Polio Eradication Programme: A Failure

Despite repeated assertions that the eradication of polio is imminent (and repeated extensions of the deadline for its eradication), the end of polio still does not seem nigh. An analysis of the reasons for the persistence of polio shows that the choice of vaccine was a mistake and the strategy needs a rethink.

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After the successful eradication of smallpox, the World Health Assembly, during its 41st meeting held in 1988, passed resolution No 28, which directed the World Health Organisation (WHO) to achieve global polio eradication by 2000, exclusively by the use of the oral polio vaccine (OPV). This resolution is known as WHA 41.28.

Two types of polio vaccines are available: (i) inactivated polio vaccine (IPV), also known as Salk's vaccine. It contains antigens derived from killed polio viruses, is administered as an injection, and is comparatively costly. It provides excellent protection, and does not cause polio in the vaccine recipients. But it is not licensed for sale in India, and (ii) OPV also known as Sabin's vaccine. It contains weakened or attenuated live polio viruses, is administered by mouth, and is comparatively cheap.

In 1988, when the global polio eradication campaign was started, OPV was chosen because it was easy to administer (given by mouth), it was cheap, it was supposed to provide long lasting protection and the onset of action was rapid. It was thought that spread of vaccine viruses through faecal matter from vaccine recipients in the community provides an additional benefit, i e, other children may develop immunity without taking the vaccine directly. This phenomenon is called herd immunity. Later studies showed that this benefit does not occur, but in India, perceptions have not changed. But even at that time two drawbacks or limitations of OPV were known. One, this vaccine does not provide protection to some children, especially in developing countries and countries with a hot climate. India qualifies on both counts. Two, the modified polio viruses some times back mutate, become neurotoxic and can cause polio, which is called vaccine associated paralytic poliomyelitis (VAPP).

Pulse polio immunisation for polio eradication in India was started in 1995. At that point of time it was known that many children had developed polio after taking the recommended doses of vaccine. It was thought that pulse polio immunisation would provide some extra doses of vaccine over and above the routine OPV doses being given, and that would take care of those children who do not respond to the scheduled number of doses of OPV.

Cases of Vaccine Failure

No studies regarding the incidence of VAPP cases occurring in India were available. Jacob John, an eminent public health specialist, had made an estimate based on the probable chances of developing VAPP according to the data available from other countries that every year about 60 children could develop VAPP, i e, polio because of vaccine [John 1996]. This was considered a "price" to be paid for polio eradication and the information was guarded as a secret from the public, because doctors had been advised to restrict the discussion regarding VAPP to academic circles only, so that pulse polio immunisation may not be affected.

Studies by B Ahuja et al (1996) and other investigators had shown that the incidence of vaccine failure, where children had developed polio after taking the scheduled number of vaccine doses, was high. The National Polio Surveillance Project (NPSP) was constituted, working under the supervision of WHO, and became fully operational by the end of 1997. NPSP became the only agency, which provides polio-related data.

I had pointed out [Paul 1999] that study of NPSP data indicated that the incidence of vaccine polio virus found in polio cases was high and on the rise, suggesting that the incidence of VAPP could be high in India. These observations were substantiated later by a study by Kohler and colleagues regarding the incidence of VAPP in India during 1999, saying that 181 children had developed polio because of OPV. Later this figure was revised to 202. These figures indicate that the incidence of VAPP was indeed more than three times the projected figure of 60 cases per year [Kohler et al 2002].

A workshop held in New Delhi on May 20-21, 2000 was attended by members from the Indian Academy of Paediatrics, the government of India, the United Nations Children's Fund (UNICEF) and WHO. I had raised the issues of poor performance of the vaccine, high number of VAPP cases and the need to make IPV available to those children who needed it because of some medical conditions. These observations were included in the background material provided to all the participants. Those associated with the polio eradication programme had presumed that polio would be eradicated by 2000, so these issues were considered irrelevant [Paul 2000; Thacker 2000].

The India Experts Advisory Group (IEAG), consisting of national and international experts, advises the government of India regarding the progress and strategy of polio eradication. For the last many years IEAG has been repeatedly reassuring the government of India that India is on the verge of polio eradication and polio virus circulation will stop in the next "few months". Polio was not eradicated in 2000, the deadline was extended to 2002, but there was a resurgence of polio cases in 2002. The deadline was extended to 2004, then to 2005 and 2006. There are indications that, as happened in 2002, the number of polio cases in 2006 may be very high. During 2005 there were only 66 virologically confirmed cases but as on August 5, 2006 there are already 153 polio cases, and the rest of the year is known as a period of high polio incidence.

