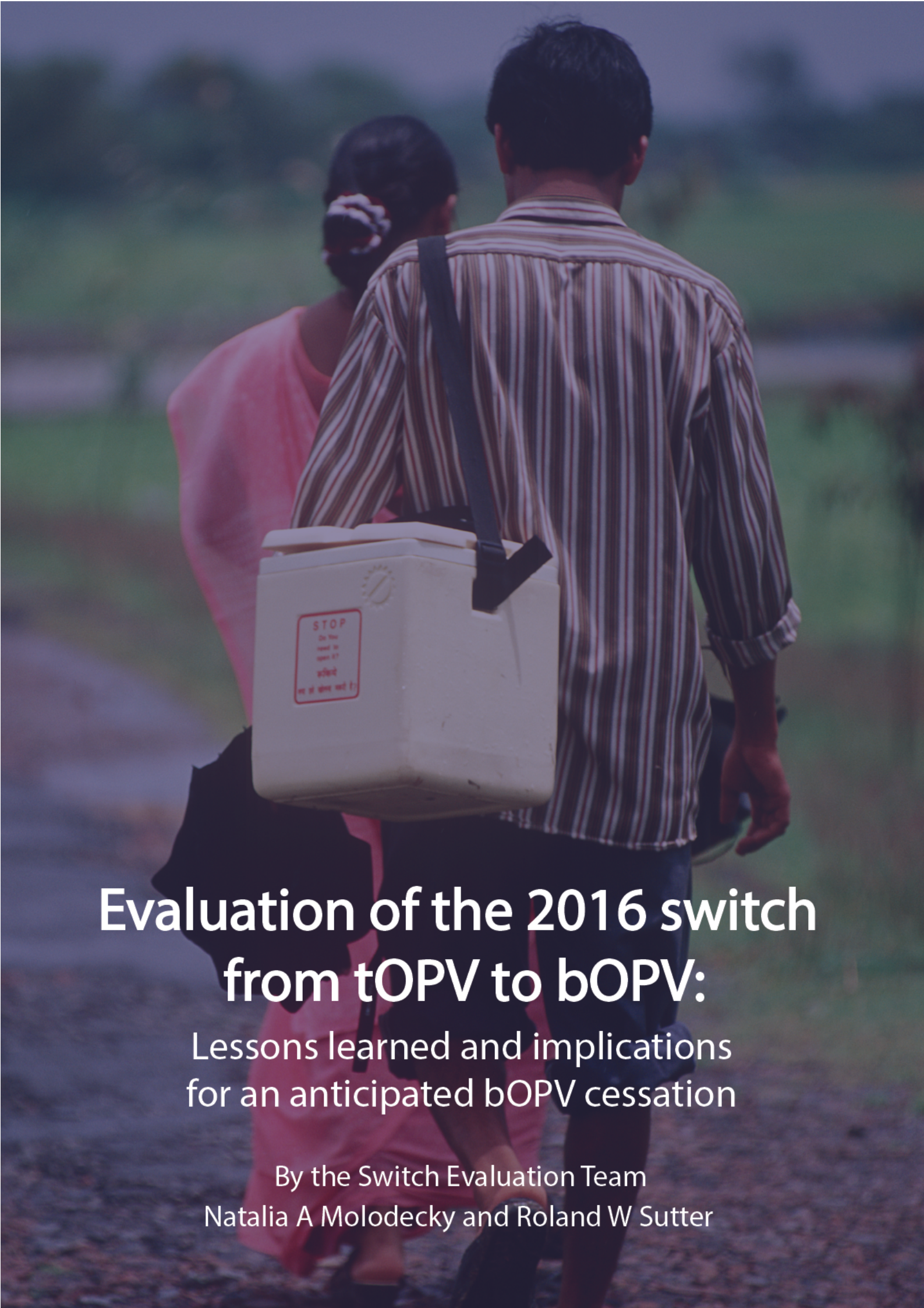


# Evaluation of the 2016 switch from tOPV to bOPV:

## Lessons learned and implications for an anticipated bOPV cessation

By the Switch Evaluation Team
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Disclaimer: This report represents the views of the Switch Evaluation Team.

Date: 30 September, 2024.

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# Contents

# Abbreviations

| | |
|---|---|
| Admin1 | Administration level 1 (the largest subnational administrative unit of a country) |
| AFP | Acute flaccid paralysis |
| bOPV | Bivalent oral poliovirus vaccine |
| bnOPV | Bivalent novel oral poliovirus vaccine |
| CDC | The Centers for Disease Control and Prevention (United States) |
| cVDPVs | Circulating vaccine-derived polioviruses |
| cVDPV1 | Circulating vaccine-derived poliovirus type 1 |
| cVDPV2 | Circulating vaccine-derived poliovirus type 2 |
| ES | Environmental surveillance |
| fIPV | Fractional-dose inactivated poliovirus vaccine |
| GPEI | Global Polio Eradication Initiative |
| ID | Intradermal injection |
| IPV | Inactivated poliovirus vaccine |
| IPV1 | IPV first dose |
| IVB | Immunization, Vaccines and Biologicals department of WHO |
| NIDs | National Immunization Days |
| Nt | Nucleotide |
| nOPV | Novel oral poliovirus vaccine |
| nOPV2 | Novel oral poliovirus vaccine type 2 |
| mOPV2 | Monovalent oral poliovirus vaccine type 2 |
| OPV | Oral poliovirus vaccine |
| OPV2 | Oral poliovirus vaccine type 2 |
| RI | Routine Immunization |
| SIAs | Supplemental immunization activities |
| SOPs | Standard operating procedures |
| SNIDs | Subnational Immunization Days |
| tOPV | Trivalent oral poliovirus vaccine |
| tnOPV | Trivalent novel oral poliovirus vaccine |
| WHO | World Health Organization |
| WPV | Wild poliovirus |
| WPV1 | Wild poliovirus type 1 |
| UTR | Untranslated region |
| VAPP | Vaccine-associated paralytic poliomyelitis |
| VP1 | Viral protein 1 |

# Data sources

Data used for the analyses within the report and Annexes extracted from the Global Polio Eradication Initiative (GPEI) Polio Information System (POLIS), on 15 May 2024[1]. Estimates of routine immunization (RI) coverage extracted from the WHO Immunization Data portal[2].

# Executive summary

In order to achieve global polio eradication, poliovirus must be removed from populations everywhere, including the Sabin viruses contained in the oral poliovirus vaccine (OPV). While OPV has played a key role in eradication (and reduced the global paralytic case burden by >99.9% since 1988, when the Global Polio Eradication Initiative (GPEI) was formed), its continued use poses a threat of re-establishing poliovirus transmission through circulating vaccine-derived poliovirus (cVDPV), in addition to an increased relative burden of vaccine-associated paralytic poliomyelitis (VAPP).

In 2015, the global health community (in the World Health Assembly, the governing body of the World Health Organization (WHO)) determined that the conditions were appropriate to withdraw Sabin oral poliovirus vaccine type 2 (OPV2). In April 2016, across a two-week window, OPV2 was withdrawn globally. It represented the largest coordinated public health effort in history, with 155 countries and territories recalling trivalent OPV (tOPV) and replacing it with bivalent (types 1 + 3) OPV (bOPV) (i.e., the "switch"), and 126 countries required to introduce at least one dose of inactivated poliovirus vaccine (IPV, which contains types 1, 2 and 3), as a risk mitigation measure, with some countries starting as early as 2012 [3].

Although evaluations in the immediate aftermath of the switch generally presented a picture of successful implementation, in the eight years since the switch we have observed continued and uncontrolled circulating vaccine-derived poliovirus type 2 (cVDPV2) transmission and a 10-fold increase in the cVDPV2 case burden compared to pre-switch era (Figure 1). The GPEI is currently in a better position to look back and evaluate where we are, why cVDPV2 is still circulating, what lessons we can learn, and how this effort may influence future OPV withdrawal efforts and secure a world free of all polio.

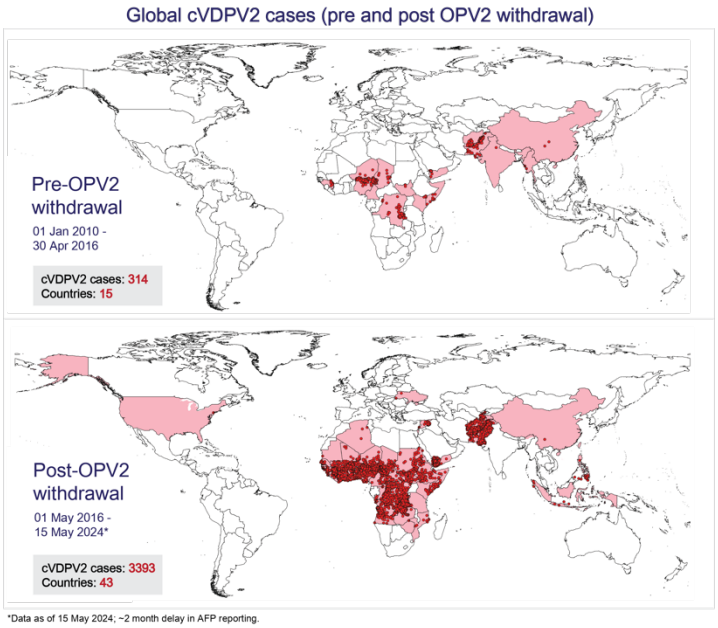



**Figure 1.** Global cVDPV2 cases pre- and post-OPV2 withdrawal. Red dots correspond to a single cVDPV2 case. Pink shading corresponds to countries reporting cVDPV2 cases.

In August 2023, a formal evaluation of the switch was commissioned by the Strategy Committee (SC), the managing body of the GPEI. Following approval of specific terms of reference, the evaluation team, consisting of Drs R Sutter and N Molodecky, was established. The evaluation commenced in August 2023 and was completed in May 2024. The objective of the evaluation was to better understand what factors led to the many and persistent cVDPV2 outbreaks following OPV2 withdrawal, in order to provide recommendations for GPEI strategy and future OPV withdrawal efforts.

The foundation for the evaluation was based on Objective 2: Immunization systems strengthening and OPV withdrawal of the Polio Eradication and Endgame Strategic Plan 2013-2018 [4]. The plan specified the main objectives of OPV2 withdrawal, triggers for executing the switch, along with prerequisites and readiness criteria that needed to be fulfilled to meet the conditions to implement the OPV2 withdrawal. The evaluation focused on these triggers, prerequisites and readiness criteria and included both qualitative and quantitative methods. Moreover, the evaluation relied on a peer-review process to ensure that the findings were accurate, and the conclusions were supported by the available data and analyses.

The findings are clear: the switch was a failure. After eight years of unsuccessful efforts, 53 countries have been infected or re-infected with cVDPV2, resulting in >3,300 children paralyzed by cVDPV2 (across 43 countries), and >$1.8 billion spent by GPEI on outbreak response.

The overriding cause of the failure was (and continues to be) the inability of the program to close out outbreaks and stop cVDPV2 transmission. Outbreak response scope, timing and quality have been insufficient, resulting in increased scope and magnitude of cVDPV2 transmission over time (with few improvements over the past few years). This, coupled with the inability of program leadership to recognize the seriousness of the evolving problem and take effective corrective action, ultimately resulted in failure of the switch.

In addition, 10 factors contributed to or exacerbated the switch failure, some of which were due to lapses in switch readiness, including:

1) IPV supply constraints, affecting IPV introduction in routine immunization (RI) and use in outbreak control, contributing to high case burden (including in lower-risk countries).
2) gaps in pre-switch poliovirus type 2 immunity in critical geographies, resulting in early seeding events and undetected transmission at the time of the switch.
3) continued and undetected cVDPV2 transmission at the time of the switch.
4) limited progress in RI coverage and lack of alternative strategies to increase coverage, leaving a weak foundation of type-2 immunity and contributing to high case burden.
5) limited stockpile of monovalent type 2 OPV (mOPV2), resulting in focused and insufficient outbreak response scope.
6) revision of outbreak control Standard Operating Protocols (SOPs), reducing the number of rounds and target population, and elimination of IPV from outbreak response.
7) Waiting for nOPV2 introduction and perceived / communicated risk of mOPV2, resulting in substantial delays in outbreak response.
8) left over tOPV vials in storage sites, potentially seeding (at least one) cVDPV2 outbreaks.
9) inadequate or late detection of cVDPV2 (both new emergences and ongoing transmission), delaying implementation of outbreak control measures.
10) delays in processing and notifying cVDPV2 acute flaccid paralysis (AFP) and environmental surveillance (ES) samples, exacerbating delayed responses.

For the anticipated bOPV withdrawal we strongly suggest adopting the following triggers for programmatic execution of cessation:

- no “persistent cVDPV” of any serotype (including cVDPV2). This requires outbreak control and elimination of all current outbreaks and endemic transmission. Persistent cVDPV is defined as circulation ≥6 months after designation of circulating [5].

  Prior to bOPV withdrawal, the program needs to demonstrate that it can control and close out outbreaks within 6 months after designation of “persistent” cVDPVs (i.e., meeting the definition of persistent cVDPV); and

- confirmation of eradication of wild poliovirus (WPV) by the Global Certification Commission (GCC).

In addition, the following 10 prerequisites should be considered:

- 1-3) Vaccine Availability: ensure sufficient stockpile quantities of all required vaccines (required vaccines to be determined based on sufficient evidence from studies on novel formulations), continue manufacturing these vaccines, and modify containment specifications to enable production, storage, and laboratory processing.

- 4-6) Population Immunity: conduct preventive supplemental immunization activities (SIAs) that reach and maintain high population immunity (with clearly defined benchmarks and methods of evaluation), design realistic outbreak response SOPs using a back-to-basics approach (with appropriate funding), and institute special strategies in consequential geographies (i.e., Yemen, Eastern Democratic Republic of the Congo, Northern Nigeria, Somalia).

- 7-9) Routine Immunization (RI): design new strategies to reach and maintain threshold levels for herd immunity, use novel OPV2 (nOPV2) in RI in consequential geographies and/or highest risk areas, and accelerate introduction and promote high coverage with hexavalent vaccine, especially in consequential geography countries.

- 10) Surveillance: further increase surveillance sensitivity and speed of detection, shipping and processing for timely notification and action.

The planning for bOPV cessation must also be strengthened. This can be done by: commissioning a plan B (of critical voices); compiling a detailed risk matrix, risk reduction and risk mitigation strategy, and contingencies for unexpected eventualities; defining *a priori* success and failure (along with follow up action in the case of failure); evaluating progress every three months; and reviewing the status at the end of Year 2 post-cessation for final determination of success or failure.

Moreover, in order to minimize risk and gain experience, a phased withdrawal by region should be considered, rather than a synchronized global cessation. For example, low-risk countries withdrawing first (European Region, Region of the Americas, Western Pacific Region), then the South-East Asian Region, followed by the Eastern Mediterranean and African Regions. Furthermore, developing new ways of rapidly determining population immunity to support real-time decision-making, streamlining the decision-making structure to facilitate

programmatic action in the field, and further research into a non-infectious vaccine that induces mucosal immunity, would help ensure a path to success.

The lessons for the GPEI are clear. At present, the program must urgently review the current outbreak control strategy, recognize the reality of the failure and make the changes needed. Achieving the two triggers for bOPV cessation may be most challenging. For the anticipated bOPV cessation, it would be better to take the time and get it right, than to rush, and fail. Another failure cannot be an option. The consequence of failure for bOPV cessation is even greater than for OPV2 (given the 10-fold higher case to infection ratio for poliovirus type 1). Closer collaboration with RI and a focus on immunization systems strengthening (including the design of new strategies to reach the unreached and minimize impact of security-compromised areas), will greatly increase likelihood of success. Furthermore, prioritizing programmatic approaches for outbreak response that incorporate innovative ideas with a consistently implemented back-to-basics strategy (one that focuses on achieving the essential principles for effective outbreak response that were used to eradicate WPV from the African Continent), will heighten the likelihood of success.

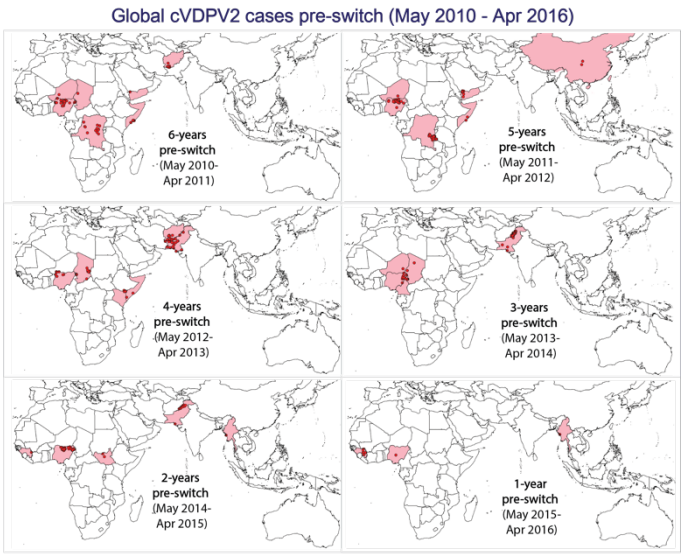
At this juncture in 2024, the program is neither ready for a next cessation attempt or in a position to rapidly control the many and large outbreaks of cVDPV2 on the African continent. Until GPEI has eliminated the chains of cVDPVs transmission (and eradicated WPV1), it should improve the enabling conditions for the anticipated bOPV cessation. At this point in time, all realistic options for achieving the triggers and prerequisites likely require at least five years of maximal effort.

Despite the substantive switch setback, achieving polio eradication is possible. Currently, we have an opportunity to capitalize on control efforts recently implemented or in development that may facilitate cVDPV2 elimination, including increased population immunity due to large amounts of mOPV2/nOPV2 used, adoption of a two-dose IPV RI schedule in many countries, and new vaccine products (including novel OPVs, ideally as combination products, and hexavalent vaccine) on the horizon. Together, these policies and products provide a robust foundation for immunity, and in conjunction with a re-commitment to eradication, coupled with improved conditions for programmatic action, will accelerate cVDPV2 elimination and lead us to global polio eradication.

# 1. Background and rationale

In 2023, the Strategy Committee (SC), the managing body of the Global Polio Eradication Initiative (GPEI), commissioned a formal evaluation of the 2016 global withdrawal of oral poliovirus vaccine type 2 (OPV2) and switch from trivalent (tOPV) to bivalent (bOPV) oral poliovirus vaccine (OPV) (the "switch"). While the switch was initially perceived to be a success, the global cVDPV2 case burden has increased approximately 10-fold compared to the pre-switch era. The evaluation was intended to generate critical lessons learned and guide the direction of the GPEI, including future OPV withdrawal efforts (i.e., bOPV).

In order to achieve global eradication of polio, poliovirus needs to be removed from populations everywhere, including the Sabin viruses in oral poliovirus vaccine (OPV). While OPV has played a key role in polio eradication and reduced the global polio case burden by >99.9%, its continued use is not compatible with eradication. OPV is a live-attenuated vaccine. It is genetically unstable and can revert rapidly back to neurovirulence and transmissibility after weeks of replication in a single vaccinee or after prolonged replication in a community, causing vaccine-associated paralytic poliomyelitis (VAPP) and circulating vaccine-derived polioviruses (cVDPV), respectively. The continuing VAPP burden due to tOPV (around 200-400 cases each year[6]) was becoming more and more unacceptable to parents and health care providers [7]. Moreover, cVDPVs, typically emerging and spreading in populations of low immunity were becoming increasingly concerning and would increase due to decline in preventive supplementary immunization activities (SIAs). With declining wild poliovirus (WPV) cases and a relatively larger cVDPV case burden, withdrawal of OPV became increasingly urgent since continued use of Sabin type 2 in OPV2 appeared to do more harm than good [6]. Since the last detection of indigenous wild poliovirus type 2 (WPV2) was in 1999 (certified as eradicated in 2015) and cVDPV2 outbreaks were reported each year (Figure 2), OPV2 was selected as the first Sabin vaccine serotype to be withdrawn globally.




| | 6-years pre-switch (May 2010-Apr 2011) | 5-years pre-switch (May 2011-Apr 2012) | 4-years pre-switch (May 2012-Apr 2013) | 3-years pre-switch (May 2013-Apr 2014) | 2-years pre-switch (May 2014-Apr 2015) | 1-year pre-switch (May 2015-Apr 2016) |
|---|---|---|---|---|---|---|
| cVDPV2 cases | 56 | 71 | 58 | 73 | 39 | 9 |
| Countries with cVDPV2 cases | 7 | 6 | 6 | 5 | 5 | 3 |

**Figure 2.** Annual global cVDPV2 cases in the six years pre-OPV2 withdrawal, May 2010 and Apr 2016. Red dots correspond to a single cVDPV2 case. Pink shading corresponds to countries reporting cVDPV2 cases.

