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COMMENTS

Polio programme: let us declare victory and move on

Neetu Vashisht, Jacob Puliye

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Abstract

It was hoped that following polio eradication, immunisation could be stopped. However the synthesis of polio virus in 2002, made eradication impossible. It is argued that getting poor countries to expend their scarce resources on an impossible dream over the last 10 years was unethical.

Furthermore, while India has been polio-free for a year, there has been a huge increase in non-polio acute flaccid paralysis (NPAFP). In 2011, there were an extra 47,500 new cases of NPAFP. Clinically indistinguishable from polio paralysis but twice as deadly, the incidence of NPAFP was directly proportional to

doses of oral polio received. Though this data was collected within the polio surveillance system, it was not investigated. The principle of primum-non-nocere was violated.

The authors suggest that the huge bill of US$ 8 billion spent on the programme, is a small sum to pay if the world learns to be wary of such vertical programmes in the future.

> *"For of all sad words of tongue or pen, the saddest are these: 'It might have been'!"*
>
> *John Greenleaf Whittier (1807-1892)*

January 12, 2012, marked a significant milestone for India. It was the first anniversary of the last reported wild polio case from India. Keeping the country free of polio for a whole year was a feat that is a tribute to the Government of India and its 2.3 million vaccinators, who visited over 200 million households to ensure that the nearly 170 million children (under five years in age) were repeatedly immunised with oral polio vaccine (OPV) **(1)**. India's

programme has largely been self financed. The country has thus far spent more than Rs 120 billion (US$2.5 billion US$ 1 = Rs 50) on polio eradication after the programme started here in 1994 **(2)**. The $2.5 billion spent by India must be seen against $2 billion spent by the United States of America on world-wide polio eradication **(3)**, the $1.3 billion expended by Bill Gates **(4)**, and the $0.8 billion raised by the loudest voice for polio eradication – Rotary International – over the last 20 years **(5)**.

The celebrations of January 12, 2012 would have been accompanied by a collective, massive sigh of relief because a new 'name and shame' policy has been adopted by the World Health Organisation (WHO), apparently without approval **(6)**, to boost the eradication effort. In this vein, the acronym PAIN has been used, while referring to the polio-endemic countries of Pakistan, Afghanistan, India and Nigeria. While the exact origin of this oft-repeated acronym is unclear **(7**, **8)**, India will be happy to be rid of the opprobrium.

Internationally, supporters of eradication desperately needed a victory in India to drum up enthusiasm, at a time when commitment to the programme had been flagging, and funding was rapidly drying up. With a $410 million shortfall in the funds available, this gap threatens to undermine eradication efforts **(9)**. While India chalked up a year of being polio free, four other countries, Angola, Chad, the Democratic Republic of Congo and Sudan, have had year-long outbreaks. Another 13 countries have had recent infections – eight in Africa, along with Nepal, Kazakhstan, Tajikistan, Turkmenistan and Russia **(10)**. The ethics of spending so much on polio eradication has been challenged by Richard Horton, editor of *The Lancet***(11)**, and Arthur L Caplan, director of the University of Pennsylvania's bioethics centre **(12)**. Besides, former supporters of the programme are now questioning its feasibility **(13**, **16)**.

History and origin

Professor William Muraskin, the noted historian who specialises in problems of international health policy and infectious disease, has written in his book *Polio Eradication and its discontents* that the polio programme was primarily designed to prove the fundamental usefulness of eradication as a public health tool by the *Pan American Health Organisation* (PAHO) – the incubator of eradication campaigns **(17)**.

It is noteworthy that the Pulse Plus programme was begun in India with a $ 0.02 billion grant from overseas in 1995 **(18)**, at a time when experts in India felt that polio eradication was not the top priority for the country. Four years into the programme of eradication, in 1998, Dr T Jacob John wrote, “Today poliomyelitis is not the number one priority of public health in India. However, we must eradicate it for the sake of the rest of the world.” **(19)**. Having accepted the grant of $ 0.02 billion, India has spent a hundred times as much. This is a startling reminder of how initial funding and grants from abroad distort local priorities.

Terminology: eradication versus elimination versus control

The first step in understanding the issue is to clarify what the term eradication implies as distinct from elimination and control of disease.

