

## Preparing for the withdrawal of all oral polio vaccines (OPVs): Replacing trivalent OPV (tOPV) with bivalent OPV (bOPV)

In May 2012, the World Health Assembly declared the completion of poliovirus eradication to be a “programmatic emergency for global public health” and called on the Director General of WHO to develop a comprehensive polio endgame strategy. The Global Polio Eradication Initiative’s *Polio Eradication and Endgame Strategic Plan 2013-2018*, approved by the Executive Board of WHO in January 2013, requires the phased removal of all oral polio vaccines (OPVs). This will eliminate the risks of vaccine-associated paralytic polio (VAPP) and circulating vaccine-derived poliovirus (cVDPV).

**If not already underway, planning for OPV cessation must start now, while efforts are being intensified to interrupt transmission of the remaining strains of wild poliovirus.** Preparation for the removal of OPVs includes introducing at least one dose of inactivated polio vaccine (IPV) into routine immunization programmes in all countries by the end of 2015.

**The *Endgame Plan* requires the removal of all OPVs in the long term, beginning with a switch from trivalent OPV (tOPV) to bivalent OPV (bOPV), removing the type 2 component (OPV2) from immunization programmes.** After all wild polioviruses have been fully eradicated, then all OPVs will be withdrawn.

**The current target date for the switch to bOPV is April 2016**, during the ‘low’ season for poliovirus transmission in many countries with endemic polio or recent polio cases.

### The rationale for OPV withdrawal

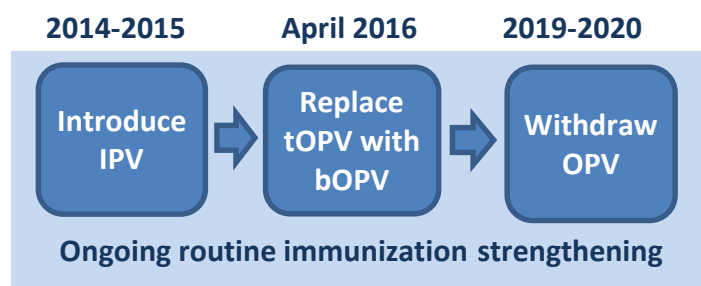
Currently, 145 countries use tOPV to vaccinate children against polio in their routine immunization programmes.

tOPV contains all three poliovirus serotypes (1, 2 and 3), and the use of this vaccine has led to the eradication of wild poliovirus type 2 (WPV2), with the last case occurring in 1999. The last detected case of WPV3 was in 2012. Furthermore, four of the six WHO regions have been certified as polio-free.

**Even as the remaining strains of wild poliovirus are being eradicated, the switch from tOPV to bOPV will be a major step to combat cVDPV and VAPP.** Over 90% of cVDPV cases, and approximately 40% of VAPP cases, are due to the type 2 component of tOPV. The type 2 component of tOPV also interferes with the immune response to poliovirus types 1 and 3.

Given the risk the type 2 component of tOPV poses to a world free of WPV2, tOPV will be replaced in routine programmes and supplementary immunization activities (SIAs) by bOPV. bOPV contains type 1 and 3 serotypes only, to help stop transmission of WPV1 and 3, and to reduce the risk of VAPP and cVDPVs.

The introduction of IPV will help to reduce risks associated with the withdrawal of OPV type 2, facilitate interruption of transmission with the use of monovalent OPV type 2 in the case of outbreaks, and hasten eradication by boosting immunity to poliovirus types 1 and 3.



## Preparing for the switch

The primary risk associated with the cessation of use of type 2 OPV is the re-introduction of disease-causing type 2 poliovirus into a population with increasing susceptibility to type 2 poliovirus. **The switch from tOPV to bOPV must therefore be globally synchronized to minimize the risk of new cVDPV type 2 emergence.**

**As soon as possible, countries are advised to develop operational plans for implementing the switch,** involving all relevant national entities (for example, the Inter-agency Coordination Committee).

Early preparation of national plans will help establish clear timelines for:

- **Vaccine supply planning, including close ongoing management and monitoring of tOPV inventories and requirements up to April 2016**
- Calculating projections of bOPV needs
- Procuring bOPV (for self-procuring countries)
- Planning and budgeting the collection, transport, storage, and proper disposal of tOPV once withdrawn from the cold chain
- Training health workers on the rationale and process of the switch
- Communicating with local experts and other stakeholders

## Registration of bOPV for routine use

Currently, bOPV is only licensed for use in supplementary immunization activities. Based on clinical data, the labelling of bOPV is expected to be revised by mid-2015 to enable use of this vaccine in routine immunization. While formal licensing and national registration procedures are underway, countries will be encouraged to accept the use of this vaccine on the basis of WHO prequalification.

## Planning for a final procurement of tOPV

**Countries should plan their forecasts and procurement in a way that aims to minimize any residual tOPV stocks on hand by April 2016, while avoiding stock-outs prior to the switch.** Minimal tOPV stocks will reduce the costs and logistics of disposal of all remaining unused tOPV after the switch.

**For countries procuring through UNICEF or PAHO Revolving Fund, close coordination and sharing of stock levels with UNICEF and PAHO country offices is critical to minimizing excess stocks of tOPV remaining in April 2016.** For self-procuring countries, forecasts should be shared and jointly reviewed with vaccine suppliers to help facilitate the timely procurement of appropriate amounts of tOPV and bOPV for the transition. WHO and UNICEF will be available to facilitate this process as required.

Technical assistance and guidance on aspects such as operational planning, stock management, and communications will be shared in due course.

### KEY DATES

#### March 2015

National authorities begin operational planning.

#### May 2015

The World Health Assembly considers a resolution on the switch.

#### End September 2015

SAGE reviews the status of pre-requisites and makes the final decision to proceed with the switch in April 2016, or to postpone until 2017.

#### October 2015

National plans finalized.

#### April 2016

Expected date for switch from tOPV to bOPV.

#### April and May 2016

Validation of the removal of all tOPV.

#### From May 2016

tOPV will no longer be used globally, neither in routine immunization, nor in SIAs.