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Polio Vaccinations: People with Disabilities in Institutional Settings as Test Subjects

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Abstract

In the 1940s and 1950s there was significant attention given to the prevention of poliomyelitis (infantile paralysis) in the United States. Ongoing research led to the development of both a 'killed' virus vaccine and a live virus vaccine. Researchers made meaningful contributions to the implementation of effective vaccinations in order to eradicate this disease. However, the quiet story is that those researchers required the participation of people in institutions, most often people with intellectual and developmental disabilities, as test subjects. These individuals were critical contributors to the goal of developing and applying the vaccine. As volunteers or not, with permission granted or not, they are necessarily part of story of the success of the development of the polio vaccination.

Poliomyelitis, often referred to simply as polio or infantile paralysis, posed a significant public health threat forovera century. Sporadic cases appeared in Europe and the U.S. throughout the 1800s, but the first recognized epidemic in the U.S. occurred in Vermont in 1894, with 132 confirmed cases. By the 1940s, polio had reached epidemic proportions, devastating families and communities [1]. In 1943, for example, there were over 10,000 new cases and 1,000 deaths reported [2]. The most famous victim was Franklin Delano Roosevelt, who contracted polio at age 39, twelve years before becoming president. The disease's impact peaked in the early 1950s, with 1952 marking one of the worst years; there were 21,969 cases in the U.S. alone, and more than 60,000 globally. In the U.S., over 3,000 deaths were recorded, and thousands more people were left paralyzed, many reliant on iron lungs (Drinker respirators) to breathe [3,4]. The societal response to polio outbreaks included the closure of public swimming pools, the cancellation of public gatherings, and temporary school closures to curb the spread [5,6].

Initially, polio was incorrectly believed to primarily affect White populations. Some even speculated that Black Americans might be immune, but this was soon disproven, and it became clear that all racial and ethnic groups were vulnerable. This realization reinforced the need for universal protection, as highlighted in Turner's [7] research on the Tuskegee study.

The announcement in 1955 that Jonas Salk had developed a safe and effective polio vaccine marked a monumental moment in public health. Albert Sabin's development of an oral polio vaccine in 1961 further revolutionized the approach to immunization. The oral vaccine was easier to administer and helped facilitate mass vaccination campaigns, contributing significantly to the control and eventual near- eradication of polio in the United States. By 1971, a dramatic decline in polio cases was evident, with only one documented case in the country, showcasing the success of these vaccination efforts [8].

While there are numerous histories of the race to a polio vaccine, the particular focus herein is of the quiet heroes of this vaccination race, the people in residential facilities who voluntarily or involuntarily served as research subjects in the quest for public health. The use of children with intellectual and developmental disabilities, for example, became central in the creation of vaccines for polio and other diseases [9]. The use of people in institutional settings provided an opportunity for researchers to have access to subjects without the need to go to elaborate efforts to secure test subjects and receive approval to use them.

Early Research on Polio Vaccinations

The early research into polio vaccinations highlights a complex and controversial history. In the 1930s, scientists including and

Park (1936) and Kolmer (1936) [10,11] engaged in early efforts to develop immunizations [12]. Kolmer's (1936) [11] live virus approach studies involved inoculating 42 monkeys. None became ill and so as a consequence he then continued to inoculate people, including 23 children between eight months and 15 years of age at Temple University's Philadelphia Hospital. When the trials expanded to include children who were vulnerable, the emergence of polio cases and other adverse reactions raised significant ethical and safety concerns [12-16]. James Leake, a representative of the Public Health Service, presented evidence at a 1935 conference to the effect that Kolmer's live virus vaccine had resulted in the deaths of children: "I beg you (Dr. Kolmer) to desist from the human use of this vaccine. According to my count,1 fatal case occurred 6 days after the second dose, another fatal case 6 days after the second dose, and 12 days after the first dose, 2 paralytic cases and 1fatal case 8 days after the first dose, a fatal case 9 days after the first dose, another fatal case 10 days after the first dose, a paralytic case 11 days after the first dose, and another paralytic case 14 days after the first dose" [17].

