues at one meeting, Dr. Gaylord Anderson, director of the School of Public Health, addressed the need to take risks in public health.

We have a lot of calculated risks. Just because we have many children getting drowned every summer, we don't forbid swimming. Just because children are killed in automobile accidents, we don't forbid automobile riding. Just because something went wrong with one or two lots of vaccine, we don't forbid vaccination. Some of us think it could have been done in a better way. The Salk vaccine program is two or three years ahead of where it should be. Every known safeguard that can be put around the vaccine for the second injections will be thrown around it except one, and that will be that it be given to a large number of children before we get our share

²⁸⁰ BOH and Scientific Advisory Committee on Poliomyelitis, *Minutes*, May 13, 1955, MHC, p.126.

²⁸¹ BOH, *Minutes*, May 13, 1955, MHC, p. 127. ²⁸² BOH, *News Release*, May 16, 1955.

of the lot. That is the last test. Can you give it to children? No test quite is as accurate as the human test." 283

When the first batch of Salk vaccine from NFIP arrived, Dr. Chesley was hesitant about distributing for fear of a live virus in the batch. Two or three vials of the vaccine were taken in the dark of night to the office of Dr. Jerome T. Syverton, head of the department of bacteriology and immunology in the College of Medical Sciences at the University of Minnesota. Through Dr. Silverton's cooperation and help, the virulence of the vaccine was tested. No live vaccine was found, and the board felt more at ease about distribution.²⁸⁴

The first Salk polio vaccinations in Minnesota were given on May 20, 1955. Within the next month, 112,115 first and second grade children, out of 145,374 enrolled, received their first dose of vaccine. This was done using 288 clinics throughout the state.²⁸⁵

Dr Dean Fleming, head of the disease prevention and control division, was designated as poliomyelitis surveillance officer for Minnesota. He worked with the U.S. Public Health Service in providing information for the national poliomyelitis surveillance program. ²⁸⁶ Four centers in Minnesota were established to receive reports of cases of polio. They were located in the departments of health in Minneapolis, St. Paul, Duluth and Rochester. The division was assisted with its work by Dr. Leonard Schuman and Dr. Herman Kleinman as well as two medical students funded by NFIP. Every case of polio was followed, especially whether or not the child had received the vaccine in May. Households were contacted and in the department laboratory viruses were isolated and identified for antibody testing. ²⁸⁸

Out of the 112,000 children vaccinated, there were only two cases of paralytic polio during the summer of 1955. By comparison, there were eight cases of paralytic polio in the 33,259 non-vaccinated children in the same age group. The data indicated the vaccine was effective and gave hope that this dread disease might be conquered.²⁸⁹

Another Hard Decision: Who Should Receive the Limited Supply?

The board didn't know when another shipment of vaccine would come, but it knew it had to be ready to make hard decisions when the vaccine arrived. It needed to determine whether to use the shipment to give a second dose to those who had already received one or whether to give the vaccine to those who had not yet had any. Information about the vaccine was constantly changing. Based on what was known in June 1955, Dr. Anderson didn't support the idea of a second dose:

²⁸³ BOH, *Minutes*, June 17, 1955, MHC, p. 141.

²⁸⁴ BOH, *Minutes,* January 31, 1961, MHC, pp. 19-20.

²⁸⁵ BOH, *Minutes*, 1955, MHC, p. 187.

²⁸⁶ BOH. *Minutes*, June 17, 1955, MHC, p. 135.

²⁸⁷ Ibid., p. 136.

²⁸⁸ BOH, *Minutes*, September 8, 1955, MHC, p. 214. ²⁸⁹ Ibid., p. 214 and p. 218.

Dr. Salk's protocols show the immunizing effect coming within two weeks of the first shot. Three weeks later you don't find much more immunity that you did after the first two weeks...which screams live virus to the heavens. A second shot given very shortly afterwards is not very important. I think immunity came from the first injection. ²⁹⁰

Dr. Anderson led the continuing discussion, which emphasized that the board must be prepared to make a decision quickly:

Anderson: "Personally, I would be very glad if we didn't get any vaccine until the end of the summer. I don't think we would be jeopardizing anybody by withholding it. That, I wish to say, is a personal belief. Some of the other members of the Committee may not share it with me. If, at the time you are faced with it and you want advice on the second shot, I will be glad to get the Committee together at that time. The situation is changing by the hour or by the day now. Any decision reached today might be completely out of date by tomorrow."

W. W. White, M.D.: "Maybe in the face of your opinion, if we should get a batch of vaccine, maybe the thing to do would be to say we can't get it yet, and sort of stall."

Boynton: "I think there is another point there, too, and that is public opinion. I think the Board would have to make its decision one way or another. I don't see how we can stall."

Bosch: "Administratively, I don't see how we can stall. On the day the second shot becomes available we must say either we are going to use it or we aren't going to use it."

