

Interim Guidance on the use of Trivalent Oral Polio Vaccine (tOPV) for the response to Type 2 Circulating Vaccine-Derived Poliovirus (cVDPV2)

(Addendum to the Standard Operating Procedures for Response to a Poliovirus Event or Outbreak, version 3. 1)

Context

Following the global certification of wild poliovirus type 2 (WPV2) eradication in 2015, the GPEI planned and implemented a global withdrawal of trivalent oral polio vaccine (tOPV) and replacement with bivalent oral polio vaccine (bOPV) in April-May 2016. Termed 'the switch,' this global effort impacted both country immunization systems and supplementary immunization activities (SIAs). The GPEI anticipated a limited number of type 2 vaccine-derived poliovirus (VDPVs) outbreaks emerging in the post-switch period could be controlled through supplementary immunization activities (SIAs) using Sabin OPV (e.g. mOPV2). However, inconsistent pre-switch intensification efforts to boost immunity against poliovirus type 2, a global IPV shortage in 2016, and the uneven quality of outbreak response activities have resulted in considerably more VDPV2 emergences and cVDPV2 outbreaks than predicted.

In addition to these cVDPV2 outbreaks, the continued transmission of WPV1 and periodic emergence of cVDPV1 and cVDPV3, have led to concurrent circulation of different poliovirus types in several countries.

Therefore, in April 2020, the Strategic Advisory Group of Experts on immunization (SAGE) recommended the use of tOPV in areas of co-circulation of type 1 and 2 polioviruses, or areas at high-risk of co-circulation in order to avoid the need to conduct dual monovalent OPV type 2 (mOPV2) and bivalent OPV (bOPV) SIAs (1).

Purpose and scope of this document

The purpose of this Interim guidance on the use of Trivalent Oral Polio Vaccine (tOPV) is to provide context and policy guidance on the use of tOPV in response to Type 2 Circulating Vaccine-Derived Poliovirus (cVDPV2). Guidance in this document relies on scientific evidence and expert consensus, with consideration of epidemiology, operational realities, including vaccine supply, vaccine acceptance, and country context.

This guide is for national governments and public health decision-makers that coordinate responses to poliovirus events and outbreaks, and their global, regional, and country-level partners.

This document is an addendum to the "Standard Operating Procedures: Responding to a poliovirus event or outbreak", Version 3.1' (SOPs) (2). It provides interim guidance for the use of tOPV in line with the 'Polio Endgame Strategy 2019 – 2023' (3) and the addendum 'Strategy for the Response to Type 2 Circulating Vaccine-Derived Poliovirus 2020 – 2021' (4). It should be used in conjunction with the comprehensive operational guidance on 'tOPV Management, Monitoring, Removal, and Disposal (Without VVM); an addendum to mOPV2 Technical Guidance' (5).

Recommendation for utilization of tOPV (strategy & scope)

tOPV can be made available to countries for cVDPV2 outbreak response in subnational areas where there is co-circulation or high risk of co-circulation of cVDPV2 with cVDPV1, cVDPV3 or WPV1 in order to avoid the need to conduct dual mOPV2 and bOPV campaigns.¹

While this recommendation is made to ensure children are protected from both wild and vaccine-derived polioviruses of all three types, trivalent OPV will only be used as an outbreak response tool in select countries which agree to its use, and not in routine immunization. tOPV should not replace bOPV use in routine EPI schedules at this time.

Operational considerations – which elements of the SOPs remain the same?

Definitions, outbreak response standards, and protocols, including response timing and scale of campaigns required for high-quality SIAs, remain the same as detailed in the outbreak response SOPs v3.1 (2).

Since tOPV contains a live type 2 poliovirus, tOPV will be subject to the same usage controls that are currently followed for mOPV2 use before, during, and after a campaign.²

The vaccine is manufactured to the same specifications as when the use of tOPV was stopped globally in 2016. However, the evaluation of VVM compatibility for WHO prequalification has changed; this has no relationship to the safety, stability, or immunogenicity of tOPV when kept at 2-8°C or at -20°C: the vaccine is stable for six months at 2-8°C and two years at -20°C but is more sensitive to heat above 8°C. The fact that a VVM will not be included on the newly-produced tOPV in no way affects the quality and safety of the vaccine itself.

Before the campaign

Requesting vaccine: Use of tOPV will require the same authorizations process and restrictions as required for use of mOPV2.³ Countries must present a risk assessment and vaccine request form (7) for consultation by the Advisory Group on mOPV2/tOPV Provision (Advisory Group). The Advisory Group will rapidly review the risk assessment and vaccine request and recommend a course of action to the WHO Director-General. Upon approval, the tOPV vaccine stock with the shortest shelf life will be released by UNICEF from the global stockpile for immediate use but would require

- Submission of a special request form to access the vaccine from a global stockpile, with release contingent on WHO Director-General approval (see below).
- Maintain normal procedures for shipping and storage requirements (cold chain) as well as precise storage, temperature, and transaction records at all supply chain levels (applies throughout the SIA).

During the campaign

- Maintain containment between SIA rounds.

¹ For further details, see tOPV Management, Monitoring, Removal and Disposal (Without VVM)

² For further details, see tOPV Management, Monitoring, Removal and Disposal (Without VVM)

³ See 'Requesting Vaccine' page 35, Standard Operating Procedures Responding to a poliovirus event or outbreak: Version 3.1 <http://polioeradication.org/tools-and-library/field-resources-for-polio-eradicators/gpei-tools-protocols-and-guidelines/>

After the campaign

- Requires proper disposal after all immunization response rounds are completed as per GPEI recommendations.

