Review

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T Jacob John , Dhanya Dharmapalan * , Norbert Hirschhorn , Robert Steinglass

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Review

Global Polio Eradication Has Failed: A Tragedy of Errors Over 37 Years

T Jacob John [1], Dhanya Dharmapalan [2,*], Norbert Hirschhorn [3] and Robert Steinglass [4]

[1] (retired), Christian Medical College, Vellore, Tamil Nadu 632004, India

[2] Independent researcher, Mumbai, India

[3] Independent consultant, Minneapolis, USA

[4] Independent immunization advisor, Marshall, North Carolina, USA

* Correspondence: drdhanyaroshan@gmail.com; Tel.: +919820274280

Abstract

Background: The global polio eradication initiative of 1988 has not succeeded after 37 years of intense efforts. The original targets for eradication were the three antigenic types of wild poliovirus. Type 2 was eradicated on time in 1999, type 3 was eradicated in 2012, but type 1 is yet to be eradicated. Moreover, as a consequence of the immunization strategy, new targets for eradication have emerged in the form of vaccine-derived polioviruses. We scrutinize the reasons for these failures to design actions to expedite eradication. **Methods:** A review of the design of the eradication strategy and immunization tactics was done to analyse the present complex situation with both wild and vaccine viruses needing eradication. **Results:** The safe and highly efficacious inactivated poliovirus vaccine (IPV), as compared to the live oral polio vaccine (OPV) with problems of safety and efficacy, was not utilized to benefit the eradication programme. Instead, OPV was chosen for exclusive use, not based on epidemiology nor vaccinology. That error was followed by more errors. The tragic consequence was vaccine-failure polio and iatrogenic polio affecting thousands of children in countries relying on OPV. **Conclusion:** The failure to complete polio eradication is due to the incorrect path taken by the polio eradication initiative. The right path, namely the exclusive use of IPV, must be adopted without delay to eradicate both wild and vaccine-derived polioviruses.

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Introduction

The World Health Organization (WHO), with headquarters in Geneva, Switzerland, has six Regional Offices. Before 1988, the Regional Offices of the Americas, Western Pacific and Europe had resolved to eliminate polio in their Regions by 1990 (Americas), or 2000 (Western Pacific and Europe) [1]. The remaining three – Africa Region (AFR), Eastern Mediterranean Region (EMR) and South-East Asia Region (SEAR) -- were assigned to the WHO headquarters to catch up and eliminate polio by the year 2000 [1].

Until 2000, the WHO initiative for global polio eradication was operationalized by the Expanded Programme on Immunization (EPI) [2]. After failing to reach the target of 2000, the period of 2001 to 2005 was proclaimed to be the 'End Game' by the director of EPI at the Institute Pasteur, Paris on 28 June 2000. Eradication was to be achieved by 2002 with global certification of eradication in 2005 [3]. During this period, responsibility for polio eradication was shifted to the Global Polio Eradication Initiative (GPEI), a new section in the Department of Vaccines and Biologicals, WHO, Geneva [4]. GPEI WHO expanded to become formally a partnership of WHO, UNICEF, U.S. Centers for Disease Control and Prevention (CDC) and Rotary International. The Bill & Melinda Gates Foundation became a major partner shortly afterwards and Gavi, the Vaccine Alliance more recently.

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By 2000, the former three Regions had eliminated polio caused by the natural wild polioviruses (WPVs) types 1, 2 and 3 [5]. Countries using the Salk inactivated poliovirus vaccine (IPV) exclusively had eliminated all polio, whereas many countries using the Sabin oral polio vaccine (OPV) could eliminate WPV polio but continued having a few cases of 'vaccine-associated paralytic polio' (VAPP) annually [6]. The USA used OPV exclusively from 1966 but added IPV in 1997 and withdrew OPV in 1999. It succeeded to be totally polio-free from 2000, complying with the target date of the polio eradication resolution [6]. New Zealand switched from OPV to IPV in 2002 to eliminate VAPP [7]. Several other countries followed suit.