The different concepts have been described by Dowdle **(20)**:

> Control is the reduction of disease to a locally acceptable level as a result of deliberate efforts; continued intervention is required to maintain the reduction.
>
> Elimination is reduction of the incidence of a disease to zero in a defined geographical area as a result of deliberate efforts. Even after elimination, continued intervention is needed to maintain the incidence at zero.
>
> Eradication is the permanent reduction to zero of the worldwide incidence of infection as a result of deliberate efforts such that intervention is no longer needed.
>
> Extinction is said to have occurred when the specific infectious agent no longer exists in nature or in the laboratory.

Eradication spares future generations the risk of infection and renders further vaccination unnecessary. Eradication is thus considered an investment with resultant huge savings from not having to vaccinate any more **(6**, **21)**. Caplan, in his essay entitled ‘Is disease eradication ethical?’, has noted that eradication may be public health’s greatest rhetorical weapon and unmatched in its ability to command funding, popular support, the attention of politicians and positive media coverage **(12)**. The stakes involved portend relief forever as well as the ability to relax humanity’s guard against the disease **(12)**.

Synthetic polio makes eradication impossible

The charade about polio eradication and the great savings it will bring has persisted to date. It is a paradox, that while the director general of WHO, Margret Chan, and Bill Gates are trying to muster support for polio eradication **(22)** it has been known to the scientific community, for over 10 years, that eradication of polio is impossible. This is because in 2002 scientists had synthesised a chemical called poliovirus in a test-tube with the empirical formula C332, 652H492, 388N98, 245O131, 196P7, 501S2, 340. It has been demonstrated that by positioning the atoms in sequence, a particle can emerge with all the properties required for its proliferation and survival in nature **(23**, **24)**. Wimmer writes that the test-tube synthesis of poliovirus has wiped out any possibility of eradicating poliovirus in the future. Poliovirus cannot be declared extinct because the sequence of its genome is known and modern biotechnology allows it to be resurrected at any time *in vitro* . Man can thus never let down his guard against poliovirus. Indeed the 18-year-old global eradication campaign for polioviruses will have to be continued in some format forever. The long promised "infinite" monetary benefits from ceasing to vaccinate against poliovirus will never be achieved **(24)**. The attraction that 'eradication' has for policy makers will vanish once this truth is widely known.

The elephant in the room: the problem of non-polio Acute Flaccid Paralysis (AFP)

It has been reported in the *Lancet* that the incidence of AFP, especially non-polio AFP has increased exponentially in India after a high potency polio vaccine was introduced **(25)**. Grassly and colleagues suggested, at that time, that the increase in AFP was the result of a deliberate effort to intensify surveillance and reporting in India **(26)**. The National Polio Surveillance Programme maintained that the increased numbers were due to reporting of mild weakness, presumably weakness of little consequence **(27)**. However in 2005, a fifth of the cases of non-polio AFP in the Indian state of Uttar Pradesh (UP) were followed up after 60 days. 35.2% were found to have residual paralysis and 8.5% had died (making the total of residual paralysis or death – 43.7%) **(28)**. Sathyamala examined data from the following year and showed that children who were identified with non-polio AFP were at more than twice the risk of dying than those with wild polio infection **(27)**.

Data from India on polio control over 10 years, available from the National Polio Surveillance Project, has now been compiled and made available online for it to be scrutinised by epidemiologists

and statisticians **(29)**.

This shows that the non-polio AFP rate increases in proportion to the number of polio vaccine doses received in each area. Nationally, the non-polio AFP rate is now 12 times higher than expected. In the states of Uttar Pradesh (UP) and Bihar, which have pulse polio rounds nearly every month, the non-polio AFP rate is 25- and 35-fold higher than the international norms. The relationship of the non-polio AFP rate is curvilinear with a more steep increase beyond six doses of OPV in one year. The non-polio AFP rate during the year best correlates to the cumulative doses received in the previous three years. Association (R2) of the non-polio AFP rate with OPV doses received in 2009 was 41.9%. Adding up doses received from 2007 increased the association ($R2 = 55.6\%$ $p < 0.001$) **(30)**. Population density did not show any association with the non-polio AFP rate, although others have suggested that it is related to polio AFP **(31)**.

