History of Medicine and Ethics

The history of polio vaccination with "Sabin's OPV" 60 years after its introduction in Italy: an unforgivable "delay"

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Summary

In the spring of 1964, polio vaccination with the oral vaccine developed by Albert Sabin began in Italy. Polio was feared in the world and in Italy. Thus, between 1957 and the beginning of 1958, Italian children began receiving the "Salk vaccine", though the results were not particularly convincing. In July 1960, the international scientific community was able to verify the data from the mass testing of the Sabin vaccine. It became clear that the OPV, could prevent the virus from multiplying, thereby providing greater protection and determining the eradication of the disease. In 1960 over 70 million people in the USSR alone had already received the oral vaccine and mass vaccination in the USA would start in March 1961. However, in Italy there was no similar initiative; only later the new vaccine was accepted but was not made compulsory at the beginning. As a result of the commission's report, registration of the "Polioral" vaccine, was authorized in September 1962 but the sale of the vaccine was not authorized until November 1963. At the beginning of 1964, the production of "Polioral" started and the product was marketed and on the 1 st of March 1964, anti-polio vaccination with the "Sabin anti-polio vaccine" also began in Italy.

This manuscript focuses on a crucial issue about a historical delay for public health and it points out as the preparation and diffusion of the Sabin polio vaccine demonstrates that decisions regarding health treatments, and specifically vaccination campaigns, must be based exclusively on the results of clinical studies and on independent evaluation by the scientific community. This process ensures trust in vaccines, adequate protection of public health andcitizens' well-being.

Background

In the spring of 1964, polio vaccination with the oral vaccine developed by Albert Sabin began in
Italy. Sabin's name became known to Italians on the occasion of the 3rd International Polio Conference, which was held in Rome in September 1954. At the Conference, two speakers aroused keen public interest: the American bacteriologist, Jonas Edward Salk (1914-1995), professor of virology at the University of Pittsburgh, who presented his Studies on non-infectious vaccines in poliomyelitis, and a Polish naturalized American professor, Albert Bruce Sabin (1906-1993), director of the Children's Hospital Research Foundation of the University of Cincinnati, who discussed non-virulent viruses for immunization against poliomyelitis [1, 2] (Fig. 1).

In the same year, John Franklin Enders, Thomas Huckle Weller and Frederick Chapman Robbins were awarded the Nobel Prize for Physiology and Medicine "For their discovery of the ability of poliomyelitis viruses to grow in cultures of various types of tissue" [3]. Indeed, at the end of the 1940s, the research group directed by Enders succeeded in cultivating the polio virus in large quantities

Fig. 1. Albert Sabin examining a control preparation of his vaccine at the Sclavo Institute (Photo: University Museum System of Siena - SIMUS).

in the laboratory, thereby laying the foundations for the development of future vaccines. Over the next few years, several researchers carried out various studies aimed at producing a vaccine against polio. An apparently rare clinical condition that occurred only sporadically before the end of the 19th century, the disease spread globally after the beginning of the 20th century. "At its height, from 1950-1954, poliomyelitis resulted in the paralysis of some 22,000 U.S. citizens each year, equivalent to an average annual rate of 14.6 per 100,000. Many thousands were left permanently disabled by the disease, while many others suffocated as a consequence of respiratory paralysis" [4].

The American writer Philip Roth (1933-2018), in his novel Nemesis, described the public anxiety at the time: "People are up in arms. People are terrified. Everybody is frightened for their children" [5].

Given the growing number of cases and the public's rampant fear, virologists claimed that a vaccine was the only hope. Building on the results obtained by Enders, Jonas Salk developed his Inactive Vaccine (IPV) against polio at the beginning of the 1950s. Based on a virus that had been killed with formaldehyde, this vaccine was injected intramuscularly and favored the appearance of antibodies, thereby eliciting immunity to the disease. In 1952, Salk had already administered his vaccine to 43 children. Meanwhile, in 1953, the United States suffered its largest polio epidemic, with 58,000 cases and 3,100 deaths. Despite fears and doubts regarding the vaccine, awareness that it was needed was steadily growing.

On April 26, 1954, the first large blind clinical trial ever performed began, which involved nearly 2 million children. It took a year to complete the analysis of the results, and on April 12, 1955, Salk's inactivated vaccine (IPV) was declared to be effective. The fight against polio had apparently been won [6].