After the so-called End Game also failed, in 2006, a director at WHO was appointed to head the GPEI [8]. We highlight here the EPI's and GPEI's failure to eradicate polio mainly in lower- and middle-income countries (LMICs) in AFR and EMR. As these countries strictly follow WHO prescriptions for polio vaccination, the cause-and-effect of the inputs and outcome merits serious scrutiny. Despite guiding the policy shift from OPV to IPV in the home country in 1997, the U.S. CDC continued supporting the exclusive use of OPV by GPEI in LMICs in AFR, EMR and WPR.

The polio eradication project has failed in three ways over these 37 years (1988 to 2025) and counting [9,10]: (1) Despite partial successes, WPV-polio has not been eradicated globally; (2) Because of the widespread use of OPV, hundreds of children continue developing vaccine-associated paralytic polio (VAPP) annually ; and (3) Ironically, GPEI's vaccination tactics have resulted in the opposite outcome to eradication, viz., the introduction of new genetic variants of vaccine viruses, called vaccine-derived polioviruses (VDPVs) causing sporadic polio, and circulating VDPVs (cVDPVs) causing recurrent polio outbreaks in AFR and EMR [11].

Our purpose in enumerating the errors and their consequences in the public domain is to exert strong and urgent policy, financial and moral influence on the GPEI and their well-meaning partners and funders. They must immediately commit to stop causing any more polio in the name of its eradication and fast-track the completion of the programme.

The Tragedy and the Errors That Led to It

The tragedy is not only not eradicating polio, but also causing iatrogenic polio in thousands of children during the past 25 years that should have been completely avoided.

If any such paralysing incident had occurred in a single child in the context of healthcare, it would have been deemed 'medical negligence' and the victim monetarily compensated.

The tragedy is that such incidents have occurred on a large scale in the context of public health, in which no individual can be called to account for the rampant 'public health negligence' and no victim (or family) is deemed eligible for any compensation despite disability or death. The leaders of the programme, while responsible for implementation, do not appear to be accountable to any higher authority.

The magnitude of the tragedy is enormous. There have been thousands of cVDPV-2 polio cases in recurrent outbreaks since 2005, in over 30 countries, while there has been no natural WPV-2 globally since 1999 [10]. There have also been several polio outbreaks caused by cVDPV-1 and a few outbreaks caused by cVDPV-3 in countries despite having no WPV-1 or WPV-3 polio [12]. All these were completely avoidable and cannot be condoned.

Two Fundamental Errors Misguided GPEI to Adopt a Wrong Path

The right path to polio eradication was to introduce a 3-dose schedule of IPV (preferably as a combination vaccine of DTP plus IPV) and one year later to withdraw OPV as illustrated by the USA example [6,13,14]. If this process had begun in the mid-1990s and a switch from OPV to IPV been completed by 1997, EPI could have succeeded to eradicate polio by 2000.

Among the many errors that led to the failure, two stand out as fundamental. Declaring war without knowing the enemy nor properly assessing the weapons at hand is asking for defeat. The EPI attempted to eradicate polio without understanding the epidemiology of WPV polio, especially

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its transmission route, and chose OPV without verifying its safety and effectiveness. Instead of revising policy, GPEI continued on the wrong path. Therefore, the failure is not surprising.

The EPI, launched by WHO in 1974, had six target diseases for prevention and control, including measles and polio [15]. By 1988, data had been collected over 14 years on the age distribution of measles and polio, both viral diseases, in order to understand their comparative epidemiology, discern the route of transmission, and determine the safety and effectiveness of tOPV (trivalent oral polio vaccine).

The route of measles transmission is respiratory, without any controversy. Measles was known to be highly contagious. Prior to the introduction of immunization, the median age of measles in rural Africa was in the range of 2.5 to 5 years [16]. The median age of measles in India was also 2.5 years [17].

The median age informs about the contagiousness, or 'force of infection', of the causative agent. The median age of polio was 11-13 months in India [18,19]. Polio attacked children twice as early as measles did. More widespread and nearly always affecting infants and young preschoolers, polio was seemingly more contagious than measles and thus had to be respiratory-transmitted. The assumption that its transmission was faecal-oral was a fundamental error, reflecting the lack of diligence of those who ideated that hypothesis without understanding the epidemiology of childhood diseases targeted by the EPI [20].

