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# **The 1955 Salk Polio Vaccine and the 1957-61 Niles Leukemia Cluster: A Flawed Investigation by the U.S. Public Health Service**

by

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*Shortly before his death in December, 1997, the author asked that this article be published. A Visiting Professor of New York Medical College, Department of Community and Preventive Medicine, Valhalla, New York, he was also Director of Public Health, Oak Park, Illinois, from 1949 to 1974 and editor of Child & Family from 1967 to 1997. He was a co-author of the December, 1999 article by Michele Carbone in Cancer Research, "Unique Strains of SV40 in Commercial Poliovaccines from 1955 Not Readily Identifiable with Current Testing for SV40 Infection."*

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## **Abstract**

A 1963 U.S. Public Health Service study of the 1957-1961 leukemia cluster of eight children in Niles, IL, gave cursory attention to the possible role of the Salk polio vaccine in the etiology of the leukemia. Entitled "Leukemia among Children in a Suburban Community," and published in the *American Journal of Medicine*, 34:796-812 June, 1963, the study was reprinted as a "Classic in Oncology" in *CA — A Cancer Journal for Clinicians*, 40, 1:27-50 Jan.-Feb., 1990. Focusing on the physical environment of the school and church community to which six of the children belonged, the study either overlooked or ignored the presence of live polio virus in the first two inoculations received by first and second graders in Chicago and its suburbs in the spring of 1955. Had the

investigators considered the 1955 vaccine as a vector of the disease, their conclusions might have been other than to say the etiology of the leukemia cluster could not be determined.

### **Introduction**

Niles, a small suburb of Chicago, Illinois, is famous in epidemiologic cancer literature for its cluster of eight cases of leukemia which developed in children from 1957 to 1961. Six of these cases attended the town's Roman Catholic parochial elementary school. One case, a pre-school child, had two older siblings who attended the same school. The eighth case attended a neighboring public elementary school and was a close friend and contact of one of the six parochial school cases; both were in the 4th grade at the time. The leukemia cases were diagnosed between the autumn of 1957 and the summer of 1960. During the 1960-61 school year the parochial school in Niles had 2,723 students and the incidence of childhood leukemia in the community was 21.3 cases per 100,000 population. This contrasted with a rate of 4.6 cases of leukemia per 100,000 children in the rest of Cook County including Chicago, but excluding Niles.

That something unusual was happening in this small community with a child population of 7,076 was first noted by a local woman returning from her fourth funeral of a leukemia child in the first three months of 1961. As she subsequently informed the author of this article, her observation led her to inquire of the Chicago American Cancer Society whether there was a "cancer epidemic or something in their area." At the request of the Society, she gathered the data on leukemia cases associated with the local parochial school. This information was relayed by the Cancer Society to the Centers for Disease Control and Prevention in Atlanta (then known as the Communicable Disease Center) which assigned a medical officer to study the outbreak.

The investigator was one of a cadre of recently graduated medical students who were repaying the federal government for subsidizing part of their medical education. He had been recruited by the new Polio Surveillance Unit which had been established following the Cutter Salk-vaccine polio outbreak that occurred shortly after the introduction of the Salk vaccine in April, 1955. Given the title "Epidemic Intelligence Service Expert," he and the other members of this unit served under Alexander Langmuir, M.D., of the United States Public Health Service (USPHS) who was chief of the Poliomyelitis Surveillance Unit. The study published as a result of this investigation was co-authored by the Director of the Argonne Cancer Research Hospital of the University of Chicago who was specialized in Internal Medicine and radiology and who worked on the



project on a part-time basis. The Illinois Cook County Health Department was a cooperating agency.

Upon its completion, the authors' detailed investigation was submitted to the *American Journal of Medicine* on July 27, 1962 under the title "Leukemia among Children in a Suburban Community" and was published in June, 1963 (34: 796-812).<sup>1</sup> In 1990 the study was reprinted as a "Classic in Oncology" in *CA — A Cancer Journal for Clinicians*.<sup>2</sup> In his introduction to the reprinted article, Curtis Metlin, Ph.D., Chief of Epidemiologic Research and Director of Cancer Control at Roswell Park Memorial Institute in Buffalo, NY, wrote that "[t]he expert and thorough approach of the investigators marks this report as a model of epidemiological analysis and a classic in oncology."<sup>3</sup> He emphasized that "rather than focusing on a single theory, they evaluated a range of etiologic factors."<sup>4</sup> He added that "to have so thoroughly searched and failed to find the common exposure that would account for the cancer cluster may have provided equally important information on the lack of communicability of childhood leukemia."<sup>5</sup>

### Analysis

The authors judged from the beginning that: "[t]he cluster of eight cases of leukemia among children in Niles cannot reasonably be attributed to the effects of a random distribution. These cases constituted a clearly defined micro-epidemic that occurred within a particular community and affected a particular segment of that community's population. Although obscure in etiology, this micro-epidemic presents several distinct epidemiologic features."<sup>6</sup>

In their discussion of epidemiologic features the authors made clear that "[a] conspicuous feature of the eight cases was the absence of direct personal contact among the children or their families."<sup>7</sup> As a result of their inability to find any signs of an infectious process, the authors shifted their attention to the school building itself and conducted a thorough study of the surrounding physical environment. None of their findings, however, cast any light on the etiology of the micro-epidemic.

