

GPEI POSITION STATEMENT: USE OF THE NOVEL ORAL POLIO VACCINE TYPE 2 IN LIGHT OF SHELF-LIFE OF 12 MONTHS OR LESS

April 2021

Novel Oral Polio Vaccine type 2 (nOPV2) is a modified version of the existing type 2 monovalent OPV (mOPV2). nOPV2 has been shown in clinical trials to provide comparable protection against poliovirus while being more genetically stable, therefore making it less likely to be associated with the emergence of VDPV2 in low immunity settings.

nOPV2 is being rolled out under a WHO Emergency Use Listing (EUL), that enables its rapid deployment in countries experiencing a VDPV2 detection or outbreak, and that have met the readiness criteria. nOPV2 is currently being used for outbreak response, and an emergency stockpile of vaccines has been established. The nOPV2 currently supplied to the Global OPV Stockpile has shelf life of 12 months from the time the vaccine is filled in vials. Consequently, upon release from the Global OPV2 Stockpile it will have shelf life of less than 12 months.

Under the *Strategy for the Response to Type 2 Circulating Vaccine-Derived Poliovirus 2020-21*, which emphasizes optimizing the management of available vaccine stocks, and in the context of expanding cVDPV2 outbreaks globally, vaccine supply must continue to be judiciously managed so as to meet the current high demands.

In connection with this, GPEI highlights the imperative of utilizing these stocks and notes:

1. That the vaccine is safe and effective, at minimum, up until the expiry date on the label of the vial, provided that the VVM has not reached its endpoint, and all necessary conditions for transportation and storage of the vaccine are maintained.
2. That countries are encouraged to accept the vaccine for use in responding to VDPV2, despite relatively short remaining shelf life.
3. That nOPV2 stability data is being generated to allow extension of shelf-life for future batches of the nOPV2.
4. That the vaccine should be managed in accordance with the standards laid out in the nOPV2 Management, Monitoring, Removal and Disposal (in 50 dose vials with VVM type 2) Technical Guidance developed by the GPEI¹

The GPEI is committed to utilising nOPV2 effectively, maintaining high-quality supplementary immunization activities, and looks forward to continuing to support all countries in stopping cVDPV2 outbreaks.

¹ <https://polioeradication.org/wp-content/uploads/2021/02/nOPV2-Vaccine-Handling-Technical-Guidance-20201103-ENG.pdf>