Leake's written report as part of the conference proceedings may have been toned down and was not as harsh as the verbal presentation. Some reports indicated that he may actually have accused Kolmer of murder [13,17]. A subsequent agreement reached in 1946 to identify the various types of polio viruses was a pivotal moment in the development of an effective vaccine. Recognizing that a successful vaccine would need to provide immunity against all identified virus types was crucial for ensuring comprehensive protection. This research confirmed the existence of three core types of the polio virus, which laid the groundwork for future vaccine development [18-21].

Among the foremost researchers on the development of polio vaccine, four are noteworthy for their contributions. Each one also accessed residents in institutions as test subjects for their research. These four included Howard Howe, Jonas Salk, Albert Sabin, and Hilary Koprowski.

Howard Howe

A pioneer in polio vaccine research was Howard Howe of Johns Hopkins University, who, along with colleagues [19] had confirmed the three basic immunological types of poliomyelitis, later verified by Sabin (1955) [19,21]. Subsequently, Howe produced a polio vaccine using a dead virus which he tested on chimpanzees, which was deemed to be safe and successfully produced antibodies against polio [18,22]. Four months later, the chimpanzees were then given what would otherwise have been a lethal dose of the polio virus to confirm that the protection provided by the vaccines had been successful [23].

Howe tested the vaccine on children in 1952 at the Rosewood State Training School in Maryland, an institution for people with intellectual disability. Rosewood was an obvious choice because of its proximity to Johns Hopkins, and because the people at the Training School could serve as a readily available research sample for his vaccination.

Howe (1952) [22] administered the vaccination to six children with intellectual disability at Rosewood. He had described the children as including "low grade idiots" or "imbeciles" and who had been identified as with congenital cerebral palsy, hydrocephalus, and microcephaly. The six children were initially vaccinated with a killed, thus dead, virus [23,24]. Howe (1952) reported success with treatment of these children (22). He noted that "both children under five years of age and chimpanzees develop readily demonstrate neutralizing antibodies . . . following the injection of small quantities of . . . formalin inactivated poliomyelitis virus" (p. 275). The initial use of the residents of an institution had been deemed a success.

The question of informed consent for participation was not addressed and likely not obtained. As Heng and Sullivan (2017) noted, such consent would have required that participants: would have sufficient information on which to base a decision; would understand the information related to the procedure or intervention; and would be able to appreciate the consequences of either giving or withholding their consent.

Jonas Salk

Salk built on the early work of others in vaccine development. He conducted experiments by injecting monkeys with both known and unknown strains of the virus, monitoring their responses to assess the vaccine's effectiveness [25]. His efforts led to the development of a vaccine that was found to be safe and effective. Similar to the work of Howard Howe, Salk's vaccine utilized a killed virus, specifically using formaldehyde to destroy the live virus [26]. In 1954, he inoculated himself, his wife, and his children who thus became the first humans to receive his vaccine [3].

Salk might also have been influenced by Howe's research in his selection of subjects for trial vaccinations. In 1952, he began testing his vaccine at the D.T. Watson Home for Crippled Children in Pennsylvania, near Pittsburgh [12,28,29]. The Watson Home had been established in 1917 as a residential school for children with disabilities [29]. The Watson Home was near to the University of Pittsburgh and could provide the test subjects needed.

Beginning in 1952 Salk, assisted by the medical director of the Watson facility, began the initial human testing of his polio vaccine here. Salk first met with the children and their parents to discuss the process and answer their questions [30]. The initial group included 43 children [28,31]. The children involved in the vaccination study had varying levels of immunity to polio, with some having already been affected by the disease and others being completely susceptible, while some had congenital physical conditions [25,30]. Salk's research demonstrated that his vaccine was effective in promoting the development of antibodies in both groups, regardless of their prior exposure to polio. This finding was significant in understanding the vaccine's ability to provide protection against the disease [26,32,33].

Salk continued his research at the Polk State School in western Pennsylvania, an institution for people with intellectual

and developmental disabilities, located about 1½ hours from Salk's laboratory at the University of Pittsburgh. It afforded access to test subjects at the facility. At Polk, Salk first inoculated children who were already polio victims with a vaccine derived from the same virus type present in their blood to assess their immune response. Following this, he vaccinated other children who had not previously contracted polio and who lacked protective antibodies. The results were promising, as none of the vaccinated children developed polio, despite a small risk that some residual live virus might remain due to the vaccine's formaldehyde treatment [2,6,33]. Widespread use of the vaccine followed within the next several years, and the rate of occurrence of polio was diminished by 98% by 1961 [30].

