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The role of a genetically stable, novel oral type 2 poliovirus vaccine in the poliomyelitis endgame

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ABSTRACT Poliovirus infection causes paralysis in up to 1 in 200 infected persons. The use of safe and effective inactivated poliovirus vaccines and live attenuated oral poliovirus vaccines (OPVs) means that only two pockets of wild-type poliovirus type 1 remain, in Afghanistan and Pakistan. However, OPVs can revert to virulence, causing outbreaks of circulating vaccine-derived poliovirus (cVDPV). During 2020–2022, cVDPV type 2 (cVDPV2) was responsible for 97–99% of poliomyelitis cases, mainly in Africa. Between January and August 2022, cVDPV2 was detected in sewage samples in Israel, the United Kingdom and the United States of America, where a case of acute flaccid paralysis caused by cVDPV2 also occurred. The Pan American Health Organization has warned that Brazil, the Dominican Republic, Haiti and Peru are at very high risk for the reintroduction of poliovirus and an additional eight countries in Latin America are at high risk, following dropping vaccination rates (average 80% coverage in 2022). Sabin type 2 monovalent OPV has been used to control VDPV2 outbreaks, but its use could also lead to outbreaks. To address this issue, a more genetically stable, novel OPV2 (nOPV2) was developed against cVDPV2 and in 2020 was granted World Health Organization Emergency Use Listing. Rolling out a novel vaccine under the Emergency Use Listing in mass settings to contain outbreaks requires unique local regulatory and operational preparedness.

Keywords Vaccine-preventable disease; poliomyelitis; health policy; poliovirus vaccines; outbreaks.

Poliomyelitis is a devastating and still much feared disease across the world. Infections caused by polioviruses result in paralysis in up to 1 in 200 infected people and death in 10 to 20 people per 200 cases (1). Following the introduction of safe and effective inactivated poliovirus vaccines (IPVs) and live attenuated oral poliovirus vaccines (OPVs) in the late 1950s and early 1960s, polio cases have dropped globally by 99.9%. Two of the three poliovirus serotypes have been declared globally eradicated: wild-type poliovirus type 2 (WPV2) in September 2015 and WPV3 in October 2019 (2). WPV1 remains endemic only in pockets in Afghanistan and Pakistan. However, the number of cases caused by WPV1 infection has decreased, as noted during the March 2023 meeting of the Strategic Advisory Group of Experts on Immunization (3).

Of more urgent concern has been the striking increase in cases of poliomyelitis caused by circulating vaccine-derived poliovirus type 2 (cVDPV2), which have included person-to-person transmission after a global switch was implemented in April 2016 from the trivalent OPV to bivalent types 1 and 3 OPV (bOPV) that excluded type 2 (4). To maintain immunity levels to WPV2, high-risk countries were encouraged to introduce IPV into their routine immunization programs prior to making the switch (4). The surge in cVDPV2 shows that residual, oral, live attenuated type 2 vaccine virus continues to circulate, allowing OPV2 to revert to virulence through loss of attenuating mutations following replication in the human intestine. The risk is highest in places with poor sanitation and, most importantly, persistently low vaccination coverage (1). Of the 689 cases of paralytic poliomyelitis reported during

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the 12 months to 28 March 2023, 29 (4.2%) were caused by WPV1, 165 (23.9%) by cVDPV1 and 495 by cVDPV2 (71.8%); these cases were reported from 20 countries, mostly in Africa (5). The high proportion of cases of poliomyelitis caused by VDPV2 suggests ongoing circulation of the trivalent OPV-derived type 2 virus and person-to-person transmission. As most poliovirus infections are asymptomatic (1), cases of paralysis indicate that many more people in the affected regions have been infected, and the problem has been vastly underestimated.

However, the detection in 2022 of VDPV2 in sewage samples in Israel (January–June 2022), the United Kingdom (February–August 2022), and the United States of America (April–August 2022), and a case of acute flaccid paralysis (AFP) caused by VDPV2 in an unvaccinated individual in New York in June 2022 clearly demonstrate that poliomyelitis remains a global threat (6, 7).

With respect to Latin America, there have been no outbreaks caused by WPV or cVDPV in more than 20 years. The last outbreak, with 21 paralytic cases, started in Haiti, and was followed by cases in the Dominican Republic during 2000–2001, and it was associated with cVDPV1. The last time a WPV isolate was detected was in São Paulo from sewage surveillance in 2014, and it was likely imported during the World Cup soccer championship because the isolate was genetically linked with transmission in Equatorial Guinea.