Edgar Huenekens, M.D.: "I feel as Dr. Anderson does, that the second shot can't do any harm. Then I don't see why we shouldn't give the second shot."

Anderson: "The only thing is – if it turns out that the lot of Parke-Davis vaccine we got wasn't effective, then there might be danger in the second shot." 291

The need to make a decision as to who should receive the next shipment of vaccine came in August when NFIP advised the board that the second dose of vaccine would arrive the end of the month. When should it be released? Who should receive it? To answer these questions, the board held a joint meeting with the poliomyelitis technical advisory committee on August 26, 1955. Committee members present for this major decision were: Dr R. L. J. Kennedy, pediatric professor, Mayo Foundation, Rochester; Dr. J. T. Syverton, professor and head, bacteriology and immunology department, University of Minnesota; Dr. C. O. Kohlbry, pediatrician in charge of school health program, Duluth; and Dr. Gaylord Anderson, Mayo professor and director, School of Public Health, University of Minnesota.

Some advisory committee members thought release of the vaccine should be delayed until October 1 or October 15. One who didn't agree was Dr. Syverton:

You have nothing to lose and everything to gain by giving that second dose to the children. From a theoretical standpoint you stand to lose by delay. Now you propose to delay that further, and unless it is for the convenience of the physician, it is not good from the point of view of the children. I see no reason why the second dose shouldn't be given at the earliest possible date."

²⁹⁰ BOH, *Minutes*, June 17, 1955, MHC, pp. 141-142.

²⁹¹ Ibid.

²⁹² BOH and Poliomyelitis Technical Advisory Committee, *Minutes*, August 26, 1955, MHC, p. 155.

The issue was put to vote, and in a close decision the advisory committee members present voted in favor of delaying release of the vaccine until October 1 or 15.293

While the surgeon general and the national advisory committee had designated the fiveto-nine age group as the first priority group for receiving polio vaccine, it was possible to recommend a deviation. The group discussed whether or not it should give one dose to many people, rather than two doses to a selected few.

Kennedy: "From your standpoint, isn't it true that it is your task to do the most good for the most people? If you have a certain amount of material to spread among a certain group, are you in a position to give it to as many individuals as possible rather than give it all to a limited number, leaving the population without any very good idea as to when they are going to be able to get polio vaccine from their doctor or anywhere else? We might give a single dose for first the 5-9 group and then the others in the 20 year age group and pregnant women."

Boynton: "If we are going to give one dose to a lot of people, are we going to do as good a job? Presumably there won't be any more vaccine for several months."

Anderson: "You have the question of efficacy of the second dose if you wait too long."

Syverton: "I would think, looking at this (cases reported in 1955), that all children under 10 should be given two injections."

Dr. Leonard Schuman: "You couldn't cover all. You would need over one million doses." 294

A vote was called - one dose or two? Kennedy and Kohlby voted for one dose. Syverton voted for two.

Though the advisory committee had made a decision, the discussion continued:

Boynton: "It does seem to me that if we are trying to put on an immunization program to give one dose to as many persons as possible with the available vaccine when you are most apt to get greater immunity from two doses - it seems to me that if we give just one dose, I wonder whether we are giving the public a false sense of protection, whether we are doing as good a job as we think we can do. Would it be the same as giving one dose of typhoid vaccine in the face of an epidemic when we think two or three should be given?"

Dr. R. L. J. Kennedy: "Your statement carries weight only if you have an abundant supply of vaccine. If you stop a program because material isn't available, that is a different matter."

Boynton: "Is it better to get to everybody under 19 years of age or to give two doses to all those under 10?"295

The board did not fully accept the advisory committee's recommendations. It decided to release the polio vaccine as soon as possible after it was received. ²⁹⁶

The board approved the following distribution plan:

²⁹³ Ibid., p. 158. ²⁹⁴ BOH and Poliomyelitis Technical Advisory Committee, *Minutes*, August 24, 1955, MHC p. 162.

²⁹⁵ Ibid., pp.164-165.

²⁹⁶ BOH. *Minutes*, August 26, 1955, MHC, pp. 167-170.

1. First priority group will be expanded to include ages 0 to 4, 5 to 9 and pregnant women.

2. Vaccine will be distributed as soon as received so this expanded group can receive their first dose soon. The expanded group will receive its second dose after the demand for the first dose has been met.

3. Each subsequent age group will be vaccinated with 2 doses of vaccine.

4. If the Surgeon General does not approve this plan, the 5 to 9 age group and pregnant women will be vaccinated as outlined above. The 0 to 4 age group will be given second priority. 297

The second shipment of Salk vaccine from NFIP arrived September 12, 1955.²⁹⁸ That vaccine was used immediately to provide a second injection to 106,753 first and second grade students.²⁹⁹

Other Barriers to Access

Children were not charged for the vaccine received through the NFIP program, but they were charged \$0.50 for vaccine provided by the federal government, if they could pay it. The revenue collected made it possible to purchase vaccine and syringes. The federal Poliomyelitis Assistance Act of 1955 allotted the State of Minnesota \$593,448 to use towards immunizing the estimated 1,111,005 Minnesotans included in the birth-19 age range and pregnant women. 300

Gov. Orville Freeman was concerned about the 33,000 first and second graders who did not take advantage of the first shot of Salk vaccine and of those who might not be able to afford it. He expressed his concerns at a luncheon with the board on September 8. When told that any of those children could, within the next couple weeks, get the vaccine at a doctor's office, he replied: "That same group is going to be the least likely to go to a doctor or public official."