Decline in Polio Incidence

The number of polio cases in India was 13,000-38,000 per annum during the 1980s; currently, polio cases have dramatically declined. This reduction is incorrectly being attributed to polio vaccination only; however, the 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 acute flaccid paralysis (AFP) were labelled as polio cases, but no follow up was done. (b) From 1997 onwards, an AFP case has been labelled as polio in the presence of one or more of the following: (i) wild polio virus detected in stool sample, (ii) residual paralysis observed after a period of 60 days of onset of paralysis, (iii) the patient has died, or (iv) the patient is lost to follow up. For example there were 10,408 and 9,587 reported AFP cases during 1990 and

1999, respectively. In 1990 all 10,408 cases (100 per cent) were labelled as polio cases, but in 1999 only 2,817 cases (29 per cent) were labelled as polio cases. (2) Immunity induced by polio vaccine. (3) Immunity induced by wild polio viruses after natural infection, very small number of infected individuals develop paralysis, others may develop immunity. (4) VAPP cases are not mentioned in the data made available. (5) Under-reporting due to cases of polio being wrongly discarded because if wild polio viruses are not detected in stool samples of AFP cases, some such cases are discarded as non-polio even without 60 day follow up [Paul 2004b]. (6) Lack of exposure to wild polio viruses because of improvement in hygiene and sanitation. It may be pertinent to mention that the incidence of polio declined appreciably from the third decade of the 20th century in England, America and industrialised countries of Europe, i e, long before polio vaccines became available during the late 1950s.

It is difficult to tell how many cases of polio have actually been prevented by OPV. In children who have taken OPV and have not developed polio, it is being presumed that polio has been prevented by OPV. It is possible that many of these children had developed immunity after infection by polio viruses, as not all children develop paralysis. It is also possible that these children had not come in contact with polio viruses. Only serological studies can ascertain the facts.

Role of the Unvaccinated Child

Absence of 100 per cent vaccine coverage of the eligible population is projected as a major reason for failure of the polio eradication programme, but this is not true. This issue needs some clarification.

The year 2004 was declared a year for the final push to polio. In an article titled 'Polio Eradication: A Mirage?' published in December 2004 issue of *Indian Journal of Clinical Practice* I had stated: "It is certain that polio will not be eradicated in 2004, and the blame would be put on the parents who had not taken their children for vaccination" [Paul 2004c].

For a vaccine preventable disease, where the causative organism spreads from human to human, 100 per cent immunisation of the population is not essential. This is the basic principle of epidemiology. Immune individuals may provide protection to non-immune individuals without inducing immunity, essentially by breaking the transmission of infection or lessening the chances of a susceptible individual coming into contact with an infected individual [Paul 2004a]. This is how IPV, measles vaccine, Hib vaccine, etc, provide additional benefit, like OPV does.

A non-vaccinated child may develop polio or immunity following wild polio virus infection. On the other hand such a child may not be infected by wild polio virus because of lack of exposure to it. Thus not every non-vaccinated child may participate in wild polio virus circulation. A child who has received many doses of OPV and has not developed immunity can also participate in wild polio virus circulation. But the blame for failure of the eradication programme is put on only those children who have not taken the vaccine.

Can Polio Be Eradicated by the Current Vaccine?

In an article entitled 'Can Polio Be Eradicated from India through Present Polio Eradication Programme?' published in August 2003 issue of *BMJ-South Asia* edition [Paul 2003], I had stated: "Polio cannot be eradicated by the present polio eradication programme, as polio cases will continue to occur because of vaccine failure and VAPP. Studies should be undertaken immediately to find the causes for vaccine failure so that appropriate remedial steps may be taken. Similarly, efforts should be made to reduce the incidence of VAPP."

A member of the Case Classification Committee of NPSP had replied thus: "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 round the corner despite setbacks and difficulties" [Srivastava 2003].

The project manager, NPSP-WHO, had also defended the programme: "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 programme will succeed in India" [Wenger 2003].

The chairman, Polio Eradication Committee of the Indian Academy of Paediatrics, also rejoined, "I disagree with Dr Paul's audacious prediction that India will not succeed to eradicate polio unless his three directives are followed" [John 2003].

The three suggestions (referred to above as directives) were: (1) find the reasons for the high incidence of vaccine failure with OPV and take appropriate remedial measures, (2) introduce IPV on a selective basis with immediate effect to reduce the incidence of VAPP, and (3) develop some modalities or methodology so that AFP cases are correctly classified and the correct number of polio cases is known. If these or some other similar measures are not taken soon, polio eradication will remain a distant dream and we will have to postpone the deadline for polio eradication again and again on one or another pretext.

