

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 variant 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 variant poliovirus (cVDPV2)—which account for most of the cVDPV cases globally—are a major challenge to achieving eradication. As of 27 December 2023, 308 cases of cVDPV2 had been reported for the year, compared to 689 cases in 2022 and 685 in 2021. Cases remain significantly lower than the peak of 1,082 cases reported in 2020.

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). The unprecedented global decline in childhood immunization rates following the COVID-19 pandemic also exacerbated this issue.

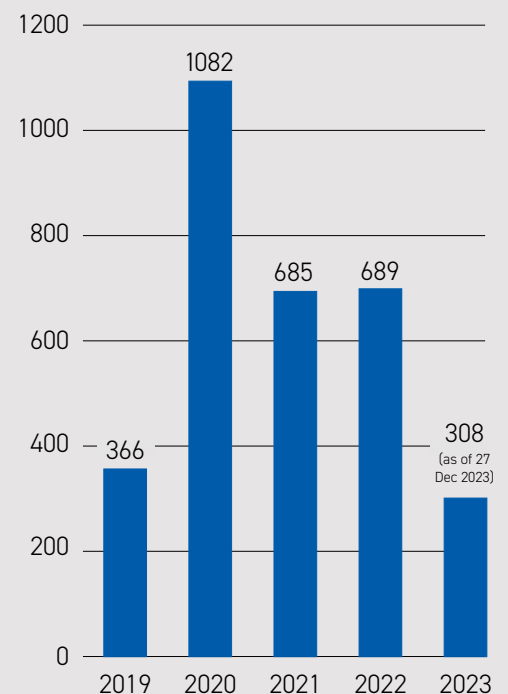


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Improving and Innovating to Stop cVDPV2

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, 2019-2023





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nOPV2: The Power of Innovation

GPEI is also continuing to support the rollout of an innovative 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 have demonstrated to be just as safe and effective in protecting against type 2 polio while being more genetically stable, decreasing the likelihood of new cVDPV2 outbreaks.

To date, nOPV2 has been used during outbreak response in 35 countries under EUL (see sidebar), predominantly in the African region which is most affected by cVDPV2. The vaccine's recent WHO Prequalification will allow for more streamlined regulatory approval for nOPV2 use in countries that need it.

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, prioritizing use of nOPV2 where possible. In situations where there is co-circulation of poliovirus strains, trivalent oral polio vaccine (tOPV) may be the more appropriate vaccine choice.

Following PQ, countries do not have to meet the strict readiness and monitoring requirements that were needed under EUL to use nOPV2. GPEI will continue to support governments to navigate this new regulatory process, while working closely with the vaccine's manufacturer (Bio Farma Indonesia) and finalizing plans to open an additional facility in India (Biological E) to increase supply.

nOPV2 has proven to be a critical tool for more sustainably stopping cVDPV2. However, its success, like any polio vaccine, depends on the ability to rapidly implement immunization campaigns that reach every child, and maintain strong disease surveillance.

WHO Emergency Use Listing (EUL) to Prequalification (PQ)

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 involved careful and rigorous analysis by WHO and independent experts of available data on quality, safety, efficacy, and performance, including manufacturing performance (e.g. yield and stability).

In December 2023, after reviews of nOPV2 safety, effectiveness and genetic stability data, as well as quality assurance checks of manufacturing sites, nOPV2 earned full licensure from Indonesian regulatory authority (Badan POM) and WHO Prequalification (PQ), marking the end of its EUL use phase. Achieving prequalification means it will be easier for more countries to access and use nOPV2 in response to type 2 variant polio outbreaks.

nOPV2 has become the first vaccine to move from use under an EUL pathway to full licensing and PQ, paving the way for other new tools and innovations like it.

Rollout



nOPV2 rollout began in March 2021 in an initial group of countries which met strict criteria to use the vaccine. As of December 2023, nearly 1 billion doses of nOPV2 have been administered in 35 countries.



After nearly three years of use, estimates show that nOPV2 is 80% less likely to seed new variant polio outbreaks compared to mOPV2.



Throughout its field use, nOPV2 has proven to be as safe to use and effective at stopping outbreaks as its predecessor, mOPV2, but, importantly, is more genetically stable, making it the tool of choice to stop cVDPV2 for good.