Gov. Freeman did not want any barriers to stand in the way of a child being immunized:

Gov. Orville Freeman: "There is a distinction between going through the school line and paying fifty cents and going to the doctor's office."

Barr (Deputy Executive Officer): "People who can't pay go to the county for care. The doctor is used to taking care of those people. If he has a welfare patient sometimes he gets paid and sometimes he doesn't."

Freeman: "The group I am talking about is the group who wouldn't take it because they would have to pay to have it administered. They just wouldn't go to the doctor's office. I have heard that this is the question, directed toward the medical profession: "If the doctor gets the vaccine free, why can't he give the shots free?" 302

²⁹⁷ Ibid., pp. 190-191.

²⁹⁸ BOH, *Minutes*, September 12, 1955, MHC, p. 314.

²⁹⁹ BOH and Scientific Advisory Board, *Minutes*, December 5, 1955, MHC, p. 370.

MDH Disease Prevention and Control Division, memo to Poliomyelitis Advisory Committee, August 26, 1955, MHC, p. 171.

³⁰¹ MDH, *Minutes,* September 8, 1955, MHC, p. 220.

³⁰² BOH, *Minutes*, September 8, 1955, MHC, pp. 224-225.

More Decisions on Distribution

On December 5, 1955, the board had another joint meeting with the scientific advisory committee on poliomyelitis to discuss distribution of limited supplies of vaccine. Twenty-seven persons were present to determine the first priority group for this vaccine and if they should authorize use of the vaccine for second injections. Opinions continued to differ as to whether the vaccine should be given to as many as possible or two doses to a smaller number.

Vik Wilson, M.D.: "It seems to me that with this given amount of Federal aid vaccine we would do a most effective job for the people of Minnesota if we would give shots at least six months apart to the kiddies under 10 years of age."

Karl Lundeberg, M.D.: "Suppose we play this very cagily and say, 'Let's do a good job with a few kids. It seems to me we are telling parents of other kids, 'No, you can't have it.' These older children have been denied this protection during the day of grace and then they have to get polio come next summer, and what is our excuse then? It would be all right if we had used up our vaccine. But if we don't and still deny some of these other older children—I would like to restate my belief that we would be safest in broadening the base for the first shot and then pick up the second shot."

It was another difficult decision that potentially meant life or death for Minnesota citizens. Though much more was known about polio vaccine now than when the advisory committee first met nearly two years earlier, information was still limited. It knew that just one dose did help prevent polio, but it wasn't sure to what extent. It wasn't certain whether or not a second dose was essential. With ample supply, the decision might have been easier, but the supply was limited.

Several proposals for distribution were considered, and the advisory committee recommended extension of the base up to age 19 years of age. It also authorized a second dose at the discretion of the physician. The board approved the committee's recommendations.³⁰⁴

Several months later the board had to change its decision. On April 19, 1956, at the advice of the advisory committee, the board withdrew its authorization for a second dose of Salk vaccine, as demand was high and the supply still low. A large number of children had not yet received their first injection. The board decided it was important to give some protection to the maximum number of persons in the eligible age groups.³⁰⁵

In July 1956 the board was faced with another policy decision regarding the distribution of polio vaccine. Funds for polio vaccine were limited, and members wondered if they should use up all their vaccine and then let people obtain vaccine through commercial channels or if they should retain a certain amount for selected populations. Dr. Fleming thought the funds should be used up to purchase and distribute vaccine. Dr. Habein

³⁰³ BOH and Scientific Advisory Board, *Minutes*, December 5, 1955, p. 363.

St. Paul Dispatch, Tuesday, December 6, 1955.
 BOH, Minutes, April 19, 1956, MHC, pp. 76-79.

wondered if the board should retain some funds to purchase vaccine for those who couldn't afford it.

Three choices were available: purchase vaccine and distribute all, purchase vaccine and retain some, purchase and distribute some vaccine but retain some of the money for later use. Gaylord Anderson thought the board should use up all the money and purchase vaccine and store the vaccine.

All evidence I have indicates that it will store for a long time. You might as well buy it up and store it during the coming year for needs I don't think anyone has produced any evidence that the stuff deteriorates rapidly. I would simply say, handle it the way you do anything else, on a continuing basis. Personally, I have always been of the opinion that when you are dealing with disease prevention the Board of Health has a responsibility for making this material available, no matter what.