The EPI and GPEI did not epidemiologically explore the transmission route of polio even after targeting it for eradication. Every globally ubiquitous and exclusively vaccine-preventable infectious disease is respiratory-transmitted, and polio is no exception [21–24].

The second fundamental error was the design of vaccination tactics for polio eradication in 1988. Since 1974, the EPI had been accumulating information regarding the low protective efficacy of trivalent OPV (tOPV) for polio control and its safety-risk for causing VAPP. In 1968-69, the WHO had commissioned studies on the vaccine efficacy (VE) of tOPV in India, resulting in two lessons. One, the VE of tOPV was disappointingly low and, two, VE increased with additional doses along an arithmetic progression principle different from the prime-boost principle of other vaccines [25,26]. With the median age of polio as 12 months, the three-dose standard tOPV schedule did not control polio and would not eradicate polio, for which special tactics had to be designed in EPI. In 1984, EPI recommended one more dose to be given at birth [27].

The Indian studies showed that the VE of tOPV was not uniform against the three types. Against type 2, five 5 doses were sufficient to elicit near-100% VE, whereas 13-14 doses were needed for types 3 and 1 respectively [5,22]. As it would require more than 12 doses to predictably protect children from polio (caused by WPVs 1 and 3), and as the median age of polio was 12 months, it was not feasible to eradicate polio using tOPV [21]. This problem was peculiar to LMICs, especially those in the tropical zone, and well documented even before the launch of EPI.

When it came to raising the bar from polio control to eradication, the EPI had to factor in these realities as potential roadblocks and design special tactics. Despite showing that low VE was a general problem in LMICs implementing the EPI, the policy of only 3 or 4 doses during infancy inexplicably continued [28]. The 'inconvenient facts' were simply ignored – and no more studies were conducted, commissioned or outsourced. The lack of seriousness with which EPI and GPEI viewed the accumulating scientific data was a sign of the lack of trust in science -- an attitudinal flaw that ultimately led the programme to fail.

More Errors Were Committed Even Along the Wrong Path

The EPI had continued on the wrong path throughout the 1990s, despite availability of IPV as part of a combination vaccine with diphtheria-pertussis-tetanus antigens [13,14,29]. In 1999, after high coverage with tOPV through EPI, supplemented with several rounds of tOPV campaigns targeting newborns to 5 years, WPV-2 was eradicated with the last case in Aligarh, Uttar Pradesh, India [30]. Thereafter there was no need for OPV type 2. Knowing that OPV type 2 was a major cause of VAPP in the vaccinated and the commonest cause of 'contact VAPP,' medical ethics called for its

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withdrawal from tOPV [31]. Treating a non-existent disease is medical malpractice. Vaccinating against a nonexistent pathogen with an unsafe vaccine is also medical malpractice. Using a vaccine that carried zero benefit but the risk of VAPP was not rational. Continuing to administer tOPV has resulted in the tragedy of cVDPV-2 polio outbreaks that are highlighted in this paper.

Caused by poliovirus types 1, 2 and 3, polio is one disease for healthcare, but three for public health. Since three pathogens without cross-protective immunity were to be eradicated, the strategy should have been tailored to face an eventuality of sequential eradication. If such thinking had escaped attention during initial planning, it became imperative and urgent when WPV type 2 was apparently eradicated in 1999 [30].

Among the three types of vaccine polioviruses, type 2 was notorious for silent spread and reversal to neuro-virulence, as had been documented in Mogilev, Byelorussia, in the late 1960s [32] and in Egypt from 1983 to 1993 [33]. GPEI had to carefully manage the withdrawal of type 2 vaccine poliovirus from tOPV. Knowing that the entire population of countries that were using tOPV had achieved their highest level of herd immunity for type 2 poliovirus in 1999; that every birth cohort after 1999 would add more than 100 million non-immune children; and that WPV-2 was absent from silent circulation, the time period of 2000 to 2002 was a unique opportunity to stop use of type 2 vaccine safely [31]. Such an opportunity would never come again.

