The switch from trivalent to bivalent oral polio vaccine

18th December, 2015
Objectives of the Polio Eradication & Endgame Strategic Plan 2013-2018

1. Detect and interrupt all poliovirus transmission

2. Strengthen immunization systems, introduce inactivated polio vaccine (IPV) and withdraw oral polio vaccines (OPV)

3. Contain poliovirus and certify interruption of transmission

4. Plan polio’s legacy
Objective 2 - Three distinct stages

Introduce
- at least one dose of IPV into routine immunization (126 countries)

Switch
- tOPV to bOPV (156 countries & territories)

Withdraw
- bOPV & routine OPV use

Before end 2015

2016

2019-2020

Ongoing STRENGTHENING of routine immunization services
OPV will be removed in a phased approach, beginning with the removal of type 2 poliovirus strain in a switch from tOPV to bOPV.
Currently, the risks associated with the type 2 component of tOPV outweigh the benefits

- Since 1999, naturally occurring type 2 wild poliovirus has not been detected

- The type 2 component of tOPV:
  - Causes > 90% of vaccine-derived polio viruses (VDPVs)
  - Causes approx. 30% of vaccine-associated paralytic polio (VAPP) cases
  - Interferes with immune response to poliovirus types 1 and 3 in tOPV
SAGE October 2015 recommendations

All 156 OPV-using countries and territories must switch within a 2-week switch window (from 17 April to 1 May)
Switch Planning for India

2 weeks global Switch window by SAGE
17th Apr, 16-1st May, 16

W1 W2 W3 W4

National Switch Date 25th April, 16
Switches to bOPV
Recall & Disposal of tOPV and validation

Only bOPV is used

bOPV distribution starts 2 weeks before
Components of a successful switch

- Reducing excess while avoiding stock-outs
  - Stock inventories
  - Procurement
  - Smaller deliveries

- Minimizing time that tOPV & bOPV are in cold chain together

- Safely disposing of all tOPV

- Ensuring tOPV is not used after the Switch

- Making sure milestones are met

- Ensuring national withdrawal of tOPV

- Stock inventories

- Procurement

- Cold chain plan

- Site selection

- Disposal methods

- Timing

- Storage

- Collection of tOPV

- Process Monitoring

- Reporting

- Site Visits

- Monitoring
Role of DCG(I)/CDSCO /State Drug Controller

• Ensure bOPV supplies in open market two weeks prior to switch date and with drawl of tPOV from open market after switch.
• Share list of suppliers of tOPV and bOPV in private market.
• Sensitize the manufacturers on switch including timelines, overlap period of tOPV and bOPV, etc
• All existing license for tOPV to be modified/cancelled to ensure that tOPV should not be supplied for use post switch except in exigency condition as and directed by the MoHFW.
• Initiate communications with State and District drug controllers to
  – Ensure availability of bOPV 2 weeks prior to switch and secondary packaging of bOPV not to be opened before switch date.
  – Recall of tOPV immediate after switch from open market and destroy.
  – Monitor switch in private OPV supply chain
• Role of Clearing & Forwarding agents (CFA) critical in private setup
Global Action Plan (GAP) for laboratory containment

Phase I: Preparation for containment of poliovirus type 2

Phase II: Poliovirus type 2 containment period
  - Phase IIa: Containment of WPV2
  - Phase IIb: Containment of OPV2/Sabin2 poliovirus

Phase III: Final poliovirus containment
  - Phase IIIa: Final containment of all WPV
  - Phase IIIb: Final containment of all OPV/Sabin polioviruses
Role of CDL Kasauli

• Govt. of India will not accept any tOPV from 1st March 2016 onward, therefore all testing of tOPV to be completed and report submitted by middle of Feb, 2016 for GoI supply

• No batch testing of tOPV after March 2016 even for private market.

• All tOPV to be destroyed and no tOPV should be stored after the switch date.

• Testing for bOPV should be fast tracked to ensure timely supplies immediately after switch.
Vaccine Manufacturer /Distributors etc

- Ensure tOPV supply till Feb 2016 as per supply timeline and qty.
- No supplies of tOPV after 1\textsuperscript{st} March 2016 in Government and after 1\textsuperscript{st} April 2016 in private market.
- Ensure availability of bOPV in private market from 10\textsuperscript{th} April 2016.
- Destruction of tOPV and type 2 polio bulk in consultation with DCG(I).
Role of Partner – WHO, UNICEF, Rotary etc

• Support Government in implementation of switch

• Independent monitoring of switch implementation and feedback to Government of India for any corrective measures.
Role of IMA / IAP

• Communication about the switch date to its members nationwide

• Ensure availability of bOPV 2 week prior to switch date and not be used before switch.

• Ensure tOPV not used after switch date and disposal & destruction of tOPV stock after switch.

• Participation and cooperation of private sector in switch validation
Communication Planning for Switch

- Communication plan for switch has been prepared for public sector health staff
- Similar communication plan for Private facilities/Staff to be prepared.
- IMA/IAP to build mechanism for the communication to their members nationwide
Switch Monitoring and Validation

• NCCPE assigned also as “National Switch Monitoring and Validation Committee”.

• For 2 weeks after the Switch Day, independent Switch Monitors will visit a sample of service points and storage facilities to confirm all facilities are free of tOPV.

• Validation process will also include private sector facilities.

• IMA/IAP and CDSCO to provide support in switch validation.
For successful implementation:

- tOPV supplies to be regulated and removed after switch (Manufacturers, CDSCO, CDL Kasauli)
- bOPV supplies to be secured (Manufacturers, CDSCO, CDL Kasauli)
- bOPV testing to be fast tracked (CDL Kasauli)
- Communication planning for open market (IMA/IAP)
- tOPV removal to be validated (CDSCO, IAP, IMA)
Thank you