The question remained as to whether or not the board should authorize the giving of a third dose of vaccine. While Dr. Anderson thought the vaccine had a lasting quality, he was less certain about the immunization itself:

I would feel that as of the 1st of September if you got vaccine and there was a need for it I would not hesitate to use it. Otherwise, I don't see any need for using it up now We don't know how long this vaccination is going to last. I haven't much faith in its lasting qualities, if it is of a nonliving character. There is no sense in giving a booster shot right at the end of the season. Better give it when it is going to be needed. That is a 'yes and no' answer, I confess, but I didn't know how to answer it now.³⁰⁸

At the October 3, 1956, board meeting Dr. Fleming reported there had been a marked drop in requests for polio vaccine. The board wondered if it should release its stores for a third dose. Dr. Barr said he saw no good reason for doing this. He thought that if the board authorized a third dose it would be gone over night. Within a few months, however, adequate supplies became available.

<u>Transition from Selected Distribution to General Promotion</u>

As the supplies of polio vaccine increased, people of all ages were encouraged to receive the vaccination. The board produced a news release to help overcome public apathy among adults towards vaccination. Many needed encouragement. To set an example, physicians in the department offered polio vaccinations to departmental staff at a nominal cost.³¹⁰

³⁰⁶ BOH, *Minutes,* July 10, 1956, MHC, pp. 166-170.

³⁰⁷ Ibid., p. 170.

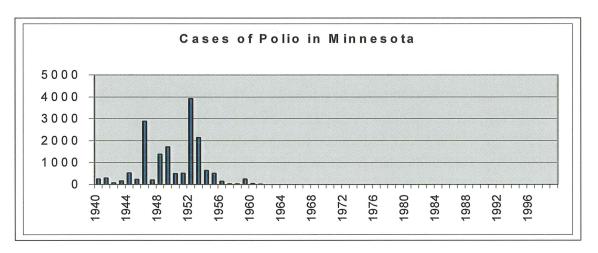
³⁰⁸ Ibid.

³⁰⁹ BOH, *Minutes,* October 3, 1956, MHC, p. 200.

³¹⁰ BOH, *Minutes*, January 31, 1957, MHC, p. 8.

NFIP embarked on a campaign in 1957 to cover the entire nation. It had been cleared with the American Medical Association and would be cleared with state and local medical societies. The department had strong support from Gov. Orville Freeman who backed a program to immunize all people in the state against polio. Such a campaign had not been possible earlier due to the shortage of vaccine. Dr. Fleming was hesitant about organizing such a program, as the department was not in a position to administer such injections. He thought it might be better for the department to establish a fund for those who needed.³¹¹

By 1957, the department was able to look back on a successful campaign against polio. Minnesota was one of only three or four states that had used up its total allotment of funds from the U.S. Public Health Services for polio vaccine. Polio was still occurring in patients who were immunized, but not paralytic polio. During the first seven months of 1957, 12 cases occurred. Eight of the persons had received polio vaccine, but none of the cases was paralytic. Four of the cases had not received the vaccine, and three of these were paralytic. 313



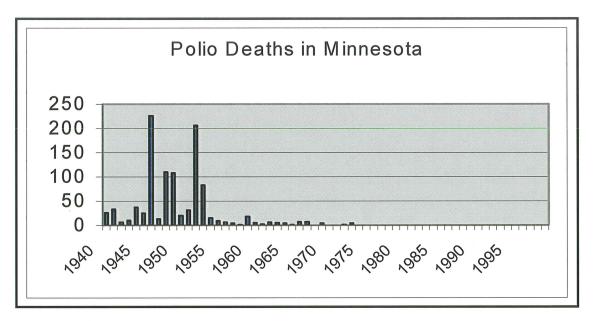
There were still questions of safety about polio vaccine, but by 1961 most citizens were willing to be vaccinated. A survey of 600 persons was taken asking them: "If you had a chance, would you yourself be willing to take part in the test by taking the oral polio vaccine, or not?"c Seventy-three percent said they would be willing. The 27 percent who said they wouldn't, cited their reasons: "the new vaccine is not perfected yet and may not be safe," "I'm too old," "I already have had Salk vaccinations," and "I don't believe in taking drugs." When the survey was repeated in 1962, the percentage of people willing to take part in a test had dropped to 54 percent. This was probably due to the unfavorable publicity Type III vaccine was receiving.

³¹¹ BOH, *Minutes,* July 30, 1957, MHC, p. 123.

³¹² BOH, *Minutes,* April 4, 1957, MHC, p. 35.

³¹³ BOH, *Minutes*, July 30, 1957, MHC, p. 122. ³¹⁴ MDH, *Minnesota's Health*, Vol. 15, No. 4, April 1961, p. 4.

³¹⁵ MDH, *Minnesota's Health*, Vol. 16, No. 10, December 1962, pp. 1-2.



