

Polio eradication: experts have misled us

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Abstract

In 1988 the World Health Assembly passed resolution WHA 41.28 which committed the WHO to the global eradication of poliomyelitis by 2000. India is among the few remaining countries where despite pulse polio immunization (PPI) campaigns for the past eleven years, polio has not been eradicated. There has been very high incidence of vaccine failure with OPV; children are known to have developed polio despite taking many doses of OPV. No efforts have been made to discover the reasons for poor vaccine performance. OPV can cause Vaccine Associated Paralytic Poliomyelitis (VAPP) due to neurotoxic mutant vaccine polioviruses. Although incidence is extremely low in immunocompetent individuals, this risk is very high in those who are immunocompromised. Failure to provide IPV can be construed as a deliberate action to put some persons at avoidable risk of developing polio. The India Experts Advisory Group (IEAG) has seemingly misled the nation for many years with repeated assurances that polio will be eradicated very soon. Deadlines for polio eradication have been extended from 2000 to 2002, 2004, and then 2005. No serological studies have been conducted during this time to discover if the vaccine is generating sufficient antibody protection in vaccine recipients. IPV has not been made available in India due to frivolous excuses that include IPV, being injectable, has to be administered by trained personnel and carries all the complications of injections. Rather than acknowledging the ineffectiveness of polio vaccine, the experts erroneously blame failure of the program on those children who had not participated in the pulse polio immunization, implying that wild poliovirus circulation is maintained because of these non-participants.

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1. Introduction

In 1988, the World Health Assembly passed resolution WHA 41.28 promoting the global eradication of poliomyelitis by the year 2000 exclusively by providing oral polio vaccine (OPV).

The Polio Eradication Committee of the Indian Academy of Pediatrics has reassured the members of the Indian Academy of Pediatrics many times through its published bulletins that polio is on the verge of being eradicated and needs only a “Final Push.” India Experts Advisory Group (IEAG), consisting of eminent national and international experts, has repeatedly reassured the Ministry of Health (Government of India) that wild poliovirus circulation will stop within the few months.

Despite deadlines for polio eradication being extended many times, polio has not been eradicated and it is unlikely to be eradicated in near future. Wild polio viruses had been restricted to six countries in 2004 namely India, Pakistan, Afghanistan, Egypt, Niger and Nigeria. However, during 2005, wild polioviruses have been found in twenty countries.

In the January 2004 issue of the Bulletin of Polio Eradication Committee of IAP, on page 3, it was stated: “The outcome of our efforts in the coming few months will decide which way the program will go—the small pox way or the malaria way? Already, voices of concern regarding prudence of adopting an eradication approach are emerging from different quarters. Hence, many things are on stake—the reputation of nation, the resolve, commitment, and the patience of its people, the strategy and competence of enforcing agencies, and the ambition of scientific fraternity to overpower yet another killer disease in

future! And also at stake is credibility and reputation of your own organization IAP.”

Page 4 continues: “India has reached the critical period in our efforts to eliminate the transmission of wild polioviruses. All partners in polio eradication are getting ready for the ‘final push’ to ensure the achievement of virus elimination during this critical period of December 2003 through April 2004. All States, District and Local Branches of IAP and indeed every member should participate in this historic event of the final push.”

“So far the number of cases in November have been so few that it is still possible to see the last case of wild-virus-polio in 2003 itself. If that does not happen, then it should happen in the first quarter of 2004, but we all must work hard to make it happen, and to make sure that this opportunity, the best ever in our history, is not missed.”

In the year 2003 the author had expressed concern regarding polio eradication by this vaccine and strategy [1].

