Polio endgame-global switch from tOPV to bOPV.:A Critical Step In Polio Eradication.

* Dr. Liza Bulsara, **Dr. Sunil Mhaske ,*Dr. Amit Italiya

***Dr.Vishnu Kadam

*Post Graduate Student, ** Prof & Head, ***Professor

Corresponding address : Dept. of Paediatrics, Vikhe Patil Institute of Medical Sciences, Ahmednagar, Maharashtra.

Mail id - liza.bulsara@gmail.com

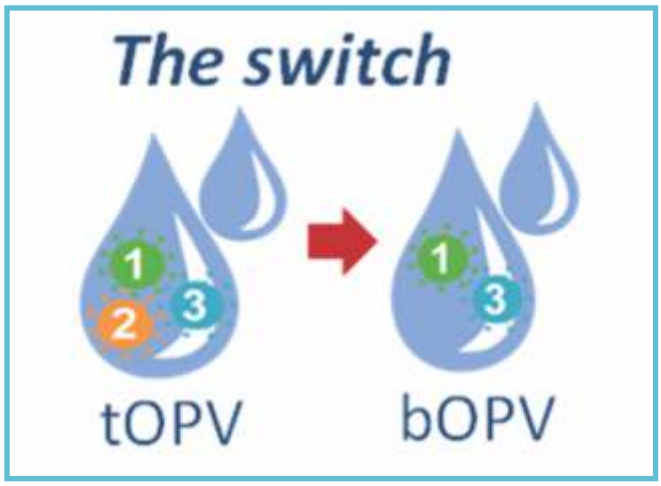
Mobile No. - 9922290209

Abstract :

Globally, polio cases have reached an all-time low, and type 2 poliovirus (one of three) is eradicated. Oral polio vaccine (OPV) has been the primary tool, however, in rare cases, OPV induces paralysis. In 2013, the World Health Assembly endorsed the phased withdrawal of OPV and introduction of inactivated poliovirus vaccine (IPV) into childhood routine immunization schedules. Type 2 OPV will be withdrawn through a globally synchronized "switch" from trivalent OPV (all three types) to bivalent OPV (types 1 and 3). The switch will happen in 155 OPV-using countries between April 17(th) and May 1(st), 2016. Planned activities to reduce type 2 outbreak risks post-switch include the following: tOPV campaigns to increase type 2 immunity prior to the switch, monovalent OPV2 stockpiling to respond to outbreaks should they occur, containment of both wild and vaccine type 2 viruses, enhanced acute flaccid paralysis (AFP) and environmental surveillance, outbreak response protocols, and ensured access to IPV and bivalent OPV.

Keywords : eradication; immunization; inactivated polio vaccine; oral polio vaccine; polio; poliomyelitis; switch

Introduction : Since the release of the Polio Eradication and Endgame Strategic Plan 2013-2018, planning has begun worldwide to expedite the interruption of all poliovirus transmission and build stronger systems for the delivery of lifesaving vaccines. In preparation for the eventual removal of all OPVs, WHO recommended in its position paper of January 2014 (Weekly Epidemiological Record, 28 February 2014) that all OPV-using countries begin strengthening immunization systems and introduce at least one dose of Inactivated Polio Vaccine (IPV) into routine programmes by the end of 2015 [1,2]. The global focus is now expanding to plan for the replacement of trivalent OPV (tOPV) with bivalent OPV (bOPV) in all OPV - using countries.



[Fig No. 1 : The switch from (tOPV) to (bOPV)]

Rationale for OPV cessation : OPV is made with attenuated (weakened) polioviruses. On extremely rare occasions, the vaccine can cause cases of vaccine-associated paralytic polio (VAPP) and circulating vaccine-derived polioviruses (cVDPVs). To prevent cVDPVs and VAPP, OPV must be withdrawn as soon as possible after the end of wild poliovirus (WPV) transmission[3].

tOPVcontains all three poliovirus serotypes (1, 2 and 3), and the use of this vaccine has led to the successful eradication of wild poliovirus type 2 (WPV2), with the last case occurring in 1999. Today, over 90% of cVDPV cases, and approximately 40% of VAPP cases are due to the type 2 component of tOPV. With at least one dose of IPV in place as a risk mitigation measure, OPVs will be removed in a phased approach, beginning with removal of the type 2 poliovirus strain in a switch from tOPV to bOPV. bOPVcontains types 1 and 3, and therefore will continue to protect against transmission of WPV1 and WPV3[4]. Once all wild polioviruses have been fully eradicated, then all OPVs will be withdraw.