Not withdrawing type 2 vaccine virus at that time exemplifies the lack of forethought during the planning stage. There appears to have been little understanding of the overall benefits versus risks of the tOPV, despite choosing it as the single tool for polio eradication. The consequence began showing up as the emergence and spread of cVDPV-2 in Nigeria in late 2005 and has continued to date.

As soon as the cVDPV-2 outbreak was detected in Nigeria in 2005-2006, type 2 vaccine virus should have been withdrawn globally. Nature had given a second warning, and that was also ignored. At that time, GPEI could have changed tactics by making a switch from tOPV to bOPV (bivalent OPV) globally and hoped for the best, namely, no new emergence of cVDPV-2. In case of such emergence in Nigeria, tOPV could have been re-introduced to control it, IPV introduced as 3 doses during infancy, and tOPV withdrawn by design to prevent all future emergences of cVDPVs.

Procrastination to withdraw type 2 vaccine virus globally led to endemic prevalence of cVDPV-2 in several countries, broad geographic spread, and episodic polio outbreaks. Obviously cVDPV-2 had captured the niche vacated by WPV-2. There was only one right response: to introduce IPV into EPI, 3 doses during infancy and a booster in the second year, and then withdraw tOPV altogether.

However, yet another error was committed. The tOPV to bOPV switch was made in 2016, and disappointingly without first preparing the child populations in all OPV-using countries with the full schedule of IPV. Instead, just one dose of IPV was given just prior to the switch. That was most unwise, because one dose can only prime the immune system and not assure protective immunity. Not preparing the world to preempt the evolution and emergence of fresh cVDPV lineages, as warned by the Mogilev study, was a huge tactical error. GPEI knew the risk, but just one dose of IPV was prescribed to mitigate it [34].

In 2012, WPV-3 was globally eradicated with the last cases in India (2010), Pakistan (2011) and Nigeria (2012) [35]. As soon as it was confirmed after 3 years of waiting period without any further virus isolation, OPV type 3 should have been withdrawn for the same reasons explained earlier. Not withdrawing type 3 from bOPV was another in the series of errors. Of the three types, type 3 vaccine virus is by far the most common cause of VAPP. Since GPEI does not divulge the numbers of VAPP, we cannot know how many children have been paralysed due to OPV-3 VAPP each year for the 13 years since its eradication.

Since 2012, WPV-1 alone has survived GPEI's war on polio and that in only Afghanistan and Pakistan. The correct course of action was, and is, the replacement of OPV with IPV, accompanied by a serious commitment to strengthen 'routine immunisation' under the EPI, as advised by the 1988 Resolution [36]. Had that been done then, the world would have been polio-free a decade ago. Had

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that been done soon after the 1988 WHA Resolution, in all probability, eradication could have been achieved on target before the dawn of the millennium.

Why Is WHO Biased in Favour of OPV?

To understand the special interest WHO has in OPV, we must explore its history, recently revisited by Orsini D and Martinin M [37]. We quote: *"Sabin created his vaccine at the Children's Hospital in Cincinnati, where he subsequently tested it on 10,000 monkeys and 160 chimpanzees, as well as on himself, on his daughters, and on young volunteers recruited from among the inmates of the federal prison of Chillicothe in Ohio."* When Sabin was ready to conduct a vaccine trial to measure its safety and efficacy, polio had already been well controlled in the USA, using Salk vaccine that was licensed in April 1955. The Salk vaccine had undergone an exemplary vaccine trial in USA and Canada during 1954 on 1,829,916 children [38].

Thereafter the scene shifted to Geneva. The WHO Expert Committee on Poliomyelitis, meeting in July 1957, approved Sabin's virus strains for large scale trials and prescribed the details of vaccine manufacture for them [39]. In other words, WHO actually converted Sabin strains into the 'oral polio vaccine' (OPV) under its authoritative direction. OPV is as much a WHO vaccine as it is a Sabin vaccine.