Albert Sabin

Unlike Howe and Salk, Sabin was developing an attenuated live virus vaccine, believing that only a living virus would be able to guarantee immunity. Because it would be oral, it would be superior to an injection, easier to administer, less expensive, and could facilitate mass immunization efforts. It was administered through the use of sugar cubes which offset the bitter taste of the vaccine itself [2-4,27].

Sabin (1955) [21] first tested these live virus strains on humans, including himself, his family, and his research associates. Then, rather than using subjects with disabilities, Sabin instead opted to recruit prisoners from the Chillicothe Penitentiary, a prison that was close to his research laboratories at the University of Cincinnati [21]. Thus, Sabin's initial testing was done on inmates, who would be said to be volunteers, at the prison. The American Medical Association in 1952 had prohibited the research use of convicts but had not enforced that rule. Consequently, they could become unwilling or subtly coerced subjects with consent neither needed nor given [34].

Sabin's first trial was on 30 prisoners (27). He (1955) reported on his efforts at Chillicothe:

Most of the men who were fed the experimentally segregated attenuated poliomyelitis viruses...were available for a check on the level of their antibody six months after ingestion of the virus. In all instances the titers (e.g., measures of antibodies in the blood) were either the same or higher at 6 months than at three months. In a number of instances... higher titers occurred in those volunteers who were fed for a second time a virus three months after the initial ingestion of another type [21].

Sabin (1955) further noted that:

The studies that were carried out on chimpanzees... gave new indications of resistance and convalescent chimpanzees and further indicated that tests on human beings would not be very significant except in children or adults who happened to be without antibody for this virus. Although there is a possibility of doing such tests on a small scale at Chillicothe,... I did not want to jeopardize the work on poliomyelitis at Chillicothe by proposing a

new type of experiment [21].

Sabin (1955) consistently referred to the people who participated in this study as volunteers. With this research, Sabin is said to have offered the volunteers \$25 to participate and to have promised the participants some days off of their sentence [3]. This may have constituted an interesting take on the concept of volunteerism and one that bears some distant resemblance to offering release from a state institution for people with developmental disabilities in exchange for an agreement to undergo sterilization [35].

In October 1955, a new series of tests were scheduled on another group of twenty "volunteers" at the facility [21,36].

In a letter to the warden at Chillicothe, Sabin (1956a) noted:

I greatly appreciate your kindness and offering to check the enclosed lists and call the men together.... As I mentioned, the information that would be desirable to have before calling the men would be:

- 1. That they are all at least 21 years of age;
- 2. That there is no contraindication to their service as

volunteers from the administration point of view! And that they will not be leaving the institution very shortly after April 12, and for that reason it would be helpful if the date of possible release be indicated on the sheet opposite the man's name. On Friday, March 23, I should like to be able to inoculate nine volunteers with their first shot of vaccine [36].

The United States delayed approval of Sabin's vaccine, in part because of the Cutter incident (see below). The vaccine was next used in the Soviet Union, where over 60 million Russians took his vaccine before more than several hundred Americans did. While developing his vaccine, Sabin was in contact with Hillary Koprowski, who was also researching the use of live viruses. However, efforts at collaborative work were impacted by professional disagreements [37,38].

Hilary Koprowski

As with Howe, Salk, and Sabin, Hilary Koprowski was also a pioneering scientist in the fight against polio and was instrumental in the development of a polio vaccine. Working at Lederle Labs in Pearl River, New York, Koprowski focused on creating an oral polio vaccine, a groundbreaking concept. Inspired by his success with the yellow fever vaccine, Koprowski used a similar approach of attenuating the virus to make it less virulent, so it could stimulate an immune response without causing disease. His oral polio vaccine, developed in 1948, showed promising results in animal trials [37]. In a bold step, he administered the vaccine to himself, which led to a measurable antibody response against polio virus [27]. Unlike Salk's vaccine, which used an inactivated (killed) virus, Koprowski's approach was, as was Sabin's, with a live but attenuated virus, showing promising immune responses without causing disease in the tested [39,40]. Koprowski's early successes

with live-virus vaccines provided a crucial proof of concept to help pave the way for the eventual widespread success of vaccination programs [40].