In an article published in the April 7, 2005 issue of *Nature* entitled 'A Global Call for New Polio Vaccines' the WHO experts had stated that the end was near but eradication would not be as simple as was once thought. The experts had further stated: "As the world nears eradication, the need for new polio vaccines is greater, paradoxically, than at any time in the past 17 years…Specifically, the world now needs OPV for Type 1, 2 and 3 polio virus, and a new type of inactivated polio vaccine (IPV) that is manufactured from stocks of weakened live polio virus strains rather than from wild polio virus, as is current practice."

Arita et al (2006) have made similar observations: "The question is, should WHO proceed with its current global eradication programme, in view of all the difficulties and uncertainties identified in the paper? Our answer is 'No'."

Understanding the Problem with the Vaccine

This shows that apprehensions regarding the capability of current vaccines to eradicate polio are not baseless. IEAG, comprising national and international experts, advises the government of India regarding polio eradication progress and strategy. It is an irony that IEAG has consistently maintained that the current OPV will eradicate polio soon. Even during the meeting held on December 5 and 6, 2005 it concluded that India could achieve polio eradication using OPV by early 2006.

It is difficult to understand how polio eradication was envisaged. The vaccine's efficacy has not been evaluated. The reasons for the 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 imagine that a vaccine and strategy which had not worked for nine years (1995-2003) was expected to eradicate polio in the 10th year, 2004. Yet 2004 was assigned for the final push to polio.

Soon afterwards, I had observed: "On the other hand it can be said that the present eradication programme ensures that polio cases will continue to occur because of vaccine failure and due to mutant vaccine polio viruses. Infected immuno compromised children will continue to spread wild as well as mutant vaccine polio viruses for a prolonged period in the community" [Paul 2005].

People wonder why, when smallpox and polio both are caused by viruses and smallpox could be eradicated, there should be any problem with polio eradication. Smallpox virus was only of one serotype, but there are three different serotypes of polio viruses, known as Type 1, 2 and 3. The three types of viruses need three different vaccines. Type 2 vaccine happens to be the most effective, Type 1 is least effective and Type 3 is intermediate in effectiveness. Thus, in fact, we are fighting against three viruses, not one virus only as was the case with smallpox. With IPV, all the three components are almost equally effective against their respective viruses. The second difference is that every individual who got infected by the smallpox virus used to develop the disease with tell-tale signs, although the degree of manifestation was variable: mild, moderate or severe. In the case of polio, one in 100-200 infected persons develops paralysis; thus, 99 to 99.5 per cent of infected persons remain unknown to health workers and may spread the infection in the community.

The third difference is the efficacy of the vaccines. Smallpox vaccine provided protection to 95 to 98 per cent of vaccinated persons after one dose. Three doses of IPV provide protection to 100 per cent of vaccinated persons and two doses to about 98 per cent of vaccinated persons.

The fourth difference is that smallpox vaccine was genetically a stable vaccine; heat and other adverse factors could make it less potent, but there was no mutation whereby vaccine viruses reacquire the ability to cause the disease. On the other hand, OPV is known to be genetically less stable, i e, some vaccine viruses mutate and reacquire the ability to cause disease, the phenomenon being known in the case of polio as VAPP, as has been explained earlier.

The only similarity between smallpox vaccine and OPV is that both are live vaccines, i e, the viruses contained in the vaccine have been modified. On the other hand IPV does not contain polio viruses, but contains some elements from the killed viruses, which have the property to generate antibodies to provide protection against paralysis.

What do we do now? The following are some of the options available to us.

(1) Find the reasons why children are showing poor response to OPV and then take appropriate remedial measures, if feasible.

(2) Switch to IPV. It will not be easy to procure a huge quantity of the vaccine required for our country in the near future. Even if we manage to procure the vaccine in the required quantity, and manage to make arrangements for its administration, it is doubtful that many parents will agree to their children being given this injectable vaccine now because of the past performance record of the eradication programme.

(3) Wait for some new vaccine, which is more effective and safe. It may take many years to develop such a vaccine.

Thus, polio eradication in the near future is not possible; we will have to acknowledge this fact.

Rather than asking when polio will be eradicated, the apt question would be: can polio be eradicated with the current vaccines? The experts have repeatedly reassured the government and the nation that polio eradication is imminent, but it has not materialised. It would be incumbent on the experts to tell us what the observations or indicators were on the basis of which polio eradication was being envisaged, otherwise it would make their intent suspect. EPW

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