In the last days of April 1955, however, just two weeks after distribution of the vaccine had started, a serious accident occurred. Two batches of the vaccine produced in the laboratories of "Cutter" (a Berkeley pharmaceutical company) contained residues of live poliovirus: 192 cases of paralytic polio occurred among vaccinated children and their family members, and 11 people died [7].

The incident prompted the government to suspend the vaccination program and to revise federal requirements for vaccine production. Above all, it generated profound public mistrust of vaccines and led to the suspension of studies on the development of new vaccines [8, 9].

Meanwhile, at the University of Cincinnati, Albert Sabin was also working on a vaccine. However, he adopted a completely different approach; he prepared a vaccine from a live attenuated virus obtained through various passages of the virus in culture so that it lost its pathogenicity. This was the beginning of the Oral Polio Vaccine (OPV).

Commercial interests in the United States, however, led to a sort of boycott of the OPV, and Sabin was forced to carry out his large-scale testing in the Soviet Union. From 1959 to 1961, millions of children were vaccinated with his vaccine, 77 million in the USSR alone. These first vaccinations yielded gratifying results. Nevertheless, despite these good results, the National Foundation for Infantile Paralysis preferred to continue its prevention campaigns with Salk's preparation, which had been perfected [10]. Only in 1960, thanks to an important endorsement by the WHO, there was a trial of the "Sabin vaccine" undertaken in the United States. This ushered in a new era of the polio vaccine, and the USA definitively replaced Salk's vaccine with Sabin's. Sabin's vaccine was cheap to produce and very easy to administer on a sugar lump to children. The method of administration of the Sabin vaccine inspired the popular song, written by the Sherman brothers, in the film "Mary Poppins", the refrain of which states: "Just a spoonful of sugar helps the medicine go down in a most delightful way" [11].

Poliomyelitis in Italy: a tragic delay in the acceptance of Sabin's vaccine

Polio was also feared in Italy, where between 4,000 and 8,000 cases occurred every year. Thus, between 1957 and the beginning of 1958, Italian children began receiving the "Salk vaccine", however the results were not particularly convincing. In the same period, during the International Conference on Polio held in Copenhagen in July 1960, the international scientific community was able to verify the data from the mass testing of the Sabin vaccine. It became clear that the OPV, which acted directly at the intestinal level, where the first infection occurs, could prevent the virus from multiplying, thereby providing greater protection and determining the eradication of the disease. Almost a year earlier, on the 4th of September 1959, Sabin himself had held a conference in Milan entitled "Present status of field trials with an oral, live attenuated Poliovirus Vaccine", during which he had explicitly stated: "In none of the preliminary studies, involving several thousand children and adults, was there any evidence that multiplication of the vaccine strains in susceptible persons was associated with any distinct illness" [12].

A few months later, at the Institute of Health in Rome, Sabin presented a report entitled: "Results of mass vaccination with a live polio vaccine in various parts of the world"; in which he fully confirmed the positive data obtained. He added that in 1960 over 70 million people only in the USSR had already received the oral vaccine. He also announced that mass vaccination in the USA would start in March 1961. But in Italy, by contrast, nothing changed. The Minister of Health at the time, Camillo Giardina (1907-1985), by speaking in October 1960 in Rome at the International Congress of Pediatrics publicly stated that, as the sole person responsible for safeguarding public health, he would not allow Italian children to be used as guinea pigs in experiments aimed at authorizing the Sabin vaccine, which was still in the experimental phase. Thus, the vaccine was not registered in Italy, nor was its manufacture authorized for export purposes.

A few months later, on May 17, 1961, the newspaper "L'Avanti!" announced that a Polish- American scientist,

Albert Sabin, had eradicated polio in the USA, the USSR and some Eastern and European countries, while in Italy thousands of children continued to die owing to the use of an inefficacious vaccine. The front-page headline caused a political and social storm, and Italians were divided between those in favor and those against the Sabin vaccine. Those who were against the Sabin vaccine went so far as to claim that the viruses used in the Sabin vaccine, even though attenuated, immunized the recipient, but could prove dangerous for the rest of humanity. That is, the vaccine became a sort of "virus-laden bomb": a spreader of disease.

The only option therefore was to vaccinate the entire Italian population in a very short time. In fact, Sabin's vaccine induced extraordinary immunity. The attenuated virus replicated in the same way as the original virus; however, owing to the modifications made in the laboratory, it lost its ability to reach the central nervous system. Unfortunately, in one case out of 750,000, the attenuated virus "retro-mutated" as it replicated, returning to its original form. In this way, it recovered its ability to reach the central nervous system causing poliomyelitis, that was very similar to the disease caused by the "true" virus, especially in subjects with a diminished capacity to produce antibodies. For this reason, once the emergency phase of the epidemic had passed, vaccination campaigns went back to using the Salk vaccine, which, being prepared from an inactivated virus, was unable to replicate and could not therefore give rise to a retro-mutation [13, 14].