Operational considerations — which elements of the SOPs are different?

Before the campaign:

- The heat sensitivity and absence of a VVM on the label of tOPV requires freezer storage space at the lowest possible level, closest to the vaccinator. Utilizing long-range passive cold chain equipment and continuous temperature monitoring devices are also important to protect vaccine. Availability of these equipment should be verified during the gap analysis of the cold chain equipment inventory before the OB response. For detailed operational guidance see tOPV Management, Monitoring, Removal and Disposal; an addendum to mOPV2 Technical Guidance (6).
- Orientation to front-line health workers prior to a campaign on use of tOPV (absence of VVMs), particularly in the countries where public discourse around vaccine safety or hesitancy may present a risk to vaccine acceptance. Reassure FLWs on safety of tOPV in the absence of VVMs. These activities may be incorporated in the vaccinator and social mobilizers training, and include FAQs, training aides.
- Health journalists and public health establishment need to be aware of the rationale for tOPV use in outbreak response (i.e. not reversing “the switch”) and fully support it resolving any potential concerns.

During the campaign:

- As there is no VVM, therefore, implementing countries should follow strict temperature management procedures in addition to the usage protocols in tOPV Management, Monitoring, Removal and Disposal; an addendum to mOPV2 Technical Guidance (6).
- Although preventing vaccine wastage is important, due to the absence of VVM and need for maintaining full accountability for a vaccine under containment, MDVP is not recommended during tOPV campaigns.
- Monitor digital and social media spaces and communities for rumors linked to tOPV vaccine attributes and perceptions of safety.

After the campaign:

- Report quantities of all tOPV vials together with temperature data verification reports to the next higher level
- Retrieve and ensure all unusable vials are disposed of at Regional or National level, according to the Technical Guidance on mOPV2 Vaccine Management, Monitoring, Removal, and Disposal and the local Regulations for health waste disposal.
- Provide support to FLWs to resolve caregiver refusals to do lack of confidence in tOPV/different vial – absence of VVM, linking support of public health community, doctors, health influencers.

Frequently Asked Questions

During the switch tOPV was stopped globally, why are we using it again?

In 2020, four years after the global switch to bOPV, the world is facing increasing cVDPV2 outbreaks in parts of Africa, Southeast Asia, and the Middle East. Monovalent Sabin OPV2 (mOPV2) has been the vaccine available for responding to these outbreaks. In some countries, the length and large scale of mOPV2 responses have displaced planned bOPV SIAs; other countries have had concurrent ongoing WPV1 circulation or concurrent cVDPV1, 2, or 3 circulations that complicate response planning due to alternating bOPV and mOPV2 delivery. Furthermore, the cost of delivery of the cVDPV2 responses is considerable. For these reasons, trivalent OPV (tOPV), which protects against all three types of poliovirus, will be available for cVDPV2 response with only a modest price difference for the vaccine.

Q. Why did the VVM for tOPV not meet the requirements for tOPV?

In the context of tOPV prequalification, review of the submitted stability data showed that the stability curve for tOPV did not match the curve of the VVM itself when tested at 37°C. The vaccine itself has not changed from production prior to 2016, it is manufactured to the same specifications as before the use of tOPV was stopped globally; rather, it is the evaluation of VVM compatibility for WHO prequalification which has changed.

This has no relationship to the stability or immunogenicity of tOPV when kept at 2-8°C or at -20°C: the vaccine is stable for six months at 2-8°C and for two years at -20°C. Countries wishing to use tOPV should be assured that tOPV remains effective and immunogenic. tOPV from PT Bio Farma is a prequalified vaccine and complies with all requirements for safety, immunogenicity and stability.

Q. How can you be sure that tOPV is safe and effective, even without a VVM?

The tOPV vaccine itself has met all prequalification requirements. The prequalification process is based on specifications exacted by the Expert Committee on Biological Standardization (ECBS), an independent body that issues established, international norms and standards for the production and control of biological products. These norms and standards govern the contents used in the production of OPV and ensure that the purity of the vaccine meets all the technical criteria established by the ECBS, as verified through state-of-the-art technology. The fact that VVM will not be included on the newly-produced tOPV in no way affects the quality and safety of the vaccine itself.

Q. How can vaccinators, healthcare providers and parents be assured of tOPV's efficacy, without a VVM?

Provided that recommended storage (cold-chain) procedures remain in place, i.e. that the vaccine is deep frozen in central/regional cold stores, it is always kept at temperature of 2°C to 8°C in the health center refrigerator or in vaccine carriers/cold boxes fitted with frozen icepacks when, and provided that stated shelf-life/expiration dates are adhered to, the vaccine remains potent, safe and efficacious.

It is important to note that even if expired vaccine were to be administered inadvertently, this would not present a safety issue to children. Only efficacy would be affected, i.e. a non-effective dose would be administered, but one which is not harmful to children.

Q. Should we do anything differently while conducting tOPV supplementary immunization activities (SIAs) with the VVM-less vaccine?

Yes. The heat sensitivity and absence of a VVM on the label of tOPV requires freezer storage space at the lowest possible level, closest to the vaccinator. Utilizing only the long-range passive cold chain equipment and continuous temperature monitoring devices are also important to protect tOPV.

References

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