The globally synchronised withdrawal of OPV2 occurred in April 2016, across a two-week period, in all 155 OPV-using countries and territories (Figure 3). It represented one of the largest coordinated public health efforts in history, as well as the largest recall of a medicinal product and the fastest introduction of a vaccine (i.e., inactivated poliovirus vaccine, IPV) at the time. Routine immunization (RI) switched from tOPV to bOPV and subsequent campaigns could

only use bOPV. All remaining OPV2-containing vaccines were to be destroyed as they posed a risk of seeding new cVDPV2 outbreaks.

As a risk mitigation measure (primarily to reduce the paralytic burden caused by poliovirus type 2 in a world where OPV2 contribution to type 2 humoral and mucosal immunity was no longer available), all OPV-using countries in 2016 were required to introduced at least one dose of IPV into RI.

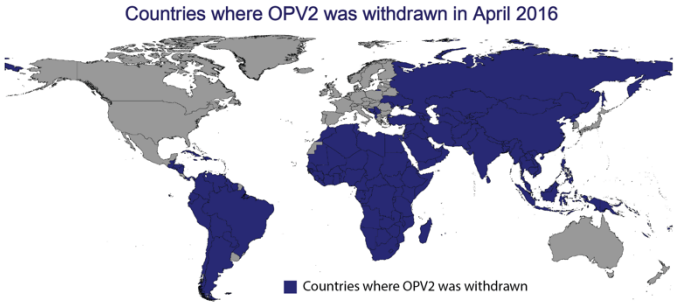



**Figure 3.** Countries where OPV2 was withdrawn in April 2016.

It was well-understood that the first two years following OPV2 withdrawal were critical, as susceptible birth cohorts accumulated and type-2 mucosal immunity waned rapidly, especially in tropical countries with suboptimal hygiene and sanitation. In this context, any cVDPV2 outbreaks needed to be rapidly controlled before the virus could spread and infect other geographies, thus preventing a downward spiral of vaccine use leading to new cVDPV2 seeding, requiring more vaccine.

OPV2 withdrawal marked a turning point in global polio eradication. With OPV2 cessation, the GPEI entered the polio end game, trying to eliminate the vaccines that brought the initiative to the brink of success. Evaluations were conducted immediately following OPV2 withdrawal [3], highlighting the success of the effort. The early evaluations reported that the many prerequisites and readiness criteria for a successful switch had largely been met (Annex A). However, eradication is unforgiving and an all-or-nothing goal, as demonstrated by WPV, whereby the >99.9% reduction in cases still qualifies as a failure. Similarly, the switch must be judged on outcome and not on effort.

Since OPV2 withdrawal, there have been >3,300 cVDPV2 cases across 43 countries globally (Figure 4). This contrasts with approximately 300 historic cases across 15 countries leading up to the switch across a similar duration of time (Figure 4). A 10-fold increase in cVDPV2 cases has been observed since the world withdrew OPV2, the intention of which was to wipe out the cVDPV2 case burden. Historically, the program would observe <80 cVDPV2 cases annually across fewer than 10 countries, and since 2019, we have been observing >500 cVDVP2 cases annually across >20 countries. The worst-case scenario materialized, making it difficult for the GPEI to effectively respond.

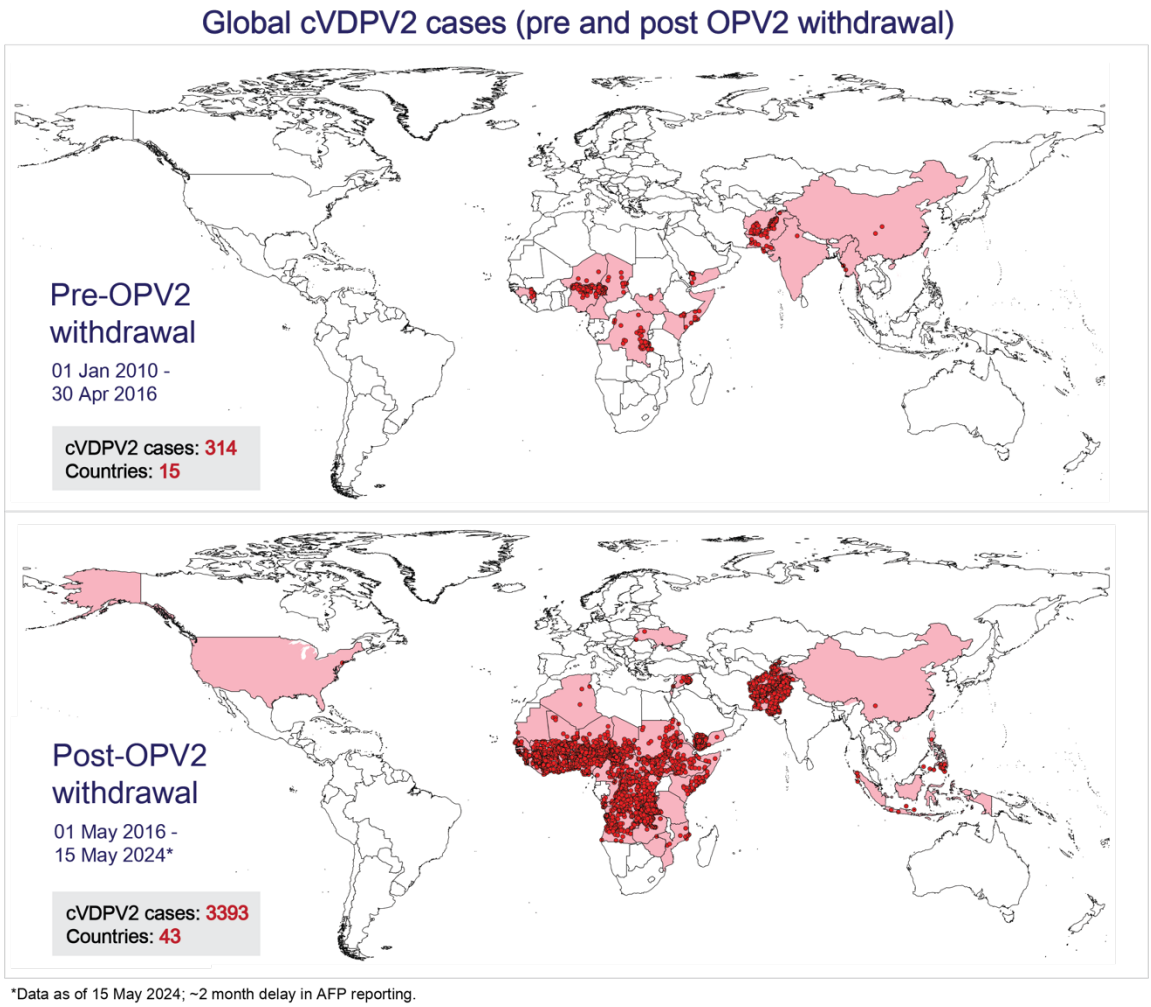
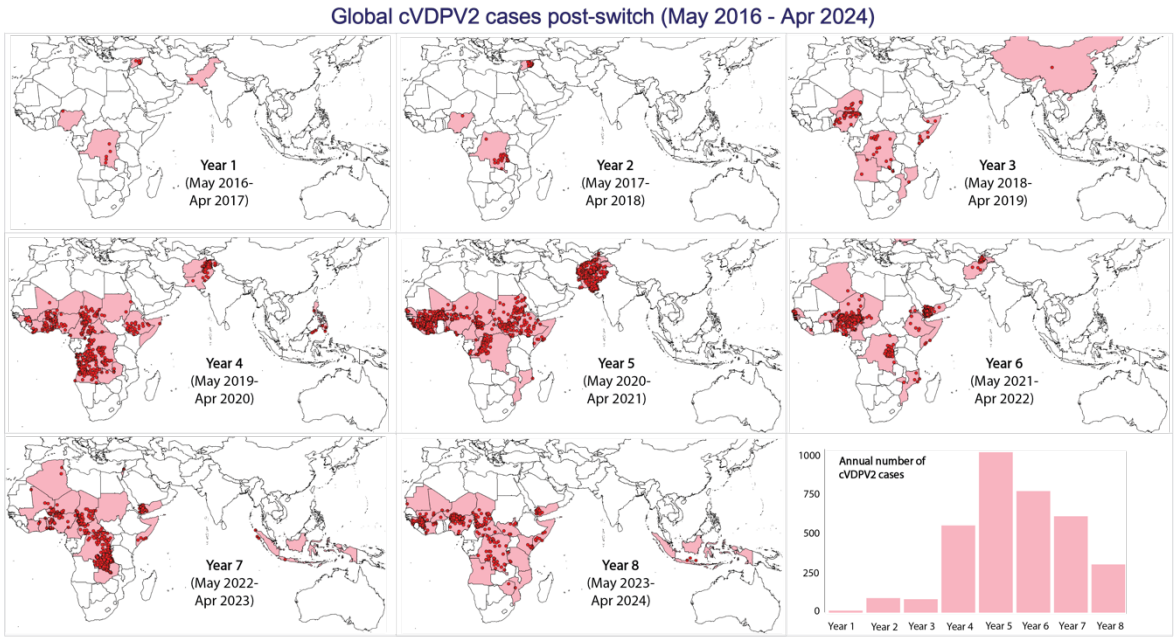



**Figure 4.** Global cVDPV2 cases pre- and post-OPV2 withdrawal. Red dots correspond to a single cVDPV2 case. Pink shading corresponds to countries reporting cVDPV2 cases.




| | Year 1 (May 2016- Apr 2017) | Year 2 (May 2017- Apr 2018) | Year 3 (May 2018- Apr 2019) | Year 4 (May 2019- Apr 2020) | Year 5 (May 2020- Apr 2021) | Year 6 (May 2021- Apr 2022) | Year 7 (May 2022- Apr 2023) | Year 8 (May 2023- April 2024) | Overall (May 2016- Apr 2024) |
|---|---|---|---|---|---|---|---|---|---|
| cVDPV2 cases | 13 | 91 | 84 | 544 | 1001 | 758 | 601 | 301 | 3393 |
| Countries with cVDPV2 cases | 4 | 3 | 7 | 21 | 24 | 20 | 20 | 20 | 43 |

Data as of 15 May 2024.

**Figure 5.** Global cVDPV2 cases post-OPV2 withdrawal, by year between May 2016 and April 2024. Red dots correspond to a single cVDPV2 case. Pink shading corresponds to countries reporting cVDPV2 cases.

In the first two years following OPV2 withdrawal, the global cVDPV2 situation was promising with only four infected countries (Democratic Republic of the Congo (DRC), Nigeria, Pakistan and the Syrian Arab Republic) and cVDPV2 cases being focused to select geographies within these countries (Figure 5). While outbreaks in Pakistan and the Syrian Arab Republic were interrupted quickly, ongoing transmission (and seeding) in Nigeria and DRC posed formidable challenges, with local and cross-national spread into neighboring countries. This, coupled with the detection of "silent" transmission in seven countries, led to larger scope of transmission, surpassing the pre-switch era. The turning point for the program occurred between Years 3 and 4, with an increase in the cVDPV2 case burden from 84 cases (from 7 countries) to 544 cases (from 21 countries). With >80% of the entire cohort susceptible, the program was in unchartered territory. In Year 5, a peak case burden of >1,000 cases was observed, and transmission was beginning to appear endemic-like. These patterns have continued, but with detections becoming increasingly more divergent, indicating ongoing and long-term cVDPV2 transmission. While there has been progress over the past year, much work remains to be done.

In order to move forward, the GPEI must better understand what has led to the continued and uncontrolled cVDPV2 outbreaks post OPV2 withdrawal. This is important not only to address current programmatic issues to interrupt cVDPV2 transmission, but to inform strategy and planning for bOPV withdrawal. Emerging challenges with circulating vaccine-derived poliovirus type 1 (cVDPV1) parallel those we observed with cVDPV2 in the years leading up to the switch. The program must ask itslef, "Is it better prepared as to not repeat history?". With the 10-fold

higher case to infection ratio for poliovirus type 1 (i.e., 1/200 versus 1/2000 [8]), there is a greater consequence of bOPV cessation failure.

While many evaluations were conducted immediately following OPV2 withdrawal [3], currently at eight years since the switch from tOPV to bOPV, the program is in a better position to look back and evaluate what worked, what didn't work, and which factors contributed most to the epidemiology we have observed. With findings from the evaluation, the GPEI is in a better position to chart a path forward to success and a world free of poliovirus.

# 2. Objective and methods

The objective of the present evaluation was to better understand what factors led to the continued and uncontrolled cVDPV2 outbreaks following OPV2 withdrawal, in order to provide recommendations for GPEI strategy and future OPV withdrawal efforts. The timing of this evaluation coincided with the initial planning phase of bOPV cessation.

The evaluation was based on approved terms of reference (TORs) and conducted by an external team of two polio experts. The evaluation team was composed of Drs R Sutter and N Molodecky and funded by the US Centers for Disease Control and Prevention (CDC), a GPEI core partner organization. The evaluation started in August 2023 and was completed in May 2024. The evaluation team was external to GPEI and was asked to conduct a formal review.

The foundation for the evaluation was based on Objective 2 of the Polio Eradication and Endgame Strategic Plan 2013-2018 Immunization systems strengthening and OPV withdrawal [4]. The plan specified the main objectives of OPV2 withdrawal, which were to strengthen immunization services in "focus countries", introduce IPV, and withdraw OPV2 globally. The plan also specified a trigger for executing the switch, along with prerequisites and readiness criteria that needed to be fulfilled to meet the conditions to implement the OPV2 withdrawal. Subsequently, some of the prerequisites were clarified as readiness criteria [9].

The trigger, prerequisites and readiness criteria devised in advance of the switch included: confirmation of WPV2 eradication; validation of elimination of "persistent" cVDPV2; bOPV licensed for RI; sufficient bOPV product for all OPV-using countries; globally-coordinated cessation of all tOPV use; all remaining stocks of tOPV collected and destroyed; phase II biocontainment for all type-2 cVDPV and WPVs; sufficient supply and affordable IPV options for all OPV only-using countries; introduction of at least one dose of IPV in OPV only-using countries; strengthened RI coverage (10% annual increase in high risk areas); high type-2 immunity in all geographies; type 2 poliovirus surveillance and response protocols; surveillance capacity to detect cVDPV; and mOPV2 stockpile and response capacity.

These trigger, prerequisite and readiness criteria were evaluated (both quantitatively and qualitatively) by following a model (by the American Evaluation Society) that is organized into the following seven evaluation steps (Figure 6):

1. Identifying elements for evaluation (trigger, prerequisites and readiness criteria);
2. Determining a standard against which to evaluate each element (directly obtained from the Strategic Plan 2013-2018). In instances where a standard was not specified in the Plan, the evaluation team proposed standards to a sounding board of global polio experts for review, modification and endorsement;
3. Evaluating the standard versus what was achieved;
4. Estimating the implication of a failing standard;
5. Determining the relevance of the failing standard (to the planned bOPV cessation);
6. Compiling the lessons learned (for bOPV cessation); And
7. Drawing policy implications and making recommendations.

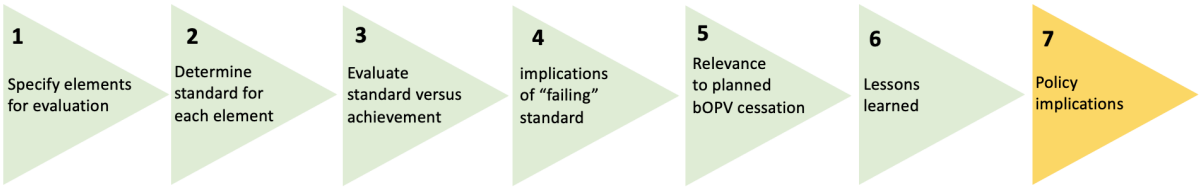



**Figure 6.** Steps of the evaluation process.

The peer review process and the gathering of public comment was a high priority in the evaluation process and included input from key stakeholders. A sounding board of senior polio experts from around the world was established to provide ongoing detailed comment and guidance on the respective evaluation and the implications for the bOPV cessation. Specifically, the board reviewed the newly proposed trigger and prerequisites for the bOPV cessation.

In addition, calls for public comment (using WHO POL LISTSERV) were issued at the beginning and near the end of the evaluation process. Preliminary findings were discussed individually with each of the GPEI core partner organizations (the World Health Organization (WHO), Rotary International, the US Centers for Disease Control and Prevention (US CDC), the United Nations Children's Fund (UNICEF), Bill and Melinda Gates Foundation (BMGF) and Gavi, the Vaccine Alliance). The WHO Regional Offices for Africa (AFRO) and the Eastern Mediterranean (EMRO) were consulted for regional and country-level perspectives. Donor agencies were also briefed.

After concluding the quantitative and qualitative evaluation, preliminary findings and recommendations were presented to several audiences for comment and suggestions, including the BOCeT (bOPV Cessation Evaluation Team) on 18 January 2024, GPEI's Strategy Committee (SC) on 1 February 2024 and the SAGE (Strategic Advisory Group of Experts on Immunization) Polio Working Group on 7 February 2024, the full SAGE on 12 March 2024. Donors were briefed on 22 March 2024. In addition, the draft report was made available for public comment on the GPEI website. After careful consideration of all inputs, the evaluation team finalized this report of their findings.

Although many contributed to making the findings more succinct and actionable, the final conclusions and suggestions contained in the report are owned entirely by the evaluation team.

# 3. Findings

The conclusions of the evaluation are unambiguous: the switch was a failure. After eight years of programmatic efforts, 53 countries were infected or re-infected with cVDPV2, >3,300 children were paralyzed by cVDPV2 (across 43 countries), and the GPEI expended >$1.8 billion just on outbreak response. To contrast, between January 2010 and 30 April 2016 a total of 318 cases were detected globally in 15 countries.

While many geographies (including the Americas, most of Europe and SE Asia) and key countries (India, Bangladesh) remained cVDPV2 free post switch, these areas historically did not pose challenges with cVDPV2 outbreaks. There were only two countries that remained cVDPV2 free post switch, where cases had been reported between January 2010 and April 2016 — India and Myanmar, which reported only 1 and 2 cVDPV2 cases, respectively, during this entire pre switch period.

Although evaluations in the aftermath of the switch generally presented a picture of successful implementation, it has been eight years since and we have been unable to stop cVDPV2 transmission. The scope and magnitude of cVDPV2 transmission has increased over time, with modest improvements over the past year (Figure 7). Moreover, we continue detecting highly divergent virus, indicating ongoing and long-term cVDPV2 transmission (Figure 8). While continued seeding of new cVDPV2 emergences (despite extensive nOPV2 use) is concerning, ongoing transmission remains the greatest challenge (Figure 8-9).

While OPV2 cessation was a monumental undertaking of unprecedented scale, it must be judged on the outcome and not on the tremendous effort. As with the eradication of WPV, which is an all or nothing event (and despite >99.9% reduction in poliomyelitis cases, WPV continues to circulate in Afghanistan and Pakistan, thereby being classified as an unachieved goal), the same principle must apply to cVDPV2 elimination.

The single overriding cause of the OPV2 cessation failure was (and continues to be) the inability of the program to close out outbreaks. While seeding of new cVDPV2 outbreaks has played an important role, it has been the program's inability to stop transmission that has been the greatest contributor to the switch failure. Equally important, the inability of program leadership to recognize the seriousness of the evolving problem and take effective corrective action, ultimately resulted in failure of the switch.

Below we provide a summary of our findings, including the key factors that led to the switch failure, as well as the factors that contributed to or exacerbated it. Details are presented in Annex A and B.

