

Technical brief: nOPV2

This document summarizes key operational considerations for the use of nOPV2 in outbreak response as a quick reference for EPI managers, immunization focal points, and field staff. Additional materials and resources can be found at <http://polioeradication.org/nOPV2>

What You Need to Know about nOPV2

- nOPV2 is a modified version of the existing OPV2 vaccine (also known as the Sabin OPV type 2 vaccine, or mOPV2) that provides comparable protection against poliovirus type 2 while being more genetically stable.
- Data to date indicate that the vaccine's safety profile is similar to mOPV2. Its increased genetic stability as compared to mOPV2 means that there is a decreased risk of nOPV2 reverting to a form that could cause paralysis in areas with low immunization coverage. Based on a review of safety and preliminary genetic stability data from initial campaigns held in Nigeria, Liberia, Benin and Congo, SAGE has endorsedⁱ, a transition to the next rollout phase for the vaccine.
- Given the urgent public health need to address cVDPV2 in polio-affected countries, the vaccine is being made available through WHO's Emergency Use Listing (EUL) procedure since 2020.ⁱⁱ
- nOPV2 is a live type 2 poliovirus and can currently be handled outside of GAPIII containment requirements for the purposes of production, quality control testing, clinical trials, stockpile, and outbreak response. This is a provisional determination (per the Containment Advisory Group) based on the initial clinical trial results, and recommendations may change as new information becomes available.ⁱⁱⁱ
- To use nOPV2 for outbreak response, countries need to meet certain requirements under the EUL. These requirements are described in detail in [Preparing for nOPV2 use: an overview on requirements for countries](#).

When to Use nOPV2

- **nOPV2 is to be used in cVDPV2 outbreak response only.** There are no plans to use nOPV2 in routine immunization, where the use of bivalent oral polio vaccine (bOPV) and/or inactivated polio vaccine (IPV) should continue as planned.
- **nOPV2 can be used as part of integrated campaigns** with other vaccines and non-vaccine interventions (e.g. Vitamin A).
- **An interval of 4 weeks between campaign use of nOPV2 and other OPVs** in the same area is required (i.e. bOPV/mOPV2/tOPV)

Target Population

As is the case with current outbreak response campaigns, the target population for nOPV2 SIAs will usually be children less than five years of age; however, an expanded age group (up to 10 or 15 years, or the whole population depending on local context) should be considered if there is evidence of virus circulation among older age groups.

Administration, Presentation and Packaging

- Like mOPV2, **a dose of nOPV2 consists of two drops of the vaccine, delivered orally.**
- **The liquid is similar in colour to mOPV2, and the same type of dropper dispensers will be used.** The vaccine may present a colour varying from slightly yellow to light red colour due to a slight variation of pH; however, this does not affect the quality of the vaccine.
- **The labelling and packaging design is distinct** to differentiate nOPV2 from other oral polio vaccines, although they will not be used together in the field.
- **nOPV2 is supplied in 50-dose vials** to help facilitate timely and effective vaccine production. Wastage rates continue to be assessed and vial size could potentially be changed in the future.



nOPV2 50 dose vial. Photo: Bio Farma

Cold Chain and Vial Management

- **nOPV2 should be kept in the cold chain at all times. It should be kept in a freezer at -20°C for as long as possible, until it is being used.**
- **nOPV2 is labelled with a vaccine vial monitor (VVM).** It will be important to check the VVM before each use and discard the vial if the colour of the square is the same as or darker than the surrounding circle.
- Like mOPV2, **nOPV2 is subject to specific containment requirements including the tracking and inventory all full, partial and empty vials.** Following completion of outbreak response, thorough inventories of nOPV2 infectious and potentially infectious materials must be conducted.^{iv}
- **As with other oral polio vaccines, vaccine carriers with solidly frozen icepacks are required for transporting the vaccine from health facilities to outreach sessions where refrigeration is not available.**
- **GPEI does not recommend implementing multi-dose vial policy (MDVP) for outbreak response, including for nOPV2 campaigns,** for several reasons. For example, the implementation of MDVP reduces the precision of accountability reporting, and although preventing vaccine wastage is important, maintaining full accountability for a vaccine under containment such as nOPV2 is imperative for the GPEI.^v

Monitoring and Evaluation

In addition to standard post-campaign monitoring, special post-deployment monitoring requirements apply to nOPV2 use under the EUL. To ensure countries are ready to meet these requirements, they must be verified prior to use of nOPV2. The full list of requirements for verification can be found in [Preparing for nOPV2 use: an overview on requirements for countries](#). Links to pre- and post-campaign checklists to support implementation of these requirements can also be found within this document.

Safety, Immunogenicity, and Side Effects

Data from the clinical studies conducted to date show nOPV2 to be well tolerated in adults, young children, and infants, with no indication of any increase in general safety risk compared to mOPV2. Immunogenicity of nOPV2 was found to be non-inferior to mOPV2 in infants, meaning that nOPV2 is expected to be as effective in preventing paralytic disease as the current vaccine. **Review of safety data on the first 65 million doses of nOPV2 use for outbreak response by the independent Global Advisory Committee on Vaccine Safety (GACVS) concluded that, based on the available data, there were no obvious red flags or safety concerns.**

nOPV2 Dose Release Process

nOPV2 vaccine supply will be released by the GPEI through a two-phase process:^{vi}

- **Verification of country readiness,** assessed through a dedicated GPEI Readiness Verification Team
- **Release of the vaccine and establishment of any additional specifications for outbreak response (e.g. target age):** Led by the nOPV2 Release Group (nRG) this group reviews the outbreak-specific risk assessment and advises on release of nOPV2 from the global stockpile, taking into account factors such as available supply, country-level and regional poliovirus epidemiology, and other potential considerations relevant to the specific context of the outbreak. The release of the vaccine is done on approval of the WHO Director-General.

ⁱ [October 2021 SAGE Meeting Highlights](#). 2021.

ⁱⁱ [Recommendation for an Emergency Use Listing \(EUL\) of novel Oral Polio Vaccine type 2 \(nOPV2\)](#). 2020.

ⁱⁱⁱ [Addendum to the Report of the Teleconference of the Containment Advisory Group \(CAG TC3\) on nOPV2 candidate vaccines and S19 – poliovirus type 2 strains](#). 2018.

^{iv} [WHO Global Action Plan to minimize poliovirus facility-associated risk after type-specific eradication of wild polioviruses and sequential cessation of oral polio vaccine use](#). 2014.

^v [Novel OPV2 \(nOPV2\) Management, Monitoring, Removal and Disposal \(in 50 dose vials with VVM type 2\): Technical Guidance](#). 2021.

^{vi} For more information, see: [nOPV2 Readiness Verification and Dose Release Process](#). 2021.