After testing the safety of the vaccine by having his family, and himself, exposed, he then administered it to residents with intellectual disability at Letchworth Village in Rockland County, New York in 1950 [42,43]. Letchworth, opened in 1911 to be a model for compassionate care, ultimately warehoused as many as 5,000 residents before closing in 1996 [42]. As noted previously with the research of Howe and Salk, Letchworth combined the dual benefits of proximity to Koprowski's laboratories, and the availability of institutional residents as research subjects. George Jervis, the administrator of Letchworth, contacted Koprowski for help amid growing concerns about a potential polio outbreak at the facility. He was particularly worried about the spread of the disease due to unsanitary conditions. The proximity of several polio cases in nearby towns further heightened the concern. Jervis asked if Koprowski would permit the use the vaccine to immunize the children and staff at Letchworth. This intervention in the early 1950s would be the first human immunization with the oral polio vaccine as part of a larger effort to determine its safety, efficacy, and ability to stimulate immunity against poliovirus, particularly in populations at high risk [39,44].

On February 27, 1950, the first child (described as a nonimmune male "volunteer") received this first vaccine immersed in cod liver oil and immersed in chocolate milk; it was reported to be swallowed without difficulty. Polio antibodies were then detected in the child's blood. Subsequently it was given to a second boy, and they monitored the boys for several weeks. After two successful outcomes, it was given to eight other "volunteers." None displayed signs of illness and all had antibodies in their blood [44]. A decision was made to extend the trial to 19 other children who also ingested the vaccine and became immunized [45]. Seventeen of the 20 children developed antibodies to the virus while three others already had antibodies. None were reported to have developed complications [39]. Initial reports were positive; the vaccination at Letchworth was thus a key event in the development of the vaccine [28]. None of the children developed polio from swallowing the live virus vaccine and none had experienced complications, although there had certainly been risk [41].

There was a requirement at that time that the federal government approved the marketing of drugs, but not their testing. While the tests were approved by the Letchworth administration, this fact left open the question of whether permission was obtained for research. Klein [5] reported that Koprowski requested permission of the State Department of Health for permission to test the effectiveness on children with intellectual disability in New York.

Rivers and Benison (1967, p. 465-466) noted that:

The State Department of Health wrote to me (Rivers) and asked what I thought of doing such a test and I wrote back and told them I was opposed to it. At first, I didn't think that the safety test that Dr Koprowski had done were anything to write home about, and second, I personally did not approve of using mentally defective children for such a test period [18].

It appears that Koprowski did not seek formal permission to conduct these experiments, because he knew that he would be refused. Koprowski's [46], wife summarized his recollections of this process, noting that he realized he would never get permission from the State of New York. Given these regulatory hurdles, the option was parental consent to test the vaccine on their children. However, there was no mention in his original report of that consent being sought or granted [39,47,48].

Koprowski et al. (1952) [39] described the vaccines at Letchworth Village as "volunteers." The definition of what constituted a volunteer appears to be at significant variance from the way that they were described by Sabin in his work in Ohio [21,36]. Nevertheless, he referred to them as "volunteers," though their ability to provide informed consent was at best limited. The case of "Volunteer No. 1," a six-year- old boy who required a stomach tube for vaccination, underscores the vulnerability of the subjects involved. The other nineteen "volunteers" had similar multiple disabilities [6,39]. The research reaffirmed the notion that residents in institutions could serve as human guinea pigs [33].

The decision to use this vulnerable population sparked significant national and international backlash once the results of the trials became public. At the time, clinical consent laws were more permissive than they are today, but even within the context of those more lenient regulations, the ethics of using institutionalized children in medical experiments raised serious questions. Koprowski faced condemnation for his choice of subjects, as the children at Letchworth were not able to give informed consent. Rivers, of the Rockefeller Institute, expressed concern about the ethics of the Letchworth experiments, particularly about the use of children with intellectual disability as test subjects. However, he did acknowledge that such practices were not unusual at the time for using vulnerable populations in medical research; "you might even say it was standard practice" [18].