In 1959 the polio advisory committee recommended that the department create a plan for distributing vaccine on short notice, in the event of another polio epidemic. The board authorized the staff to draw up such a plan. 316

There never was another epidemic. In 1967, for the first time in the department's history there were no reported cases of polio in the state

Minnesota's Role in Polio Vaccine Studies

While the board and the advisory committee were making difficult decisions about the use of polio vaccine, the department's public health laboratory was setting off a spark that would help create worldwide interest in oral polio vaccine.

A revival in polio vaccine research and a new era of virology began in 1949 when Dr. John F. Enders, a bacteriologist at Harvard University, discovered polio virus could be grown in monkey kidney tissue cultures. In 1953 the laboratory established a tissue culture laboratory for the isolation of the polio virus. Dr. Henry Bauer, director of the laboratory, hoped to be prepared to do more laboratory work when there was a polio outbreak.

In 1955 Dr. Bauer set up a virus laboratory. Funding was received from the U.S. Public Health Service and later from the Sister Kenny Institute and Lederle Laboratories. Dr. Bauer was very pleased with the results and said: "I think by this spring we will have a much better insight into what this polio season is about, which will give us some direction for next year as to how we should go about these things. We are quite pleased with the way this thing is going along." 320

³²⁰ BOH. *Minutes*, September 8, 1955, MHC, p. 230.

³¹⁶ BOH, *Minutes,* August 11, 1959, MHC, p. 214.

³¹⁷ Unpublished report on polio by Dr. Henry Bauer.

³¹⁸ BOH, *Minutes*, December 18, 1953, MHC, p. 60. ³¹⁹ BOH, *Minutes*, October 3, 1956, MHC, p. 198; and January 13, 1959, MHC, p. 8.

The board was supportive of the innovative work that was being done in the department. Dr. Frank Krusen, board president, said: "I think the people of Minnesota owe a real debt of gratitude to Dr. Bauer and his staff for what they have done. I think a vote of thanks would be in order." The motion was passed. 321

When continuation of the lab's program was discussed later in the year, the board showed its strong approval of the work that was being done:

James Halvorson, M.D: "I think they should be commended for the tremendous job they have done and that we should instruct Dr. Barr to do everything in his power to maintain this service that has been set up."

Boynton: "I was going to say the same thing. I think Dr. Bauer deserves a great deal of commendation and credit for having set this laboratory up in the short time he had to do it. I think certainly it should be continued, and with the polio vaccination program in the unstable state it is now, the only way we are ever going to learn and know anything about the value of it and the pitfalls of it is to continue this sort of a surveillance program, and the laboratory part is extremely important." ³²²

In 1957 Dr. Bauer conducted an oral attenuated polio virus study, carried out jointly with Dr. M. Da Silva of the University of Minnesota, and Drs. Harold Cox and J.M.Ruegsegger of Lederle Laboratories. The vaccine used was the Cox vaccine, developed by Dr. Harold Cox. The study involved 25 infants, their parents and siblings. The infants were given the living polio virus and received no ill effects. Results compared very favorably with the Salk vaccine, and all infants demonstrated satisfactory antibody response. Results

The work done in Minnesota drew attention from other parts of the world. A polio outbreak in South America was starting, and the Pan-American Sanitary Bureau was interested in Minnesota's study because they concluded the Salk vaccine, due to its high cost, was not a satisfactory solution to the problem in Latin America. They thought the best solution would be a live vaccine which could be given by mouth and which could interrupt the spread of the more pathogenic viruses.

Dr. Bauer proposed an additional orally attenuated live polio virus vaccine study. Residents of the University Village, a crowded university housing development near the health department, would be involved. Half would be fed the virus vaccine and half would be given a placebo.

While supportive of Dr. Bauer's efforts, the board was concerned about its liability in case of any illness in the study participants, either from polio or another condition. Mr. Brower, a lawyer, reduced some concerns when he explained that a project of this kind would come through a gift of money, and the conditions and terms would be stated with

³²¹ Ibid., p. 231.

³²² BOH, *Minutes,* November 1, 1955, MHC, pp. 329-330.

³²³ BOH, *Minutes*, April 4, 1957, MHC, p. 34; July 30, 1957, MHC, p. 124; October 9, 1957, MHC, p. 199.

MDH, "Summary of Oral Polio Vaccine Trials in Minnesota (1957-1960)," May 1960, p. 1.

³²⁵ BOH, *Minutes*, October 9, 1957, MHC, p. 199.

the money to indicate liability. It would be up to the governor or state treasurer to accept the gift, so the state would have responsibility for it.

Boynton: "I still have some reservations about the State Board of Health, as a State organization, undertaking this kind of a research project, which it is, with as little work having been done on this as has been done. Less than 1,000 people have been fed this vaccine to date. There are so many unknowns in it, and I think the responsibilities which we assume if we undertake this are so great--I have great reservations."

