



Post-eradication immunization policy for poliomyelitis

The purpose

The ultimate goal of disease eradication is to interrupt circulation of the target organism on a global scale such that control measures can be discontinued.¹ As with smallpox eradication, there will be benefits and challenges to stopping polio immunization. Stopping immunization would eliminate side effects such as vaccine-associated paralytic polio (VAPP). From an economic perspective, cessation of polio immunization could save hundreds of millions of dollars every year.

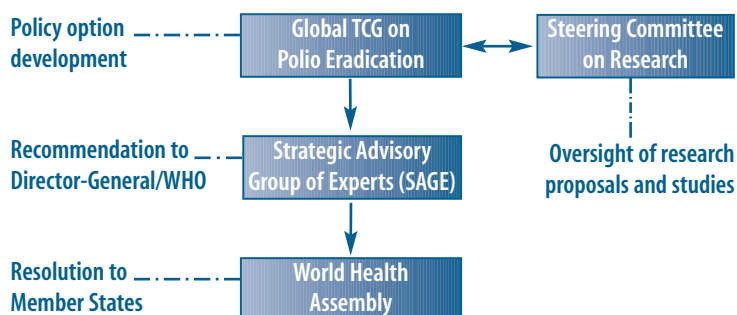
Many of the challenges to stopping polio immunization are similar to those faced by smallpox, including effective laboratory containment of the virus. Unlike smallpox, post-eradication immunization policy for polio is further complicated by the fact that oral polio vaccine (OPV) has caused paralytic polio outbreaks and there has been long-term excretion of vaccine-derived poliovirus from immunodeficient persons. Thus the challenge to stopping OPV would be: 1. protecting susceptible populations from possible outbreaks due to circulating vaccine-derived poliovirus (cVDPV) and 2. minimizing the risk of a poliovirus reintroduction from immunodeficient persons, laboratories or vaccine production sites in the future.

The process

Given the need for international consensus on a post-eradication immunization policy for polio, the final decision will rest with WHO Member States represented at their annual meeting, the World Health Assembly (WHA). Through broad consultation and an extensive programme of work, the Global Technical Consultative Group for Poliomyelitis Eradication (TCG) is developing potential policy options for consideration by WHO's Strategic Advisory Group of Experts (SAGE), prior to eventual presentation to the World Health Assembly.

The agenda of work developed by the TCG includes programmatic work, new scientific research, and policy development, to be completed by 2002, 2003 and 2004 respectively. All relevant programmatic data will be collected by WHO and UNICEF on issues such as inactivated poliovirus vaccine (IPV) price, production capacity, potential introduction costs, the frequency of VDPV circulation and VDPV surveillance. Overseen by the TCG's Steering Committee on Research, new scientific data will be generated on key issues such as the efficacy of IPV in developing country settings and the frequency, significance and potential impact of long-term vaccine virus excretors. To support policy development, the political, economic and operational implications of each of the potential policy options will be evaluated.

The process for developing post-eradication immunization policy for polio



Surveillance confirms that polio outbreaks due to circulating vaccine-derived polioviruses (cVDPV) are rare, but possible. An estimated 10 billion doses of oral polio vaccine (OPV) were administered worldwide between 1997 and 2001; only two episodes of polio outbreaks due to cVDPV have been confirmed in that period: in Hispaniola (2000-1) and the Philippines (2001).

Recognizing that it will take time to collect these data, and to establish an international consensus on post-eradication immunization policy for polio, plans have been made to continue using OPV in most countries for the foreseeable future.



The progress

Since 1997 the TCG and its technical advisers have studied the evolving issue of post-eradication immunization policy for polio, supplemented by several meetings of experts to address specific issues.

In March 1998, WHO convened the first meeting of experts on stopping polio immunization, which concluded that “Vaccination with OPV should stop and vaccination with IPV can stop when there is (a) sufficient assurance of the global eradication of wild type polioviruses, (b) suitable laboratory containment of remaining stocks of wild polioviruses, and (c) evidence that VDPV will circulate for only a limited period in the post-vaccination era.” The sixth meeting of the TCG identified a further criteria: that a global stockpile of vaccine is available if needed, with a clear strategy for its use.

In January 2000, WHO convened a second meeting of experts on “New polio vaccines for the post-eradication era”, which concluded that the development of a new vaccine would pose formidable regulatory and manufacturing challenges. Consequently, a meeting in September 2000 on regulatory challenges to licensing vaccines for the post-eradication era focused on monovalent OPVs (for controlling type-specific outbreaks) and IPV based on Sabin strains (to replace the wild poliovirus strains currently used in IPV).

The detection of two polio outbreaks caused by circulating VDPV - in Hispaniola in 2000-2001 and the Philippines in 2001 – gave new urgency to post-eradication immunization policy development and highlighted the challenges to maintaining polio surveillance and immunization in countries/regions that are polio-free.

In May 2001, WHO convened a steering committee to guide, monitor and evaluate the ongoing research agenda for post-eradication policy development, under the direction of the TCG. New research was already commissioned by November 2001.

In the January 2002 edition of *Clinical Infectious Diseases*,² the TCG summarized the current status of the polio “endgame” and noted that, though challenging, there are compelling reasons for discontinuing OPV as soon as possible following eradication. Three scenarios for stopping OPV were outlined:

1. coordinated discontinuation of OPV (with or without IPV, depending on national decision);
2. replacement of OPV with IPV in all countries;
3. development of new live vaccines that would not cause VAPP and would not be transmissible.

The TCG stated that WHO’s three-part agenda of work must be completed before a final decision can be made as to the feasibility of the most appropriate strategy.

The challenges

Coordinating post-eradication immunization policy – many countries may want to stop immunization against polio as soon as circulation is interrupted globally. However, individual country decisions to stop or continue OPV use could place populations at risk from cVDPVs.

Vaccine security in the pre- and post-eradication eras – as global certification approaches, an increasing number of countries may wish to use IPV, though production capacity is currently limited. At the same time, sufficient OPV must be available for routine immunization for the foreseeable future and for stockpiling against outbreaks in the post-eradication era. The appropriate range and quantity of vaccines must be ensured.

Funding for timely completion of the research agenda – the research agenda involves an ambitious programme of work requiring more than US\$ 1 million per year. The timely completion of necessary research is essential to define options and make policy decisions on stopping polio immunization.

Sustaining the surveillance infrastructure and immunization coverage – see fact sheet on *Certification of global polio eradication*.

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Further reading

Report of the meeting on the scientific basis for stopping polio immunization, Geneva, 23-25 March 1998, WHO/EPI/GEN/98.12.

New polio vaccines for the post-eradication era, Geneva, 19-20 January 2000, WHO/V&B/00.20

“Polio vaccines for the post-eradication era: regulatory and biosafety issues”, 20-21 September 2000 (in print).

Report of the sixth meeting of the Global Technical Consultative Group for Poliomyelitis Eradication, Geneva, 7–10 May 2001, WHO/V&B/01.32.

2. “Endgame” Issues for the Global Polio Eradication Initiative, CID 2002:34 (1 January 2002)

After certification of polio eradication, individual decisions by countries to stop or continue oral polio vaccine (OPV) use could place populations that no longer use the vaccine at risk of exposure to circulating vaccine-derived polioviruses (cVDPV). For this reason, any cessation of OPV use would require an internationally coordinated approach.