Low regional rates of poliovirus immunization, including in Latin America, leave a pool of individuals potentially susceptible to infection by WPV and especially by cVDPVs from previous vaccination with trivalent OPV. In the Region of the Americas, vaccination coverage of the third dose of poliovirus vaccine has fallen from 87% in 2016 to 79% in 2022 (8). The Pan American Health Organization (PAHO) has warned that Brazil, the Dominican Republic, Haiti and Peru are at very high risk for reintroduction of polio due to low vaccination rates, and Argentina, the Bahamas, Bolivia (Plurinational State of), Ecuador, Guatemala, Panama, Suriname and Venezuela (Bolivarian Republic of) are at high risk. Sporadic cases of VDPV (i.e. not circulating variants) or vaccine-associated paralytic poliomyelitis are reported occasionally from Latin America. In Brazil, where polio vaccination coverage in 2022 was as low as 52% (9), a case of AFP was reported in October 2022, temporally related to bOPV vaccination of a previously unvaccinated child. Sabin-like type 3 poliovirus was detected in the child's stool (10). In March 2023, a case of paralytic polio associated with VDPV1 (i.e. not a circulating variant) was reported from Peru. Such sporadic cases do not cause alarm until they become outbreaks with evidence of person-to-person transmission, but they do highlight the importance of surveillance and readiness. Records of polio cases, however, might not be completely correct as various stakeholders including PAHO do not consistently report to the centralized polio information system known as POLIS.

IPV, with or without bOPV, is now the vaccine of choice in most countries, including in Latin America. IPV effectively protects a vaccinee against paralytic disease, is not shed and thus cannot induce VDPVs, but it is poor at inducing intestinal mucosal immunity. Thus, if IPV-vaccinated people become infected by WPV or cVDPV, they will be asymptomatic but can still shed poliovirus in stool, facilitating transmission and leaving unimmunized and immunocompromised people susceptible to poliomyelitis. Poliovirus surveillance plays a critical role in achieving eradication. Fast detection of circulation of WPV or, more likely, VDPV is critical to stopping a potential outbreak. AFP surveillance is important, but case detection might occur too late. A study from Israel estimated that after importation of WPV1, more than 7 000 people became infected but there was not a single paralytic case (11). Environmental surveillance conducted by sampling sewage and wastewater is the method of choice to ensure earlier detection of poliovirus. Prado et al. assessed the value of wastewater-based epidemiology and its application in Latin America, including for surveillance of poliovirus circulation (12). Wastewater-based epidemiology complements clinical surveillance systems. Wastewater-based epidemiology makes it possible to detect early warning signals of a possible outbreak, identify circulation of both residual WPV and VDPV before symptomatic cases are detected, monitor spatial and temporal trends of infectious diseases, and produce real-time and representative epidemiological information in an area (12).

Because the induction of mucosal immunity by IPV is limited, Sabin type 2 monovalent OPV (mOPV2) has been routinely used to control cVDPV2 outbreaks. However, because of its genetic instability and remote risk of reversion to virulence, mOPV2 can propagate further outbreaks, contributing to a vicious cycle. To address this issue, a scientific consortium was formed in 2011, with scientific and funding support from the Bill & Melinda Gates Foundation, to develop more genetically stable, novel OPVs (nOPVs), thus maintaining the advantages of the Sabin OPV but decreasing the risk of reversion to virulence and, hence, to VDPVs. The first candidate vaccine was a novel OPV2 (nOPV2). Clinical development included an adult phase-1 containment study performed by the University of Antwerp, Belgium, in a specially designed containment facility known as Poliopolis. All pivotal pediatric studies were performed in Panama using a unique design by setting up a prospective historical control group of mOPV2 vaccinees. Since nOPV2 study material became available only in 2018 – that is, 2 years after WHO had banned the routine use of Sabin mOPV2 – it was not possible to directly compare head-to-head in the same trial nOPV2 and Sabin mOPV2. To reduce comparison bias as much as possible scientists from Latin America and the Bill & Melinda Gates Foundation designed this prospective historical control study – that is, they prospectively vaccinated children with Sabin mOPV2 in 2016 while it was still allowed – followed by phase 2 trials for nOPV2 in 2018 at the same sites, with the same investigators in Panama, using exactly the same protocol, the same inclusion and exclusion criteria and study procedures, and, importantly, they performed parallel laboratory testing on the same runs of the stored mOPV2 samples from 2016 and the new nOPV2 samples from 2018 to allow for valid comparisons (13). Shedding analysis showed that nOPV2 was more genetically stable and had a lower risk of reverting to virulence – the cause of outbreaks of cVDPV – compared with mOPV2 (13). Also, nOPV2 could not be detected in wastewater in the neighborhoods close to the trial sites (14). WHO authorized the use of nOPV2 to control outbreaks of cVDPV2 through its Emergency Use Listing (EUL) procedure in November 2020 after the phase 2 studies were completed. A recent clinical trial in Bangladesh confirmed the safety and immunogenicity nOPV2 in infants negative for type 2 poliovirus, which could pave the way for inclusion in the Essential Programme on Immunization (known as EPI) in high incidence areas (15).