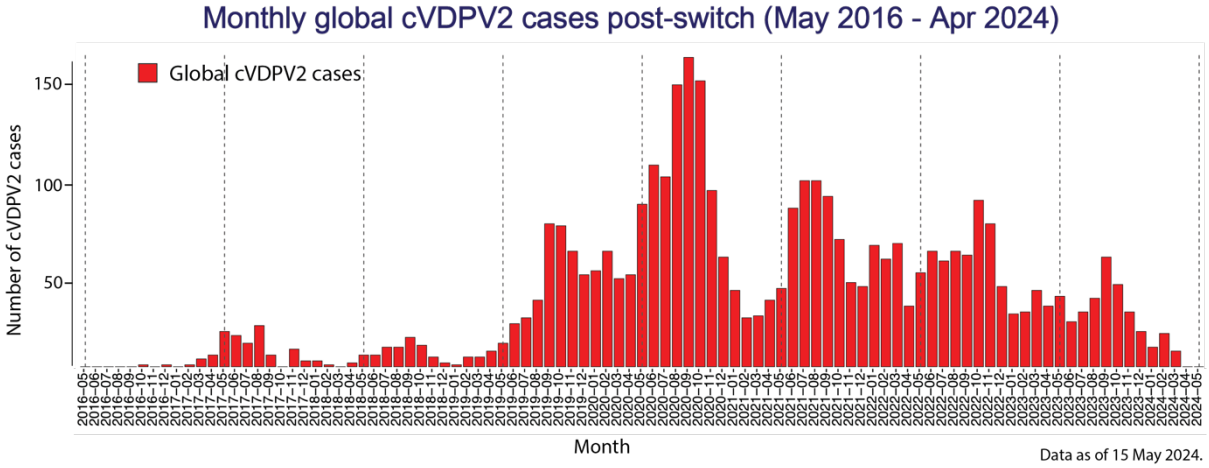
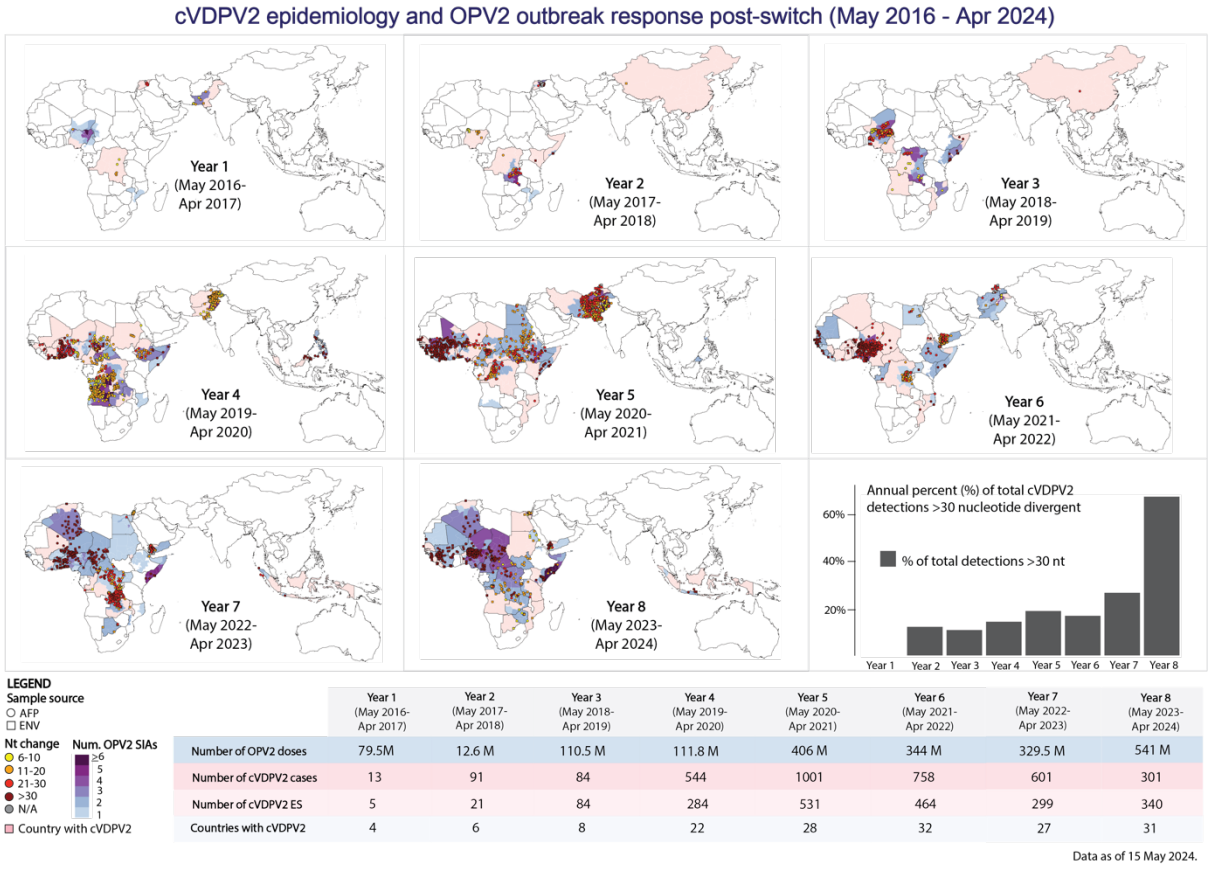
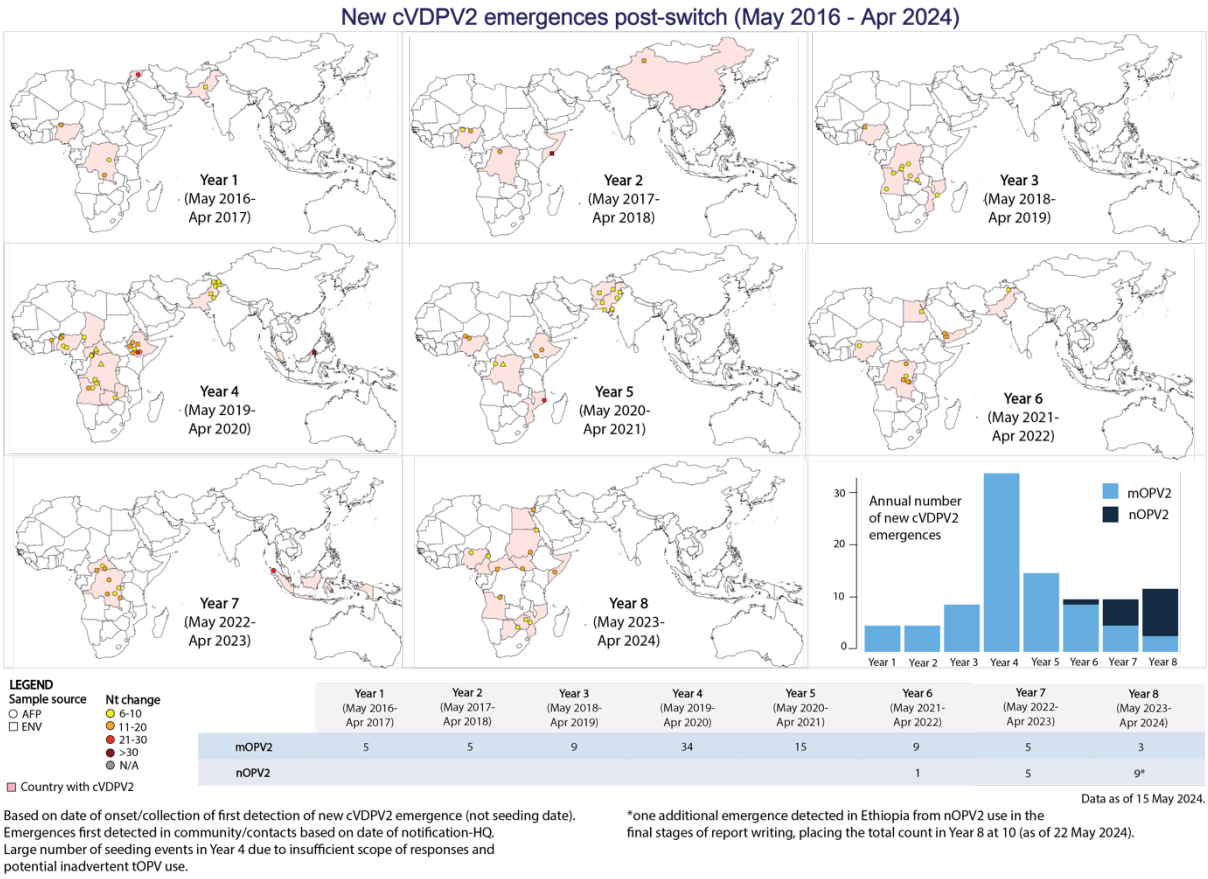



**Figure 7.** Monthly global cVDPV2 cases post switch, between May 2016 and April 2024. Reporting delay of AFP cases is typically approximately 2 months.




| | Year 1 (May 2016- Apr 2017) | Year 2 (May 2017- Apr 2018) | Year 3 (May 2018- Apr 2019) | Year 4 (May 2019- Apr 2020) | Year 5 (May 2020- Apr 2021) | Year 6 (May 2021- Apr 2022) | Year 7 (May 2022- Apr 2023) | Year 8 (May 2023- Apr 2024) |
|---|---|---|---|---|---|---|---|---|
| Number of OPV2 doses | 79.5M | 12.6 M | 110.5 M | 111.8 M | 406 M | 344 M | 329.5 M | 541 M |
| Number of cVDPV2 cases | 13 | 91 | 84 | 544 | 1001 | 758 | 601 | 301 |
| Number of cVDPV2 ES | 5 | 21 | 84 | 284 | 531 | 464 | 299 | 340 |
| Countries with cVDPV2 | 4 | 6 | 8 | 22 | 28 | 32 | 27 | 31 |

**Figure 8.** Yearly cVDPV2 epidemiology and OPV2 responses post switch, between May 2016 and April 2024. cVDPV2 detections include AFP cases (circles) and ES (squares). Colours indicate nucleotide (nt) change from Sabin.




| | Year 1 (May 2016- Apr 2017) | Year 2 (May 2017- Apr 2018) | Year 3 (May 2018- Apr 2019) | Year 4 (May 2019- Apr 2020) | Year 5 (May 2020- Apr 2021) | Year 6 (May 2021- Apr 2022) | Year 7 (May 2022- Apr 2023) | Year 8 (May 2023- Apr 2024) |
|---|---|---|---|---|---|---|---|---|
| mOPV2 | 5 | 5 | 9 | 34 | 15 | 9 | 5 | 3 |
| nOPV2 | | | | | | 1 | 5 | 9* |

Data as of 15 May 2024.

Based on date of onset/collection of first detection of new cVDPV2 emergence (not seeding date). Emergences first detected in community/contacts based on date of notification-HQ. Large number of seeding events in Year 4 due to insufficient scope of responses and potential inadvertent tOPV use.

*one additional emergence detected in Ethiopia from nOPV2 use in the final stages of report writing, placing the total count in Year 8 at 10 (as of 22 May 2024).

**Figure 9.** Yearly new cVDPV2 emergences post switch, between May 2016 and April 2024. First cVDPV2 detections within a new emergence group, including both those first detected in AFP cases (circles) and ES (squares). Colours indicate nucleotide (nt) change from Sabin.

Nucleotide (nt) diversity from parental Sabin strain is used as a measure to estimate the duration of viral replication, under the assumption of a molecular clock of approximately 1% (or $\geq$10 nt emanating from a sequence window of approximately 900 nt in viral protein 1 [VP1]) mutations per year. Nt change per se is unrelated to paralytic rate (i.e., reversion to neurovirulence), and is tracked in a different region of the viral genome (i.e., VP1 region). Loss of the attenuating mutations (in the 5' untranslated region, UTR) are typically assumed to occur quickly, resulting in viral transmission and paralytic rate indistinguishable from WPV.

## 3.1 Key factors in the switch failure

### 3.1.1 Key factor 1: Insufficient outbreak response scope, timing and quality, resulting in increased scope and magnitude of cVDPV2 transmission, impacting vaccine supply and surveillance.

**Requirement:** Sufficient capacity to stop cVDPV2 outbreaks post switch, ensuring timely, high quality responses of sufficient scope.

**Evaluation and implications:** The program's lack of capacity to stop cVDPV2 outbreaks (especially in the first three years, when there was a foundation of type-2 immunity), was the greatest contributor of continued and uncontrolled cVDPV2 outbreaks, straining vaccine supply and surveillance capacity.

It was well understood that the first two to three years post switch would be critical to interrupting any cVDPV2 transmission, when a foundation of type-2 immunity from pre-switch OPV2 use remained. While early cVDPV2 outbreaks in Pakistan and the Syrian Arab Republic were interrupted quickly (due, in part, to their close adherence to the original outbreak response SOPs, with numerous large-scope OPV2 and IPV responses), the failure to stop the early outbreaks in Nigeria and DRC resulted in cascading cycles of transmission, response and seeding. If the early detections in Nigeria and DRC had been successfully interrupted, as was done in Pakistan and the Syrian Arab Republic, the global narrative of the switch result would be very different. While 'silent' transmission would have continued in geographies such as Somalia (which remains one of the most difficult areas to interrupt transmission), virus remains fairly localized in these areas with limited exportations to other countries. Recognizing the likelihood that some detection of virus post switch is inevitable (despite best efforts at consistently sensitive surveillance and high levels of immunity across all geographies), being able to interrupt early transmission while base levels of immunity are high is essential.

Moreover, in the eight years since the switch, cVDPV2 transmission has increased both in scope and magnitude, and despite modest improvements in the past couple of years, there has been an increased detection of highly divergent virus, indicating ongoing transmission. In high-risk countries, such as DRC, we have seen an increase in transmission and case burden over the

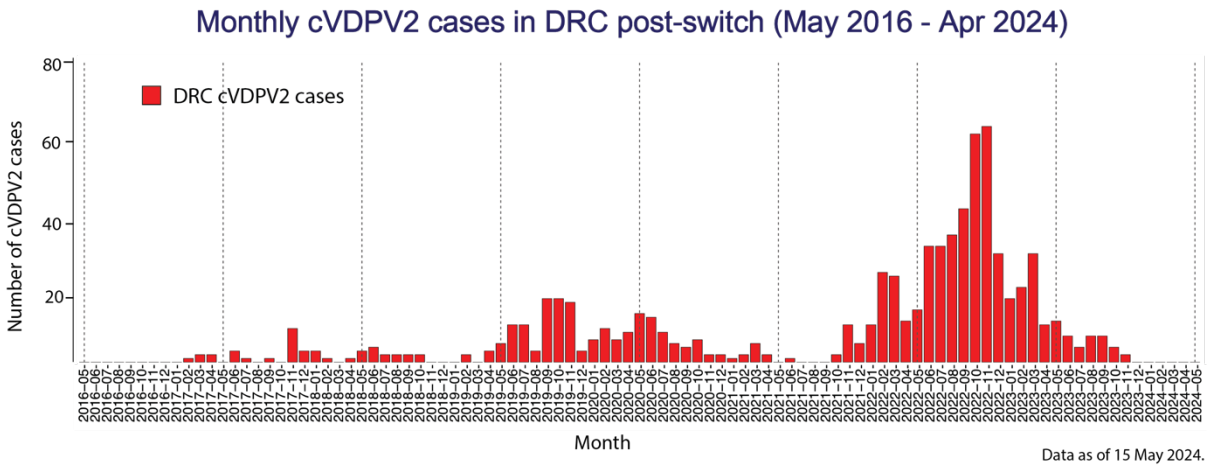



**Figure 10.** Monthly cVDPV2 cases in the Democratic Republic of the Congo (DRC) post switch, between May 2016 and April 2024. Reporting delay of AFP is typically ≥2 months.

past few years, not a decline (Figure 10), indicating the program still has not learned how to close out cVDPV2 outbreaks in these critical geographies.

Insufficient outbreak response capacity (i.e., sub-optimal quality, scope and timing of response) has been the greatest barrier to interrupting cVDPV2 transmission. Quality of OPV2 responses has remained sub-optimal in many of the highest-risk countries (Figure 11). While most of these countries successfully interrupted WPV, their capacity to conduct high quality responses has declined. This, coupled with a reduced perception around the urgency of interrupting cVDPV versus WPV, has resulted in sub-optimal quality of outbreak response, failing to interrupt ongoing transmission and preventing seeding events. Moreover, insufficient quality remains in these geographies because the basic essentials for outbreak response are not consistently being achieved. These essential principles include: ensuring the country is actually ready to implement the response, that funds are available at the field level on day 1 of the campaign (and not simply at the province or district level) to ensure vaccinators and monitors/supervisors are able to go where they need to, that data is used for action (e.g., GIS mapping for monitoring) to ensure presence of vaccinators and monitors in the interior and remote areas, and training quality is sufficient to ensure implementers are empowered with the knowledge and skills to effectively do their job. While innovation has a role to play, the basic essentials for outbreak response need to be consistently achieved to ensure sufficient quality.

While the program's focus has typically been placed on addressing issues with quality, ensuring adequate scope and timing of responses, which are inextricably linked (i.e., substantial delays in response lead to outdated, and therefore insufficient, scope), are critically important and often overlooked, despite being more directly in the programs' control. Over the past eight years, inadequate scope and timing were greater issues than quality (especially in DRC, Chad, Angola and Burkina Faso), contributing most to the increased scale of cVDPV2 transmission (Figure 11). This is particularly true in Year 4 (which was the turning point for the program), when 42% and 44% of cVDPV2 detections were outside of the response scope following 2 OPV2 SIAs and the next OPV2 SIA was >3 months from notification to HQ, respectively. In comparison, 26% of cVDPV2 detections were inside the response scope following 2 OPV2 SIAs (i.e., breakthrough), indicating insufficient quality (definitions and brief methods described below). There are many factors that led to insufficient scope and timing of response (including vaccine supply constraints and waiting for nOPV2 due to communicated/perceived risk of mOPV2), which will be highlighted in the subsequent sections.

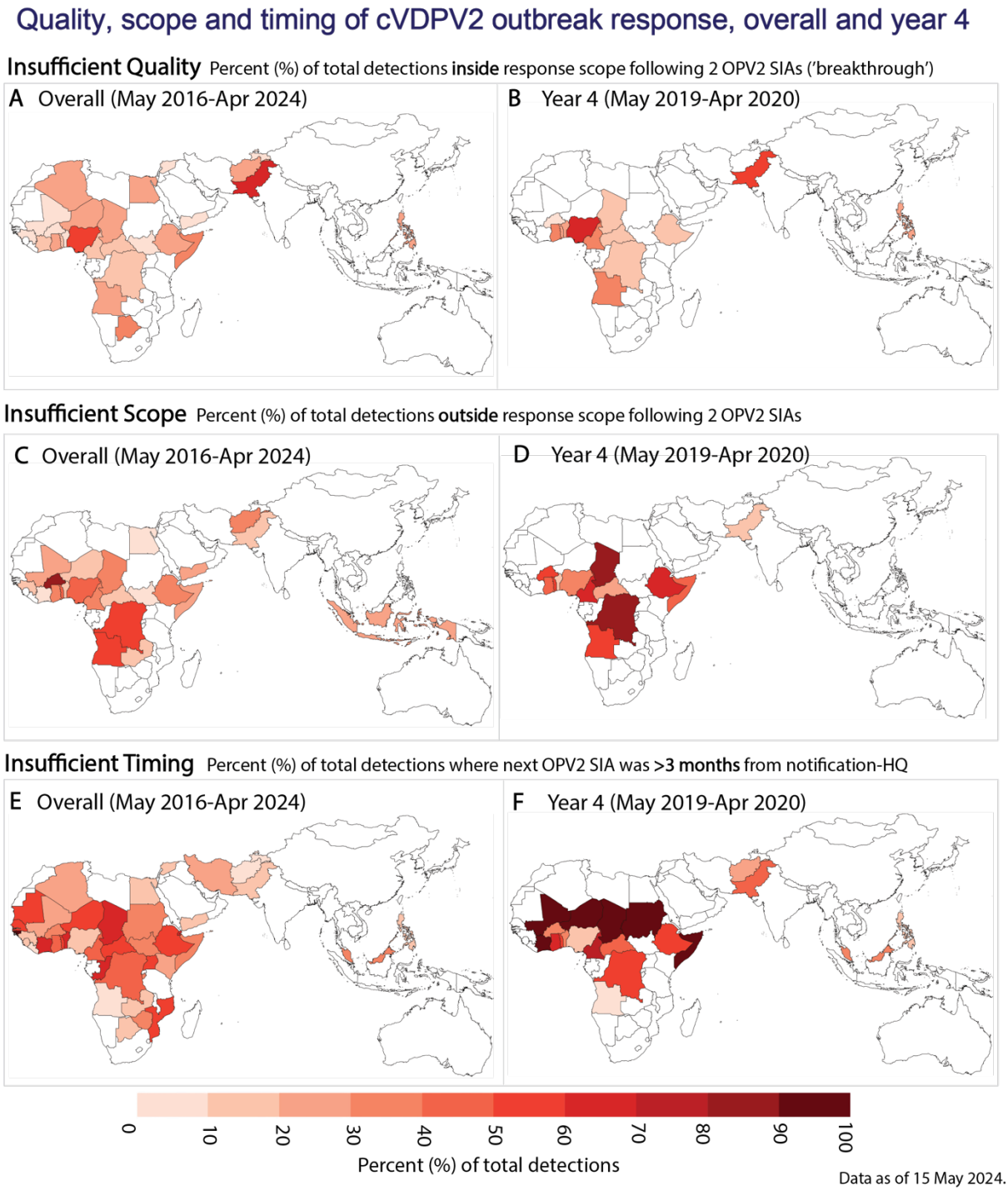



**Figure 11.** Outbreak response capacity, including precent (%) of total cVDPV2 detections due to insufficient quality, scope and timing, overall (between May 2016 and April 2024) and in Year 4 (between May 2019 to April 2020). Detections include those both from AFP and ES. A-B. Percent of total detections inside response scope following 2 OPV SIAs, Overall and in Year 4. C-D. Percent of total detections outside response scope following 2 OPV2 SIAs, Overall and in Year 4. E-F. Percent of total detections where next OPV2 SIA was >3 months from notification-HQ, Overall and in Year 4.

