

# CURRENT SCIENCE

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GUEST EDITORIAL

## Polio elimination: India's success story

Global eradication of an infectious disease illustrates the ultimate human mastery over a microbial pathogen. We have two successful precedents, smallpox in humans and rinderpest in cattle, both achieved through vaccination. The next vaccine-preventable human disease so targeted is polio, earlier known as 'Infantile paralysis' – *bala-graha-dosha* in ancient Indian medical literature. Polio is caused by polioviruses, types 1, 2 or 3. Natural or wild polioviruses (WPVs) have to be removed from humans for elimination (local) and eradication (global).

In 1988, the World Health Assembly (consisting of Ministers of Health of all nations) resolved to eradicate polio by the year 2000. The project was led by four partners (World Health Organization, UNICEF, Rotary International and US Centers for Disease Control) and managed by the Global Polio Eradication Initiative (GPEI). By 2000, WPV-2 was globally eradicated. As for WPV-1 and WPV-3, all except five countries also succeeded. The target year was then reset as 2005, but India, Pakistan, Afghanistan and Nigeria failed again.

There were two obstacles: 'biomedical' (low efficacy of trivalent oral polio vaccine [tOPV] and high intensity of poliovirus transmission) and 'socio-political' (low routine immunization coverage and inability of the system to reach large proportions of children). Biomedical problems in Uttar Pradesh (UP) and Bihar were considered the world's worst, on account of which many experts predicted India would never succeed. UP and Bihar had the highest density of under-five population, maximizing the speed of WPV circulation; they had the lowest level of sanitation/hygiene, resulting in multiple gut infections that minimized the efficacy of OPV. India's victory in January 2011 is indeed a cause for celebration, a boost for the sagging morale of GPEI. India has proved that eradication is feasible.

The socio-political obstacles in Pakistan, Afghanistan and Nigeria are formidable with no access to children in many pockets on account of violent conflicts. In Pakistan, several health workers were shot dead while immunizing children. India did not have such security problems, but immunization was not reaching a few millions of children of migrating families in search of work or working in

brick kilns, sugarcane fields or simply in transit in trains or buses. Once that was recognized, remedial measures were taken, contributing immensely towards success. The way we overcame biomedical obstacles is a story with important lessons.

There are two vaccines against polio, inactivated poliovirus vaccine (IPV, Salk) and live, infectious, but attenuated oral poliovirus vaccine (OPV, Sabin). Indian scientists were pioneers among developing nations on polio epidemiology and prevention by vaccination, including documenting comparative merits and defects of IPV and OPV. Polio paralysed an average of 500 children daily in India. Against WPV types 1 and 3, tOPV had very low efficacy. To improve efficacy we needed repetitive doses, pulse campaigns and giving single-type (monovalent) OPV types 1 and 3 (mOPV-1 and mOPV-3). IPV on the other hand, was highly effective even with just two doses. These lessons demanded our own country-specific strategy, but decisions were made on the basis of opinion fit for Western nations. In problems without scientific studies in India, many a times policy-makers would be right in adopting tactics from the West, but in the case of polio they made bad mistakes as we had already shown during 1970s and 80s why the western tactics would fail here.

For three decades the policy-makers ignored Indian science on polio – allowing over 3 million children paralysed unnecessarily and delaying polio elimination by 11 years. Finally, when GPEI accepted Indian ideas, our Government was forced to fall in line. If in policy decisions scientific evidence is neither sought nor used when available, why should we do research? The low research output from medical colleges and universities is partly due to the lack of demand and rewards. The satisfaction derived from seeing one's research making a difference is the greatest reward, and it costs nothing. Where there is demand, supply will follow.

Faced with continuing high prevalence of polio in India even in 1994, WHO designed and funded a National Polio Surveillance Project (NPSP) outside of the Health Ministry's Expanded Programme on Immunization and entrusted polio elimination to it, stipulating the exclusive

use of OPV. UP and Bihar had three formidable obstacles for eliminating polio using tOPV: low routine tOPV coverage (failure to vaccinate) and its very low protective efficacy (failure of the vaccine); at the same time the speed and intensity of transmission of WPV-1 and WPV-3 were so high that infants got polio before 7–10 doses could be given. In an unprecedented manner all players came together and worked in unison and took India to the victory stand.