A member, Case Classification Committee of National Polio Surveillance Project (NPSP) had stated: “This is in reference to the ‘view point’ on the subject of polio eradication in India by Dr. Yash Paul. Not many would agree with his concern that ‘polio free India still remains a distant dream’. Majority of the experts believe that polio eradication in our country is just around the corner despite setbacks and difficulties [2].” The Project Manager, NPSP-WHO had stated: “Thus, the outbreak of 2002, and the problems of polio eradication were not caused by failure of OPV or occurrence of VAPP, but failure to vaccinate children adequately.... The number of polio cases between March and July 2003 in these states (Uttar Pradesh and Bihar)

is at its lowest ever. Successes like these clearly demonstrate that polio eradication program will succeed in India [3].”

In the July 2004 issue of the Bulletin of Polio Eradication Committee, the editorial stated, “Polio eradication - Success is just around the corner” and “Friends, we request all of you to become proud partners in this Final Push to Polio.” In November 2004 issue of Bulletin the Editorial was captioned “Wild Virus Now Confined to its last Citadel; Let’s Shut all the Exit Points.”

The March 2005 editorial was entitled, *Target U.P. and Bihar - Defeat Polio In Final War!*

The June 2005 editorial, *Polio Eradication in India: Victory in Sight*, stated that with continued efforts of the same intensity, especially in Bihar and U.P., ‘0’ polio status could be reached by the end of 2005. It further stated, “The first half of 2005 has brought some cheer and hope among all the weary workers who had been toiling hard for polio eradication for a decade.”

The year 2005 has passed now and polio cases are still occurring. The experts do not agree that vaccine has performed poorly and instead insist that that continuing polio cases are due to lack of 100% vaccine coverage.

The India Expert Advisory Group for Polio Eradication at its thirteenth meeting (May 3-4, 2005 in New Delhi) concluded: “(i) India has made its most important progress and (ii) Polio can be interrupted completely in 2005 (page 10 of the June 2005 issue of bulletin of Polio Eradication Committee).” IEAG at March 26-27, 2004 meeting had previously concluded that transmission of wild polioviruses could be stopped in the country within months.

The situation projected by these experts suggests that the goal of polio eradication is not only achievable, but simply awaiting for the unvaccinated population to step forward and grab it. The nation has been misled by the experts into believing that polio is poised for eradication but then deadlines for polio eradication have been extended many times.

An attempt has been made to raise those issues on which we have been misled by the experts, e.g., (i) decline in number of polio cases is being attributed only to OPV; whereas, there are many factors which have resulted in lowering the number of polio cases, (ii) lack of 100% vaccine coverage is being projected as the main reason for failure of the eradication program, which is incorrect, and (iii) there is very high incidence of VAPP—but these facts are suppressed.

2. Impact of OPV on incidence of polio

The National Polio Surveillance Project (NPSP) became fully operational by end of 1997. The number of polio cases reported for years 1998 to 2005 are given in Table 1.

The number of polio cases in India was 13000-38000 per annum during the 1980s [4]; presently, polio cases have dramatically declined. This reduction is incorrectly being attributed to polio vaccine only; however additional reasons for the reduction in the incidence of polio include the following:

1. Change in the diagnostic criteria

A. Up to 1996: All reported cases of flaccid paralysis were labeled as polio cases,

B. 1997 onwards: An AFP Case is labeled as polio in presence of one or more of the following: (i) wild poliovirus detected in stool sample, (ii) residual paralysis observed after a period of 60 days of onset of paralysis, (iii) patient died, or (iv) patient lost to follow-up. For example there were 10408 and 9587 reported AFP cases during 1990 and 1999, respectively. In 1990 all 10408 cases (100%) were labeled as polio cases, but in 1999 only 2817 cases (29%) were labeled as polio cases.

2. Immunity induced by polio vaccine.

3. Immunity induced by wild polioviruses after natural infection.

4. VAPP cases are not mentioned in the available figures.

5. Under reporting due to cases of polio being wrongly discarded because if wild polioviruses are not detected in stool samples of AFP cases, such cases are discarded as non-polio even without 60-day follow up [5].

6. Lack of exposure to wild polioviruses because of improvement in hygiene and sanitation. It may be pertinent to state that the incidence of polio declined appreciably from the third decade of the twentieth century in England, America and industrialized countries of Europe, i.e., long before polio vaccines became available during the late 1950s.