Definitions and methods of determining insufficient quality, scope and timing of responses: Each cVDPV2 detection through acute flaccid paralysis (AFP) or environmental surveillance (ES) may be classified as resulting from insufficient quality or scope based on the OPV2 supplementary immunization activities (SIAs) implemented or absent in the previous six months (from date of onset or collection, factoring in a 21-day buffer) in the particular admin1. If ≥2 OPV2 SIAs were implemented in the admin1 of the detection in the previous six months, it would be classified as resulting from insufficient quality. If ≥2 OPV2 SIAs were implemented within the country's national boundaries, but not in the admin1 of the detection, in the previous six months, it would be classified as resulting from insufficient scope. Different emergences were not separated, as outbreak response does not differentiate between emergence groups but bases responses simply on presence or absence of detections. Moreover, whether subsequent detections within the OPV2 response zone are due to ongoing transmission or new emergence, both indicate insufficient quality. Similarly, whether subsequent detections outside of the OPV2 response zone (but within national boundaries) are due to ongoing transmission or new emergence, both indicate insufficient scope of response. Detections of insufficient quality and scope are mutually exclusive. Insufficient timing was defined as >3 months between when the detection was notified to HQ and the subsequent OPV2 SIAs in the admin1. Detections may be classified as being due to insufficient quality or scope and insufficient timing.

While there were a large number of countries that successfully interrupted cVDPV2 outbreaks post switch (either stemming from emergences within or outside their country borders, including Afghanistan, Angola, Benin, Botswana, Burundi, Cameroon, Central African Republic, Chad, Congo, Cote d'Ivoire, DRC, Djibouti, Egypt, Eritrea, Ethiopia, Gambia, Ghana, Guinea-Bissau, Iran, Kenya, Liberia, Malaysia, Mali, Mozambique, Niger, Nigeria, Pakistan, Philippines, Senegal, Sierra Leone, Somalia, South Sudan, Sudan, the Syrian Arab Republic, Tajikistan, Togo, Uganda, Ukraine, Tanzania, Yemen and Zambia), the majority (>60%) of these countries reported subsequent outbreaks, including due to seeding from their OPV2 outbreak response. Continued seeding of new outbreaks, despite ability to stop current cVDPV2 transmission, indicates the outbreak response was ultimately unsuccessful. In DRC, there have been 26 distinct cVDPV2 emergences detected in the eight years since the switch, 22 of which were seeded from OPV2 use within the country borders. While approximately 70% of them have been successfully interrupted, the continued re-seeding of outbreaks at concerning rates indicates sub-optimal outbreak response capacity. Similarly, in Nigeria, there have been 14 distinct cVDPV2 emergences detected, all of which were seeded from OPV2 use from within the country. While all but two of these outbreaks have been since interrupted, the NIE-ZAS-1 emergence from July 2020, persists and has resulted in >760 cVDPV2 cases across 15 countries.

Pakistan and Afghanistan have been perceived as a success case example, with Pakistan interrupting cVDPV2 transmission twice (first in 2017 and then its 2019-2021 outbreak), demonstrating that it is possible to fully stop cVDPV2 transmission (and prevent re-seeding of virus, perpetuating the transmission cycle) in the highest risk geographies with sufficient outbreak response capacity, even under conditions of very low baseline immunity. However, despite the ultimate interruption of cVDPV2 transmission in these two countries, the outbreaks persisted for two years, with 15 distinct emergences and >500 cVDPV2 cases. Pakistan and

Afghanistan are in a unique situation as they have retained their capacity to respond to outbreaks due to continued WPV1 transmission. This retained capacity for outbreak response, coupled with the large-scope of OPV2 SIAs and frequent IPV use in these countries (and the outbreak timing coinciding with COVID-19 lockdowns, potentially decreasing transmission due to reduced movement patterns [10]), increased their ability to repeatedly stop cVDPV2 transmission. In contrast, the response capacity in Nigeria was reduced following its eradication of WPV (last WPV case reported in 2016) and polio transition plans removing preventive bOPV SIAs in non-endemic countries, thereby limiting campaigns apart from OPV2 outbreak response. This contributed to a decreased capacity in Nigeria to conduct rapid and effective responses. Ensuring capacity for outbreak response remains is critical for successful future OPV withdrawals.

Lessons for bOPV withdrawal: Outbreak response capacity must be improved before future withdrawal efforts. It will likely be the critical factor determining success or failure of the GPEI. These countries interrupted WPV, indicating that stopping transmission in these populations is possible. Focusing on the essential principles for effective outbreak response (i.e., back-to-basics approach), and ensuring they are consistently achieved will be critical to closing out outbreaks. Ensuring sufficient outbreak response capacity in the context of transition planning is paramount to retain existing functions.

### 3.1.2 Key factor 2: Inability of GPEI leadership to recognize the seriousness of the evolving problem and take effective corrective action

Requirement: Not considered. There was an absence of clear strategy to formally evaluate the progress of the switch and a lack of clearly defined benchmarks for success or failure.

Evaluation and implications: In the eight years since the switch, there have been ongoing and uncontrolled cVDPV2 outbreaks. The overall magnitude and scope of transmission has increased, and highly divergent virus continues being detected. The GPEI faced a turning point between Years 3 and 4 post switch, where cVDPV2 transmission expanded from 8 to 22 countries, and cVDPV2 case burden increased from 84 to 544. At this point, cVDPV2 transmission was spreading across national boundaries, the OPV2 stockpile vaccine was running low, and the increased number of cVDPV2 detections (coupled with the timing of the COVID-19 pandemic) was putting a strain on surveillance (leading to further delays in notification and outbreak response). Without a planned evaluation strategy and clearly defined benchmarks for tracking success or failure, it was difficult for the GPEI to take swift corrective action. Moreover, in addition to an absence of strategy to evaluate the progress of the switch, in Year 3, there were no formal evaluations to determine how best to course correct. The 'perfect storm' in year 4 (i.e., explosion of transmission, supply constraints of OPV2, strain on surveillance resulting in delayed notification) required drastic strategy changes and a sobering look at the global situation to chart a realistic path forward. Lack of drastic action led to a peak annual case burden of >1,000 cVDPV2 cases across 24 countries in Year 5. Still, despite these continued challenges, there was a lack of dramatic changes to GPEI strategy. In Years 6 and 7, 758 and 601 cVDPV2 cases were reported, respectively, across 20 countries in each of these two years. While the GPEI relied on introduction of nOPV2 in 2021 to be the 'magic bullet' and resolve the issues, seeding has continued with the more genetically-stable vaccine, with at least

15 cVDPV2 emergences [seeded in 10 countries; resulting in 94 cVDPV2 cases] seeded from nOPV2 use since March 2021 (as of 15 May 2024).

**Lessons for bOPV withdrawal:** This evaluation is coming at nearly eight years following the switch. A formal review at Years 2 or 3 could have ensured corrective measures were implemented before transmission of cVDPV2 became endemic-like in many high-risk countries. Ensuring continuous evaluation of progress and course correction, as needed, is essential for a successful bOPV withdrawal. The lack of flexibility and premature application of containment limited the option of the program to bring back tOPV (and reverse the switch). A clear strategy to formally evaluate the progress of the switch, with clearly defined benchmarks for success or failure (and resulting action) is required before any future OPV withdrawal.

## 3.2 Factors that contributed to or exacerbated the switch failure

There were 10 factors that contributed to or exacerbated the switch failure, some of which were due to lapses in switch readiness.

### 3.2.1 IPV supply constraints, affecting IPV introduction in routine immunization (RI) and use in outbreak control, contributing to high case burden (including in lower-risk countries)

**Requirement:** As a risk mitigation measure, at least one dose of IPV was expected to be introduced into RI of all OPV using countries prior to the switch. IPV was also initially recommended for outbreak response, to be used in the second SIA targeting a large scope. The rationale was to quickly close humoral immunity gaps (and boost mucosal immunity in the case of SIAs), with no risk of seeding.

**Evaluation and implications:** By 2015, it had become clear that there would not be sufficient IPV supply to ensure its full introduction into RI of all OPV using countries. At the time of the switch in 2016, the program had secured only half of the required supply of IPV (i.e., 233 million doses, a shortfall of 208 million doses [11]; Figure 12). Despite the shortage of IPV, and its introduction into OPV-using countries being deemed a prerequisite, the decision was made to proceed with the switch.

Given the limited supply of IPV, countries were prioritized for introduction into RI based on historic

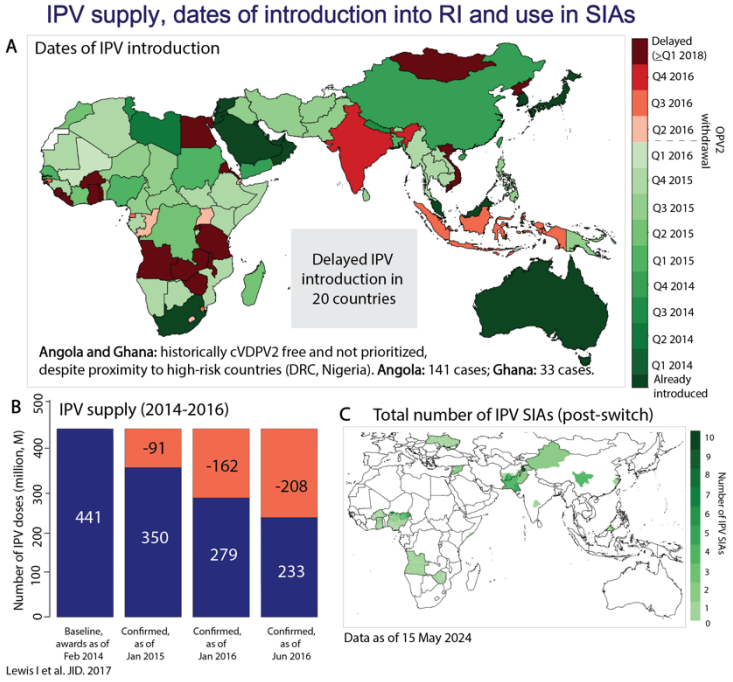



**Figure 12.** IPV supply, dates of introduction into RI and use in SIAs. A. Dates of IPV introduction. B. IPV supply between 2014 and 2016. C. Total number of IPV SIAs post switch.

cVDPV2 outbreaks and ongoing WPV1 transmission. Supply constraints resulted in delayed RI IPV introduction into 20 countries, deemed to be lower risk (Figure 12). In addition, 16 countries faced stock-outs impacting their IPV delivery. Some of these de-prioritised countries (historically free of cVDPV2) reported large cVDPV2 outbreaks. For example, Ghana and Angola, historically free of cVDPV2, were not prioritized for IPV, despite their close proximity to the program's highest-risk countries (DRC, Nigeria). Both countries reported large cVDPV2 outbreaks (Angola: 141 cVDPVD2 cases between April 2019 and February 2020, and Ghana: 33 cVDPV2 cases between July 2019 and September 2022).

Moreover, due to supply shortage, IPV was quickly removed as a recommended tool for cVDPV2 outbreak response[12]. Despite the high cVDPV2 case burden globally, there has been limited IPV use in cVDPV2 outbreak response. Since OPV2 withdrawal, IPV has been used as an adjunct in outbreak response in only 14 countries globally (Figure 12). In the African Region, which has contributed to approximately 71% of global cVDPV2 cases since the switch, only six countries have conducted IPV SIAs, four of them as catch-up due to delayed IPV introduction (Angola, Ghana, Burkina Faso and Zimbabwe), Nigeria (recently WPV1 endemic) and Burundi. Similarly, in the Eastern Mediterranean Region (approximately 27% of global cases), apart from Pakistan and Afghanistan, which remain WPV1 endemic, only the Syrian Arab Republic and Somalia have conducted IPV SIAs.

While the use of fractional IPV (fIPV), as a dose sparing strategy, was recommended by the Strategic Advisory Group of Experts on Immunization (SAGE) in 2017 [13] and could have potentially addressed the early supply constraints of IPV, it was only adopted into RI in select countries [14] (i.e., India, Nepal, Sri Lanka, Bangladesh, Ecuador, and Cuba) and its use in cVDPV2 outbreak response was limited to India, Pakistan and Nigeria. The greatest barrier to widespread use of fIPV in both RI and SIAs was operational feasibility of vaccine administration though the intradermal (ID) route. While ID adapters facilitating the ease of administering fIPV are available and have demonstrated safety and injection quality, the costs of devices have largely limited its widespread use. Furthermore, as ID fIPV is considered off-label, it requires additional approvals for use in country, increasing the complexity of use.

Lessons for bOPV withdrawal: Ensuring sufficient IPV supply for RI (and outbreak response) across all countries (even those deemed lower risk) is critical in advance of global OPV cessation. This may include adoption of new strategies (e.g., fIPV), especially for outbreak control, that ensure continued sufficient supply of IPV. Careful consideration must be taken to clearly define prerequisites in advance of any future switch and outline appropriate course of action if they are not met.

### 3.2.2 Gaps in pre-switch poliovirus type 2 immunity in critical geographies, resulting in early seeding events and undetected transmission at the time of the switch

**Requirement:** Type-2 immunity at the time of the switch was expected to be high in order to reduce the risk of cVDPV2 emergence and spread. To ensure high immunity, countries were required to implement tOPV SIAs prior to OPV2 withdrawal. Type-2 immunity was estimated in early 2015 to guide the number of tOPV SIAs required.

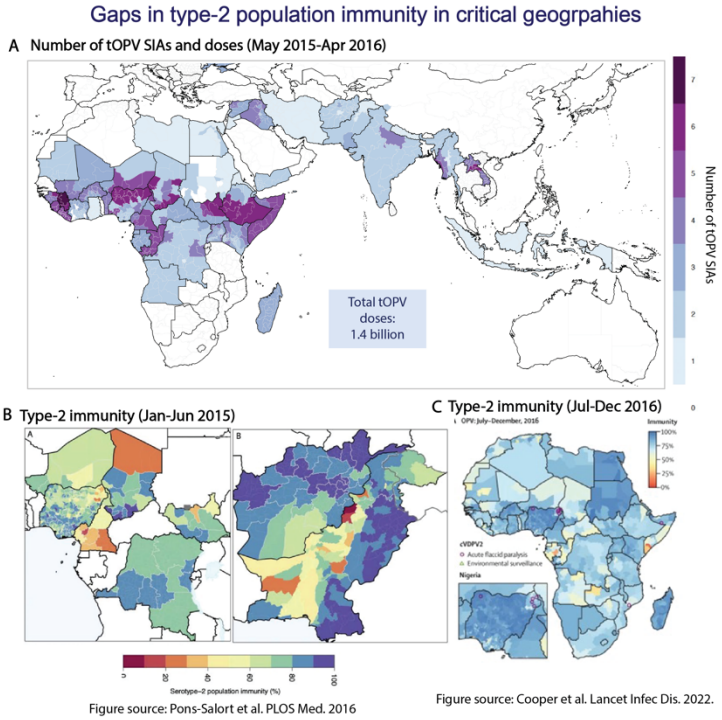



**Figure 13.** Gaps in type-2 immunity pre switch. A. Number of tOPV SIAs and doses between May 2015 and April 2016. B. Type 2 immunity in high risk countries between January to June 2015. Source: Pons-Salort et. al. PLOS Med 2016. C. Type 2 immunity across the African Continent between July to December 2016. Source: Cooper et al. Lancet Infec Dis. 2022.

**Evaluation and implications:** In 2015, known poliovirus type 2 immunity gaps were identified in many high-risk geographies (Figure 13) [15]. While most countries conducted ≥2 tOPV National Immunization Days (NIDs) in the year leading up to the switch (with additional rounds in the highest-risk areas), pockets of low immunity remained [16]. Estimates of coverage and immunity (modelled using vaccine dose histories in non-polio acute flaccid paralysis cases) were overestimated at National levels and not fully scrutinized at lower levels; thereby underestimating the proportion of susceptible children in some high-risk areas. These remaining pockets of susceptibility are supported by early cVDPV2 detections in Nigeria, Pakistan and DRC (all of which were seeded from pre-switch tOPV use), and later detections in Somalia, the Syrian Arab Republic and the Philippines, which remained "silent" at the time of the switch.

The rush to fulfil requirements in advance of the switch, led to inadequate immunity and critical seeding events that set the program up for failure. For example, in DRC, 2 NIDs were conducted back to back in March and April 2016 following nearly one year without OPV2 SIAs. Seeding events were detected approximately one year later, which resulted in cascading cycles of transmission and seeding. DRC has reported >700 cVDPV2 cases since the switch with cases reported in 70 out of 96 total months.

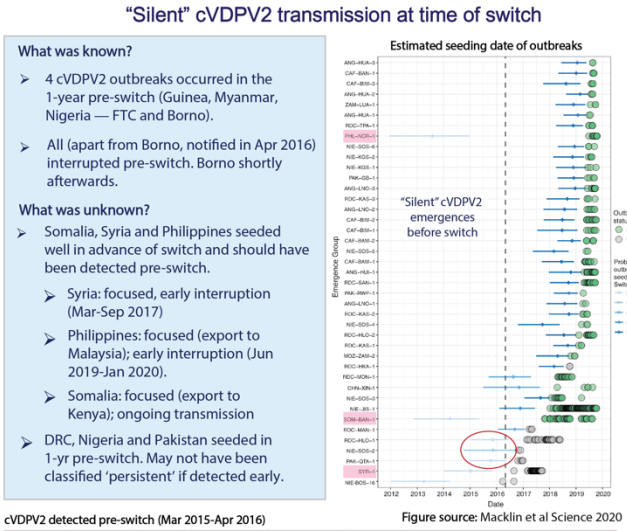
Moreover, there was a lack of clearly defined benchmarks for determining the level of immunity required prior to the switch (especially at finer spatial resolutions), and limited methods of estimating population immunity in focused higher-risk areas. Therefore, while overall, there was high baseline type-2 immunity in advance of the switch, it was difficult to determine and evaluate the susceptibility in higher-risk pockets.

**Lessons for bOPV withdrawal:** Leading up to OPV withdrawal, additional focus to increase and maintain immunity in priority countries is required (especially known pockets of low immunity),

with numerous OPV SIAs spread throughout the year prior to withdrawal. Clearly defined benchmarks and methods of evaluation (down to a finer spatial resolution) are required to have confidence in the level of immunity prior to any future switch.

### 3.2.3 Continued and undetected cVDPV2 transmission at the time of the switch

**Requirement:** In advance of the switch, all countries needed to be free of persistent cVDPV2 (i.e., cVDPV2s of the same genetic lineages in circulation for ≥6 months). The criteria specified that the period of absence of persistent cVDPV2 was between March and September 2015, to allow for decision-making. If detected, the switch was to be delayed until at least April 2017. There was no information provided on action for detections between October 2015 and April 2016.




cVDPV2 detected pre-switch (Mar 2015-Apr 2016)

| Country | Admin1 | Source | Date of onset/coll. | Date of notif. to HQ | Nt change | Comments |
|---|---|---|---|---|---|---|
| Guinea | Kankan | 6 cases | 20.07.2015-14.12.2015 | 04.09.2015-18.02.2016 | 22-27 | 7 tOPV SIAs (Sep 2015-Apr 2016). **Interrupted transmission before switch.** |
| Myanmar | Rakhine | 2 cases | 16.04.2015, 05.10.2015 | 11.11.2015 | 13-15 | 5 tOPV SIAs (Dec 2015-Apr 2016). **Interrupted transmission before switch.** |
| Nigeria | FCT | 1 case | 16.05.2015 | ? | 13 | 3 tOPV SIAs (Jul 2015-Apr 2016). **Interrupted transmission before switch.** |
| | Borno | 1 ES | 23.03.2016 | 29.04.2016 | 32 | |

Figure source: Macklin et al Science 2020

**Figure 14.** Silent cVDPV2 transmission at the time of the switch. Estimated seeding date of outbreaks from source: Macklin et al. Science. 2020.

**Evaluation and implications:** Four cVDPV2 outbreaks were detected between March 2015 and April 2016 (Guinea, Myanmar, Federal Capital Territory, Nigeria, and Borno, Nigeria). All were interrupted pre switch, using tOPV SIAs, apart from Borno, notified in April 2016, which was interrupted shortly afterwards. Based on the cVDPV2 detected pre-switch, this criterion was largely met, as all known detections were interrupted before the switch (apart from the aforementioned Borno detection).

However, there were at least three outbreaks that went undetected, including in Somalia, the Syrian Arab Republic and the Philippines, with cVDPV2 seeded in these geographies well in advance of the switch (Figure 14) [17]. These undetected outbreaks remained fairly focused in scope and/or were interrupted shortly after detection (except for Somalia, which has had continued transmission for about 10 years, despite being relatively focused in scope). The Syrian Arab Republic outbreak was interrupted early (between March and September 2017) and remained focused; the Philippines outbreak was interrupted early (between June 2019 and January 2020) and remained focused (apart from exportation to Malaysia); and the outbreak in Somalia also remained focused (apart from exportation to Kenya).