The international incidence of non-polio AFP is said to be 1 to 2/100,000 in the populations under 15 **(32**, **33)**. The benchmark of good surveillance is the ability to detect one case of AFP per 100,000 children even in the absence of polio **(34)**. In 2011, an additional 47,500 children were newly paralysed in the year, over and above the standard 2/100,000 non-polio AFP that is generally accepted as the norm. **(32**, **33)**. It is sad that, even after meticulous surveillance, this large excess in the incidence of paralysis was not investigated as a possible signal, nor was any effort made to try and study the mechanism for this spurt in non-polio AFP. These findings point to the need for a critical appraisal to find the factors contributing to the increase in non-polio AFP with increase in OPV doses – perhaps looking at the influence of strain shifts of entero-pathogens induced by the vaccine given practically once every month.

From India's perspective the exercise has been extremely costly both in terms of human suffering and in monetary terms. It is tempting to speculate what could have been achieved if the $2.5 billion spent on attempting to eradicate polio were spent on water and sanitation and routine immunisation. Perhaps control of polio, to the level of elimination, may well have been achieved as it has been in more developed countries. When the US was badly mired in Iraq in 2005, Joe Galloway suggested that the US must simply declare victory, and then exit **(35)**. Perhaps the time is right for such an honourable strategy with regard to polio eradication.

Strategy for the future

Eckard Wimmer has noted the WHO's current policy calls for cessation of OPV vaccination three years after the last case of poliovirus-caused poliomyelitis. Injectable polio vaccine (IPV) will replace OPV in countries which can afford it. The risks inherent in this strategy are immense. Herd immunity against poliomyelitis will rapidly decline as new children are born who have not been infected with wild-type viruses or were not vaccinated, a situation that has never existed in human history. Thus, any outbreak of poliomyelitis will be disastrous, whether it is caused by residual samples of virus stored in laboratories, by vaccine-derived polioviruses, or by poliovirus that is chemically synthesised with malignant intent **(24)**.

The huge costs of repeated rounds of OPV in terms of money and non-polio AFP shows that monthly administration of OPV must cease. The low incidence of non-polio AFP in places given less than six doses, suggests that routine immunisation is relatively safe. Our resources are perhaps better spent on controlling poliomyelitis rather than trying to eradicate the disease. Routine immunisation must be strengthened and perhaps one or two rounds of pulse polio may be needed.

The problem however is that the manufacturers of OPV may cease to produce the vaccine – a scenario that was predicted for India eight years ago **(36)**. The Government of India is in a quandary, having given up its capacity to manufacture OPV indigenously, on misguided advice from overseas **(37)**. It is now dependent on international manufacturers for its supplies. India needs to urgently ensure that adequate supplies of the vaccines that it requires are available for our children, so that this eradication adventure does not transform itself into an epidemic disaster.

Conclusion

The polio eradication programme epitomises nearly everything that is wrong with donor funded 'disease specific' vertical projects, at the cost of investments in community-oriented primary health care (horizontal programmes) **(38)**. Gilliam has described how vertical programmes undermine broader health services through duplication of effort (each single disease control programme requires its own bureaucracy), distort national health plans and budgets and, because salaries of donor-funded vertical programmes are often more than double those of equally trained government workers, lead to a diversion of skilled local health personnel from primary healthcare, causing an 'internal brain

drain' **(39)**. We have seen how polio, that was not a priority for public health in India, was made the target for attempted eradication with a token donation of $ 0.02 billion. The Government of India finally had to fund this hugely expensive programme, which cost the country 100 times more than the value of the initial grant.

De Maeseneer and colleagues suggest that vertical programmes have unwittingly increased the incidence of other diseases and broken the first rule of medicine-primum non nocere- first do no harm. They cite the example of HIV and hepatitis caused by WHO-endorsed immunisation programmes against other diseases **(40)**. With polio eradication there was a huge increase in non-polio AFP, in direct proportion to the number of doses of the vaccine used. Though all the data was collected within an excellent surveillance system, the increase was not investigated openly. Another question ethicists will ask, is why champions of the programme continued to exhort poor countries to spend scarce resources on a programme they should have known, in 2002, was never going to succeed.

In the final analysis, if the right lessons have been learnt and the world does not repeat these mistakes, the costs may yet be justified.

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Neetu Vashisht ***(puliyel@gmail.com)***
(mailto:puliyel@gmail.com)
Department of Paediatrics
St Stephens Hospital, Delhi 110054

Jacob Puliye ***(puliyel@gmail.com)***
(mailto:puliyel@gmail.com)
Department of Paediatrics,
St Stephens Hospital, Delhi 110054

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