An introduction to the switch from trivalent to bivalent oral polio vaccines

February 2015
Contents

1. Rationale for OPV withdrawal
2. Timelines for switching from tOPV to bOPV
3. Programmatic implications of the switch
Children paralyzed by polio

Type 2 polio eradicated
(WPV)
Vaccine-derived polio outbreaks (circulating VDPVs) 2000-2013

Type 2 (478 cases)
Type 1 (79 cases)
Type 3 (9 cases)
World Health Assembly resolution 65.5

“Declares polio eradication a programmatic emergency for global public health...

...“urges the Director General to rapidly finalize a polio endgame plan...

“...and inform Member States of the potential timing of a switch from trivalent to bivalent OPV for all routine immunization programmes”

(May 2012)
# Coming dates for the Endgame Plan

<table>
<thead>
<tr>
<th>Date</th>
<th>Event Description</th>
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<tbody>
<tr>
<td>May 2015</td>
<td>World Health Assembly consider a resolution on the OPV switch</td>
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<tr>
<td>December 2015</td>
<td>At least 1 dose of IPV introduced into routine immunization programmes in all countries</td>
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<tr>
<td>April 2016</td>
<td>Withdraw type 2 OPV globally</td>
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<td>2020?</td>
<td>After all wild polioviruses have been fully eradicated, withdraw all OPVs</td>
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Rationale for switching from trivalent OPV to bivalent OPV

Currently, the risks associated with the type 2 component of tOPV outweigh the benefits

• Since 1999, type 2 wild poliovirus has not been detected

• The type 2 component of tOPV:
  – Causes more than 90% of vaccine-derived polio viruses (VDPVs)
  – Causes approx. 40% of vaccine-associated paralytic polio (VAPP) cases
  – Interferes with the immune response to poliovirus types 1 and 3 in tOPV

• IPV introduction 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
  – Hasten eradication by boosting immunity to poliovirus types 1 and 3
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Milestones towards the switch

May 2015, World Health Assembly (WHA):
• Discussion on progress achieved towards OPV2 withdrawal in April 2016
• The WHA may consider a resolution calling on member states to prepare to implement the switch

October 2015, Strategic Advisory Group of Experts (SAGE):
• SAGE will assess the epidemiology of persistent type 2 circulating VDPVs as part of a readiness review.
General steps for the switch

**Readiness criteria**

- IPV is introduced in all countries by end 2015
- bOPV is licensed for use in routine immunization
- Surveillance and response capacity are implemented for WPV2 detection; a type 2 mOPV stockpile is established
- Phase 1 containment activities are completed, with appropriate handling of residual type 2 materials
- WPV2 global eradication is verified
- Assessment of persistent type 2 cVDPVs

**Synchronized switch**

- Replace tOPV with bOPV globally in a 2-week span in April 2016
- No use of tOPV after this period
Switch window example: April 2016 in a country

The country selects a ‘National Switch Day’ from this window:

Week 1

Global switch
2-week window

Week 2

e.g. National Switch Day: stop tOPV use

disposal and validation 2-week window

Week 3

e.g. National Validation Day: all tOPV disposed

Week 4

Global validation
2-week window
Global synchronization and planning

To minimize the risk of any type 2 cVDPV re-emergence or outbreaks from the use of tOPV, the switch will need to take place everywhere worldwide within a 2-week period.

Implications for tOPV supply planning:
• tOPV stocks needed for national routine immunization only until March 2016
• Countries should coordinate with their relevant supplier to plan around the switch
• The last in-country distribution of tOPV should take place 4 weeks before the switch date
• Important to avoid tOPV stock-outs in the weeks before the switch
• Countries should enhance stock monitoring and management capacity starting in 2015

Implications for bOPV:
• 3-6 months of supplies of bOPV should be planned for and received in countries from January 2016 onwards
• New bOPV stocks should be kept at central level, stored separately until distribution
• Supply may be distributed to vaccination points starting 2 weeks before the national switch date

Countries should not switch before the global switch window.
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Mitigating risks before the switch

High population immunity is necessary for successful OPV cessation, to help reduce the risks of cVDPV emergence.

Higher risk countries will conduct tOPV SIAs in Q4 2015 and Q1 2016, at national and/or subnational level.

The plan for risk mitigation SIAs was discussed and agreed by SAGE in October 2014.
Principles of tOPV withdrawal

Requires a complete global replacement of tOPV by bOPV

Overall process steps: switch $\rightarrow$ recall $\rightarrow$ dispose $\rightarrow$ validate

- **Switch**: tOPV is removed from the (private and public sector) cold chain and replaced with bOPV on the National Switch Date
- **Recall**: tOPV is transported to collection points
- **Dispose**: tOPV stocks are safely disposed
- **Validate**: national and international monitors supervise the process and validate the complete absence of tOPV stock on National Validation Day (2 weeks after National Switch Date)

Manufacturers will not supply any more tOPV starting a short period before the switch.
Country level considerations

Planning and management
• **Now:** Forecast quantities for supply and procurement of bOPV and tOPV
• Coordinate with national committees and private sector, for both routine immunization and supplemental campaigns
• Develop a national operational plan by mid 2015

Regulatory
• Initiate process for national licensure of bOPV licensure (in countries that require it)
• Note that bOPV is the same as tOPV for volume, heat sensitivity, VVM, and wastage

Implementation, monitoring, logistics, communication
• Establish a ‘switch support team’ to implement the plan
• Adapt workplans, communication and training materials to local context and language
• Update data tools
• Update information systems to monitor activities at all levels
Preparation underway at a global level

• **Involving vaccine manufacturers** and national regulatory authorities on bOPV licensure and supply. Consulting on presentations and labelling

• Developing **procurement and distribution strategies** to minimize stocks of tOPV while avoiding stockouts prior to the switch date, including with self-procuring countries

• Developing and disseminating Switch protocol **templates, workplans, communication and training materials**

• Seeking endorsement of the switch by WHO member states through an expected **World Health Assembly discussion in May 2015**

• Establishing **monitoring systems at all levels** to track progress
Next steps for switch planning and communications

Switch implementation working group (under the IMG)
Coordinating planning, preparations, and technical assistance.

Communications and training
Disseminating information and hosting webinars from Q1 2015 to inform planning and developing materials for health worker training

The Switch Protocol: an implementation guide
• The Protocol will be published in early 2015
• Regional briefings/trainings will help build awareness and capacity
• Liaison with UNICEF country offices and relevant manufacturers for self-procuring countries vital to implementation and supply strategies
• Countries will be responsible for monitoring stock levels and adjusting the frequency and/or quantities of tOPV deliveries to minimize risk of excess stocks and stock-outs at country level.
• Country pilot exercises will help refine preparations, guidance, and information collection systems
COMING SOON!

OPV technical background, communications and training materials:
http://www.who.int/immunization/diseases/poliomyelitis/endgame_objective2/en/
THANK YOU

For more information:
http://www.who.int/immunization/diseases/poliomyelitis/endgame_objective2/en/