As no studies have been conducted in the recent past regarding antibody generation by OPV, it is difficult to assess how many cases of polio have actually been prevented by vaccine.

3. How effective is OPV?

“Efficacy of any vaccine should be evaluated on the basis of the balance between the positive and negative contributions made by a vaccine in terms of prevention of the disease, failure to prevent the disease, and the adverse effects caused by the vaccine. For OPV the parameters to be evaluated are: (i) how many cases of polio have been prevented? (ii) how many cases of polio occurred despite adequate number of OPV doses (i.e., failure to prevent polio or vaccine failure)? and (iii) how many cases of vaccine associated paralytic poliomyelitis (VAPP) have been caused by OPV?” [6]

Many polio cases are known to have occurred even after many doses of OPV, and high incidence of VAPP has been observed in India, but no serological studies have been recently performed to evaluate the antibodies generated by OPV. It is being presumed that those children who received OPV and did not develop paralytic polio are protected by the vaccine. In reality, their protection could be (1) attributed to immunity provided by the wild polioviruses circulating in the community, and/or (2) lack of infection because of improvements in hygiene and sanitation.

4. Is 100% vaccine coverage necessary?

Park’s Textbook of Preventive and Social Medicine (18th ed., 2005, page 164) states, “The vaccine is excreted in the feces and secondary spread occurs to household contacts and susceptible contacts in the community. Non-immunized persons may therefore, be immunized. Thus widespread ‘herd immunity’ results, even if only approximately 66 per cent of the community is immunized [7].”

In a joint publication of Indian Academy of Pediatrics and UNICEF entitled *Together We Make India Polio Free* (page 7) it is stated, “The advantages of OPV are ... (vaccine polioviruses) can spread from one child to another, inducing herd immunity.”

OPV can provide additional benefits to those non-immune in the community through (i) herd immunity where secondary spread of vaccine polioviruses may induce immunity or (ii) herd protection by stopping the circulation of wild polioviruses in community [8].

Thus 100% vaccine coverage is not essential for polio eradication, effective vaccine is required for polio eradication. Data mentioned on page 15 of the June 2005 issue of Bulletin of Polio Eradication Committee of the Indian Academy of Pediatrics are presented in the Table 2 which puts the issue in correct perspective.

5. Blame game

It appears that all those associated with the polio eradication program had realized that the program would ultimately fail, so they began looking for an escape route, i.e. searching some scapegoats.

The author had stated: “It is certain that polio will not be eradicated in 2004, and the blame would be put on the parents [9].” This was published in the December 2004 issue of *Indian Journal of Clinical Practice*, the manuscript had been submitted in July 2004.

Hindustan Times a national newspaper carried the news (October 23, 2004) that in Aligarh, 425 Muslim families refused to administer polio drops (OPV) to their children. It stated that the World Health Organization, UNICEF, and the Aligarh health department have failed to mobilize the Muslim community towards polio drive.... Due to this, the polio drive in Aligarh met a setback in recent days which is a matter of great concern in connection with goal of total elimination of polio disease.

Hindustan Times on November 11, 2004 published the story *Morale booster for UP antipolio workers*, stating, “... interestingly, 68% of these mobilizers are women. There are few, who come from families which have paid for their resistance to polio drops.” Rohilla Begum is one of them, who told *HT*: “Ten years ago I had many notions against polio drops and did not give it to my daughter. Now she is 12 and a polio victim. I have now decided to work day and night to eradicate it.”