Other undetected outbreaks (DRC, Nigeria, Pakistan) were seeded from tOPV use in the one year leading up to switch. If these had been detected pre-switch, they may not have been classified as persistent. These seeding events in DRC and Nigeria resulted in cascading effects of transmission and seeding, setting off many of the ongoing cVDPV2 outbreaks.

**Lessons for bOPV withdrawal:** Maintaining and further enhancing surveillance is critical in advance of OPV withdrawal. Clear definition, time window and action following detections is required. Determining how to address any detections not classified as 'persistent' leading up to the switch will be important, with a clearly defined strategy to prevent ongoing transmission.

### 3.2.4 Limited progress in routine immunization (RI) and a lack of alternative strategies to increase coverage, leaving a weak foundation of type-2 immunity and contributing to high case burden

**Requirement:** To ensure impact of IPV in RI, 'sufficient' coverage was required, with emphasis on system strengthening (target of 10% increase in RI coverage annually in the highest risk geographies, outlined in the GPEI Polio Eradication and Endgame Strategic Plan 2013-2018 [4]).

**Evaluation and implications:** The GPEI (in partnership with the Immunization, Vaccines and Biologicals (IVB) department of WHO) continues to set targets for improvements in RI without achieving substantial progress. The lack of progress in RI system strengthening in high-risk countries limited the benefit of IPV and contributed to the high cVDPV2 case burden. Coverage of the first dose of IPV (IPV1) has remained <80% at the national-level across high-risk geographies, with many countries reporting coverage <60% and <50% (Figure 15), along with substantial sub-national heterogeneity. While the COVID-19 pandemic negatively impacted RI systems (mostly between 2020-2022), resulting in cohorts of children not receiving vaccinations (including IPV), the effect on case burden has likely only materialized over the past two years, following the peak annual cVDPV2 case burden in Year 5.

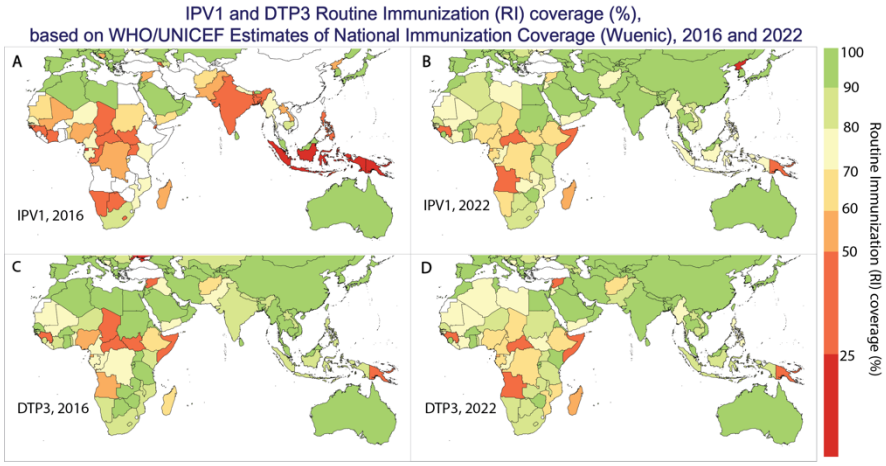



**Figure 15.** IPV1 and DTP3 Routine Immunization (RI) coverage (%), based on WHO/UNICEF Estimates of National Immunization Coverage (WUENIC), 2016 and 2022.

Despite limited improvements in RI coverage, there has been an absence of the adoption of innovative approaches to improve reach of IPV (e.g., extended outreach using fIPV through house-to-house modalities, routine catch-up SIAs with IPV in conjunction with other vaccines in the RI system, i.e., measles).

Strong RI systems are critical to mitigate the impact of cVDPV outbreaks. Egypt provides an excellent example as to what can be achieved with a solid foundation of RI (Figure 16). Egypt has consistently high (>95%) and homogeneous RI coverage. The country reported a cVDPV2 outbreak between 2020 and 2022. Despite many cVDPV2 detections in ES across the country, and seeding events due to the sub-optimal quality of four OPV2 NIDs (plus additional rounds in select areas), no cVDPV2 cases were reported. Egypt was treated as a success story, despite transmission persisting for around two years. The foundation of IPV provided Egypt with time to interrupt transmission and "get things right", without facing the immediate consequence of cases. In the absence of strong RI, cVDPV2 case burden in Egypt would have been high. In contrast, DRC with RI as low as 38% (and no IPV SIAs), reported >700 cVDPV2 cases. Strong RI will be of even greater importance for cVDPV1 (due to a higher-case to infection ratio).

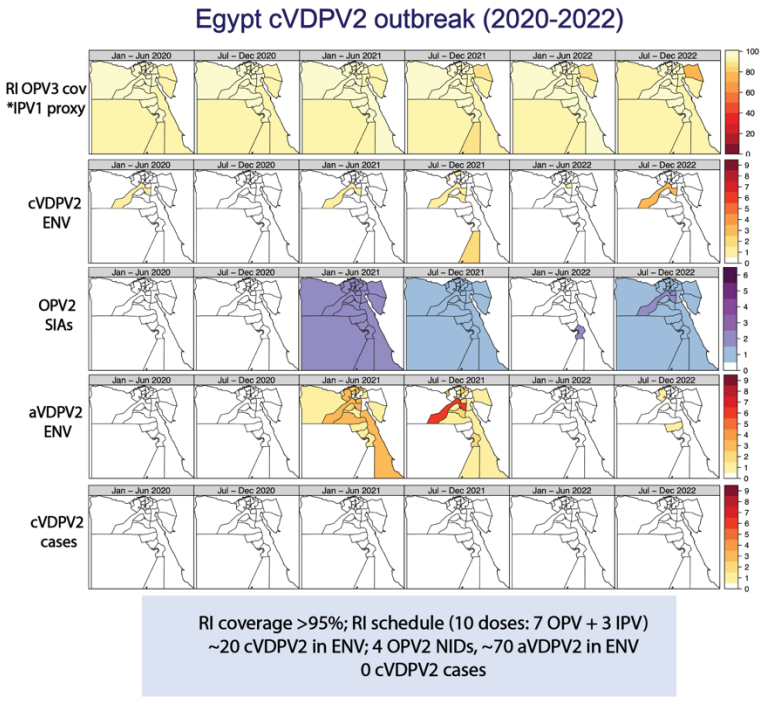



**Figure 16.** cVDPV2 outbreak in Egypt between 2020 and 2022.

**Lessons for bOPV withdrawal:** Strong RI systems are critical to prevent case burden from cVDPV outbreaks. Greater improvements in high-risk geographies are essential in advance of bOPV withdrawal. Stronger collaboration and coordination between GPEI and EPI is essential, as are innovative approaches to reaching children with IPV (e.g., door-to-door fIPV SIAs).

### 3.2.5 A limited stockpile of mOPV2 vaccine, resulting in focused and insufficient outbreak response scope

**Requirement:** A global stockpile of mOPV2 was required to respond to cVDPV2 outbreaks. Due to the strict containment protocols formulated in advance of the switch and the resulting discontinuation of OPV2 bulk production, the stockpile needed to be sufficient in order to adequately respond to any and all cVDPV2 outbreaks in the post switch era.

**Evaluation and implications:** The initial plan (based on UNICEF's 2009 tender [18]) was to secure 750 million mOPV2 doses; however, this was modified in the two to three years leading up to the switch, with 519 million mOPV2 doses ultimately determined to be a sufficient stockpile. The mOPV2 stockpile requirements were based on the expected number of cVDPV2 outbreaks post switch (i.e., three outbreaks in the first year, with declining risk in each subsequent year; Figure 17). Observed outbreaks from pre-switch tOPV use were in close alignment with expectations. What the plans didn't account for was the lack of capacity to stop outbreaks (and continued seeding of new cVDPV2), resulting not in a decline, but ever-increasing outbreak magnitude, case burden and number of infected countries.

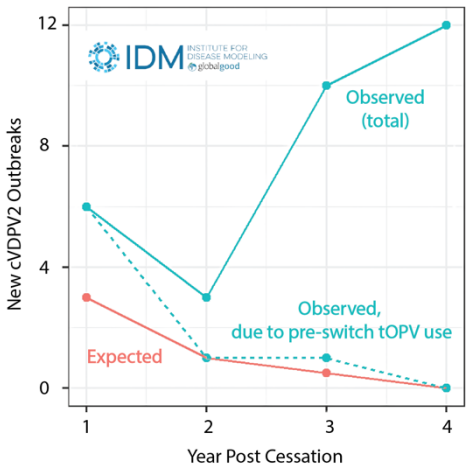
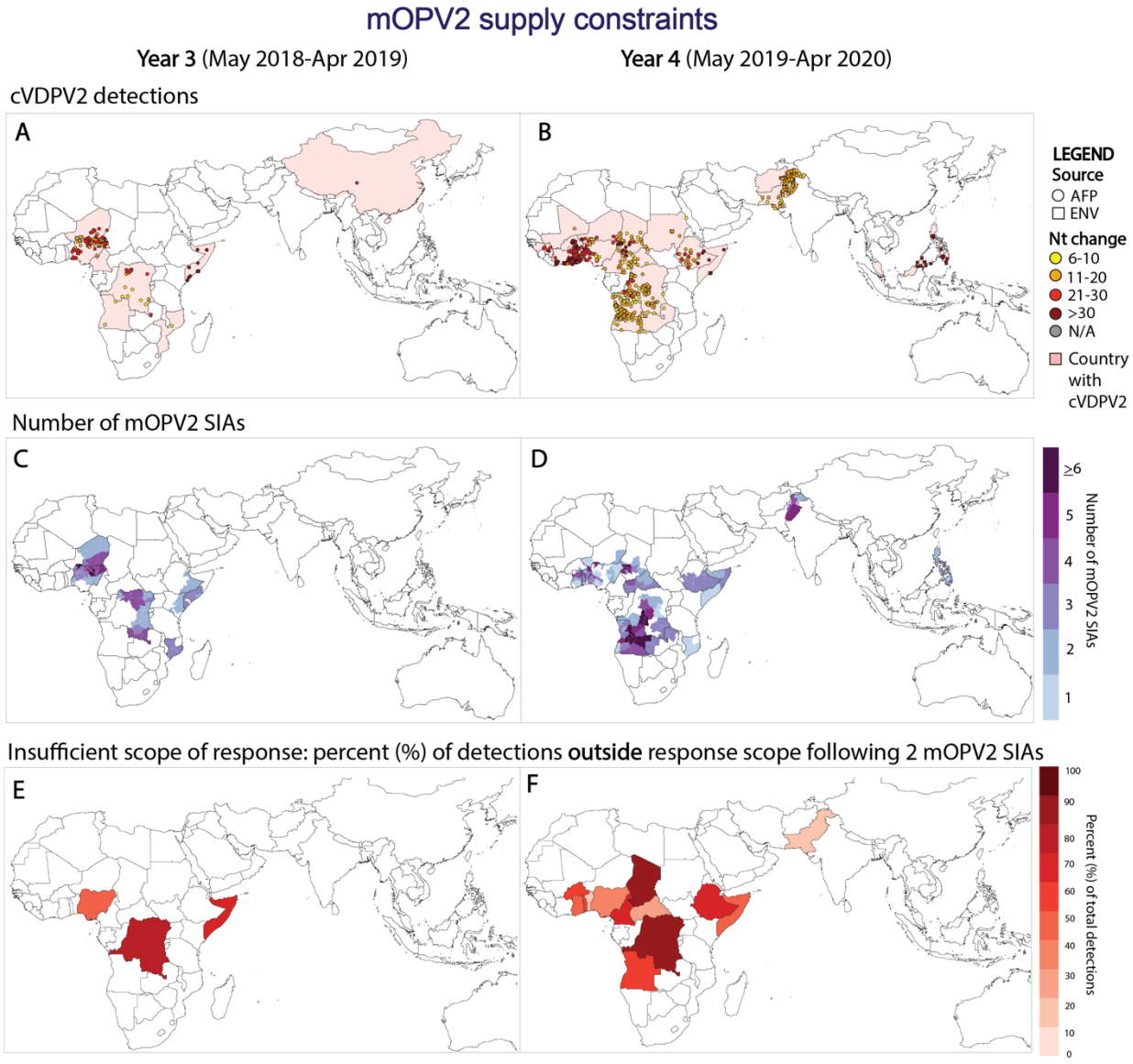



**Figure 17.** Expected and observed cVDPV2 outbreaks post switch. Source: Institute for Disease Modelling (IDM).

The worst-case scenario materialized and the program quickly began running out of outbreak control vaccine (i.e., mOPV2), without the ability to rapidly procure more. Because of the containment priorities, the production of mOPV2 bulk had already been discontinued by the manufacturers. By the end of Year 3, >200 million mOPV2 doses had been used and transmission was expanding (Figure 18). The strain on the mOPV2 stockpile drove focused outbreak responses, and in Year 4 nearly half of all detections were outside of the response scope following 2 OPV2 SIAs (with scope particularly inadequate in DRC, Figure 18).

Despite a substantial increase in cases and infected countries between Years 3 and 4 after the switch (i.e., from 84 cVDPV2 cases in seven countries, to 544 cases in 21 countries), the number of mOPV2 doses used in these two years was nearly the same (i.e., around 110 million). The focused scope of responses in Year 4 led to a peak of cVDPV2 transmission and cases in Year 5, with >1,000 cVDPV2 cases reported across 24 countries. Supply constraints were addressed by Year 5 (and novel OPV2 (nOPV2) became available and was used extensively), resulting in larger responses (>400 million doses used in Year 5); however, transmission was already widespread and endemicity established in many countries.

**Lessons for bOPV withdrawal:** Ensuring sufficient supply of essential OPV vaccines (in addition to IPV) is critical for a successful switch, allowing for responses to be driven by epidemiology and not supply constraints. Continuing to manufacture these OPV vaccines at pre-switch levels will be essential and will ensure a continuing increasing stockpile after bOPV withdrawal and the option to reverse the OPV cessation, if required.




G

| | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 | Year 6 | Year 7 |
|---|---|---|---|---|---|---|---|
| mOPV2 doses remaining | 439.5 M | 426.9 M | 316.4 M | 204.6 M | (201.4 M) | (545.4 M) | (874.9 M) |
| Total mOPV2 doses used | 79.5 M | 92.1 M | 202.5 M | 314.4 M | 720.4 M | 1.06 B | 1.39 B |
| Annual mOPV2 doses used | 79.5 M | 12.6 M | 110.5 M | 111.8 M | 406 M | 344 M | 329.5 M |
| cVDPV2 cases | 13 | 91 | 84 | 544 | 1001 | 758 | 601 |
| Countries with cVDPV2 cases | 4 | 3 | 7 | 21 | 24 | 10 | 20 |

**Figure 18.** mOPV2 supply constraints post switch. A-B. cVDPV2 detections in Years 3 and 4. C-D. Number of mOPV2 SIAs in Years 3 and 4. E-F. Percent of detections outside of response scope following 2 mOPV2 SIAs. G. Yearly mOPV2 doses, number of cVDPV2 cases and countries reporting cases.

### 3.2.6 Revision of outbreak control SOPs reducing the number of rounds and target population, and eliminating IPV from outbreak response

**Requirement:** Appropriate cVDPV2 outbreak response protocol was required, ensuring clear guidance to countries on scope, timing and frequency of SIAs.

**Evaluation and implications:** Supply constraints resulted in a substantial reduction in the recommended number and scope of mOPV2 SIAs and removal of IPV from outbreak response guidelines (Table 1). The initial cVDPV2 outbreak response guidelines developed in advance of the switch included 5+ SIAs of a minimum two million population target and IPV included in the second SIA. By mid-2017, the guidelines cut both the number of SIAs and scope in half, with IPV no longer recommended. While the reduced number of SIAs was informed by research [19], the reduced scope was largely driven by supply constraints, as it was well understood that the scope would need to increase with time from the switch due to the increasingly susceptible populations. The greatest impact on reduced scope was in DRC, which conducted highly focused responses that failed to capture the extent of transmission.

OPV2 response guidelines

| Date | Number of SIAs | Timing | Scope/target | Vaccine |
|---|---|---|---|---|
| **V2.0 (01 May 2016 – 30 Apr 2017)** **developed pre-switch* | SIA1<br>SIA2 (mOPV2+IPV)<br>SIA3<br>SIA4<br>(SIA5+ in high-risk areas) | <14 days<br>2-3 week intervals (if SIA2 includes mOPV2+IPV may require up to 4 weeks) | 500,000<br>Min. 2 million (SIA1-SIA5+)<br>For SIA2 (mOPV2+IPV), IPV in expanded high risk subpopulation (Min 2 million) | mOPV2 (+IPV for confirmed transmission in high-risk areas). |
| **V2.3 (01 May 2017 – 31 Oct 2017)** | SIA1<br>SIA2<br>(SIA3+ if necessary) | <14 days<br>2-3 week intervals | 1-2 million children | mOPV2.<br>fIPV no longer recommended. |
| **V2.4 (01 Nov 2017 – 30 Apr 2018)** | SIA1<br>SIA2<br>(SIA3+ if necessary) | <14 days<br>2-3 week intervals | 1-2 million children | mOPV2.<br>fIPV no longer recommended. |
| **V3.0 (Dec 2018/Jan 2019)** | SIA1 (R0)<br>SIA2 (R1)<br>SIA3 (R2) | <14 days<br>2-3 week intervals | 200,000 – 500,000<br>1-2 million children | |
| **V3.1 (Jan 2020)** | SIA1 (R0)<br>SIA2 (R1)<br>SIA3 (R2) | <14 days<br>2-3 week intervals | 100,000 – 400,000<br>1-4 million children | |
| **V4.0 (Mar 2022)** | RR<br>SIA1<br>SIA2<br>Mop-up | <14 days<br><28 days<br><45 days (latest <56 days)<br><21 days after SIA2 | 100,000 – 400,000<br>Min. 2-4 million<br>Min. 2-4 million<br>Based on SIA1/2 quality | mOPV2 or nOPV2 or tOPV to be used.<br><br>IPV not recommended. |

**Table 1.** OPV2 response guidelines, including the details of revisions to the number, timing, scope and vaccine recommendations for outbreak response.

Messaging to countries for reduced scope of mOPV2 response centered on the risk of seeding from mOPV2 use (which had serious implications that will be discussed in the next section), while messaging for removal of IPV from guidelines focused on its use as only a tool for RI. This messaging was reinforced by the strict measures for releasing vaccine through the mOPV2 Advisory Group. This created confusion at the country level and impacted their ability to propose and implement appropriate and effective outbreak control plans.

**Lessons for bOPV withdrawal:** Guidelines should be driven by epidemiology, and not continuously change unless there is critical new information or vaccine products (e.g., nOPVs).

### 3.2.7 Waiting for nOPV2 introduction and perceived/communicated risk of mOPV2, resulting in substantial delays in outbreak response

**Requirement:** No requirement.

**Evaluation and implications:** At the time of the switch, nOPV2 was not available, but as development progressed it was perceived as a 'magic bullet' (despite now detecting at least 15 cVDPV2 emergences [across 10 countries] seeded from nOPV2 use, resulting in 94 cVDPV2 cases). Once nOPV2 became available in 2021, countries were willing to wait to receive the vaccine, given the perceived and communicated risk of mOPV2 (coupled with the promise of nOPV2). Many countries substantially delayed outbreak responses as they waited for nOPV2 to be available, and once it was ready for use, supply constraints resulted in additional delays (Figure 19).

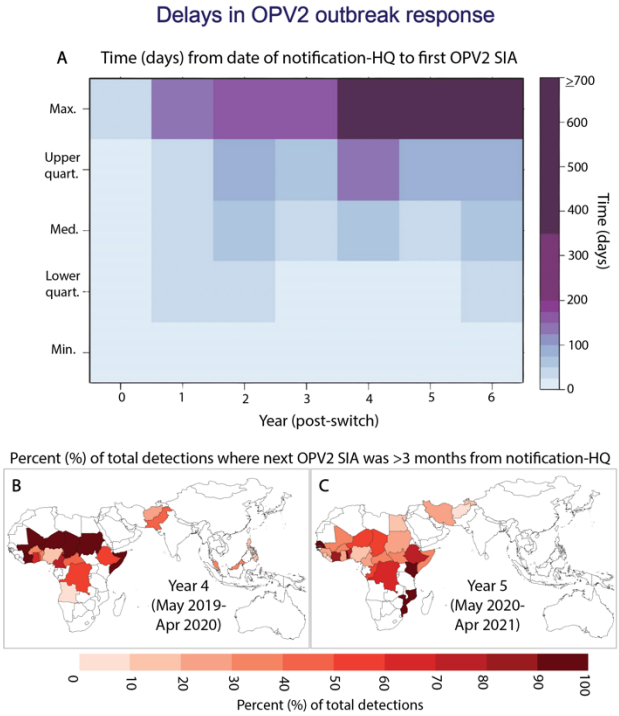



**Figure 19.** Delays in OPV2 outbreak response. A. Time (days) from date of notification-HQ to first OPV2 SIA. B-C. Percent of total detections where next OPV2 SIA was >3 months from notification-HQ.