The risk was that years of research might be nullified because of an untrue and unverifiable statement. Fortunately, this did not happen, and the vaccination campaign continued. However, while the rest of the Western nations were moving towards replacing the Salk vaccine with the Sabin vaccine, Italy was still lagging behind. Only in December 1963, with the first Moro Government and Minister of Health Giacomo Mancini (1916-2002), vaccination with the Sabin vaccine began in Italy.

Given the need to proceed quickly, the Council of State authorized private negotiations to identify the company that would produce the vaccine. The choice fell upon the Tuscan Serotherapy and Vaccinogenic Institute, which had been founded 60 years earlier in Siena by Achille Sclavo (1861-1930) [15, 16], and which offered the most competitive price nationally and internationally.

The close relationship between Albert Sabin and Sclavo's Serotherapy and Vaccinogenic Institute

On inviting Sabin to a conference in Milan in 1959, Augusto Giovanardi (1904-2006), professor of Hygiene and Bacteriology and director of the Institute of Hygiene and of the Institute of Virology of the University of Milan, mentioned a small but important Italian producer of vaccines; this was the Serotherapy and Vaccinogenic Institute of Siena, which Achille Sclavo had founded in 1904 [17].

Fig. 2 Albert Sabin in a meeting with the managers of the Sclavo Institute in the early 1960s (Photo: University Museum System of Siena - SIMUS).

It should be remembered that Giovanardi's teacher, the hygienist Donato Ottolenghi, had been one of Sclavo's students, and Giovanardi himself had taught hygiene from 1938 to 1942 at the University of Siena, occupying the very chair that had been held by Achille Sclavo. He therefore knew very well the potential of the Sienese Institute of which he was a consultant.

Sabin visited the Sienese Institute several times and appreciated the high technical level achieved by the company and the constant updates implemented to create a product that complied with the regulations of the time (Fig. 2). He therefore chose the Institute to produce his vaccine and sent 50 ml of each of his three original strains to the Sclavo Institute for free, to enable the vaccine to be produced in Italy as soon as possible.

However, Minister Giardina remained wary of the Sabin vaccine and, in the newspaper "Corriere della Sera", reiterated the statement he had made a few months earlier: "The Minister of Health will never allow new medicines to be tested on the Italian population unless it has been confirmed with certainty that these drugs are not harmful" [18].

Nevertheless, work at the Sclavo Institute continued. The Minister then sent two inspectors to the Institute, who sequestered the batches of vaccine that had already been made, and ordered that production had to be suspended. The following months were very difficult for the Institute, which had invested a substantial amount of money. Meanwhile, the public was gradually becoming convinced of the efficacy of the Sabin vaccine, which was now also being used successfully in the USA.

The new Minister of Health, Angelo Raffaele Jervolino (1890-1985), set up a parliamentary commission to report to the Superior Council of Health on Sabin's vaccine. The new vaccine was accepted but was not made compulsory. As the vaccine contained live attenuated viruses, the commission also recommended to extend the treatment to all members of the vaccinee's family, who were most directly at risk of contagion by the vaccine virus [19]. As a result of the commission's report,

registration of the "Polioral" vaccine, as requested by the Sclavo Serotherapy and Vaccinogenic Institute, was authorized in September 1962 [20]. However, sale of the vaccine was not authorized until November 1963.

The Sclavo Institute's "Polioral" vaccine begins to be exported worldwide

At the beginning of 1964, production of "Polioral" – the name under which the vaccine was registered (patent N. 151731, deposited by the Tuscan Sclavo Serotherapy and Vaccinogenic Institute on 10 th September 1959 and granted on 9 th November 1960) – started in Siena and the product was marketed. The Sclavo Institute delivered the vaccines at a rate of one million doses per day, and on the 1st of March 1964, in the presence of the President of the Republic Antonio Segni (1891-1972), anti-polio vaccination with the "Sabin anti-polio vaccine" also began in Italy (Fig. 3).

Fig. 3. The Sabin oral polio vaccine is shipped worldwide from the Siena Virology Center. (Photo: University Museum System of Siena - SIMUS).