On the other hand, Project Manager, NPSP-WHO had stated: “The author (Yash Paul) pins blame for the outbreak of 2002 largely on the high incidence of failure of OPV (Oral Polio Vaccine), based primarily on the observation of cases of polio in children who had received several, and in some cases many doses of OPV. This frequently heard statement results from making the wrong conclusions from observing a phenomenon that logically MUST occur in any eradication program using vaccine which is not 100% protective (and no vaccine is). In the final stages of such a program, most cases of disease will be ‘well vaccinated’. To illustrate why this occurs, we can model the Indian situation using the assumption of a vaccine with 95% efficacy (one that protects 95% of children who receive it). In the early stages of an elimination program, because most children are not vaccinated, cases in vaccinated

children will be relatively few. However, in the final stages of the eradication program a different pattern is seen. In this end stage, most children are vaccinated, and relatively few unvaccinated, due to intensified immunization efforts such as are now underway in India. If, for example, we assume that 95% of the Indian birth cohort of 35 million children is vaccinated with the vaccine, that leaves 5%, or about 1.75 million, unvaccinated, and thus, unprotected. If the remaining 95% who are vaccinated, 5%, or another 1.66 million will also not be protected because the vaccine only protects 95% of those vaccinated. Thus, among the total 3.41 million unprotected children, 1.66 million, or nearly 50% are vaccinated. One would expect, then, that among all cases of polio at this stage of the program, nearly 50% would be vaccinated. Thus, finding a high proportion of cases among vaccinated children does not mean the program is not working—on the contrary, it means that the program is nearing completion (see Table 2) [3].”

Wild polioviruses replicate and multiply in the gut of non-immune individuals and maintain circulation in the community. On the other hand viruses fail to replicate and multiply in immune individuals and die a natural death, thus circulation of viruses is stopped as has been shown in the Table 3.

Still, blame for polio eradication failure is put on those children who had not participated in pulse polio immunization, and their parents who are made to feel guilty—no role is attributed to those children who had failed to develop immunity because of vaccine failure.

6. Reasons for failure of eradication program

High incidence of vaccine failure and vaccine associated paralytic poliomyelitis (VAPP) are the real reasons for failure to eradicate polio even those associated with polio eradication program attribute it to lack of 100% vaccine coverage.

6.1 Vaccine failure

Vaccine failure with OPV can occur due to poor quality of vaccine or presence of some inhibitors in the gut or other factors in the vaccinee.

The quality of OPV can be affected during manufacture, transportation, or storage. In the vaccine recipients, malnutrition as well as immunosuppression due to disease or drugs can be reasons for poor response to OPV. It is a well known fact that in India and many other developing countries, doctors, quacks and practitioners of other systems of medicine administer corticosteroids even for trivial ailments. This could also be a reason for very high incidence of vaccine failure and VAPP in India. Table 4 shows the number of OPV doses received by polio cases.

6.2 VAPP

Incidence of VAPP in immunocompetent individuals is very low, but this incidence increases in immunocompromised. Since inactivated polio vaccine (IPV) is not available in India, immunocompromised children are being administered OPV resulting in alarmingly high incidence of VAPP. The projected number of VAPP cases for India was 60-75 per year; however, between 120 and 206 VAPP cases have been reported during

1998 and 2003. Due to some under-reporting, the author estimates about 300 VAPP cases occur every year in India [5].

7. Was polio eradication expected

Polio had been eradicated from China, Nepal, Bhutan, Bangladesh, Myanmar and Sri Lanka, all neighboring countries of India during two to three years of pulse polio immunization campaigns. Pulse Polio Immunization was started in India in October 1995, but we had failed to eradicate polio after nine years of concerted efforts. Still, 2004—the tenth year of pulse polio immunization—was declared as the year for the “Final Push” to polio eradication in India [9].

It is difficult to understand how polio eradication was envisaged. The vaccine’s efficacy has not been evaluated. The reasons for high incidence of vaccine failure have not been determined. No measures have been taken to reduce the incidence of VAPP. It is equally difficult to understand how a vaccine and a strategy which have not worked in the last nine years (1995–2003) will eradicate polio in the tenth year. It seems that those associated with the eradication program are interested only in continuation of the program [10].