Though needed to cover all etiologic possibilities, the investigators' intense focus on the locus of the disease sidetracked any further search for an infectious process in the children themselves. But before having abandoned their search for an infectious process, the investigators did take a careful immunization history of each child leukemia case. These histories showed that each was fully immunized against diphtheria, pertussis, and tetanus (DPT), as well as against small pox and that each child had received "at least three polio vaccine inoculations before the onset of

illness.”<sup>8</sup> It was found that the children’s immunizations did not differ from those received by other children in the parochial school and in the surrounding community.

The investigators seemed to recognize, however, that as a newer vaccine, the Salk vaccine fell into a different category than the traditional long-established childhood vaccines, *viz.*, DPT and small pox. This was clearly manifest when they singled out the polio vaccine for comment observing that “the interval between the most recent Salk dose and the leukemia onset varied from two to eighteen months.”<sup>9</sup>

This variation in onset interval apparently led the investigators to rule out the possibility that the Salk vaccine was the vector of the infectious agent. And this was as far as they pursued such a possibility as they had chosen the short incubation period of the common contagious diseases of childhood as the incubation norm for leukemia. If they had instead taken as their model a disease such as tuberculosis in which the lapse of time between the initial infection and the manifestation of the disease is much longer — many months or years — they might have correlated these leukemia cases with the first inoculation instead of with the third and most recent inoculation.

Had they done so, they would have found that six of the eight leukemia cases had received their first Salk vaccine inoculation not in Niles but in other sections of Chicago and Cook County and that for this first inoculation each child would have received the same vaccine, *viz.*, the free 1955 Salk Polio vaccine provided to United States school children by the National Foundation for Infantile Paralysis (NFIP). In Cook County the vaccine used was from one manufacturer and the first inoculation was given shortly after the April 12 internationalized television announcement that the Salk vaccine had been approved for use. One should recall that on May 7, 1955, the USPHS had to suspend its vaccination program temporarily in order to re-examine the safety of the Salk vaccine. This re-examination was called for after the manufacturer experienced difficulties in carrying out the recipe devised by Jonas Salk for the polio-virus inactivation process. The vaccination program was not fully resumed until May 24, 1955. However, on May 26, 1955, the manufacturer of the vaccine used in Cook County stopped manufacture after having detected live polio virus in the vaccine.

All the Niles leukemia cases thus would have received their first inoculations between April 12, 1955 and May 26, 1955. Therefore it may be seen that the interval between polio inoculation and the onset of leukemia in the Niles children did not vary between child and child so much as the investigators had supposed. Instead of a putative incubation



period which varied between 2 and 18 months, one finds a putative incubation period which varies between roughly 2 and 5 years.

The newly-licensed Salk vaccine had been used for less than two years before the first cases of leukemia developed among the Niles school children. Let us remember that within three weeks of the Salk vaccine's first use both major and minor epidemics of polio had occurred. The major epidemics occurred in California, Idaho, and Utah and were immediately recognized as such by both public health physicians and the laity. On the other hand, the pre-seasonal micro-epidemics (an increased rise and fall in polio cases), which developed in about ten states were never publicized either by the NFIP or the USPHS. These micro-epidemics were, however, noted in the *Bulletin of the American Association of Public Health Physicians* and, there, were denoted as the "Salk Vaccine Post Inoculation Phenomenon."<sup>10</sup> This phenomenon was independently confirmed in a 1956 report by the President of the Health Ministry of West Germany where similar micro-epidemics of polio after vaccination programs had been observed.<sup>11, 12, 13</sup>

### Conclusion

In summary, the three essential points that the authors of the 1962 Niles study either overlooked or ignored were: 1) the turbulent history of the Salk vaccine following its introduction, 2) that in every community in the Chicago area except one, every first and second grader, with rare exception, received two inoculations of the Salk vaccine in the spring of 1955, and 3) that the manufacture of Salk vaccine allotted to Illinois was discontinued by its manufacturer on May 26, 1955 after the discovery of live polio virus in the vaccine.<sup>14</sup>

Overlooked or ignored also was the manner in which the Salk vaccine had been licensed on April 12, 1955, the same day it was announced in a highly publicized program out of Ann Arbor that the vaccine was "safe, effective and potent." These words were taken from the *Francis report*, which was a summary of the 1954 nationwide field trial and which had been released as a press communiqué.<sup>15</sup>

On that day of the licensing of the Salk vaccine, April 12, 1955, the full report of the field trial had not, however, yet been made available to the USPHS licensing board for review.<sup>16</sup> Thus the USPHS licensing board approved the vaccine without having read the full report on which its decision was to have been based. If all or even some of this available information had been taken into account by the authors of the USPHS Niles study, the conclusions of the study regarding the possible role of the Salk

polio vaccine in the Niles leukemia cluster might have been other than to say that the etiology of the leukemia could not be determined.

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**Epilogue:** In 1963, when the article "Leukemia among Children in a Suburban Community" was published in the *American Journal of Medicine*, the top officials of the USPHS had already been aware for three years that a simian virus (eventually named SV40) had been detected in the Salk vaccine by government researcher Bernice Eddy, who found that this virus caused tumors in hamsters.<sup>17, 18</sup> But not until May, 1961 did the USPHS privately order vaccine manufacturers to remove SV40 from all new vaccine.<sup>19</sup> Meanwhile the USPHS continued to allow existing vaccine contaminated by simian-virus to be used up.<sup>20</sup> Thus, SV40-contaminated vaccine was used till 1963. No reference to the SV40 contamination appears in the 1963 *AJM* article on the Niles cluster. It is unknown whether the head officers of the USPHS passed on their knowledge of the presence of the SV40 contaminant to the authors of the 1963 article.

- H.M. Dietz

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