Delays in responding to outbreaks resulted in continued and expanding transmission in many countries in Years 4 and 5, particularly in the African Region (Figure 19). In the context of increasing susceptibility and expanding transmission, this created 'the perfect storm' of factors accelerating the extent of cVDPV2 transmission.

**Lessons for bOPV withdrawal:** At the time of the switch nOPV2 was not anticipated. For bOPV withdrawal, at a minimum nOPV1 and nOPV3 must be ready, including manufacturing capacity, robust supply security (>2 manufacturers) and regulatory approvals.

### 3.2.8 Left over tOPV vials in storage sites, potentially seeding (at least one) cVDPV2 outbreak/s

**Requirement:** Following OPV2 cessation, all remaining stocks of tOPV were to be collected, destroyed and independently validated at the country level.

**Evaluation and implications:** While countries checked all National and Provincial/State storage facilities, the majority of countries only monitored <30% of health facilities (at District level or below) for tOPV (Figure 20). Substantial amounts of tOPV was found at monitored facilities (Figure 20). Collecting tOPV from the private sector was particularly difficult.

While tOPV vials were likely present in many countries, inadvertent use resulting in cVDPV2 outbreaks appears limited (Figure 20). Nearly all seeding events coincide with OPV2 use (either

at the same Administrative Level 1 (admin1), in the same country or bordering country, Figure 20). Pakistan is the exception and may have seeded its cVDPV2 outbreak in 2019 from inadvertent tOPV use. This outbreak resulted in two years of ongoing cVDPV2 transmission across Pakistan and Afghanistan, 15 emergences across these countries and >500 cVDPV2 cases.

Given the amount of OPV2 used in the highest risk geographies, it is not possible rule out inadvertent use of OPV2 (as directly attributing seeding events to specific campaigns is not possible).

**Lessons for bOPV withdrawal:** Moving forward, ensuring all OPV is collected and contained post switch, that there is better engagement with private sector, and the validation process includes a majority (if not all) health facilities will be essential.

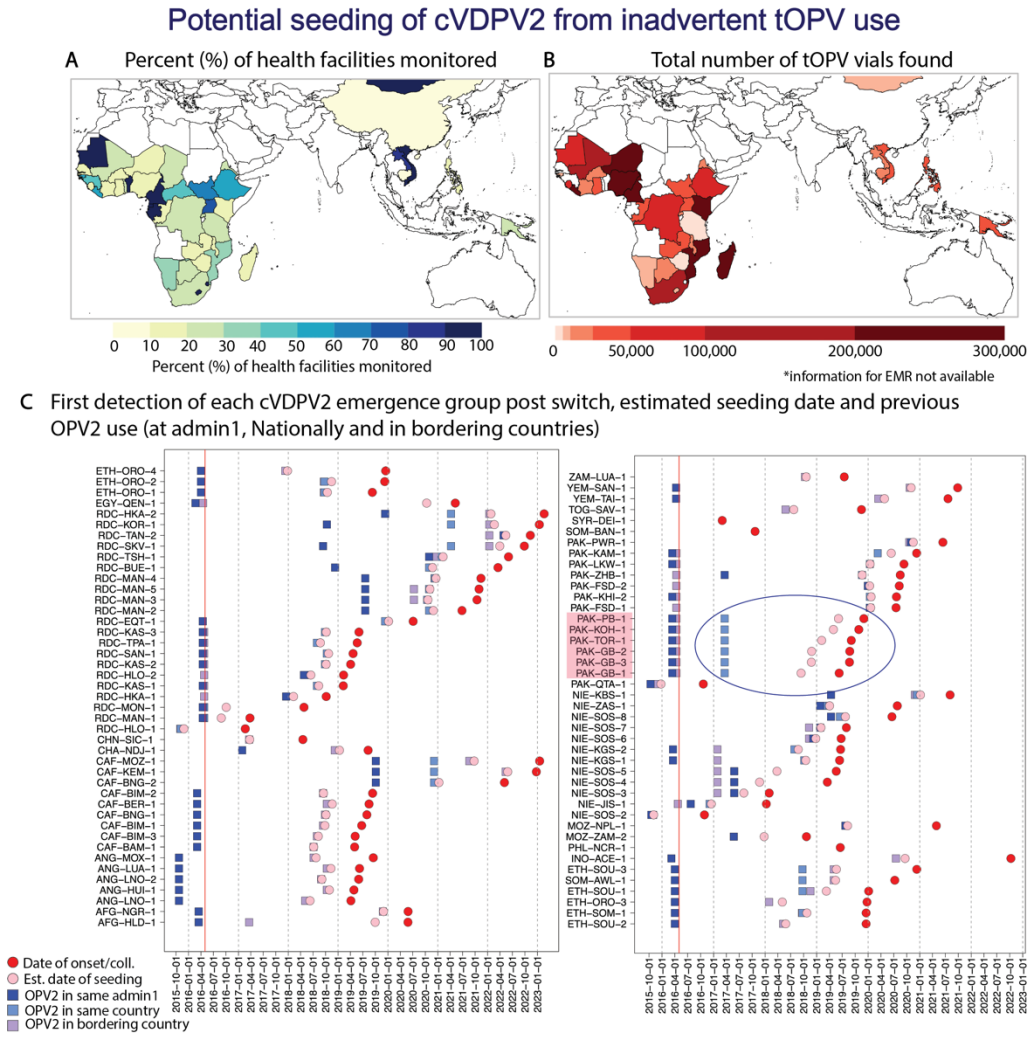



**Figure 20.** Potential seeding of cVDPV2 from inadvertent tOPV use. A. Percent of health facilities monitored for tOPV vials post switch. B. total number of tOPV vials found in the monitoring process. C. First detection of each cVDPV2 emergence group post switch, its estimated seeding date and previous OPV2 use (in the same admin1, same county and in bordering countries).

### 3.2.9 Inadequate or late detection of cVDPV2 (both new emergences and ongoing transmission), delaying implementation of outbreak control measures

**Requirement:** Surveillance capacity must be "sufficient" to detect all cVDPV2 post switch.

**Evaluation and implications:** In the post switch era, new cVDPV2 emergences have typically been detected early, especially in consequential geographies. The majority (58%) of first detections within a new emergence were between 6 and 10 nucleotide divergent, indicating early detection; however, there were substantial gaps (>20 nucleotides divergence from parental Sabin virus) in select geographies (Somalia, Ethiopia, the Syrian Arab Republic, Mozambique, Indonesia, Malaysia) indicating surveillance gaps, particularly in areas or countries with limited environmental surveillance (Figure 21).

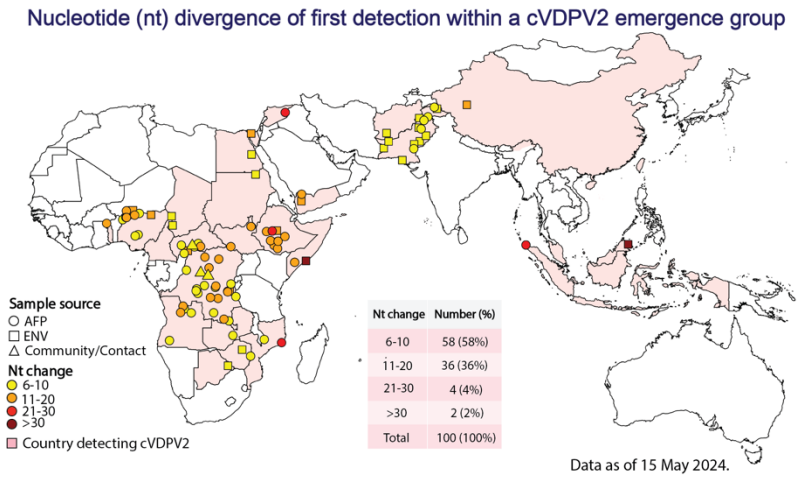



**Figure 21.** Nucleotide (nt) divergence of first detections within a cVDPV2 emergence group, between May 2016 and April 2024.

Overall surveillance quality is strong, especially the acute flaccid paralysis (AFP) surveillance arm, that covers almost every single country. The global AFP surveillance system has detected >3,300 cVDPV2 cases across 43 countries since May 2016 (Figure 22). Most countries report a non-polio AFP rate ≥2 cases per 100,000 population <15 years of age (however, there are sub-national gaps). Stool adequacy remains a greater concern, and despite improvements over the past few years in high-risk geographies (DRC, Chad), many geographies continue to fall below 80% achievement (Figure 22).

Environmental surveillance (ES) has been strengthened to support AFP, and there has been an increased frequency and scope of sampling, enabling faster detection of cVDPV2 in select geographies (Figure 22), with 33% of new emergences and 22% of new geographies (admin1) first detected through ES. In total, >2,000 cVDPV2 ES samples have been reported since May 2016, across 49 countries. However, sensitivity of ES remains sub-optimal in many high-risk countries, particularly in the African Region. In many high-risk countries, <30% of ES samples detect virus, i.e., NPEV, Sabin, WPV/VDPV. For example, in DRC, where despite reporting >700 cVDPV2 cases since the switch, have only detected cVDPV2 in 2.5% of ES samples (out of a total of >2,000 ES samples collected across 28 ES sites).

**Lessons for bOPV withdrawal:** While the program's issue was is necessarily determining which areas have virus, ensuring consistent detection and capacity to capture extent of transmission is critical. Strengthening ES sensitivity in high-risk areas (in parallel to efforts in strengthening RI, which may impact AFP surveillance sensitivity) and ensuring expansion of ES includes appropriate sites (i.e., optimization and not simply expansion) will be essential. In the context

of transition planning, surveillance (in addition to outbreak response) capacity must be maintained.

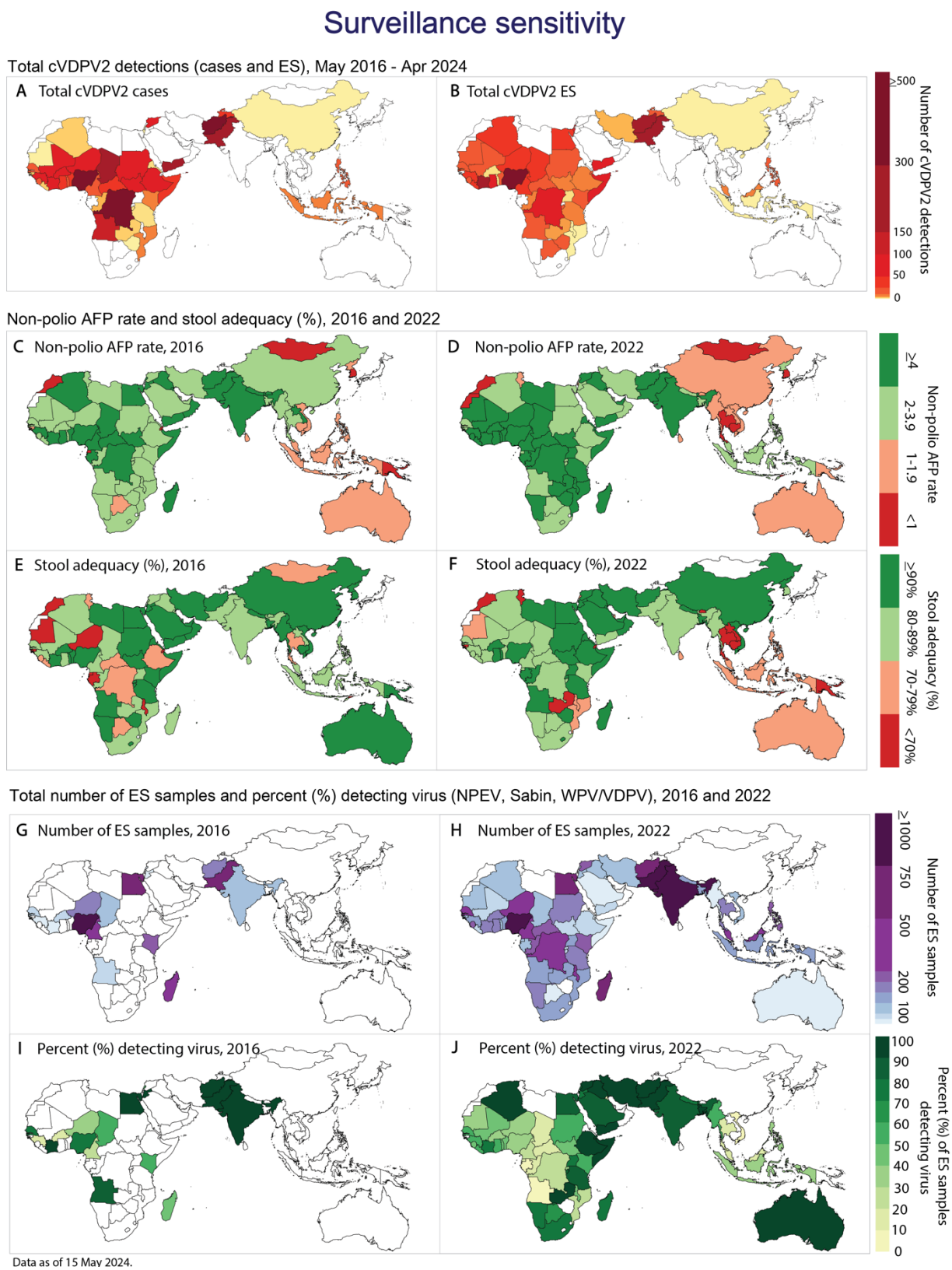



**Figure 22.** Surveillance sensitivity. A-B. Total cVDPV2 detections (cases, ES) between May 2016 and April 2024. C-D. Non-polio AFP rate in 2016 and 2022. E-F. Stool adequacy (%) in 2016 and 2022. G-H. Total number of ES samples in 2016 and 2022. I-J. Percent of ES samples detecting any virus (NPEV, Sabin, WPV/VDPV) in 2016 and 2022.

### 3.2.10 Delays in shipping, processing and notifying cVDPV2 AFP and ES samples, exacerbating delayed responses

**Requirement:** Surveillance capacity must be 'sufficient' to timely process all cVDPV2 post switch.

**Evaluation and implications:** While overall surveillance quality is relatively strong, select geographies had substantial delays in shipping and/or processing samples (a greater issue than detection for both new emergences and cVDPV2 overall). With the increased strain from high cVDPV2 burden (from Year 4 onwards), coupled with challenges in cross-border shipments due to the COVID-19 pandemic, the surveillance processing time greatly increased (Figure 23). Time to notification was >3 months in a large number of countries (including Sudan, Burkina Faso, Niger, Guinea and Cote D'Ivoire) from Year 4 onwards. Delays in notification have downstream effects in delayed response (as by the time it is notified, transmission has already spread, outdating the assessed risk and response strategy).

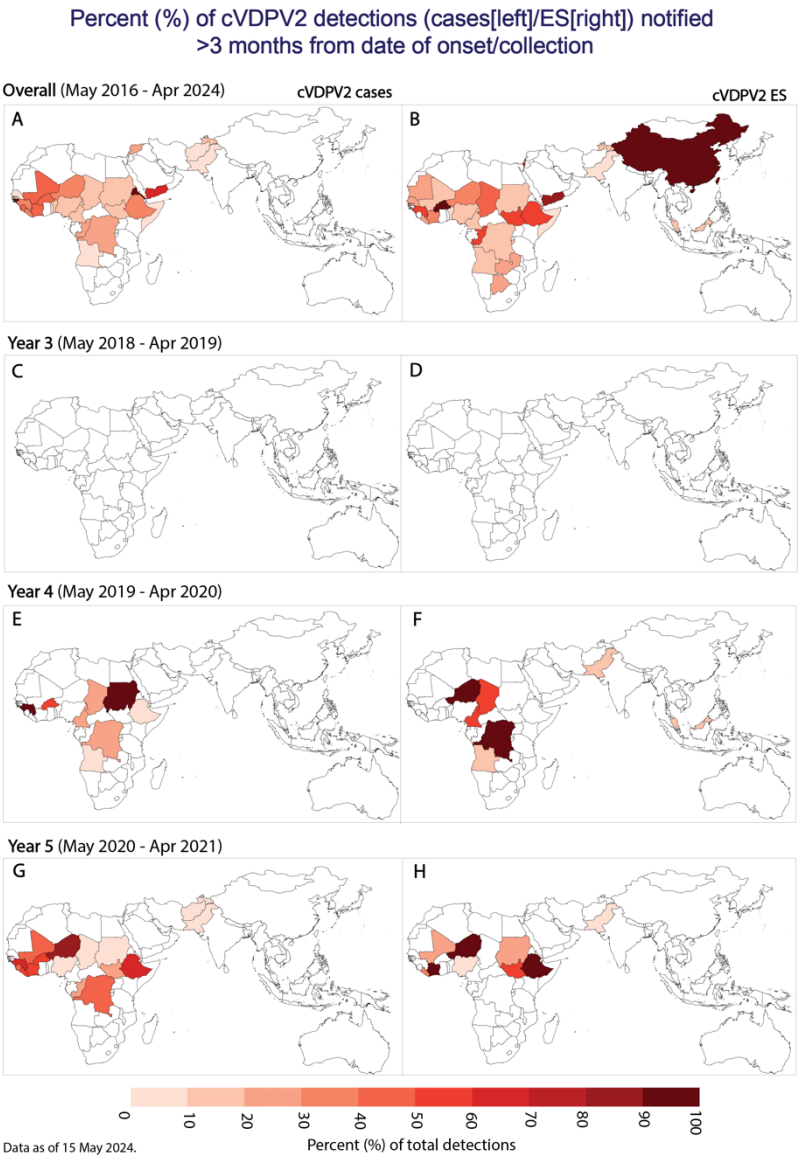



**Figure 23.** Percent of cVDPV2 detections (cases[left] and ES [right]) notified >3 months from date of onset or collection..

**Lessons for bOPV withdrawal:** Ensure surveillance processing time is consistently <3 months across countries and shorten field collection, shipment and laboratory processing time as much as possible. The surveillance system must be able to withstand an increased burden of high case numbers and ES detections. Remaining vigilant with surveillance is critical in advance of OPV withdrawal.

# 4. Recommendations

The failure of the switch is a learning platform, and any new vaccine withdrawal attempt must pass a higher bar of readiness and scrutiny to be successful and avoid the challenges of the past. This is to avoid another failure, which would have even greater consequences in the form of paralyzed cases due to the 10-fold higher case to infection ratio (1:2000 for type 2 against 1:200 for type 1 [8]) and could also cause irreparable reputational damage to the organizations involved in GPEI, influence funding and reduce the confidence of the public.

Therefore, the following guiding principles are proposed for a bOPV cessation: plan for worst-case scenario (i.e., concentrate on source versus sink, reservoir versus indicator community); assume no difference in transmissibility or force-of-infection among the three Sabin strains (once evolved to cVDPVs); and be aware and communicate: surveillance will be more sensitive for Sabin type 1, but plan for a higher case burden for type 1. The situation of Sabin type 3 is less well understood but may be more likely to be similar to type 2 [8].

The program needs to demonstrate that it can control and close out outbreaks within six months after designation of “persistent” cVDPVs. After bOPV withdrawal, type 1 and type 3 population immunity will decrease, and a race will start for virus elimination in the face of a growing susceptibility gap. Most countries currently use a RI schedule that includes three to four doses of bOPV and one to two doses of IPV. In future, IPV will be the only vaccine for polio prevention, a vaccine that has no ability for secondary spread and secondarily immunize some susceptible contacts. Therefore, the GPEI faces a “grave” risk. If the population immunity falls below threshold level for herd immunity, the unintentional or intentional reintroduction of poliovirus could cause massive outbreaks of poliomyelitis.

Therefore, for the anticipated bOPV withdrawal we propose that the following triggers must be achieved for programmatic execution of cessation: i) no “persistent cVDPV” of any serotype (including cVDPV2). This requires outbreak control and elimination of all current outbreaks and endemic transmission; and ii) confirmation of eradication of wild poliovirus (WPV) by the Global Certification Commission (GCC).

In addition, the following 10 prerequisites should be achieved before bOPV cessation can be considered. The first three address vaccine availability, the next three population immunity, the next three RI and the last surveillance.

1) Ensure sufficient stockpile quantities of all required vaccines for a worst-case outbreak scenario. Required vaccines to be determined based on comparison of bOPV with sufficient evidence from studies on novel formulations, including nOPV1, nOPV3 and bivalent nOPV (bnOPV), trivalent nOPV (tnOPV)). The opportunity costs of single serotype SIAs assign a further priority to tnOPV.

2) Continue to purchase (and make a commitment to purchase) outbreak vaccines during >5 years after bOPV cessation (and re-set the clock after each outbreak). This would allow the manufacturers to plan and maintain bulk production and fill-finish capacity.

