

CONTROVERSY

Polio eradication programme: some ethical issues

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In 1988, the World Health Assembly passed Resolution WHA 41.28, which committed the World Health Organization (WHO) to the global eradication of poliomyelitis by the year 2000, by providing immunisation exclusively with oral polio vaccine (OPV). The deadline for polio eradication from India was later extended to the end of 2002 and again to 2004. It is now 2005.

In 2000 and 2001 there were 265 and 268 virologically-confirmed polio cases respectively, in India. In 2002 the number increased to 1,600. In response to some questions raised by the author (1), Dr Jay Wenger, project manager of the National Polio Surveillance Project of the WHO (NPSP-WHO), stated: "...the outbreak of 2002 and the problems of polio eradication were not caused by the failure of OPV or occurrence of VAPP, but the failure to vaccinate children adequately. This is shown most clearly when we consider that in states like Tamil Nadu and Kerala, where immunisation coverage is high, no polio cases occurred in 2002, whereas in states like UP and Bihar, where coverage has been low, the outbreak took full advantage causing hundreds of cases of clinical disease.... Encouragingly, in the last 12 months, both the number of immunisation rounds, and the quality of the supplementary immunisation activities had increased, the latter especially in UP and Bihar. The number of polio cases between March and July 2003 in these states is at its lowest ever. Successes like these clearly demonstrate that the polio eradication programme will succeed in India."(2)

Elsewhere, Dr Jacob John, Chairman of the Polio Eradication Committee of the Indian Academy of Pediatrics, has stated: "The number of districts with polio had declined to 63 in 11 states in 2001, but in 2002 cases occurred in 146 districts in 16 states. Kerala, Tamil Nadu, Andhra Pradesh and Karnataka remained unaffected, in these states routine and pulse immunisations have remained robust through the years"(3). But during the year 2003, wild polioviruses emerged in Andhra Pradesh, Karnataka and Tamil Nadu.

In early 2004 Dr Jacob John wrote: "So far the number of cases in November (2003) 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." (4)

Final push to eradication in 2004

According to those who manage the polio eradication programme, the nation is poised for the final push to polio eradication. UNICEF is apparently encouraged

(5) by the India Expert Advisory Group, which concluded at a meeting on March 26-27, 2004 that the transmission of wild poliovirus could be stopped in the country within months. But belying the prophecies of experts, the wild polio virus continued to infect children in 2004 (table 1).

During the first quarter of 2004 there were only 10 polio cases with wild polioviruses detected in stool samples. As of September 4, 2004, there were 46 virologically confirmed and 121 'polio compatible' cases. That should have been the final number of polio cases during 2004. But as can be seen in the table, not only did cases continue to occur, there is a definite higher rise in number of polio cases in the later period. Thus, the experts' assessments have not proved correct.

Reasons for the programme's failure

One can identify the following reasons for the programme's failure: A high incidence of vaccine failure, a high incidence of polio caused by OPV, and the non-availability of inactivated polio vaccine (IPV), which contains the inactivated virus.

There had been many reports of vaccine failure in India. A study from a sentinel centre covering the years 1989 to 1994 found that 14 per cent of children who developed paralytic polio in 1989 had been fully immunised with three or more doses. This increased to 22.9 per cent in 1994 (6). In 1999, 32.1 per cent of children in Rajasthan who developed paralysis had received five or more doses of OPV beforehand (7). This went up to 58.6 per

As on: Representative period:	June 5, 2004 first three months	September 4 First six months	October 30 first eight months	November 27 first nine months	December 25 first 10 months	July 23, 2005 Full Year 2004
Virologically confirmed	10	46	77	98	121	134
Compatible cases	45	121	185	187	237	375

Year	1998	1999	2000	2001	2002	2003
OPV doses 4+	33%	40%	58%	60%	44%	51%

Year	1998	1999	2000	2001	2002
Cases	124	206	151	120	203

Data presented in these tables are taken from the website of the National Polio Surveillance Programme [cited 2005 July 23]. Available from www.npsindia.org

cent in 2000 (8). According to NPSP data from 1998 to 2003, a large number of children who developed paralysis had received four or more doses of OPV before the onset of paralysis (table 2).

OPV can cause paralysis in children because of mutant neurotoxic vaccine polioviruses known as vaccine-derived wild-like polioviruses (VDWL viruses). This is called vaccine associated paralytic poliomyelitis (VAPP). It can occur in a vaccine recipient, in which case it is called 'recipient VAPP'. If it occurs in a non-immune contact through the secondary spread of VDWL viruses, it is called 'contact VAPP'.

60 to 75 VAPP cases are expected to occur in India every year (9). In 1999 I had pointed out that a study of NPSP data suggests a high incidence of VAPP in India (10). This was borne out by more recent NPSP data (table 3). I have earlier estimated that about 300 VAPP cases occur every year (11). How many VAPP cases should we see before it merits concern or intervention? How many doses of OPV ensure protection?

With the non-availability of IPV, children whose immunity is compromised – due to disease or due to drugs – are more vulnerable to any infection, including from wild polioviruses. They also have a very high risk of developing VAPP. For this reason OPV is not recommended for such children. Wild polioviruses or mutant vaccine polioviruses can replicate for many months or years in the immunocompromised. These individuals may act as a source of infection for a prolonged period in the community.

Thus, IPV should be made available on an urgent basis for immunocompromised children in India. It will provide these children protection against polio disease. It will also provide protection to the community from these children if they become infected.

Dr Jacob John has stated: "Yash Paul is right in demanding that IPV be made available for individual use in children in whom OPV is contraindicated." (12) On June 9, 2000, I wrote an open letter to Dr Sobhan Sarkar, Assistant Commissioner, Immunisation, Ministry of Health and Family Welfare, New Delhi, stating that IPV should be made available for this high-risk population. A copy of the letter was sent to the Honorary Secretary General, Indian Academy of Pediatrics, Mumbai (7).

However, the policy remains unchanged and IPV is not available even for such children. This action has foreseeable consequences. Children are put at an unreasonably high risk of polio, and subsequently the community is also put at higher risk, despite the existence of a safe and effective vaccine, IPV.

Was polio eradication expected?

It is difficult to understand how polio eradication was envisaged. The vaccine's efficacy has not been evaluated. The reasons for a 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 will eradicate polio in the tenth year. It seems that those associated with the eradication programme are interested only in continuation of the programme.

On the other hand it can be said that the present eradication programme ensures that polio is not eradicated. Polio cases will continue to occur because of vaccine failure and due to mutant vaccine polioviruses. Infected immuno-compromised children will continue to spread wild as well as mutant vaccine polioviruses for a prolonged period in the community (13).

Role of the Indian Academy of Pediatrics

It may be argued that polio eradication in India is a part of WHO's global programme, so WHO has the prerogative to formulate the policy and the strategy. And IAP as a voluntary partner has no say in this. But Indian children are developing polio because of OPV and in spite of many doses of OPV. IAP must ensure that no avoidable harm occurs to any Indian child through any national or international programme.

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