Krusen: "I agree with you to a certain extent, but at the same time I think it is in the interests of public health to get this information and it is still a study of a limited group in limited areas and it isn't as if you were subjecting everybody involuntarily in the entire State to take part in the study."

Boynton: "That is very true."

Krusen: "So I personally feel that this is of such great value that I am going to vote in favor of it myself, knowing all of your misgivings and reservations, which I am sure are justifiable."

Harold Wente, M.D: "There is no other organization in the state that would have the opportunity to do this with the protection of the State behind them and while it is a serious obligation, it is quite a consolation to know that no private corporation or private medical group could afford to take the responsibility."

The final decision to go ahead with the study was close. Dr. Huenekens voted aye. Dr. Boynton and Mr. Peterson voted no. Other members didn't vote. The question was asked again. This time Dr. Wente and Dr. Huenekens voted aye. Dr. Boynton, Mr. Peterson and Prof. Bosch voted no. Mrs. Loevinger was undecided. Prof. Bosch said he would be willing to leave his vote to the medical members of the board, if he felt that the liability issue was satisfactorily addressed.

Brower: "I was going to say that since no state money will be used in this program, all financing being by gift, all the Board would have to do would be to recommend to the Governor, the State Auditor and the State Treasurer the acceptance of this gift, and then a complete explanation could be made of the whole program and it would be up to those three men to accept or reject it. They might want to get an opinion from the Attorney General. They might reject it on the grounds that it has too much potential liability and it might require an act of the Legislature to authorize it. The recommendation of acceptance of this gift would be all that is necessary to start it."



Marie Ford, Marion Cooney, Dr. Kleinman, Dr. Henry Bauer, Unidentified, Anne Kimball Press Conference on Polio, 1958

Krusen: "Would it be acceptable to the Board to have such a motion presented? Withdraw the previous motion and substitute a motion that we recommend the acceptance of a gift of funds to further this particular study? Would you be willing to withdraw your motion, Dr. Huenekens, and substitute this motion proposed by Mr. Brower and Prof Bosch?"

Huenekens: "I would be glad to, but I would like to know-- Would this be acceptable to you, Dr. Boynton?"

Boynton: "I think it would."

Bosch: "I would like to move that the Board recommend to the Governor the acceptance of a gift for carrying on the project of oral vaccination with the provision that (a) the project be approved by the Board's Polio Advisory Committee, and (b) that participation be on a completely voluntary basis on the part of the individuals receiving the vaccine."

The motion was passed.

Krusen: "I think this is a sound solution of this very difficult problem and does not involve the Board unduly in the situation, and we have a chance for sound advice all the way around."

Bauer: "I would imagine that would include, then, the authorization to accept funds."

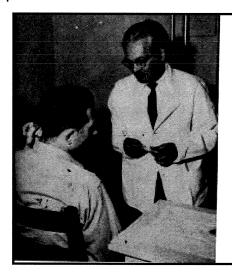
Krusen: "Yes, this implies acceptance."

Bosch: "This is actually a part of the motion."

Krusen: "It is understood, then, that it be so worded that we accept any gifts. Thank you very much, Dr. Bauer. 326

Members of the advisory committee for the laboratory were Dr. Gaylord Anderson, Dr. John Anderson; Dr. Paul Elwood; Dr. John McKelvey; Dr. L.M. Schuman; and Dr. Dennis Watson; Mario McC. Fischer, M.D., director of public health, Duluth; Karl R. Lundeberg, M.D., commissioner of health, Minneapolis; Henry M. Moen, executive secretary, Minnesota Pharmaceutical Association, St. Paul; Frank W. Moudry, secretary, Minnesota State Board of Pharmacy, Minneapolis; R.B.J. Schoch, M.D., chief health officer, St. Paul; and V.O. Wilson, M.D., district health officer, Rochester³²⁷

The second orally administered attenuated polio virus vaccine study in University Village was conducted in 1958. A total of 551 persons in 149 families were given oral capsules at three-week intervals. Of the 551 participants, 111 received a placebo, 37 received one dose, 148 received two doses, and 255 received three doses. The greatest increases in the percentage of antibody titrations occurred in children receiving the vaccine. Results indicated the attenuated live virus was not as good an antigen for adults. The study ended June 1958, without any incidents or problems. 328 329 . A letter received from Dr. W. Ritchie Russell, one of England's leading neurologists, congratulated the department for its courage in undertaking the study of orally administered live attenuated polio virus. He believed it was the only way to immunize against polio. 330



AN INMATE IS checked by Dr. Herman Kleinman of the Minnesota Department of Health. Blood samples, stool specimens, and throat swabs were taken to compare four different methods of feeding oral polio vaccine (liquid vaccine before eating, liquid after eating, capsules before eating, and capsules after eating). If stool specimens contain attenuated poliovirus, this indicates that the vaccine was successful in causing virus to multiply in the intestinal tract. Blood samples show the polio antibody level of inmates, and throat swabs indicate whether poliovirus from the vaccine was present in pharyngeal tissues. Before receiving oral vaccine, most of the 170 volunteers had little or no immunity to the three poliovirus strains.