3) Modify containment requirements temporarily (until all poliovirus type 2 has been eradicated) to contribute to eradication and not just make the world safer after eradication. These requirements need to be applied in a flexible and realistic way (i.e., cannot interfere with outbreak control, production of required vaccines, or laboratory processing, all serving the overall eradication goal). Laboratory methods should minimize reliance on live Sabin virus, should switch to S19, use pseudovirus and facilitate direct detection.

4) Conduct preventive SIAs that reach and maintain high population immunity. Current strategies must be revised to ensure sufficient number and quality of preventive SIAs. Clearly defined benchmarks and methods of evaluation are required. Develop methods to rapidly measure population immunity, including in focused high-risk areas.

5) Design realistic outbreak response standard operating procedures (SOPs) that incorporate innovative ideas with back-to-basics principles and obtain sufficient outbreak control funding for a worst-case scenario. The outbreak control scope must guide funding needs – not the opposite, and draft new SOPs to reflect this pre-requisite. Streamline decision-making of outbreak response plans and approval/release of required vaccine to facilitate timely implementation. Track progress and make refinements, as required.

6) Consequential geographies require special pre- and post-switch strategies. For the pre-switch period increase population immunity to surpass the threshold for herd immunity and develop context-specific strategies for inaccessible areas. For the post-switch period pre-position stockpile vaccines in consequential geographies and pre-approve outbreak activities, including funding.

7) Improve RI coverage to reach and surpass the threshold for herd immunity. Design new strategies (with innovative approaches for reaching children, e.g., door-to-door fIPV SIAs), and ensure closer collaboration with IVB. Consequential geographies should be assigned the highest priority, with the next highest priority to areas (state, districts) with a high proportion of zero-dose children.

8) Include nOPV2 into the pre-switch RI schedule in the highest-priority countries (or consequential geographies). For example: nOPV2/bOPV at birth, six, 10, and 14 weeks, and IPV at 14 weeks and >9 months, or, when available, nOPV2/bOPV plus hexavalent vaccine at six, 10, and 14 weeks (and an additional dose of hexavalent vaccine in the second year of life).

9) Accelerate the introduction of, and promote high coverage with, hexavalent vaccine. This introduction should prioritize high-risk countries, especially GAVI-eligible countries.

10) Further increase surveillance sensitivity and speed of detection, shipping and processing for timely notification and action. Focus on optimizing (instead of simply increasing) ES sites. Accelerate implementation of direct detection methods and

institute special strategies to reduce shipping delays in complex situations/contexts. Ensure transition plans do not impact surveillance capacity.

Furthermore, GPEI should place careful attention to plans and planning that will also help minimize potential downstream problems, such as: commissioning a plan B (of critical voices); compiling a detailed risk matrix, risk reduction and risk mitigation strategy, and contingencies for unexpected eventualities; defining *a priori* success and failure (along with follow up action in the case of failure); evaluating progress every three months; and reviewing status at the end of Year 2 post cessation for final determination of success or failure.

Moreover, in order to minimize risk and gain experience, the GPEI should consider implementation of bOPV cessation in a phased manner by region (based on risk of cVDPV1/3). For example, low-risk countries withdrawing first (European Region, Region of the Americas, Western Pacific Region), then the South East Asian Region, followed by the Eastern Mediterranean and African Regions.

# 5. Conclusions

The OPV2 cessation, the switch, has not been successful, and the world´s children continue to pay the price in terms of morbidity (i.e., paralytic disease) and mortality (i.e., death from poliomyelitis). The failure must be weighed against the >20 million children that walk today because of GPEI, supported by RI programs and the associated vitamin A distribution campaigns.

However, the GPEI must strive to do better:

- At present, many outbreaks are not being stopped, highlighting that the program must take a critical look at the current outbreak control strategy, recognize the reality of the failure and make the changes needed. Achieving the two triggers for bOPV cessation may be most challenging. In our view, the key to controlling cVDPV2 poliovirus endemicity requires a way back to the basics to ensure fundamental principles for outbreak control are consistently achieved. This, coupled with a strategy whereby NIDs are conducted when transmission is widespread, supplemented by subnational NIDs (SNIDs) when transmission becomes localized, supported by high-quality surveillance and improved RI programs.
- In the current situation, it is better to take the time to get it right, than to rush, and fail (failure, this time cannot be an option). At this point in time, all realistic options for achieving the triggers and prerequisites likely require at least five years of maximal effort (Figure 24). The program should use the time wisely to build up population immunity and find ways to maintain this population immunity above the threshold for herd immunity. This is especially important in consequential geographies.
- Instituting closer collaboration with RI will greatly increase likelihood of success. This could be very productive at all levels, in the field, and in the organizational parts of the GPEI. GPEI and RI could work closely together to extend the reach of all recommended vaccines, and

thus greatly increase the benefits of these vaccines. The current resurgence of measles, as well as diphtheria, is a stark reminder that complacency invariably comes with a price that requires payment in the form of morbidity and mortality.

- The narrative that cVDPVs are less dangerous and of secondary importance compared with WPVs (stemming from historic views that WPVs were the priority and cVDPVs were simply the rare consequence of the goal to reach eradication) must change. Epidemiologically and virologically, the risk (i.e., transmissibility) and impact (i.e., paralysis) are the same. This narrative has spread down to the operational level and has impacted the urgency of response. If the same urgency was applied to cVDPVs as to WPVs the program would be in a substantively different situation. Consider the type of response that an importation of WPV1 would elicit in DRC, and compare it with the observed cVDPV2 outbreak responses — it would clearly highlight the differing perception of equivalent viruses at the operational level.
- Moreover, the terminology used to refer to sustained cVDPV2 transmission over extended periods of time in our highest risk geographies (i.e., Yemen, Eastern Democratic Republic of the Congo, Northern Nigeria, Somalia), must reflect reality in order to allow appropriate change and action. By all traditional epidemiological definitions, many of these countries would be considered endemic and no longer categorised as outbreak countries. The GPEI must ask itself: "How many years does cVDPV2 need to circulate before it is considered endemic?" While terminology may be considered semantics, the perception is important to inspire appropriate action. An endemic label suggests a more systemic problem in a geography and greater cause for concern to act.
- Furthermore, the program must review the approach to action following initial VDPV2 detections (prior to classification of "circulating"). The classification of "circulating" necessitates confirmation of at least two VDPV2 detections, which due to delays in processing (especially for ES) often lead to loss of precious time when the virus is potentially transmitting and increasing in scope. It would be worth taking a closer look at the trigger needed for action and consider reverting to more urgent speed of action from a single indeterminate/ambiguous VDPV2, as was suggested in the initial outbreak response SOPs. While an OPV response at the early stages of indetermined classification may not be warranted, increased speed of readiness and planning may be appropriate and should be considered. Moreover, an initial IPV response would rapidly increase population immunity without the risk of seeding new cVDPVs, and may be warranted (especially in areas of high population density and strong ES).
- With adherence to the proposed triggers and prerequisites, GPEI has the capacity to succeed. To do that, additional strategies, some outlined in the proposed prerequisites, others in development, could help raise the population immunity above the threshold for herd immunity, and maintain it there, until at least five years after the last detection of poliovirus type 2 in communities. The introduction of hexavalent vaccine (with an IPV component) could be a game changer, also for polio eradication.

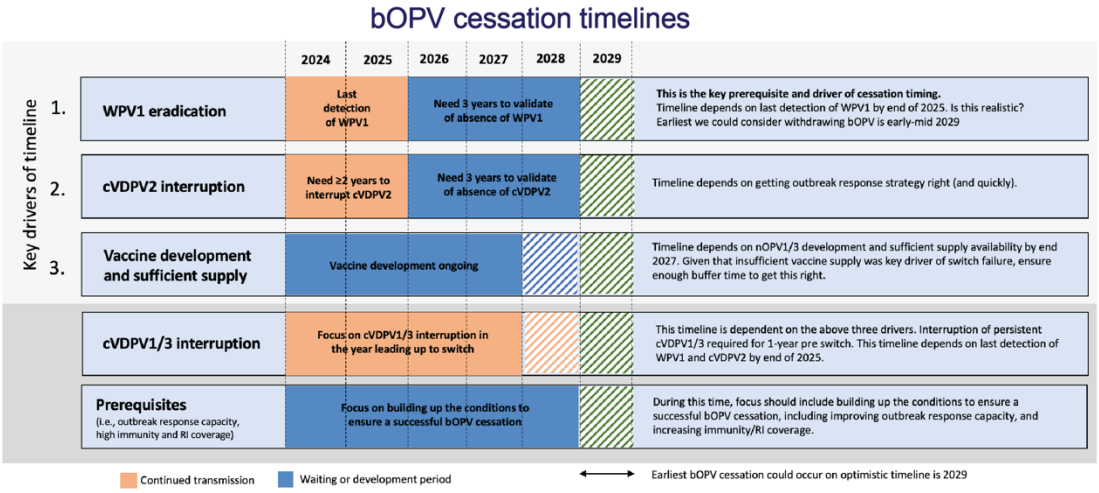



**Figure 24.** bOPV cessation timeline, based on optimistic targets.

# 6. Way Forward

At this juncture in 2024, the program is not ready for a next cessation attempt.

Until the GPEI has achieved eradication of WPV1 and eliminated the chains of cVDPVs transmission, it should improve the conditions for the anticipated bOPV cessation. These conditions include developing the critical products (especially vaccines) for a post-bOPV world, ensuring adequate manufacturing capacity and eventually filling up the required stockpiles, and developing strategies for improving population immunity, RI coverage and outbreak response capacity.

The world is a very diverse place, and eradication efforts sometimes require engagement in places where access is limited, and security is tenuous. The program should incorporate robust strategies to minimize the risk to health workers and volunteers delivering eradication strategies.

The review also noted the complicated leadership structure of GPEI and its impact on the ability to make rapid decision. Streamlining the decision-making structure, reducing the number of committees, task teams and advisory groups, could result in focusing resources, especially human resources, to be employed for directly supporting programmatic action in the field.

Innovative new programmatic approaches should be both encouraged by GPEI and be assigned a high priority. Empowering local innovations, evaluating these, and keeping the ones that worked is the hallmark of pragmatic local solutions. Moreover, focusing on a back-to-basics approach (one that focuses on consistently achieving the essential principles for effective outbreak response that enabled the program to eradicate WPV from the African continent) is required, and must be consistently achieved across all geographies.

Further research is critical. A non-infectious vaccine that would induce mucosal immunity is the “holy grail” of polio eradication product development. New ways to rapidly determine

population immunity should be developed and made available to cVDPV-endemic countries, so that the program managers in these countries are empowered in real time to make better programmatic decisions.

Furthermore, a confluence of a four-pillar strategy: RI, supplemented by SIAs, with two new elements, nOPV2 into RI, and house-to-house fIPV given during extended outreach, could substantially increase population immunity in consequential geographies.

Recognizing that pockets of low immunity will likely always exist in a complex and dynamic world, reversion of a live vaccine virus will take place despite best efforts to create a more genetically stable vaccine (due to a predictable mutation rate, no proof reading mechanism and strong biological pressure for recombination, especially in areas with high prevalence of non-polio enteroviruses), and there will always be something that is missed in some corner of the world (be it left over vials or delayed detection), the only tool that poses no risk of propagating cVDPVs is IPV. Eventually IPV will be the only tool that is available and maximizing its use now will facilitate not only the GPEI's ability to reach eradication, but strengthening RI and the transition between GPEI and EPI. Considering a GPEI strategy that features IPV more prominently and a strengthened resolve to ensure high IPV coverage would make any future switch irrelevant. Focusing on strengthening the reach and coverage of IPV through every possible modality (i.e., fixed site, extended outreach, door to door strategies) will help create a model that ensures the world's children are protected from vaccine-preventable diseases, now and into the future.

In conclusion, polio eradication is eminently doable. The eradication program has come a long way and is struggling to cross the finish line. However, the last inch, the most difficult part of this journey remains a work in progress. Collectively, we need to recommit to eradication, reinforce our efforts, double down and find the right strategies (even for inaccessible areas), to ensure that poliovirus can never find a home again in our communities.

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# Annex A: The evaluation of prerequisites and readiness criteria for OPV2 withdrawal

| **Trigger** | Code | Element | Standard | Evaluation | Implication | Lessons for bOPV withdrawal |
|---|---|---|---|---|---|---|
| Validation of elimination of persistent cVDPV2 and confirmation of WPV2 eradication | **T1** | Elimination of persistentcVDPV2 | No persistentcVDPV2 before switch | **NOT MET**<br>-cVDPV2 in Borno, Nigeria detected – 4/28/2016 reported | Outbreak response with mOPV2 led to the seeding of new cVDPV2 outbreaks | Anticipate with contingency plans and plan to deal with silent cVDPV circulation. |
| | **T2** | Confirmation of WPV2 eradication | Global Certification Committee (GCC) resolution | **ACHIEVED**<br>-20-21 September 2015 14th Meeting of GCC Bali, Indonesia | | |
| **Prerequisites** (Polio Eradication and Endgame Strategic Plan 2013–2018, 2013) **[1]** | | | | | | |
| An OPV2 stockpile and response capacity | P1 | OPV2 stockpile | Initial plan requirement: 750 million doses; procured 519 million doses including 100 million in vials and rest in bulk | **NOT MET** | Stockpile plan target not achieved – rapid depletion in Year 1 required bulk fill and finish contracts– leading to concerns about eventual stockouts | Stockpile assumptions were too optimistic. These must be tested and the margin of error must be large. |
| | P2 | Response capacity | Outbreak response SOPs and credible organization | **NOT MET**<br>-Not possible to implement SOPs of required number of rounds and vaccines | Protocol revised several times with the number of SIA rounds reduced (adjusted down because of IPV & mOPV2 supply constraints) | Eventually some countries did not adhere to guidelines leading to delayed outbreak control. |
| Surveillance capacity and an international notification requirement for all Sabin, Sabin-like | P3 | Surveillance capacity | Standard ≥2 AFP rate + ≥80% stool collection + ≥90% of cVDPV2 (≤1% nt divergence) for region or sub-regions | **NOT MET**<br>-seven silent cVDPV2s at switch time<br>-Somalia cVDPV2 emergence circulates | Undetected (i.e., silent) cVDPV2 seeded new outbreaks in increasingly susceptible populations | To avoid failure in future, surveillance must cover all inaccessible communities. |

| | | | | | | |
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| and cVDPV2 viruses | P4 | International notification requirement for all Sabin, Sabin-like and cVDPV2 viruses | All type 2 poliovirus included in mandatory IHR reporting | **ACHIEVED** | | Need to include all poliovirus serotypes in mandatory HR reporting, including novel viruses |
| Sufficient bOPV products for all OPV-using countries | P5 | Sufficient bOPV products for all OPV-using countries | No stockouts or supply constraints | **ACHIEVED** | All OPV vaccine producers stopped type 2 bulk production and switched to bOPV | Provide adequate multi-year lead time for global change |
| Affordable IPV option(s) for all OPV-using countries | P6 | Affordable IPV option(s) | -Gavi-eligible countries only<br>-Some middle-income countries (MICs) | **ACHIEVED** | -Gavi IPV support window for 73 countries (Board 1-2 June 2013) – all applied<br>- nine MICs supported by GPEI (six Western Pacific Region, three Region of the Americas) for IPV procurement and operational costs associated with IPV introduction | One size does not fit all. India received US$50 million for one-time introduction support to ensure meeting the IPV introduction timeline |
| | P7 | Affordable IPV option(s) for all OPV-using countries | ≥1 IPV dose for OPV-using countries | **NOT MET [3]**<br>-49 countries without IPV (20 delayed, 29 in stockout)<br>-only 50% IPV required supplies available | a) lack of IPV led to decreased population immunity and vulnerable to outbreaks; b) IPV basically not available for outbreak response (contrary to initial outbreak response SOPs | If vaccine is required, must ensure sufficient quantities with multiple producers; a robust production capacity; and production must continue after withdrawal |
| Phase II biocontainment for all cVDPV2 and WPVs | P8 | Phase II biocontainment for all cVDPV2 and WPVs | Phase II (inventories) achieved in all countries | **NOT MET**<br>-large quantities of type 2-containing vaccine remained in storage | Unlikely to be a major issue for overall switch failure | Only one outbreak can definitely be assigned to tOPV left over vaccine |

| | | | | | | |
|---|---|---|---|---|---|---|
| **Readiness [3]** | | | | | | |
| At least one dose of IPV in OPV-using countries | R1 | At least one dose of IPV in OPV-using countries | **SEE P6-7** | **NOT MET** | | |
| bOPV licensed for routine immunization | R2 | bOPV licensed for routine immunization | Regulatory approval in all countries for RI use of bOPV | **ACHIEVED**<br>-national licensure<br>-WHO prequalification<br>-emergency approval | Multi-year effort with bOPV manufacturers required for success approval | Start obtaining regulatory approval as early as possible for nOPV2, ntOPV, etc.<br>**RISK** |
| Appropriate containment and handling of residual type 2 materials | R3 | | **SEE P8 + O3** | | | |
| Type 2 poliovirus surveillance and response protocols and mOPV stockpile | R4 | Type 2 poliovirus surveillance and response protocols | **SEE P2-3** | | | |
| | R5 | mOPV stockpile | **SEE P1** | | | |
| Verification of global eradication WPV2 | R6 | Verification of global eradication WPV 2 | **SEE T2** | | | |
| **Other important considerations** | | | | | | |
| | O1 | Complete cessation of use of all tOPV globally must occur by a fixed date | Cessation of all OPV2 during 2-week period at end of April 2016 | **ACHIEVED**<br>-very few countries, including Egypt, postponed switch to May 2016 | Policy and implementation globally coordinated | Key area for bOPV withdrawal |
| | O2 | Cessation should be coordinated across all countries using tOPV | **SEE O1** | **ACHIEVED** | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| | O3 | All remaining stocks of tOPV at the time of cessation must be collected and destroyed (within three months) | No tOPV remaining in country storage more than three months after switch | **NOT MET**<br>-multiple countries had tOPV more than three months after switch | Highly important and likely seeded a number of cVDPV2 outbreaks; | Key issue for bOPV withdrawal – **SEE R5** |
| | O4 | The process must be documented | Each important area must be documented | **ACHIEVED** | Multiple journal supplements and articles in peer reviewed journals | |
| **Other key Issues** | | **Issue** | **What was done** | **Deficiencies / achievements** | **Supporting** | **Implications** |
| | I1 | Global Plan of Action 2013-2018 | Planning started in the 1990s, oversight and guidance provided by TCG, ACPE, and SAGE; plan of action 2013-2018 outlined principles, prerequisites and trigger point for switch and an ambitious RI target | -no plan B<br>-no definition of failure<br>-no detailed risk analysis<br>-some contingencies not exercised<br>-overly ambitious containment (leading to Sabin type 2 bulk production discontinuation) | Key WHO leadership position changed during critical phase (with similar changes in UNICEF) | New switch plan must address missing elements from 2016 switch, and should also avoid leadership changes during the most critical period/s |
| | I2 | RI target | 10% increase in RI coverage per year (in 10 highest risk countries) | **NOT MET**<br>Target too ambitious | Reliance on and cooperation with IVB was aspirational | Don´t include unrealistic goals in areas that are not controlled by GPEI |
| | I3 | Country national switch plans | 10 highest-risk countries supported for national plans development and implementation (approximately US$10 million extra funding) | Too few countries, too narrow activities, too little funding | In many countries only a small proportion of tOPV storage sites (10-20%) were actually inspected | Proper plan preparation and implementation requires adequate support |

| | | | | | | |
|---|---|---|---|---|---|---|
| | I4 | Oversight – GPEI leadership | Continually changing GPEI leadership | In the critical phase of the switch, new leadership was in charge of GPEI | Since plan definition of failure was not specified, leadership had no guidance of when to change course | Next withdrawal plan should address deficiencies from I1, and not change leadership during critical phase |
| | I5 | Oversight – Role of technical oversight committee | Numerous meetings of SAGE Polio Working Group and SAGE provided guidance (usually two working group and two SAGE meetings per year) | Technical oversite didn´t identify key plan deficiencies | Given the importance of the switch for global public health, additional review processes are recommended | Global plans need to include a plan B approach to identify potential issues and problems |
| | I6 | Insurance | Plan required ≥1 dose of IPV for all tOPV-using countries | Only about 50% of the required IPV doses were available at the switch | Despite a lack of doses, over 50 000 children were likely protected [4] | Insurance mechanisms should be included in future plans |

