

GPEI Strategy for the Response to cVDPV2 2020-2021

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.

Outbreaks of type 2 cVDPV – which account for more than 90% of cVDPV outbreaks – are now a major challenge to achieving eradication. In 2020, 1,037 cases of cVDPV2 were confirmed from 24 countries (data as of 3 March 2021), compared to 366 cases from 15 countries in 2019.

These outbreaks are driven by several factors, including low quality 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 campaigns which further hindered efforts to stop transmission across affected countries (see “Recommendations for Reporting on Polio Outbreaks” for more information).

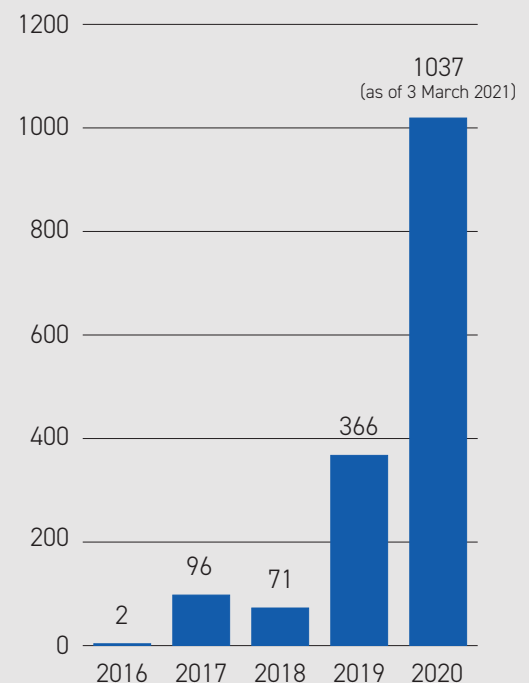


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Improving and Innovating to Stop cVDPV2

As a part of its Strategy for the Response to cVDPV2, 2020 - 2021, the GPEI is implementing a number of tactics to combat the growing threat of cVDPV2, including optimizing outbreak response with type 2 monovalent OPV (mOPV2), strengthening routine immunization through the use of inactivated polio vaccine (IPV), and accelerating the availability and further development of a new tool – type 2 novel OPV (nOPV2).

Global cVDPV2 Cases, 2016-2020





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WHO Emergency Use Listing Procedure (EUL)

Polio remains a Public Health Emergency of International Concern (PHEIC). In light of the increasing threat of cVDPV2 outbreaks to 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.

A New Tool: The Potential of nOPV2

GPEI is supporting countries experiencing or at high risk of cVDPV2 outbreaks with the rollout of 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 less likely than mOPV2 to be associated with the emergence of cVDPV2 in areas of low population immunity.

Under a WHO EUL recommendation for use (see sidebar), nOPV2 is currently available for outbreak response for an initial use period, the first step to facilitating potential broader availability of the vaccine. The GPEI continues to work to prepare governments for use of nOPV2, providing technical and communications assistance to ensure that necessary readiness and EUL criteria are met.

nOPV2 could be a critical tool for stopping cVDPV2, but the best protection against all types of polio remains ensuring all children are vaccinated in routine and supplementary immunization campaigns and maintaining strong disease surveillance.

Initial Use Period



nOPV2 is being used for an initial use period, which will last at least 15 weeks in countries with a VDPV2 detection.



To use nOPV2, countries must meet strict EUL requirements – as well as initial use criteria endorsed by the Strategic Advisory Group of Experts on Immunization (SAGE) – including for surveillance, communications, cold chain infrastructure and monitoring nOPV2's safety and effectiveness in the field.



For countries that do not currently meet initial use criteria, mOPV2 remains safe and effective and has a proven track record of stopping cVDPV2 outbreaks.



Broader Rollout Period



Throughout the initial use period, data on nOPV2's safety, immunogenicity and genetic stability is continuously collected and rigorously analyzed.



Once sufficient data is available, WHO's Global Advisory Committee on Vaccine Safety (GACVS) and SAGE will review and decide whether to conclude the initial use period and enable broader availability of nOPV2.



SAGE has endorsed, in principle, that nOPV2 become the vaccine of choice in response to cVDPV2 outbreaks after this review is complete and all requirements for nOPV2's use are met.