"From 3-4,000 cases annually in the 5-year period 1959-63, the number fell to 841 in 1964. Subsequently, the annual number of cases continued to decline: 254 in 1965, 148 in 1966, 107 in 1967, and 90 in 1968. In 1972, there were ten. This was a great victory for medicine, but for the Italian health service, it was a bitter lesson: no more delays or postponements" [1, 21] (Fig. 4).

Such a sensational case raises questions and underlines the lessons that history can offer. The first question certainly concerns the reasons behind the unfavorable attitude towards Sabin's vaccine – an attitude which led to a split in public opinion and, above all, a culpable delay which caused the death of thousands of people who could have been saved. According to the historian Giorgio Cosmacini, "The delay (in starting polio vaccination with the Sabin vaccine) cost Italy almost 10,000 cases of polio, which caused more than 1000 deaths and more than 8000 cases of paralysis" [1]. Indeed, in the three years that Italy waited for the Sabin vaccine, 8,431 people remained paralyzed and 1,087 died; this was the price for the Ministry's excessive caution towards the attenuated vaccine.

An important role in the decisions of the Italian Government was played by the heavy investment that the pharmaceutical companies had made in order to acquire the machinery necessary to produce the Salk vaccine, and the enormous stocks of that vaccine already available. Indeed, a sudden change of direction towards the Sabin vaccine would probably have meant that the existing stocks would have gone unused and the costs of the machinery would not have been recovered.

But in such a vital project as that of a mass vaccination campaign, efficient communication is also essential. Indeed, in 1964, Minister Mancini categorically stated that the most important factor in the success of the vaccination program was that of information. Mancini therefore supervised this phase himself, making personal appeals to health officials, doctors, mayors and

Fig. 4. Cases of polio reported in Italy between 1955 and 1972. In 1964, the year when vaccination with OPV started, the number of cases dropped from 2830 to 842 and never rose again.

the public [22]. Two thousand assistants and 11,000 care centers of the "Opera Maternità e Infanzia" came to the aid of Italian families in what was an unprecedented vaccination campaign. This mobilization enabled a great number of children and young people to be vaccinated in a short time (Fig. 5).

By 1965, the results were already evident: 254 cases occurred in the whole year, as against the annual average of 2,000 in the previous years.

Mancini engaged in an intense campaign of information and dissemination and involved famous cinema personalities as testimonials [22]. The objective of that colossal mobilization was to defeat polio.

In a few years, the number of polio cases dropped below 100, and the disease finally disappeared in 1983. This was the result of Sabin's vaccine and of a vast awareness-raising campaign. It was also the result of the efforts of the great Institute founded by Achille Sclavo, who "always proclaimed the right of Public Health to be understood as a true branch of Medicine (.). He conceived of it as preventive medicine, knowing full well that only an attentive government and an educated population (.) would enable an adequate safety threshold to be reached" [23]. Finally, credits are attributed to those who contributed to the project in many ways, such as Rotary International, which, as a founding partner of the Global Polio Eradication Iniziative, has been committed to the eradication of polio for over 35 years (Fig. 6).

Fig. 5. One of the posters prepared by the Ministry of Health (Archive of the Gruppo Anziani Sclavo).

Fig. 6. Gadget commemorating Sclavo SpA's donation of considerable quantities of vaccine for the campaign against polio in the world's poorest countries (Archive of the Gruppo Anziani Sclavo).

Conclusions

The story of the preparation and diffusion of the Sabin polio vaccine demonstrates that decisions regarding health treatments, and specifically vaccination campaigns, must be based exclusively on the results of clinical studies and on independent evaluation by the scientific community in order to ensure trust in vaccines, adequate protection of public health and well-being and to decrease citizens' vaccine hesitency.

A lesson that can be learned from the past is that we need to convey correct information on vaccines, on their effectiveness and on their possible side-effects in order to dispel citizens'; doubts and reduce so-called "vaccine hesitancy", a phenomenon that arose with the first smallpox vaccine, prepared by Edward Jenner [24, 25].

It is therefore necessary to implement what is now defined in the communications field as "prebunking"; *i.e.,* a method of forewarning people against potential disinformation and, above all, of fostering public skepticism towards fake news [26]. This also avoids the need for subsequent "debunking", *i.e.* the refutation of false information, which can generate insecurity in people and fuel further fears [27]. To achieve these objectives, and in particular vaccine hesitancy, information must be clear, accessible, impartial, and based on scientific data. It is also essential is to create a relationship of trust with citizens, through clear and consistent messages from competent institutions [28].