As the WHO Expert Committee had wanted large-scale vaccine trials using OPV manufactured and laboratory tested according to WHO protocols, the trials were conducted in the Soviet Union and Eastern European countries, as recorded in the WHO publication History of the Polio vaccine, 2025 [40]. We quote: *"Trials carried out in the Soviet Union, on 20 000 children in 1958 and 10 million children in 1959, and in Czechoslovakia, on over 110 000 children from 1958 to 1959, proved the vaccine was safe and effective. Independent review of the trials for the World Health Organization by United States specialist Dorothy Horstmann endorsed their findings – a crucial validation in the time of the Cold War."*

Thus, in 1958 and 1959 the WHO had endorsed OPV to be given to large numbers of children. The facts that the number of beneficiaries all ended imprecisely with four zeros, the design was flawed by way of not measuring VE, and virological testing of children with polio within 30 days of vaccination was not done to understand vaccine safety, show that these were not rigorous protocol-based vaccine trials, but rather massive vaccine roll out.

The WHO is the 'custodian' of Sabin's vaccine strains [39]. By 1984, sixteen manufacturers around the world were engaged in OPV production using "the WHO vaccine seeds" [39]. In short, WHO owns the proprietary rights of Sabin OPV and as such WHO has a special interest in OPV.

During 1976 and 1982, the WHO Expert Committee on Polio reviewed the experience of several countries, mostly in Europe, showing clearly that both IPV and OPV had high VE, but that OPV had safety problems in causing VAPP [41,42]. Nevertheless, once again, evidence was strangely discarded, perhaps because it contradicted belief (1976 and 1982). In fact, the WHO Expert Committee declared repeatedly in both reviews that OPV was one of the safest vaccines in use – meaning, safer than BCG, DTP, measles vaccine and IPV. We quote: *"The second five years of the study confirmed the conclusions reached after the first five years*, i.e., *that live oral poliomyelitis vaccine (Sabin) is one of the safest vaccines in use"* While all comparator vaccines were/are safe, OPV was not, and the assertion of safety illustrated WHO's bias in favour of OPV. In both reviews in 1976 and 1982, WHO renamed VAPP as 'persisting spinal paralysis', apparently to remove any link with vaccine in the diagnostic term.

Why was novel OPV created some years ago? Sabin strains of vaccine candidate viruses were not attenuated by laboratory manipulations, but were selected from wild poliovirus laboratory stocks. Sabin knew that natural WPVs were always a mixture of highly virulent, less virulent and avirulent virus particles and they showed descending order of 'fitness" in replication. He selectively amplified the least fit virus particles that did not show neuro-virulence upon monkey spinal cord injection [43]. The least fit virus selected out and amplified is genetically unstable and always tends to mutate towards attaining fitness during cell culture passages or during virus growth in infected children. Thus, residual neuro-virulence in vaccine strains and reversion in multiplication were unavoidable. In other words, the repeated declarations that OPV was safe was untenable and

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misleading. Gradually, the repeated emergences of VDPVs have convincingly demonstrated that the declaration of safety was untrue. As molecular techniques were available to modify the virulence-determining nucleotides in the virus genome, it was possible to make Sabin strains safer than before. The earlier false assertions of OPV's safety had misled leaders of EPI and GPEI to believe that OPV was safe.

Summary, Conclusions and Recommendations

The enduring and continuing tragedy is measured in the many thousands of children who needlessly developed polio during the 37 years of global polio eradication efforts. Since no child is reported to have developed polio after receiving 3 doses of IPV, its early adoption would have been a perfect fit for the EPI schedule of injected vaccines, especially since combination product was already available in 1988. Yet, the polio eradication project managers persisted with OPV, disregarding data on its inadequate efficacy and inherent safety problems.

The right path is to use IPV exclusively (preferably as a hexavalent combination product -- DTP+hepatitis B+*Haemophilus influenzae* type b+IPV) and refrain from introducing any live poliovirus into the community anywhere. The earlier GPEI adopts the right path, the sooner polio can be eradicated globally.

A stepwise replacement of OPV with IPV is the way forward. The steps are: revise policy; alert vaccine manufacturers to expand production by assuring procurement; introduce the full schedule of IPV country by country while strengthening EPI, where needed; and withdraw OPV once the equivalent of one year's birth cohort is reached. These steps can be staggered according to vaccine supply and not necessarily synchronized globally or regionally, since IPV is non-infectious and completely safe.

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