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Having completed the second study successfully, Dr. Bauer planned a third. The Sabin vaccine was given in three doses, six weeks apart, creating problems in administration. After the first dose, people would have to return two more times for adequate coverage. It was likely some would not return and be unprotected. One dosage would solve this problem. Dr. Bauer wanted to determine if antibody production was as effective if all

328 BOH, *Minutes,* August 13, 1958, MHC, p. 217.

³²⁶ BOH, *Minutes,* January 7, 1958, MHC, pp. 16-19.

³²⁷ Ibid., p. 92.

³²⁹ MDH, "Present Status of Oral Polio Vaccine Study," distributed with BOH *Minutes*, August 13, 1958, MHC, pp. 167-168

³³⁰ BOH, *Minutes,* January 13, 1959, MHC, p. 8.

three types of virus were given at once. Again, he used the Cox oral polio vaccine. The board approved this request. ³³¹ The third study was done in Grove East Village, St. Paul. A total of 230 persons from 65 families were involved in this study. This study indicated the trivalent form was not as effective in producing antibodies, especially for type II, however enough efficiency and advantages were present to recommend it for further attention. ³³²

A fourth study was conducted at the St. Cloud Reformatory to determine whether gastric acidity played a part in lessening the effectiveness of the oral vaccine. ³³³ One hundred seventy inmates who volunteered and participated in this study were given vaccine in either liquid form or in gelatin capsules. ³³⁴



Dr. Robert Barr, Dr. Henry Bauer and Dr. Kleinman at a polio conference in Washington, D.C., June 1959

The work done in Minnesota continued to receive recognition from outside the state and received special notice at a June 1959 conference sponsored by the World Health Organization and the Sister Kenny Foundation of Minneapolis. Dr. Gaylord Anderson reported that the high point of this five-day conference on live polio vaccine in Washington, D.C. was the presentation by Dr. Barr, Dr. Bauer and Dr. Kleinman on the oral vaccine study being done in Minnesota. Anderson said: "They gave added distinction to your Board." 335

³³¹ BOH, *Minutes,* December 4, 1958, MHC, p. 335.

MDH, "Summary of Oral Polio Vaccine Trials in Minnesota (1957-1960)," May 1960, pp. 1-2.

³³³ BOH, *Minutes*, May 26, 1959, MHC, pp. 132-133.

 ³³⁴ MDH, *Minnesota's Health*, Vol. 13, No. 7, August-September 1959, p. 2.
 335 BOH, *Minutes*, August 11, 1959, MHC, p. 214.

In 1960 a gift of \$100,000 for oral polio vaccine research made possible a fifth study, the 1960 field trials. It was at this time that the board thought it was important to refer to the oral vaccine as the Cox vaccine rather than the Lederle vaccine to differentiate from the Sabin vaccine. ³³⁶

A total of 104,288 persons participated in the 1960 field trials: 31,335 in Minneapolis, 17,042 in St. Paul, 21,700 in Duluth, 16,000 children in Meeker, Kandiyohi and Swift counties, 8,100 children in Bloomington, and 10,000 children in St. Louis Park. The studies were going very well. The department even had thoughts of licensing the polio vaccine. Dr. Carl Eklund of the U.S. Public Health Service visited Minnesota to determine if it was safe. The studies were going very well.

<u>Test Polio Pills</u> Taste Like Cherry Drops

Cherry-flavored polio vaccine that may be taken orally in the form of a pill is now under test by the Minnesota Department of Health. The "candy" vaccine is expected to be available for use early next year. 340

Popular Mechanics August 1959 Then, difficulties arose. The Cox vaccine was not approved for licensing by the Public Health Service, as it did not consider the Cox vaccine safe. In August 1960 the Public Health Service and National Institutes of Health authorized the production of Sabin vaccine. 339

Dr. Anderson, director of the University of Minnesota School of Public Health, showed strong support for the board

when he visited Surgeon General Lee Burney in Washington, D.C., on behalf of the department's work following the Public Health Service's announcement. He reported on his visit with the surgeon general to the board:

I spent about an hour with him on Friday morning. Obviously, I couldn't ask him point blank at that time to make a decision or to do anything other than to listen to me. I told him I thought their decision had put us, as well as many others, in a very awkward and embarrassing situation in that what they were essentially saying to the American public was that here in the State of Minnesota something had been fed to the public that was not safe for further use, and that I did not see that they had any evidence to back up that sort of statement. His reply, which did not satisfy me, was that their decision was based not upon any field trials or any use of the material, but upon their monkey neuro-virulence tests. This is not correct, and he seemed a bit embarrassed when I pointed out to him that on the front page of his statement he had said otherwise. His front page says that decision is based upon use of the vaccine in field trials, on monkey neuro-virulence, the viremia, and field experience with all candidate strains. It is true from that time on they say nothing about field experience. They ignore it completely.