Koprowski, in a footnote to Rivers (Rivers & Benison, 1967, p.466), commenting on the use of subjects, offered the following account:

Dr. Rivers presents a confused picture of the facts. He cannot be blamed for it because he had very little to do with the group which discovered the live virus vaccine and therefore he did not have the facts in hand. During his visit, Dr Rivers was generally enthusiastic about the original work, which by then had already been reported, and he admired the courage of those who were able to take their first step in this right direction. He voiced no

opposition to a new trial to be conducted in an institution for mentally defective children, and gave the general impression that he would support this trial wholeheartedly.

Koprowski [18] confirmed that, because the negotiations about approval had dragged on for a long time with the officials of the New York State Department of Health, his live virus vaccine trials were to be continued not in New York but in California. Thus, he opted to conduct his vaccine research on children with intellectual and developmental disabilities in that state [49]. In July 1952, he tested his oral vaccine at Sonoma State Hospital.

Sonoma had initially been established in 1883 as the California Home for the Care and Training of Feeble-minded Children and later was renamed in succession the Sonoma State Home, the Sonoma State Hospital, and then the Sonoma Developmental Center. Dating back to the late 1800s, Sonoma was California's primary institution for the "feebleminded" and was one of two such state facilities. Over the years, thousands of patients, sometimes for a few months and sometimes for decades, lived there [35,50].

Koprowski and colleagues sought and obtained permission from California authorities to test his vaccine on the children at Sonoma [48]. Thus, 61 girls and boys with intellectual disability as their primary diagnosis, were given the new vaccine. The children ranged in age from eight months to eight years of age. It was provided in a glass of chocolate milk, and it was said to be an extra treat for them. Parents, according to unconfirmed reports in news articles of the time, indicated that the subjects had been given the vaccine with their permission [50,51].

Koprowski et al. (1953; 1956) [40,49] reported that 52 of the 61 children developed antibodies, however, the live virus existed in six of the tested children's feces. These children were observed for three hours a day on a plastic mat where they were mixed together with another eight children who lacked antibodiesthose with the infected feces and those who were not immunized to see if there would be transmission of the feces. Although the mat was washed down to remove gross soils (i.e., urine, feces), it was not disinfected. Three of the non-vaccinated children became infected [40,44,48].

In spite of the controversy and the ethical concerns raised, Koprowski and his colleagues pressed forward with research into the polio vaccine and continued with clinical trials and the development of the oral polio vaccine, which would become a cornerstone of global efforts to eradicate polio. Specific studies that ensued extended the findings of the initial trials at Letchworth and Sonoma regarding the efficacy and safety of the live attenuated poliovirus vaccine [52]. Flack et al. (1956) [53], reported on the safety and efficacy of administering live attenuated poliomyelitis virus to infants. Findings included: all developed active immunity; the vaccine was safe for infants under one month of age; and contact with other infected infants did not

result in transmission of the virus to those who had not received the vaccine. The study provided evidence for its use in very young children, laying the groundwork for later widespread vaccination efforts [53].

Koprowski's continued use of institutionalized populations for his vaccine trials included conducting studies on female prison inmates at the Clinton Farms prison in New Jersey [54,55]. Many of the inmates involved in the trials were young mothers under age 21 (some of whom had their babies with them), and at that time, clinical trials involving minors considered unable to provide full informed consent were subject to strict regulations. However, the state attorney general waived the age restriction, effectively allowing the trials to proceed without the usual legal or moral safeguards that would apply. This decision raised significant ethical concerns, as the use of young women, especially those from marginalized groups such as inmates, posed serious risks regarding informed consent and potential exploitation.

Rivers (in Rivers & Benison (1967, p. 466) stated [18]:

I don't even know if you can actually call a prisoner a volunteer. Although prisoners are usually told they will get nothing out of volunteering as guinea pigs, deep down they believe they may get a commutation or reduction to their sentence....the point is, prisoners are generally adults who could weigh the pros and cons of submitting to a test, and if they arrive at a decision to participate in a test, a decision or judgment they have made, it's not made for them.