Effective communication in the healthcare field, in fact, must be able to support and promote, through the exchange of information between healthcare workers, patients and any other stakeholders, understanding, trust and collaboration.

For this reason it must include the involvement of patients in the decision-making process, the evaluation of health literacy levels, the guarantee of privacy, suitable time for communication, correct and properly documentation

of information and efficient and profitable use of technology skills.

In this way, healthcare professionals can create and establish strong relationships with patients, improve and develop patient satisfaction, increase patient safety, and deliver better healthcare outcomes.

To achieve these goals there are some key aspects of effective communication in healthcare: Clear and Concise Language, Active Listening, Non-Verbal Communication, Empathy and Respect, Cultural Sensitivity, Health Literacy, Use of Visual Aids, Collaborative Decision-Making, Timely and Accurate Documentation, Use of Technology that can support effective healthcare communication.

Concerning the communication techniques, the World Health Organization (WHO) has identified six key points for good communication, stating that it should be: "Accessible, Actionable, Credible, Relevant, Timely, Understandable (Fig. 7). To meet that goal, WHO focuses on communicating to and with key audiences who are the health decision makers – those agents who use WHO communications products to make a range of health decisions" [29].

"By integrating the principles of this framework into all WHO communications, we will stimulate innovation toward improved health outcomes, constantly challenging ourselves to identify better and more efficient ways to engage key audiences in communication and interaction" [29].

These suggestions can contribute to the eradication of polio ("Polio Eradication Strategy 2022-2026") [30].

The Strategy for the Eradication of Polio 2022-2026 provides an integrated approach to achieve the promised eradication objectives and, specifically, the following goals:

- create urgency and accountability to generate greater political will by re-envisioning the GPEI's relationship with governments and systematizing political advocacy;
- generate vaccine acceptance through context-adapted community engagement that reduces refusals and increases community commitment to child immunization;
- expedite progress through expanded integration efforts with a broader range of partners in immunization, essential health care and community services;
- improve frontline success through changes to campaign operations and outbreak response operations;
- enhance detection and response through sensitive surveillance that provides the programme with critical information for action [30].

Fig. 7. WHO principles for effective communications (Strategic Communications Framework for effective communications. WHO 2017.

Specifically, the Strategy for the Eradication of Polio 2022-2026 includes two goals: permanently interrupt all poliovirus transmission in endemic countries, and stop circulating vaccine-derived poliovirus (cVDPV) transmission and prevent outbreaks in non-endemic countries [30].

Indeed, massive vaccination supported by WHO, the United Nations Children's Fund (UNICEF), the US Centers for Disease Control and Prevention (CDC) and Rotary club through the Global Polio Eradication Initiative (GPEI) has reduced polio cases by 99% in industrialized countries including Italy, where polio vaccination is still provided for children, and it is included in the hexavalent vaccine (PNPV 2023-2025), with the aim to maintain the polio-free status [31].

Unfortunately, poliomyelitis disease poses a threat in countries such as Afghanistan and Pakistan where the wild type 1 (WP1) is still endemic or in countries where polio vaccination programs are not effective enough yet [32].

Vaccination therefore is a unique opportunity to stop the transmission of the virus, also considering the new vaccines under preparation [33, 34]. For this reason, it is imperative to respond positively to the scientific community's invitation to vaccinate against polio. Two great scientists of the past, Jonas Salk and Albert Sabin, made a precious gift to all the world's people, and especially the children - the hope of eradicating polio; it is a gift that should be welcomed.

And it is essential that this message is clearly conveyed by healthcare professionals. "Polio vaccination prevents the potentially life-altering effects of polio. The inter-professional healthcare team, including all clinicians (MDs - Medical Doctors, DOs - Doctor of Osteopathic Medicine, NPs - Nurse Practitioners, Pas - Physician Assistants), nursing staff, and pharmacists, must be aware that some parents may be reluctant to provide this vaccination for their children. […] By working as a team and utilizing open communication and data sharing, health professionals can educate the public about the risks and benefits of polio vaccination, overcome vaccine hesitancy, and contribute to patient and public health" [35].

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Authors' contributions

DO, MM: designed the study. DO: conceived the manuscript. DO, MM: drafted the manuscript. DO, MM, CM, LV: revised the manuscript. DO, MM LV, CM: performed a search of the literature. DO, LV, CM: critically revised the manuscript; conceptualization, and methodology, DO, MM: investigation and data curation. LV, CM, MM, DO: original draft preparation. Review all authors. LV, CM: editing. All authors have read and approved the latest version of the paper for publication.

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