The goal is to cease all use of OPV by 2020. Depending on the timing of the switch and the detection of further transmission of polioviruses, countries may be able to cease all use of OPV as early as 2019.OPV is extremely safe and effective at protecting children against lifelong polio paralysis. More than 10 million cases of polio have been prevented, and the disease has been reduced by more than 99%. Because it is safe, effective, and easy to administer, OPV has been used to vaccinate nearly 2.5 billion children against polio and has nearly halted transmission of the poliovirus.

About the switch from tOPV to bOPV.

All oral polio vaccines are made from attenuated (weakened) polioviruses that, in very rare cases, can

result in cases of VAPP and cVDPVs. According to monitoring data from the Global Polio Eradication Initiative(GPEI), over 90% of the approximate 750 paralytic cases due to cVDPVs between 2000 and 2012 and 40% of VAPP cases were derived from OPV type 2. To minimize the risk of continued type 2 cVDPV (cVDPV2)cases, the type 2 component of OPV (OPV2) will be phased out globally from all immunization activities[5]. Globally, all immunization programmes

that use OPV will be required to switch from tOPV to bOPV in a coordinated manner.

The Switch : The switch refers to the replacement of all tOPV with bOPV (containing types 1 and 3 only) in routine immunization and supplemental immunization activities (SIAs), in every country around the world within a 2-week time frame. Currently, the switch from tOPV to bOPV is expected to take place in April 2016. A precise date will be established at least 6 months in advance of the planned date of the switch to bOPV. This will enable national health authorities and implementers to plan appropriately. Once the switch is made, tOPV will no longer be used anywhere in the world, and manufacturers will no longer supply tOPV (production will have stopped much sooner due to production lead times). The objective of the switch is to stop the emergence of cVDPV2 and VAPP caused by the attenuated type 2 strain of tOPV. The planned withdrawal of the type 2component of tOPV is part of the global polio eradication end game strategy for 2013-2018[6,7].The earliest opportunity for the switch to occur is April 2016,during the low season of poliovirus circulation in the countries with the most recent, persistent transmission of poliovirus. Once the final decision to proceed with the switch is made, the decision is irrevocable and must be implemented by all countries simultaneously during the identified switch window. Countries will have six months to make final preparations for the switch, but the switch will proceed even if newly emerged circulating type 2 VDPVs are identified during the six months between the final decision to proceed with the switch and the execution of the switch.

Disposal of remaining inventories of tOPV : After the switch date, all remaining tOPV supplies or stocks should be collected from both public and private facilities and destroyed. There are several ways to dispose of unused tOPV vials; by encapsulation and disposal in a landfill site, direct disposal in an engineered landfill site, or through incineration in high- or medium- temperature incinerators. The collection and proper disposal of all tOPV stocks should be well-documented, and the overall switch plan should include these activities and corresponding financing[8].After the switch, the national registration of tOPV should be cancelled and only bOPV should be used in routine immunization programmes and SIAs. The accidental or deliberate use of tOPV after the switch could cause outbreaks of cVDPV2, particularly because the number of individuals susceptible to infection with poliovirus type 2 will increase after the switch. Destroying all tOPV will eliminate the risk of such cVDPV2 outbreaks.

Outbreak response : Following the switch, monovalent OPV type 2 (mOPV2) will be the vaccine of choice for responding to any cVDPV type 2 outbreak or any accidentalWPV2 release from a laboratory or facility. An initial stockpile of 5 Following the switch, monovalent OPV type 2 (mOPV2) will be the vaccine of choice for responding to any cVDPV type 2 outbreak or any accidentalWPV2 release from laboratory or facility. An initial stock pile of 500 million doses of mOPV2 is being procured and will be available prior to the switch date for outbreak response.500 million doses of mOPV2 is being procured and will be available prior to the switch date for outbreak response. No additional tOPV will be produced or available after the switch[9,10]. Countries will have access to the global stockpile of mOPV2 and should not need to establish a national stock pile.The global stockpile is being completely financed by global partners, and countries will be provided mOPV2 at no cost to them in the event of an outbreak. They will not need to procure mOPV2. No additional tOPV will be produced or available after the switch.