Since its EUL, more than 600 million doses of nOPV2 have been deployed to combat cVDPV2 outbreaks in 28 countries in

campaigns targeting mainly children up to the age of 5 years (16). While the majority of countries did not report any VDPV2 after two nOPV2 vaccination rounds, in early March 2023, there were seven reports of AFP from the Democratic Republic of the Congo and one from Burundi associated with nOPV2 (17). The appearance of AFP after nOPV2 vaccination is not completely unexpected. Although nOPV2 is more genetically stable, there is still a risk of reversion. Modeling indicates that in the same setting, the use of Sabin OPV2 would have led to 30–40 cases of AFP compared with the 8 cases reported after use of nOPV2.

There are important regulatory strategies that could be considered to ensure early access to innovative vaccines such as nOPV2 in Latin America. EUL is a risk-based procedure for assessing and listing unlicensed vaccines for use during public health emergencies including those of international concern (16).

The EUL guidelines were recently revised to improve clarity on procedural aspects. For any applicant intending to go through this procedure, four criteria should be fulfilled.

1. The target disease is serious or immediately life threatening; it has the potential to cause an outbreak, epidemic or pandemic; and it is reasonable to consider the product a candidate for an EUL assessment: in this case, poliomyelitis has been declared a public health emergency of international concern.
2. Existing products have not been successful in eradicating the disease or preventing outbreaks: in this case, Sabin mOPV2 is associated with the risk of generating cVDPV2 because of its genetic instability and risk of reverting to virulence.
3. The product is manufactured in compliance with good manufacturing practices: Biofarma in Indonesia manufactures nOPV2 and fulfills all of the requirements for good manufacturing practices (18).
4. The applicant completes the development of the product and applies for WHO prequalification once the product is licensed. Any remaining clinical trials and other testing must be under way at the time an application is made for an EUL: in this case, additional nOPV2 clinical trials are under way, including in infants who have never been vaccinated against polio (19).

It is only nOPV2 that now has an EUL. But nOPV1 and nOPV3, which are in the late stages of development, will fulfill these requirements once phase 2 data are available and files are submitted for an EUL.

Of note, it is the sole prerogative of WHO Member States to use the EUL as the basis to authorize an unlicensed vaccine at the national level. The WHO EUL pathway, with consequent acceptance by national regulatory authorities, is likely the fastest way to obtain emergency use of vaccines such as nOPV2 in a country since they can be approved while development is in progress and it can reduce the time spent on assessment, depending on the confidence in the decisions made by WHO experts. In cases in which full data from development are available, seeking approval from a regulatory system classified as at a high maturity level, based on the WHO Global Benchmarking Tool, could be an important strategy to accelerate access in low- and middle-income countries (20).

Regulatory reliance is a mechanism in which the assessments made by reference authorities may be considered in order to avoid duplicate efforts when evaluating data about the efficacy, safety and quality of medicines and other health commodities (21). After the COVID-19 pandemic, regional regulatory authorities – such as Agência Nacional de Vigilância Sanitária (or Anvisa) in Brazil (through Resolution 475, March 10, 2021) and Instituto Nacional de Vigilancia de Medicamentos y Alimentos (or INVIMA) in Colombia (through Decree 1651, August 6, 2022) – changed their regulatory norms to allow for reliance strategies to be used for vaccines approved through the EUL or high-maturity-level regulatory systems. These changes were focused on COVID-19 vaccines, but lessons learned from those strategies, such as how to make speedy decisions and avoid unnecessary duplication of work, could provide a blueprint for approving and using nOPV2, the future nOPV1 and nOPV3 and other vaccines against pathogens with pandemic potential.

The cases in the United Kingdom and United States are reminders that in a globally mobile society, poliovirus can easily spread worldwide as long as it exists somewhere in the world. No country or region, including the Region of the Americas, is safe from importation of polio and free from the risk of outbreaks. Thus, the epidemiological, medical and regulatory preparedness of PAHO and each country to deal with a potential appearance of cVDPV2 is important. Enhancing environmental surveillance and sequencing viral isolates remains crucial to gather information about the extent and origin of circulation. There is limited precedent for the management of VDPV2 transmission in populations vaccinated only with IPV. Implementing IPV booster and catch-up immunization programs that prioritize unvaccinated individuals should be an immediate first step to ensure individual protection. At its March 2023 meeting, the Strategic Advisory Group of Experts on Immunization recommended that in areas with persistent poliovirus circulation, an additional full or fractional IPV dose should be given to supplement OPV2 vaccination. Using nOPV2 instead of Sabin mOPV2 for outbreaks of cVDPV2 is preferred (3). To ensure just-in-case availability, national regulatory authorities, including in Latin America, should assess WHO's EUL requirements. If possible, an EUL should be obtained and access to stockpiles secured.