Despite these legal workarounds, the results of the trials were not entirely positive. The vaccinated inmates did not consistently develop antibodies to the polio virus, indicating that the vaccine was not as effective in this population as anticipated [44]. In summary, Koprowski's continued use of institutionalized populations, combined with the ethical and legal challenges he faced, marked a significant chapter in the history of vaccine research. While the outcomes of these trials contributed to the eventual development of the polio vaccine, they also raised important ethical concerns that would shape future medical research practices. It also illustrates the repeated emphasis on the use on vulnerable populations, and often with developmental disabilities, in research programs.

Koprowski (1960,2006) [54,55] sought to expand his testing in different parts of the world, particularly in places where the polio threat was more immediate. In Northern Ireland in 1957, he persuaded the local medical community to administer his oral vaccine to children with parental consent. Initially, the trial went well, with no ill effects reported, and the children exhibited a positive immune response. However, concerns arose when some fecal samples from the children revealed that the virus had regained some potency after passing through their digestive tracts. This finding led to worries about the potential for the virus to become more virulent after passing through

human hosts, posing a public health risk. As a result, Great Britain prohibited such trials [27]. Unable to continue his trials there, in 1958 Koprowski turned his attention to the Belgian Congo (now the Democratic Republic of the Congo).

The government of the Congo requested that Koprowski's vaccine be administered to approximately 250,000-primarily infants and young children- in a region where polio was feared to be on the verge of an epidemic. Koprowski's team arranged the trial, and the vaccine was distributed to this large population [56-58]. However, the results of the trials were deemed unreliable due to the haphazard nature of the testing, the lack of a structured regimen, and the data gathered from these trials were not scientifically robust to draw reliable conclusions about effectiveness [44]. Despite vaccinating a large population, the hastily organized trial failed to provide meaningful experimental results.

By 1960, Koprowski's oral polio vaccine was being used across four continents with 13 million vaccinated, marking significant strides in global immunization efforts [55,59,60]. However, the challenges encountered during these early trials underscored the complexities of conducting human vaccine trials in the mid-20th century [27].

Given the challenges inherent in these respective trials, and in spite of the success achieved, as Koprowski developed the first oral polio vaccine, Sabin would win the oral vaccine race, and his form of live virus was adopted for widespread use in the United States although there would be delay in terms of widespread availability [34,43].

Cutter Incident

The Cutter Incident, a pivotal event in the history of vaccine safety, highlighted both the risks of early vaccine production and the critical importance of stringent oversight. In April 1955, Salk's vaccine had been declared to be safe and effective. Soon after public release to five pharmaceutical companies, a contaminated batch of 120,000 doses from Cutter Laboratories contained live virus instead of the inactivated form. This tragic accident led to approximately 70,000 cases of muscle weakness, well over 100 with severe paralysis, and ten fatalities [27,34,61]. Initially the consequence of the Cutter incident was the suspending of the approval of vaccinations, with some fearing the vaccine more than the disease [34].

However, despite its consequences, the Cutter incident did drive significant reforms in pharmaceutical manufacturing and regulation. Federal agencies responded by strengthening safety protocols, ensuring higher standards for production and distribution. The incident served as a stark reminder of the balance between rapid innovation in public health and the necessity of rigorous standards [27]. The Cutter incident also underscored the risks that many residents of institutions had undertaken, most often involuntarily, in participating in the programs of vaccine development and application.

Conclusion

Jonas Salk won the initial major victory over the polio epidemic with his killed virus. While Koprowski had developed the initial live attenuated polio vaccines, Sabin's virus received approval as he won the race for establishing an oral vaccine, which had been approved in 1960. In 1999, a federal advisory panel recommended a return to the Salk vaccine because the killed virus approach could not accidentally result in the transmission of polio and had been associated with no confirmed cases. That recommendation was reconfirmed ten years later [2,26,30,34]. Many millions of people benefited from these triumphs.

It is important, however, to acknowledge the role that people in residential facilities-with intellectual and developmental disabilities in many cases, volunteers or not- played in this history of medical success. Their names are not noted in the pantheon of polio research, but their contributions should not be forgotten.

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