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PROTECTING AGAINST POLIO

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With wild polio virus strains reduced by 99.9% since 1988, the world is inching towards eradicating polio. But unfortunately, more children today are affected by the live, weakened virus contained in the oral polio vaccine (OPV) that is meant to protect them. The weakened virus in the vaccine can circulate in the environment, occasionally turn neurovirulent and cause vaccine-derived poliovirus (VDPV) in unprotected children. While the wild-type virus has caused 22 and 25 polio cases in 2017 and 2018 (as on October 30, 2018), respectively, in just two countries (Pakistan and Afghanistan), VDPV was responsible for 96 and 75 polio cases in more countries during the same periods. “Paradoxically, vaccination (using OPV) has become the main source of polio paralysis in the world,” notes a 2018 paper in *The Lancet*.

While circulating VDPV strains are tracked, and outbreaks and cases are recorded and shared, little is known about vaccine-associated paralytic poliomyelitis (VAPP) cases, particularly in India. VAPP occurs when the virus turns virulent within the body of a recently vaccinated child and causes polio. The frequency of VAPP cases varies across countries. With high-income countries switching to the inactivated polio vaccine (IPV) that uses dead virus to immunise children, the VAPP burden is concentrated in low-income countries which continue to use the OPV.

In spite of the World Health Organisation asking all countries using the OPV to include a “continuous and effective system of surveillance” to monitor the frequency of VAPP in 1982, India did not comply. Data on VAPP became available only years after active polio surveillance was initiated in 1997, say Jacob John, a virologist and formerly with the Christian Medical College, Vellore, and a polio expert, and Dhanya Dharmapalan in a paper published in September in the *Indian Journal of Medical Ethics.* However, even after 1997, India did not count VAPP cases. “This is because it does not add value to the polio elimination programme,” says Pradeep Haldar, Deputy Commissioner of the Immunisation Division, Ministry of Health and Family Welfare.

The justification that VAPP cases can be ignored as they are “sporadic and pose little or no threat to others” is ethically flawed. The stand that VAPP cases are epidemiologically irrelevant is ethically problematic, note Dr. John and Vipin M. Vashishtha in a 2012 paper in *Indian Pediatrics*.

Many member countries autonomously chose the IPV over the OPV, mainly to avoid any risk of VAPP. In India, the VAPP cases can be avoided once the government stops using the OPV to immunise children. “India ignored the problem of VAPP until their numbers were counted,” writes Dr. John. A paper and a letter published in 2002 in the *Bulletin* of the WHO said the number of VAPP cases in India in 1999, 2000 and 2001 were 181, 129 and 109, respectively.

The WHO had suggested a rate of 1 case of VAPP per million births and had estimated the annual global burden of VAPP to be approximately 120 cases in 2002. Under these circumstances, India’s share would been merely 25 VAPP cases per year, based on the annual birth cohort of 25 million. But the observed number of cases in India in 1999 was 181. “This indicates that the actual risk is seven times the expected number... It is reasonable to assume that there would be 400-800 annual cases of VAPP globally,” Dr. John wrote in 2002 in the *Bulletin*. That would have meant that there were 100-200 VAPP cases in India each year. The global estimated incidence of VAPP was then revised to 200-400 cases.

Despite knowing that there is a higher burden of polio caused by oral vaccines, India continued to use the OPV. “The decision to use only the OPV was faulty. Parents were obliged to accept the OPV and face the consequences of VAPP as well as VDVP,” Dr. John says.

Says Dr. Haldar: “India’s goal was to eradicate polio, and the OPV was crucial for that. The IPV produces humoral immunity (involving antibodies in body fluids) so the immunised child does not get paralysis, but it can’t stop the circulation of wild polio viruses. For instance, no polio cases were seen in Israel but wild polio viruses were detected in the environment. The viruses will continue to circulate in the community.”

Dr. John counters this: “The primary objective of polio vaccination is to prevent the disease, which the OPV failed to fully achieve. The OPV was used for eradicating purposes but without fully protecting the children. When you give a vaccine, you must ensure that the child doesn’t get polio. Only the IPV can do that. A child has to be given several doses of the OPV. Even then, the OPV doesn’t fully protect the child. There was no reason for not using both the IPV and the OPV.”

It is easier to administer the OPV than the IPV and the cost per dose of OPV is also lower than that of the IPV. However, the OPV fared poorly on two important counts: safety and efficacy. “Administering the OPV was easier than the IPV but no cost-benefit analysis was done before choosing the OPV,” says Dr. John. “Three doses protected only two-thirds of Indian children and many developed polio before they turned one year. So we had to give more doses per child.”

While high-income countries preferred the IPV, India and other low-income countries continued to rely on the OPV. India licensed the IPV only in 2006 but did not introduce it in routine immunisation.

“The reason for not switching over to the IPV is because global production was too low to meet India’s demand. India is the largest cohort. It needs 48 million doses per year to immunise all children,” Dr. Haldar says.

This is a feeble excuse. As Pushpa Bhargava noted in an article in *The Hindu* (2008), the decision to manufacture the IPV in India was taken in 1988 and a company was eventually set up with technology transfer from France. The minutes of the meeting that year in Delhi read: “Indigenous production of IPV before 1991 shall be aimed at… As new IPV programme ramps up, the OPV will ramp down.” But the plan was shelved.

The IPV is essential for post wild-type polio virus eradication, to get rid of VDPV and VAPP. The globally synchronised switch from trivalent to bivalent OPV in mid-2016 was accompanied by administering a single dose of the IPV prior to administering the OPV. “A single dose of the IPV given before the OPV prevents VAPP cases,” Dr. John says. A single dose of the IPV primes the immune system and the antibodies against the polio virus, seen in more than 90% of immunised infants, notes a paper in *The Lancet.*

With no way of monitoring VAPP cases in India, there is no way of knowing if the use of a single dose of IPV followed by immunisation using bivalent OPV has led to a reduction in the number of VAPP cases.

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