On the other hand it can be said that the present eradication program ensures that polio cases will continue to occur because of vaccine failure and due to mutant vaccine polioviruses. Infected immunocompromised children will continue to spread wild as well as mutant vaccine polioviruses for a prolonged period in the community [11].

8. Reasons for not making IPV available

A joint publication of UNICEF and IAP entitled, *Together we make India polio free* (on page 7) stated, “The sole advantage of IPV is that it carries no risk of VAPP. The disadvantages are that it must be administered by medically trained personnel, it is much more expensive, it is less effective in interrupting spread of virus, and it carries with it all the complications of injections.” The risk of VAPP has been evaluated in India and is 1 case per 4 million doses administered, overall. The risk of VAPP for any individual is greatest with the first dose (1 case per 2 million doses) and decreases with subsequent doses (1 case per 12 million doses). It is expected from the IAP members that discussion of VAPP should be restricted to academic circles and should not be unnecessarily exaggerated.

There are many points which need discussion: (i) IPV must be administered by medically trained personnel: DPT is also administered intramuscularly, and IPV DPT combination vaccine is available, (ii) it is much more expensive: so many children have developed polio despite many doses of OPV so that the cost factor becomes irrelevant. Moreover, it is much less expensive than varicella vaccine and hepatitis A vaccine, (iii) it is less effective at interrupting spread of virus: it was presumed that OPV provides benefit of herd immunity through secondary spread of live attenuated vaccine polioviruses contained in vaccine to non-immune contacts, and those who have developed immunity following vaccination will interrupt spread of virus and thus provide herd protection to non-immune individuals in society [8]. Due to the high incidence of vaccine failure, these perceived advantages of OPV are almost non-existent. On the

other hand mutant vaccine polioviruses (VDWL) are causing VAPP in children, whose number is high and secondary spread of these mutant neurotoxic vaccine polioviruses is causing VAPP in contacts. In the study by Kohler et al. [12], out of 181 VAPP cases there were 60 recipient VAPP cases and 121 contact VAPP cases, (iv) it carries with it all the complications of injections: IAP and WHO are advocating for inclusion of hepatitis B vaccine for Universal Immunization without any fear of risks of complications of injections.

Although risk of VAPP is low in immunocompetent individuals, this risk is extremely high in immunocompromised recipients or immunocompromised close contacts. A safe vaccine (IPV) exists for such individuals, but active intervention to make it unavailable to these should be construed as a deliberate action to put a section of the society to a known and avoidable risk by compelling them to take OPV. It would be difficult to find a similar example in medical history.

9. Emotional blackmail

Media is repeatedly advised to be responsible and not publish any reports or events which might undermine the trust of parents in OPV and polio eradication program. Of course, media should not sensationalize the shortcomings of the program, but, facts should not be suppressed.

Doctors are advised not to discuss VAPP with parents, because it may adversely affect the eradication program. The author had raised the issue in 1999 [13] and Chairman of the Committee on Immunization had stated, “Regarding the message that OPV is absolutely safe, we do know that it is not. However, I will not suggest that the public be alarmed by the very small risk of vaccine associated polio, a price we have accepted to pay for the control and eradication of wild polioviruses [14].”

The question is whether this sacrifice of parental autonomy, due to the absence of informed consent, is worth making for the greater good? Advocates of the eradication program believe that it is best not to inform parents of these risks because it may adversely affect vaccination rates. However, if it is indeed to be accepted that the benefits of polio eradication outweigh the withholding of information about the risks of harm, then, at the very least, an adequate compensation scheme needs to be in place for those that are harmed as a result of the program [15].

10. Role of Indian Academy of Pediatrics (IAP)

The Indian Academy of Pediatrics is the only professional body of pediatricians in India. Its primary role is to safeguard the interests of Indian children. Because of this consideration, it had voluntarily joined the polio eradication program. The Committee on Immunization of the Indian Academy of Pediatrics has been in existence since long before the Polio Eradication Committee was constituted.