From bottom up: health workers and community volunteers followed detailed ‘micro-planning’ and ensured that every child got the pulse campaign doses, reaching >99% coverage, verified by supervisors. Medical officers of NPSP followed up every child with suspected polio, preliminarily diagnosed with acute flaccid paralysis (AFP). Two consecutive-day stool samples were collected and dispatched to the designated polio laboratory. A hierarchy of laboratories had been networked under NPSP and WHO managed their proficiency by annual evaluations. An advisory body of national and international experts was created and it reviewed all information regularly and advised the governments on all aspects of surveillance and response to any detected WPV. The State Governments played their part fully. The Central Government has been spending over Rs 1000 crore annually to purchase the needed vaccines. The number of pulse campaigns in UP and Bihar was increased to 10 per year and families and workers cooperated alike.

The failure to vaccinate was solved. The failure of vaccine had to be solved.

Based on early Indian research results, mOPV-1 and mOPV-3 were licensed in 2005. Vaccine manufacturers supplied the quantities needed for extensive use in UP and Bihar. Efficacy of tOPV against WPV-2 was high, as its elimination in 1999 proved. But type-2 in tOPV also interfered with the efficacies of types 1 and 3. Fresh studies reconfirmed the high efficacy of mOPVs and then explored the efficacy of bivalent OPV (bOPV) with types 1 and 3; type-specific efficacies were found non-inferior to those of mOPVs, but significantly superior to those of tOPV. All obstacles were thus tackled simultaneously and the very last child with polio (due to WPV-1) had her onset of paralysis on 13 January 2011. In February 2012, WHO declared India ‘non-endemic’ for WPV polio. We expect the WPV-free formal certification in early 2014.

This is not the end of the journey. Way back in 1993, Indian scientific definition of global polio eradication as ‘zero incidence of poliovirus infection, wild and vaccine’

was proposed, as against the GPEI definition of ‘zero incidence of WPV infection’. That meant OPV was incompatible with eradication, finally accepted by GPEI in 2006. Most experts thought that OPV could be withdrawn after eradicating WPVs. In 1996, we predicted that vaccine viruses will have to be eradicated using IPV to complete and conclude the process. That stand was accepted by GPEI in 2012.

India’s remarkable success of elimination of WPVs hides the fact that OPV has been causing polio in many children. Polio directly caused by vaccine viruses (vaccine-associated paralytic polio [VAPP], currently over 100/year) will stop immediately as we withdraw OPV. Vaccine viruses can remain in transmission and gradually regain the properties lost during attenuation: neurovirulence and transmission efficiency. Such de-attenuated viruses are currently called ‘vaccine-derived polioviruses’ (VDPVs) that continue to cause sporadic outbreak of polio in several countries, including India. We had four such cases in 2013, all due to type-2. This is typical of the problem globally – of all global cases due to VDPVs, 85% are due to type-2.

So, a new GPEI policy has emerged in 2013: to introduce IPV in all OPV-using countries in 2015 and to replace all tOPV with bOPV in 2016. This is the first part of the ‘end game’ – global synchronous switch from tOPV to bOPV. Pakistan, Aghanistan and Nigeria will also join the end game and we hope that the introduction of IPV will expedite the elimination of WPV-1 and WPV-3 from these last bastions of wild polioviruses.

India will have to comply with WHO policy: an expert committee under the Indian Council of Medical Research has recently recommended the introduction of IPV in early 2015 prior to the tOPV to bOPV switch. While global experts are lauding India for its success, and goading India towards the end game, we know that India could and should have led the developing world – since we had all the right evidences and ideas to go precisely through this route towards a world in which no child ever gets polio due to WPV or vaccine virus.

The second part of the ‘end game’ will be the withdrawal of bOPV after the world goes over 3 years without WPV-1 and WPV-3 infection anywhere.

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