GPEI Strategy for Control of cVDPV2 2020-2021

POLIO GLOBAL ERADICATION INITIATIVE

Background

Since 1988, the world has made incredible progress in the global effort to eradicate polio, with wild polio cases dropping by 99.9%. 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.

In addition to protecting children from paralysis, OPV prevents person-to-person transmission of the virus and is vital to achieve eradication. However, in under-immunized communities, the live, weakened virus originally contained in OPV can circulate for an extended period and genetically revert into a form that causes paralysis. This is known as circulating vaccine-derived poliovirus (cVDPV). Once a cVDPV emerges, outbreak response is carried out per international guidelines in the same way as for wild poliovirus outbreaks: large-scale administration with OPV to rapidly boost population immunity. For cVDPV2 outbreaks, type 2 monovalent OPV is used to build immunity to the type 2 virus.

Following the certification of the eradication of wild poliovirus type 2 in 2015, countries around the world switched from the trivalent oral polio vaccine (tOPV) to bivalent oral polio vaccine (bOPV)—which doesn't carry the type 2 virus responsible for 90% of cVDPV outbreaks. In planning for the switch, the risk of further cVDPV2 cases was carefully considered and modelled. However, the number and scope of current outbreaks are greater than anticipated and cVDPV2 outbreaks have emerged as a major challenge in the final stage of eradication.

Quick Facts on OPV

SINCE 2010:

More than **20 billion** doses administered to more than one billion children

650,000 cases of paralysis averted every year

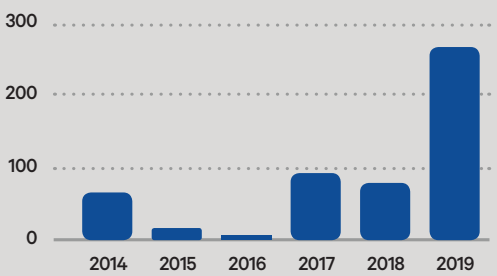
30,000 childhood deaths averted

Current Situation

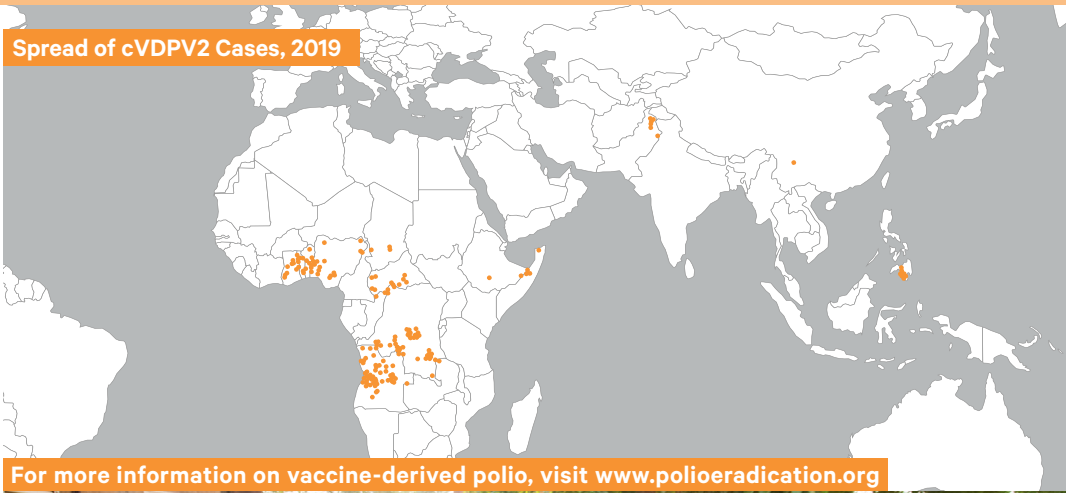
In 2020, almost four years after the global switch to bOPV, the world is facing increasing cVDPV2 outbreaks in parts of Africa, Southeast Asia, and the Middle East. In 2019, more than 260 cases of cVDPV2 were reported from 15 countries (data as of 22 January 2020).

These outbreaks are driven by several factors, including declining immunity levels to the type 2 virus among young children born after the switch, insufficient routine immunization coverage, regional migration patterns, and low-quality immunization campaigns. Additionally, the use of mOPV2 to stop cVDPV2 outbreaks has seeded new outbreaks in areas of low coverage within and on the borders of response zones.

Global cVDPV2 Cases, 2014-2019



Spread of cVDPV2 Cases, 2019



For more information on vaccine-derived polio, visit www.polioeradication.org

GPEI Strategy for Control of cVDPV2, 2020-2021

The GPEI has developed a comprehensive new strategy to stop the spread of type 2 circulating vaccine-derived poliovirus (cVDPV2) outbreaks currently affecting countries in Africa, Asia and the Middle East. The strategy acts as an addendum to the Polio Endgame Strategy 2019-2023.

THE STRATEGY AIMS TO:

Optimize outbreak response using mOPV2, currently the best available tool for combatting type 2 vaccine-derived polio.

Accelerate development of a new vaccine – novel OPV2 (nOPV2) – as a potential alternative for outbreak response and ultimately as a replacement for mOPV2.

Strengthen routine immunization by increasing coverage with inactivated polio vaccine (IPV) in high-risk areas to protect children from paralysis.

Ensure sufficient supply of OPV2 is available to reach every at-risk child, utilizing innovative strategies as needed.

Stage 1 Implement aggressive outbreak response, intensify routine immunization in high-risk areas bordering outbreak areas, and increase mOPV2 supply.

Stage 2 If approved for use via EUL, roll out the first 100 million doses of nOPV2 in areas at highest risk of cVDPV2s, while continuing aggressive response with mOPV2 in all other affected geographies.

Stage 3 Evaluate the availability and effectiveness of nOPV2 and use the best tools for continued outbreak response, while continuing to intensify routine immunization activities.

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A New Tool: The Potential of nOPV2

GPEI partners are actively engaged in the development of novel oral polio vaccine type 2 (nOPV2), a new tool that could prove critical to stopping cVDPV2 outbreaks and carries a lower risk of seeding new outbreaks. nOPV2 is a modification of the existing Sabin OPV type 2, specifically designed to improve the genetic stability of the vaccine. Studies to date suggest it would provide children with comparable protection as the current oral vaccine but with a much lower risk of mutating and causing paralysis.

Initial results from clinical trials of nOPV2 have been very encouraging. If given WHO EUL (see sidebar), nOPV2 could be available to address cVDPV2 outbreaks as early as mid-2020.

The GPEI is working with regional and country teams to prepare for possible use of nOPV2, providing technical and communications assistance as needed. The WHO Strategic Advisory Group of Experts on Immunization (SAGE) will also endorse a framework for prioritization to ensure the highest-risk areas that meet EUL criteria are the first to introduce the nOPV2 vaccine.

WHO Emergency Use Listing (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, data generated on nOPV2 will be submitted for review under WHO's EUL to expedite availability of the vaccine, potentially as early as mid-2020.

The EUL involves careful and rigorous analysis of available quality, safety, and efficacy and performance data, along with manufacturing performance (e.g., yield & stability data), and is meant to enable early, targeted use of pre-licensure products for people affected by a public health emergency. In 2019, SAGE endorsed accelerated clinical development of nOPV2 and its assessment under this procedure.

Simultaneously, full clinical development, national licensures and WHO pre-qualification for nOPV2 are also in planning stages and making progress.