The Bulletins of the Polio Eradication Committee IAP raised false hopes time and again that polio eradication was about to occur; at the same time, this committee downplayed the issues of vaccine failure and high incidence of VAPP. Sixty to 75 VAPP cases were expected to occur every year in India. As has been previously stated, this was accepted as a ‘price’ to pay for

polio eradication. However, doctors were advised to keep this as a guarded secret—to which the doctors agreed. Later, the number of VAPP cases was found to be much higher and this author raised this issue to the co-convenor of the Polio Eradication Committee who stated, “We can dare to disclose the true figures of VAPP only if we have an alternative strategy in place to implement without delay [16].”

OPV is contraindicated for immunocompromised children and those who have immunocompromised close contacts. IPV is recommended for such individuals. IPV is not licensed in India, putting such individuals to increased risk of VAPP. IAP has never raised this issue with the appropriate authority in the government. Occurrence of polio by OPV (VAPP) is not that bad, but, to talk about VAPP is certainly bad. Indian Academy of Pediatrics has not taken any initiative to ensure that no avoidable harm occurs to the Indian children because of this polio eradication program.

11. Conclusions

In 1988, the World Health Assembly passed resolution WHA 41.28, which committed the WHO to the global eradication of poliomyelitis by the year 2000. In India polio eradication is being implemented by the National Polio Surveillance Project (NPSP) under supervision of UNICEF and WHO. Indian Academy of Pediatrics (IAP) has voluntarily joined this noble cause. Deadlines for polio eradication have been extended many times. No efforts have been made to evaluate the efficacy of the vaccine and no steps have been taken to reduce the very high incidence of VAPP. The people of India are being reassured repeatedly that polio is about to be eradicated and then the deadline for polio eradication is extended, putting blame for failure of the program on those children who have not participated. No concern is being shown for the children who have developed polio because of OPV (VAPP) or through many doses of vaccine (i.e., where vaccine has failed to protect the children against disease).

The most baffling aspects of this polio eradication program are: (i) no one knows if this vaccine is providing protection, (ii) there is unacceptably high incidence of VAPP and doctors are advised not to let people know that OPV can and is causing polio in many children, and (iii) IPV is not being made available in India even for those children who are immunocompromised due to disease or drugs or who have immunocompromised close contacts, thus putting many individuals at known higher risk to develop VAPP.

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Table 1. Number of polio cases for years 1998-2005

	1998	1999	2000	2001	2002	2003	2004	2005 ¹
Virologically confirmed	1434	1126	265	269	1600	225	136	64
Compatible	2286	1680	362	286	681	370	361	261
Total	4320	2806	627	555	2281	595	497	325

¹As of January 14, 2006. Final number of polio cases which had occurred during 2005 would be known by end of April, 2006. VAPP cases have not been included.

Table 2. Vaccine doses received by AFP and polio cases

No. of doses	0	1-3	4-6	4-9	10 or more
AFP cases	0%	3%	12%	19%	66%
Polio cases	0%	14%	21%	58%	7%

Source : June, 2005 issue of Bulletin of Polio Eradication Committee of Indian Academy of Pediatrics.

Table 3. Wild polioviruses circulation

Wild Polio Viruses	Immune	Non-Immune	
		Unvaccinated	Vaccine Failure
OPV doses	0–many	0	many
Replication	No	Yes	Yes
Multiplications	No	Yes	Yes
Shed in feces	No	Yes	Yes
Spread infection	No	Yes	Yes
Can develop polio	No	Yes	Yes

Table 4. Polio cases having received number of OPV doses and number of VAPP cases in India (1998-2003)

Year	1998	1999	2000	2001	2002	2003
OPV 0 dose	13%	13%	14%	9%	15%	14%
OPV dose 1-3 doses	40%	43%	28%	31%	41%	35%
OPV doses 4+	33%	40%	58%	60%	44%	51%
VAPP cases	124	206	151	120	203	NA

Source: January 2004 issue of Bulletin of Polio Eradication Committee of Indian Academy of Pediatrics