We went on from there and discussed what evidence there was on danger of the vaccines, and it became quite apparent to me, and he essentially acknowledged it, that some of the data on comparative safety had not been presented to him. For example, the data on cases of polio in Karaganda in Russia, and in Moscow, following the use of the Sabin vaccine made in Russia.

³³⁶ BOH, *Minutes,* January 12, 1960, MHC, pp 10-11.

MDH, "Summary of Oral Polio Vaccine Trials in Minnesota (1957-1960)," May 1960, p. 2.

³³⁸ BOH, *Minutes*, May 24, 1960, MHC, p. 73.

³³⁹ Surgeon General's news release on August 24, 1960.

³⁴⁰ "Test Polio Pills Taste Like Cherry Drops," *Popular Mechanics*, August 1959, p. 91.

These data had never been presented to him by his committee. He was unaware of their existence. We discussed the report that had been turned in to him by his staff--the boys who went over from CDC--and if I did not misinterpret him, he had never seen their report. He had merely been told about their report by his advisory committee. ³⁴¹

The advisory committee met on September 28, 1960, and considered options for the board on continued studies of polio vaccine at the department, given the decision by the U.S. Public Health Service. The committee recommended that the board go forward with a divided trial, giving half the recipients Cox vaccine and half Sabin vaccine. It did not recommend that the study be dropped, but it thought the board should consider such an action because of public relations issues involved.

The advisory committee also recommended that the board ask the Public Health Service to appoint an impartial advisory committee to the surgeon general, as the current one was loaded with people who had been working with the Sabin vaccine. Two were members of the National Foundation Advisory Committee, which had put money in the Sabin vaccine.

Executive Officer Dr. Robert Barr didn't agree with this recommendation as he thought it would tend to bring discredit to the surgeon general and the Public Health Service and would only do harm.

Prof. Bosch did not think the board should use the Cox vaccine until there was clearance from the Public Health Service. The board had promised 50,000 people the vaccine late in the winter or early next spring, and it was concerned it might not be able to give the vaccine.

The board decided to see if the surgeon general would grant approval for a continued study using the Cox vaccine. ³⁴² The surgeon general wrote back to Dr. Barr on November 10, 1960:

In your letter of October 20 you picture an embarrassing position with respect to the further use of live poliovirus vaccine in the State of Minnesota because of the issuance of our release on August 24.

The release in question dealt with live poliovirus vaccine standards applicable to materials to be distributed under license; i.e., to be distributed freely and in an unrestricted way for sale in interstate commerce. The materials which you have used in Minnesota thus far have not been manufactured under license. They were supplied for purposes of controlled investigations designed to obtain information. This is perfectly proper and you are still free to carry out such controlled investigations with unlicensed biological products that are in course of development. This situation is covered both by Public Health Service and by Food and Drug Administration regulations. If, on the other hand, you wish to use licensed products only, you will have to wait until live poliovirus vaccine produced under license becomes available. "We agree with the thought expressed in the last paragraph of your letter and would add that such materials are or will be available from manufacturers for controlled investigations prior to licensing. We would be glad to be of assistance in making suggestions as to likely sources of such material. "443"

³⁴¹ BOH, *Minutes*, September 13, 1960, MHC, pp. 338-339.

³⁴² BOH, *Minutes*, October 18, 1960, MHC, pp. 361-364.

³⁴³ BOH, *Minutes*, December 19, 1960, MHC, p. 406.

With this letter, the board realized it was in a very different position and could safely proceed with the studies. ³⁴⁴

While the surgeon general gave support for continued studies with the Cox vaccine in Minnesota, its failure to be accepted for licensing resulted in the loss of financial support. Lederle Laboratories, which had been supporting much of the polio studies undertaken by the department's laboratories, reduced its financial assistance. Lederle obtained Sabin strains in August 1960 and started developing oral vaccine with these strains.³⁴⁵

The department felt a general sense of disappointment that the Cox vaccine was not accepted for general use and Minnesota's research in polio vaccine ended. There was, however, great satisfaction when looking at the polio statistics for Minnesota.

The last reported case of polio in Minnesota was in 1981, and the last death in the state attributed to polio occurred in 1973. The fight against polio continues today, but it has now become one of the quiet parts of public health. Public health workers diligently work to ensure that children are immunized against polio. The effects of their efforts are not always noted, but because of them Minnesota children of today do not fear paralysis, iron lungs or death from polio.

The World Health Organization hopes to see polio, like smallpox, eradicated in 2001. When that goal is celebrated, part of the credit is due to the public health workers in Minnesota who worked so hard to free the world of this crippling disease.

 ³⁴⁴ BOH, *Minutes*, October 18, 1960, MHC, pp. 361-364.
 ³⁴⁵ BOH, *Minutes*, July 11, 1961, MHC, pp. 307-309.