Eradication of polio is set for 2026, and in the 2022–2026 period it will cost US$ 4.8 billion to reach 370 million vulnerable children annually with poliovirus vaccines and other essential health services. So far, donors have pledged US$ 3.4 billion, of which US$ 1.2 billion was committed by the Bill & Melinda Gates Foundation at the 2022 World Health Summit in Berlin (22). Poliomyelitis can be prevented and eradicated, and a lack of funding for this effort would be tragic.

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Utilidad de una nueva vacuna antipoliomielítica oral del serotipo 2 genéticamente estable contra el poliovirus de tipo 2 en la erradicación de la poliomielitis

RESUMEN La infección por poliovirus ocasiona parálisis en hasta 1 de cada 200 personas infectadas. La utilización de vacunas con poliovirus inactivados y de vacunas antipoliomielíticas orales con poliovirus vivos atenuados (OPV) seguras y eficaces ha logrado que solo queden dos focos de poliovirus salvaje de tipo 1, en Afganistán y Pakistán. Sin embargo, las vacunas con OPV pueden revertir a la virulencia y producir brotes de poliovirus circulantes de origen vacunal (cVDPV). Durante el período 2020-2022, el cVDPV de tipo 2 (cVDPV2) fue la causa del 97-99% de los casos de poliomielitis, sobre todo en África. Entre enero y agosto del 2022, se encontró el cVDPV2 en muestras de aguas residuales en Estados Unidos de América, donde se produjo un caso de parálisis flácida aguda por el cVDPV2, Israel y Reino Unido y. La Organización Panamericana de la Salud ha advertido que, tras la caída de las tasas de vacunación (con una cobertura promedio del 80% en el 2022), Brasil, Haití, Perú y República Dominicana corren un riesgo muy alto de reintroducción del poliovirus, en tanto que otros ocho países de América Latina se encuentran en una situación de alto riesgo. La OPV monovalente de tipo 2 de Sabin se ha utilizado para controlar los brotes de VDPV2, pero su empleo también podría ocasionar brotes. Para hacer frente a este problema, se creó una nueva OPV2 (nOPV2) contra el cVDPV2, genéticamente más estable, que en el 2020 se incluyó en la lista de uso en emergencias de la Organización Mundial de la Salud. El despliegue a gran escala de una nueva vacuna incluida en la lista de uso en emergencias con el fin de contener los brotes exige una extraordinaria preparación regulatoria y operativa local.

Palabras clave Enfermedades prevenibles por vacunación; poliomielitis; política de salud; vacunas contra poliovirus; brotes de enfermedades.

O papel de uma nova vacina oral contra o poliovírus tipo 2, geneticamente estável, no estágio final da eliminação da poliomielite

RESUMO A infecção pelo poliovírus causa paralisia em 1 de cada 200 pessoas infectadas. O uso de vacinas seguras e eficazes, tanto vacinas inativadas contra o poliovírus quanto vacinas orais contendo poliovírus atenuado (VOP), significa que restam apenas dois bolsões de poliovírus selvagem tipo 1, um no Afeganistão e outro no Paquistão. No entanto, a VOP pode reverter à virulência, causando surtos de poliovírus circulante derivado de vacina (cPVDV). No período 2020-2022, o cPVDV tipo 2 (cPVDV2) foi responsável por 97% a 99% dos casos de poliomielite, principalmente na África. Entre janeiro e agosto de 2022, o cPVDV2 foi detectado em amostras de esgoto em Israel, no Reino Unido e nos Estados Unidos da América, onde também houve um caso de paralisia flácida aguda causada pelo cPVDV2. A Organização Pan-Americana da Saúde alertou que, devido à queda nas taxas de vacinação (cobertura média de 80% em 2022), o Brasil, o Haiti, o Peru e a República Dominicana correm um risco muito alto de reintrodução do poliovírus e outros oito países da América Latina correm um risco alto. A VOP monovalente Sabin tipo 2 tem sido usada para controlar surtos de PVDV2, mas seu uso também pode levar a surtos. Para resolver esse problema, foi desenvolvida uma nova VOP2 (nVOP2), mais estável geneticamente, para combater o cPVDV2. Em 2020, a nVOP2 entrou na Lista de Uso Emergencial da Organização Mundial da Saúde. A distribuição de uma nova vacina incluída na Lista de Uso Emergencial em contextos de massa para conter surtos requer medidas originais de preparação operacional e regulatória em âmbito local.

Palavras-chave Doenças preveníveis por vacina; poliomielite; política de saúde; vacinas contra poliovirus; surtos de doenças.