

cVDPV2 Outbreaks and the Type 2 Novel Oral Polio Vaccine (nOPV2)

Overview

Since 1988, the world has made incredible progress in the global effort to eradicate polio, with wild polio cases dropping by 99.9%. Wild poliovirus types 2 and 3 have been eradicated and type 1 wild polio is endemic in only two countries—Pakistan and Afghanistan. This progress is thanks to the large-scale administration of the oral polio vaccine (OPV)—an effective tool which has protected millions of children from paralysis.

OPV also prevents person-to-person transmission of the virus and is vital to achieving eradication. However, in areas with low levels of population immunity, the live, weakened virus originally contained in OPV can genetically revert into a form

that can cause paralysis if allowed to circulate for a long time. The virus then becomes known as circulating vaccine-derived poliovirus (cVDPV). Once cVDPV is detected, outbreak response is carried out in the same way as for wild poliovirus outbreaks: largescale administration of OPV to rapidly boost population immunity and stop transmission.

Outbreaks of type 2 cVDPV—which account for most of the cVDPV cases globally—are a major challenge to achieving eradication. In 2021, 682 cases of cVDPV2 were confirmed from 22 countries, a reduction from 1,081 cases in 24 countries in 2020, but nearly double the 366 cases from 16 countries reported in 2019.

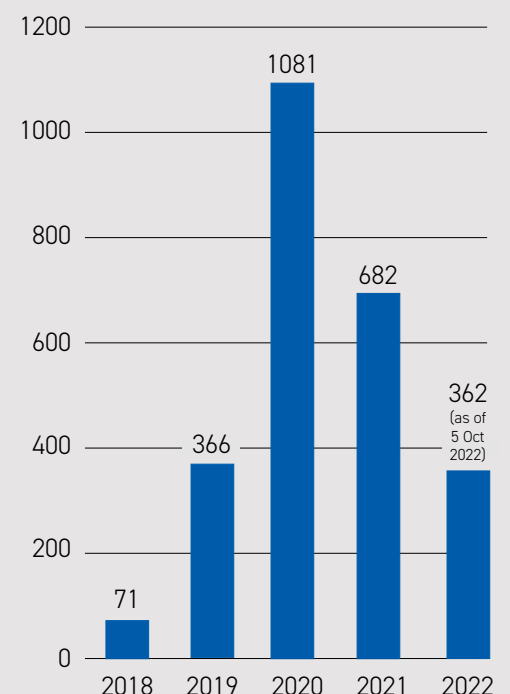
These outbreaks are driven by several factors, including low quality and delayed polio outbreak response; declining gut immunity in young children to the type 2 virus after countries switched from trivalent to bivalent oral polio vaccine (bOPV) for routine immunization in 2016; and insufficient routine immunization coverage. In 2020, the COVID-19 pandemic led to a four month pause in house-to-house polio vaccination campaigns which further hindered efforts to stop transmission across affected countries (see [“Recommendations for Reporting on Polio Outbreaks”](#) for more information).



Improving and Innovating to Stop cVDPV2

As a part of its [Polio Eradication Strategy 2022-2026](#), the Global Polio Eradication Initiative (GPEI) is implementing a number of tactics to combat the growing threat of cVDPV2, and ensure cases are detected quickly and outbreak response is improved, to halt transmission and minimize the risk of new cases. These include targeted country advocacy to ensure urgency and boost political will, the establishment of emergency response teams and infrastructure, enhanced disease surveillance, strengthened community engagement and integration of polio services with other health initiatives, and improving outbreak response speed and quality, with a focus on reaching under-immunized and vulnerable populations.

Global cVDPV2 Cases, 2018-2022





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A New Tool: The Promise of nOPV2

GPEI is also continuing to support the rollout of a new tool—type 2 novel OPV (nOPV2). The vaccine is a next-generation version of monovalent oral polio vaccine type 2 (mOPV2), that clinical trials and field use thus far have demonstrated is safe and effective in protecting against type 2 polio while being more genetically stable, decreasing the likelihood of cVDPV2 emergence in low immunity settings.

Under a WHO EUL recommendation for use (see sidebar), nOPV2 is being used for outbreak response in countries experiencing cVDPV2 outbreaks that have completed a readiness verification process. nOPV2 distribution is guided by a prioritization framework that takes into account each country's unique epidemiological and vaccine use situation.

Due to the public health emergency posed by cVDPV2 outbreaks, it is critical that all countries prioritize immediate, high-quality responses to cVDPV2 detections. WHO's Strategic Advisory Group of Experts on immunization (SAGE) has recommended that countries urgently respond to these outbreaks using available type 2 vaccine: nOPV2, or mOPV2—a vaccine which has a proven track record of stopping cVDPV2 outbreaks and protecting children from polio. In situations where there is co-circulation of poliovirus strains, trivalent oral polio vaccine (tOPV) may be the more appropriate vaccine choice.

As GPEI works to increase supply of nOPV2, GPEI continues to support governments to help prepare them for use of nOPV2, providing technical assistance to ensure that necessary readiness and EUL monitoring criteria are met.

nOPV2 is proving to be a critical tool for more sustainably stopping cVDPV2, however the best way to stop these outbreaks remains ensuring rapid, high-quality outbreak response with available vaccine, and maintaining strong disease surveillance.

WHO Emergency Use Listing Procedure (EUL)

Polio remains a Public Health Emergency of International Concern (PHEIC). In light of the public health emergency of cVDPV2 and increasing threat of outbreaks, nOPV2 received a WHO EUL recommendation for use in November 2020 to enable the vaccine's expedited availability.

The EUL procedure was created to enable the early, targeted use of yet-to-be licensed vaccines, therapeutics and diagnostics in response to a PHEIC. The process involves careful and rigorous analysis by WHO and independent experts of available quality, safety and efficacy, and performance along with manufacturing performance (e.g. yield and stability), data of an intervention. In 2019, SAGE endorsed accelerated clinical development of nOPV2 and its assessment under this procedure. Following this, in early 2020, the WHO Executive Board issued a decision urging Member States to authorize the expedited importation of nOPV2 on the basis of its EUL recommendation.

The collection and close analysis of data on nOPV2 is ongoing and will help pave the way for full licensing and WHO prequalification of the vaccine.

Rollout



nOPV2 rollout began in March 2021 in an initial group of countries which met strict criteria to use the vaccine. As of October 2022, 500 million doses of nOPV2 have been administered in 23 countries.



While nOPV2 is in use under EUL, data on the vaccine's safety, immunogenicity and genetic stability is continuously collected and rigorously analyzed.



Evidence from extensive field use continues to demonstrate nOPV2's safety, enhanced genetic stability profile, and promise as a tool to more sustainably stop cVDPV2 outbreaks. As of October 2022, 16 additional countries have been verified to use nOPV2 in the event of a cVDPV2 outbreak.