

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 under-immunized communities, 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. This is known as circulating vaccine-derived poliovirus (cVDPV). Once cVDPV emerges, 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 more than 90% of cVDPV outbreaks – are now a major challenge to achieving eradication. In 2020, 1,074 cases of cVDPV2 were confirmed from 24 countries, compared to 366 cases from 16 countries in 2019.

These outbreaks are driven by several factors, including low quality and delayed polio outbreak response; declining 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).

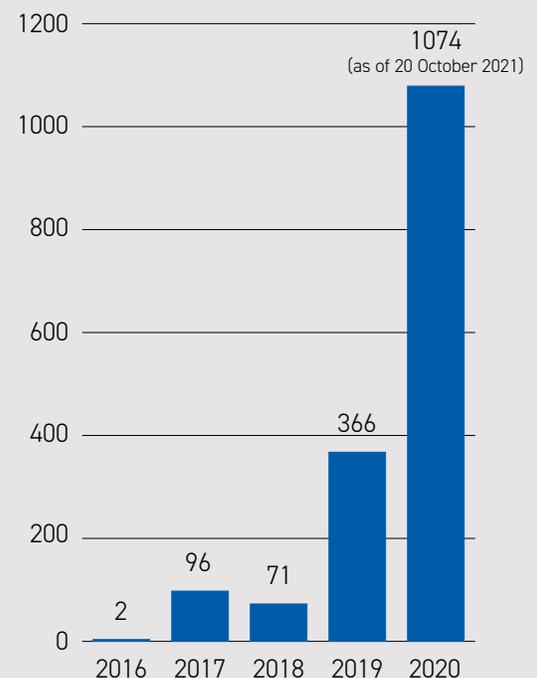


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Improving and Innovating to Stop cVDPV2

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, 2016-2020





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A New Tool: The Potential of nOPV2

GPEI is also supporting the rollout of a new tool – type 2 novel OPV (nOPV2). The vaccine is a next-generation version of mOPV2, that clinical trials have demonstrated is safe and effective in protecting against type 2 polio while being more genetically stable, which should decrease the likelihood of cVDPV2 emergence in low immunity settings.

Under a WHO EUL recommendation for use (see sidebar), nOPV2 can be used for outbreak response in countries experiencing cVDPV2 outbreaks. However, due to high levels of demand as well as the impacts of COVID-19 on nOPV2 production, release of the vaccine from the global stockpile is contingent on supply and will be guided by a GPEI prioritization framework for the near term.

Due to the public health emergency posed by cVDPV2 outbreaks, it is critical that countries prioritize immediate and 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, it 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 could be a critical tool for more sustainably stopping cVDPV2, however the best way to successfully 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 in vulnerable, under-immunized populations, nOPV2 received a WHO EUL recommendation for use in November 2020 to enable the vaccine's expedited availability.

The EUL 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 data, 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.

Simultaneously, plans for full clinical development of nOPV2 are progressing, with the ultimate goal for the vaccine to pass through WHO prequalification.

Rollout



nOPV2 rollout began in March 2021 in an initial group of countries which met strict criteria to use the vaccine. As of October 2021, more than 125 million doses of nOPV2 had been administered in eight countries.



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



Based on the review of promising safety and genetic stability data from initial outbreak response campaigns which used over 65 million doses of nOPV2, SAGE endorsed the transition of nOPV2 from the initial use phase in October 2021. This move will enable eventual broader availability of the vaccine by making it easier and faster for countries to be verified for nOPV2 use.