Key Message: Manufacturers and UNICEF will stop supplying tOPV for use beyond April 2016. Instead they will supply bOPV for use in routine immunization programs and campaigns.

All countries should stop use of tOPV and destroy remaining stocks of tOPV after Switch day in April 2016 to avoid re-emergence of circulating vaccine-derived polioviruses type 2. Ongoing use of tOPV after April 2016 may threaten or postpone the global eradication of polio.

Countries are responsible for[11,12] :

1. National Switch Date: decision-makers must establish a Switch Date during a 2 week window in April 2016 advised by SAGE, when tOPV is removed from all service points and storage facilities, tOPV is discarded, and bOPV is introduced. tOPV disposal process begins.

2. **Validating absence of tOPV :** during the 2 weeks after the Switch Date, countries must validate that all service points, public and private, and storage facilities are free of tOPV using appropriate methods of disposal as recommended in this document.
3. **National validation :** appropriate national authorities (e.g. National Switch Validation Committee) must review and affirm data to validate country free of tOPV within 2 weeks of Switch DateAll OPV using countries should begin planning for the Switch in Q1 2015 and finalize a National Switch Plan by 1 September 2015 using recommended template, leaving ~10 months to prepare and implement activities like :

- **Management/oversight :** By mid-2015, countries are encouraged to establish Switch Coordination Committees at national and subnational levels responsible for developing the Switch Plan and providing implementation oversight (e.g.,interagency coordination committee, ICC)
- **Preparation:** Countries are encouraged to hire staff (i.e. Switch Support Teams) assigned specifically to prepare and implement the Switch Plan.
- **Implementation :** training ; bOPV distribution to periphery; tOPV withdrawal and disposal.
- **Validation :** Validation of tOPV absenceby a team (i.e. Switch Monitors)independent of the Ministry of Health (MOH) and Switch Implementatio team. Data to be reviewed and affirmed by an independent body that has delegatedauthority by the MOH to validate the change.

Conclusion :

The global eradication of serotype 2 wild poliovirus demostrates the feasibility of eradicating all wild type polio viruses. Success against serotype 2 was achieved as a result of the greater immunogenicity of trivalent OPV against this sertype, particularly in lower income counties. There is no evidence that wild poliovirus serotype 1 and 3 are more transmissible then serotype 2, indeed the opposite may be the case for serotype 3. The introduction of new monovalent and bivalent OPV in 2005 and 2009, respectively, with immunogenicity equivalent to or exceeding that of the trivalent vaccine against serotype 2 therefore suggest that this serotype can also be eradicated in the near future.

The global eradication of serotype 2 wild poliovirus also highlights some of the challenges that will be faced after the eradication of all wild-type polioviruses. In particular, with the increasing use of monovalent and bivalent OPVs against serotypes 1 and 3, gaps in population immunity to serotype 2 have led to increasing incidence of poliomyelitis caused by circulating serotype 2 VDPVs. These cVDPV result from the continued use of trivalent OPV during routine immunization and in limited numbers of SIA. The polio endgame strategy addresses this challenge by calling for global, coordinated withdrawal of OPV serotypes, and eventually of all OPV. The GPEI must eradicate all polioviruses, not just wild-type poliovirus. A clear strategy for the management of post-OPV risks is also being put in place, including continued AFP surveillance, the maintenance of an international monovalent OPV stockpile and policy guidance on routine immunization with IPV to mitigate risks following a poliovirus re-emergence.

The successful reduction of the global incidence of poliomyelitis from over 1000 cases a day in 1988 to less than one a day in 2012 is a major achievement of the GPEI. The endgame strategy is designed to take the world from low incidence to no incidence. There is every reason to believe that this is possible with the continued commitment of the global health community.

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