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# Annex B: Analyses underpinning the findings from the evaluation of OPV2 withdrawal

| WHO Region | Country | Number of cVDPV2 cases post switch | Number of cVDPV2 cases from 2010 to the switch | Number of cVDPV2 ES detections post switch | Number of cVDPV2 emergences | Months with cVDPV2 detections | Months with cVDPV2 cases | Area targeted with OPV2 post switch | Total number of OPV2 doses post switch | Area targeted with IPV post switch | Total number of IPV doses post switch | Percent of cVDPV2 detections due to insufficient quality | Percent of cVDPV2 detections due to insufficient scope | Percent of cVDPV2 detections due to insufficient timing |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AFRO | DRC | 727 | 46 | 54 | 22 | 73 | 70 | 11.5406 | 258707157 | 0 | 0 | 13.32 | 57.75 | 46.09 |
| AFRO | NIGERIA | 632 | 104 | 593 | 13 | 73 | 63 | 16.911 | 1123456240 | 0.4843 | 37037120 | 57.39 | 40.65 | 18.53 |
| EMRO | AFGHANISTAN | 346 | 18 | 216 | 2 | 20 | 18 | 9.3824 | 104564047 | 0.1638 | 3595818 | 24.2 | 35.94 | 8.36 |
| EMRO | YEMEN | 231 | 9 | 59 | 2 | 32 | 23 | 3.1077 | 26874115 | 0 | 0 | 1.72 | 26.55 | 11.72 |
| AFRO | CHAD | 213 | 17 | 25 | 1 | 43 | 40 | 15.7937 | 78064302 | 0 | 0 | 28.15 | 36.13 | 60.5 |
| EMRO | PAKISTAN | 164 | 87 | 212 | 14 | 32 | 21 | 6.5455 | 282192305 | 0.3647 | 11246533 | 67.82 | 18.88 | 15.16 |
| AFRO | ANGOLA | 142 | 0 | 21 | 6 | 14 | 11 | 3.2775 | 28137106 | 0 | 1447424 | 29.88 | 56.71 | 1.83 |
| AFRO | GUINEA | 98 | 8 | 33 | 0 | 24 | 20 | 8.5074 | 32790430 | 0 | 0 | 4.58 | 16.79 | 10.69 |
| AFRO | BURKINA FASO | 74 | 0 | 2 | 0 | 19 | 16 | 8.2928 | 68198997 | 0 | 2001713 | 2.63 | 80.26 | 32.89 |
| EMRO | SYRIA | 74 | 0 | 0 | 1 | 8 | 7 | 5.4039 | 17338121 | 0.4355 | 1682328 | 1.35 | 0 | 17.57 |
| AFRO | COTE D IVOIRE | 70 | 0 | 157 | 0 | 29 | 14 | 9.0815 | 73596214 | 0 | 0 | 13.22 | 5.73 | 65.64 |
| AFRO | MALI | 70 | 0 | 10 | 0 | 22 | 20 | 9.552 | 71948877 | 0 | 0 | 1.25 | 23.75 | 27.5 |
| AFRO | SOUTH SUDAN | 66 | 2 | 6 | 2 | 17 | 16 | 13.2223 | 45796242 | 0 | 0 | 2.78 | 9.72 | 30.56 |
| AFRO | ETHIOPIA | 62 | 0 | 7 | 9 | 23 | 21 | 5.5689 | 91842585 | 0 | 0 | 27.54 | 37.68 | 59.42 |
| EMRO | SUDAN | 59 | 0 | 21 | 1 | 18 | 11 | 4.9022 | 44573788 | 0 | 0 | 0 | 0 | 32.5 |
| AFRO | NIGER | 57 | 3 | 28 | 0 | 39 | 29 | 14.8764 | 103631331 | 0 | 0 | 28.24 | 18.82 | 51.76 |
| AFRO | CAR | 44 | 0 | 22 | 11 | 30 | 24 | 11.6597 | 17633311 | 0 | 0 | 19.7 | 13.64 | 50 |
| EMRO | SOMALIA | 39 | 12 | 65 | 2 | 45 | 25 | 18.638 | 70216280 | 0.0258 | 360734 | 33.65 | 20.19 | 31.73 |
| EURO | TAJIKISTAN | 36 | 0 | 17 | 0 | 10 | 8 | 3.5912 | 6559164 | 0 | 0 | 5.66 | 0 | 5.66 |
| AFRO | GHANA | 33 | 0 | 56 | 0 | 20 | 11 | 4.955 | 30486419 | 1.00 | 3299345 | 21.35 | 38.2 | 49.44 |
| AFRO | BENIN | 30 | 0 | 19 | 0 | 26 | 22 | 8.8776 | 30801519 | 0 | 0 | 6.12 | 18.37 | 61.22 |
| AFRO | TOGO | 19 | 0 | 2 | 1 | 12 | 10 | 3.5533 | 8612715 | 0 | 0 | 19.05 | 42.86 | 57.14 |
| AFRO | SIERRA LEONE | 15 | 0 | 10 | 0 | 9 | 5 | 8.0302 | 15601133 | 0 | 0 | 0 | 0 | 12 |
| AFRO | SENEGAL | 14 | 0 | 17 | 0 | 15 | 7 | 3.2664 | 11000705 | 0 | 0 | 0 | 0 | 58.06 |
| AFRO | CAMEROON | 13 | 4 | 27 | 1 | 25 | 10 | 13.8149 | 97622355 | 0 | 0 | 12.5 | 37.5 | 40 |
| WPRO | PHILIPPINES | 13 | 0 | 22 | 0 | 8 | 5 | 1.0163 | 17081216 | 0 | 0 | 20 | 0 | 11.43 |

| | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AFRO | KENYA | 8 | 3 | 11 | 0 | 9 | 4 | 4.894 | 52144676 | 0 | 0 | 0 | 0 | 26.32 |
| AFRO | MOZAMBIQUE | 8 | 0 | 1 | 3 | 7 | 5 | 1.6904 | 12984279 | 0 | 0 | 0 | 0 | 55.56 |
| SEARO | INDONESIA | 7 | 0 | 1 | 1 | 6 | 5 | 1.341 | 60621278 | 0 | 0 | 0 | 25 | 0 |
| AFRO | CONGO | 4 | 0 | 6 | 0 | 10 | 4 | 9.092 | 12469165 | 0 | 0 | 0 | 0 | 60 |
| AFRO | ALGERIA | 3 | 0 | 45 | 0 | 23 | 3 | 0.7197 | 3873878 | 0 | 0 | 28.57 | 0 | 26.19 |
| AFRO | LIBERIA | 3 | 0 | 25 | 0 | 12 | 3 | 7.8167 | 9517131 | 0 | 0 | 0 | 0 | 7.14 |
| AFRO | ZAMBIA | 3 | 0 | 5 | 1 | 8 | 3 | 2.184 | 16653710 | 0 | 0 | 0 | 12.5 | 12.5 |
| AFRO | GUINEA-BISSAU | 3 | 0 | 0 | 0 | 3 | 2 | 1.8974 | 899211 | 0 | 0 | 0 | 0 | 100 |
| AFRO | BURUNDI | 2 | 0 | 20 | 0 | 7 | 2 | 3.00 | 11390533 | 0 | 814407 | 0 | 0 | 33.33 |
| AFRO | TANZANIA | 2 | 0 | 6 | 0 | 7 | 2 | 0.3595 | 5209764 | 0 | 0 | 0 | 0 | 0 |
| AFRO | ERITREA | 2 | 0 | 0 | 0 | 2 | 2 | 1.00 | 734217 | 0 | 0 | 0 | 0 | 0 |
| EURO | UKRAINE | 2 | 0 | 0 | 0 | 3 | 2 | 2.50 | 7967023 | 1 | 168672 | 0 | 0 | 0 |
| EURO | ISRAEL | 1 | 0 | 55 | 0 | 6 | 1 | 0 | 0 | 0 | 0 | | | |
| AMRO | USA | 1 | 0 | 30 | 0 | 5 | 1 | 0 | 0 | 0 | 0 | | | |
| AFRO | ZIMBABWE | 1 | 0 | 22 | 1 | 8 | 1 | 2.00 | 0 | 1 | 1588077 | 0 | 0 | 30.43 |
| AFRO | MAURITANIA | 1 | 0 | 10 | 0 | 9 | 1 | 4.7754 | 4547771 | 0 | 0 | 0 | 0 | 54.55 |
| WPRO | CHINA | 1 | 2 | 1 | 1 | 3 | 1 | 0 | 0 | 0.0204 | 3336286 | | | |
| EMRO | EGYPT | 0 | 0 | 31 | 2 | 16 | 0 | 6.403 | 123022047 | 0 | 0 | 22.58 | 6.45 | 19.35 |
| EMRO | DJIBOUTI | 0 | 0 | 16 | 0 | 8 | 0 | 6 | 1115343 | 0 | 0 | 12.5 | 0 | 62.5 |
| AFRO | BOTSWANA | 0 | 0 | 10 | 1 | 6 | 0 | 0 | 1103050 | 0 | 0 | 30 | 0 | 10 |
| AFRO | GAMBIA | 0 | 0 | 9 | 0 | 3 | 0 | 1.9557 | 935940 | 0 | 0 | 0 | 0 | 22.22 |
| WPRO | MALAYSIA | 0 | 0 | 8 | 1 | 5 | 0 | 0.2142 | 1866604 | 0 | 0 | 0 | 0 | 37.5 |
| EURO | UK | 0 | 0 | 6 | 1 | 4 | 0 | 0 | 0 | 0 | 0 | | | |
| EMRO | IRAN | 0 | 0 | 4 | 0 | 4 | 0 | 0.4322 | 3782013 | 0 | 0 | 0 | 0 | 25 |
| AMRO | CANADA | 0 | 0 | 2 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | | | |
| AFRO | UGANDA | 0 | 0 | 2 | 0 | 2 | 0 | 4.4639 | 43777021 | 0 | 0 | 0 | 0 | 50 |
| AFRO | MALAWI | 0 | 0 | 1 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | | | |

DRC = Democratic Republic of the Congo; Syria = Syrian Arab Republic; CAR = Central African Republic; Tanzania = United Republic of Tanzania; USA = United States of America; UK = United Kingdom.

| WHO Region | Country | Area targeted with tOPV in the 1 year pre switch | Total number of tOPV doses in the 1 year pre switch | cVDPV2 detections in the 1 year pre-switch | Number of response tOPV SIAs; interrupted pre switch (Y/N) | Silent cVDPV2 at time of switch | Estimated seeding date of silent cVDPV2 | Date of detection of silent cVDPV2 | Nucleotide change at first detection |
|---|---|---|---|---|---|---|---|---|---|
| AFRO | DRC | 3.538 | 74 416 491 | | | YES | 15-Nov | 2017-02-20 | 15 |
| AFRO | NIGERIA | 4.106 | 296 474 729 | YES | 3 (Y)* | YES | 15-Nov | 2016-10-28 | 12 |
| EMRO | AFGHANISTAN | 1.922 | 22 414 047 | | | | | | |
| EMRO | YEMEN | 2 | 12 784 400 | | | | | | |
| AFRO | CHAD | 5.054 | 24 486 665 | | | | | | |
| EMRO | PAKISTAN | 1.674 | 70 576 433 | | | YES | 15-Dec | 2016-10-20 | 10 |
| AFRO | ANGOLA | 2 | 17 116 322 | | | | | | |
| AFRO | GUINEA | 4.966 | 18 659 063 | YES | 7 (Y) | | | | |
| AFRO | BURKINA FASO | 3.5 | 28 665 345 | | | | | | |
| EMRO | SYRIA | 2.817 | 9 173 631 | | | YES | 15-May | 2017-03-03 | 22 |
| AFRO | COTE D IVOIRE | 2.7 | 26 082 701 | | | | | | |
| AFRO | MALI | 4.78 | 39 427 243 | | | | | | |
| AFRO | SOUTH SUDAN | 4.496 | 18 863 648 | | | | | | |
| AFRO | ETHIOPIA | 2.243 | 32 913 356 | | | | | | |
| EMRO | SUDAN | 1.23 | 9 738 115 | | | | | | |
| AFRO | NIGER | 3.897 | 26 639 870 | | | | | | |
| AFRO | CAR | 2.289 | 2 318 281 | | | | | | |
| EMRO | SOMALIA | 3.85 | 9 915 893 | | | YES | 14-Sep | 2017-10-22 | 38 |
| EURO | TAJIKISTAN | | | | | | | | |
| AFRO | GHANA | 0.498 | 3 459 248 | | | | | | |
| AFRO | BENIN | 4 | 12 593 018 | | | | | | |
| AFRO | TOGO | | | | | | | | |
| AFRO | SIERRA LEONE | 5 | 8 826 416 | | | | | | |
| AFRO | SENEGAL | 0.247 | 720 014 | | | | | | |
| AFRO | CAMEROON | 4.27 | 29 678 848 | | | | | | |
| WPRO | PHILIPPINES | | | | | YES | 14-Mar | 2019-06-18 | 64 |
| AFRO | KENYA | 2.514 | 27 135 056 | | | | | | |
| AFRO | MOZAMBIQUE | | | | | | | | |
| SEARO | INDONESIA | 1 | 27 823 160 | | | | | | |
| AFRO | CONGO | 5 | 6 314 673 | | | | | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| AFRO | ALGERIA | | | | | | | | |
| AFRO | LIBERIA | 5 | 5 814 128 | | | | | | |
| AFRO | ZAMBIA | | | | | | | | |
| AFRO | GUINEA-BISSAU | | | | | | | | |
| AFRO | BURUNDI | | | | | | | | |
| AFRO | TANZANIA | | | | | | | | |
| AFRO | ERITREA | 1 | 734 217 | | | | | | |
| EURO | UKRAINE | 2.5 | 7 967 023 | | | | | | |
| EURO | ISRAEL | | | | | | | | |
| AMRO | USA | | | | | | | | |
| AFRO | ZIMBABWE | | | | | | | | |
| AFRO | MAURITANIA | 2 | 1 700 131 | | | | | | |
| WPRO | CHINA | | | | | | | | |
| EMRO | EGYPT | 1.077 | 16 376 045 | | | | | | |
| EMRO | DJIBOUTI | 2 | 309 417 | | | | | | |
| AFRO | BOTSWANA | | | | | | | | |
| AFRO | GAMBIA | | | | | | | | |
| WPRO | MALAYSIA | | | | | | | | |
| EURO | UK | | | | | | | | |
| EMRO | IRAN | 0.033 | 281 875 | | | | | | |
| AMRO | CANADA | | | | | | | | |
| AFRO | UGANDA | 1.964 | 18 445 343 | | | | | | |
| AFRO | MALAWI | | | | | | | | |

| WHO Region | Country | Nucleotide change at first detection (median) | Nucleotide change at first detection (maximum) | Percent of detections with time to notification >3 months (AFP+ES) | Percent of detections with time to notification >3 months (AFP) | Percent of detections with time to notification >3 months (ES) | Non-polio AFP rate 2016 to 2023 (average) | Percent stool adequacy 2016 to 2023 (average) | Number of ES samples post switch | Percent of ES samples detecting any virus | Percent of emergences first detected by ES | Percent of new admin1s first detected by ES |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AFRO | DRC | 8 | 19 | 27.66 | 28.61 | 14.81 | 6.95 | 79.7 | 2064 | 35.37 | 4.55 | 0 |
| AFRO | NIGERIA | 10 | 16 | 15.02 | 12.03 | 18.21 | 12.74 | 96.4 | 14103 | 52.21 | 38.46 | 44.12 |
| EMRO | AFGHANISTAN | 7 | 8 | 2.49 | 4.05 | 0 | 22.86 | 93.4 | 3326 | 94.77 | 100 | 21.43 |
| EMRO | YEMEN | 13 | 15 | 71.03 | 66.67 | 88.14 | 6.89 | 86.3 | 122 | 65.57 | 50 | 15.79 |
| AFRO | CHAD | 7 | 7 | 22.27 | 19.72 | 44 | 10.39 | 85.1 | 858 | 33.33 | 100 | 5.26 |
| EMRO | PAKISTAN | 7 | 10 | 3.99 | 3.66 | 4.25 | 15.74 | 86.3 | 8261 | 95.59 | 64.29 | 42.86 |
| AFRO | ANGOLA | 9.5 | 14 | 9.15 | 7.75 | 14.29 | 2.8 | 89.9 | 881 | 36.66 | 0 | 0 |
| AFRO | GUINEA |  |  | 42.75 | 39.8 | 51.52 | 6.84 | 85.3 | 942 | 41.83 |  | 0 |
| AFRO | BURKINA FASO |  |  | 50 | 48.65 | 100 | 7.12 | 89.2 | 719 | 21.14 |  | 0 |
| EMRO | SYRIA | 22 | 22 | 21.62 | 21.62 |  | 4.81 | 85.5 | 1191 | 89.34 | 0 | 0 |
| AFRO | COTE D IVOIRE |  |  | 36.12 | 41.43 | 33.76 | 4.8 | 81.5 | 1130 | 83.19 |  | 8 |
| AFRO | MALI |  |  | 38.75 | 42.86 | 10 | 4.01 | 86.1 | 327 | 49.54 |  | 10 |
| AFRO | SOUTH SUDAN | 14.5 | 16 | 22.22 | 19.7 | 50 | 8.3 | 90.3 | 610 | 44.92 | 0 | 0 |
| AFRO | ETHIOPIA | 14 | 24 | 36.23 | 33.87 | 57.14 | 2.84 | 84.6 | 458 | 53.06 | 11.11 | 12.5 |
| EMRO | SUDAN | 6 | 6 | 13.75 | 11.86 | 19.05 | 3.12 | 95.2 | 516 | 64.53 | 100 | 6.67 |
| AFRO | NIGER |  |  | 38.82 | 38.6 | 39.29 | 5.37 | 73.3 | 2099 | 34.83 |  | 12.5 |
| AFRO | CAR | 10 | 16 | 0 | 0 | 0 | 6.97 | 74.3 | 1015 | 23.55 | 45.45 | 14.29 |
| EMRO | SOMALIA | 27 | 38 | 5.77 | 7.69 | 4.62 | 5.23 | 96.7 | 1110 | 38.56 | 50 | 14.29 |
| EURO | TAJIKISTAN |  |  | 16.98 | 19.44 | 11.76 |  |  | 28 | 64.29 |  | 0 |
| AFRO | GHANA |  |  | 0 | 0 | 0 | 5.02 | 87.5 | 1018 | 57.96 |  | 30.77 |
| AFRO | BENIN |  |  | 8.16 | 10 | 5.26 | 4.85 | 87.9 | 516 | 38.95 |  | 18.18 |
| AFRO | TOGO | 16 | 16 | 4.76 | 5.26 | 0 | 5.08 | 84.5 | 281 | 37.37 | 0 | 0 |
| AFRO | SIERRA LEONE |  |  | 24 | 40 | 0 | 3.31 | 86.2 | 514 | 47.86 |  | 0 |
| AFRO | SENEGAL |  |  | 16.13 | 7.14 | 23.53 | 2.88 | 82.8 | 940 | 57.77 |  | 14.29 |
| AFRO | CAMEROON | 6 | 6 | 15 | 15.38 | 14.81 | 6.81 | 82.7 | 3921 | 29.58 | 100 | 60 |
| WPRO | PHILIPPINES |  |  | 0 | 0 | 0 | 1.77 | 68 | 1704 | 37.27 |  | 37.5 |
| AFRO | KENYA |  |  | 0 | 0 | 0 | 2.87 | 88.4 | 1749 | 60.89 |  | 100 |
| AFRO | MOZAMBIQUE | 10 | 21 | 0 | 0 | 0 | 3.43 | 80.6 | 796 | 38.19 | 0 | 20 |
| SEARO | INDONESIA | 25 | 25 | 0 | 0 | 0 | 2.48 | 80.3 | 567 | 31.39 | 0 | 0 |
| AFRO | CONGO |  |  | 40 | 25 | 50 | 6.21 | 85.9 | 1003 | 15.85 |  | 50 |
| AFRO | ALGERIA |  |  | 0 | 0 | 0 | 3.26 | 83.8 | 604 | 87.09 |  | 25 |

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AFRO | LIBERIA | | | 25 | 33.33 | 24 | 3.2 | 91 | 202 | 50 | | 33.33 |
| AFRO | ZAMBIA | 9 | 9 | 12.5 | 0 | 20 | 3.52 | 79.7 | 1014 | 85.01 | 0 | 40 |
| AFRO | GUINEA-BISSAU | | | 100 | 100 | | 4.25 | 70.5 | 71 | 0 | | 0 |
| AFRO | BURUNDI | | | 16.67 | 0 | 10 | 2.12 | 89 | 166 | 69.88 | | 50 |
| AFRO | TANZANIA | | | 0 | 0 | 0 | 3.7 | 96.4 | 609 | 79.47 | | 66.67 |
| AFRO | ERITREA | | | 100 | 100 | | 5.58 | 95.3 | | | | 0 |
| EURO | UKRAINE | | | 0 | 0 | | | | | | | 0 |
| EURO | ISRAEL | | | 76.79 | 0 | 78.18 | | | 95 | 100 | | 100 |
| AMRO | USA | | | 96.77 | 0 | 100 | | | 31 | 96.77 | | 0 |
| AFRO | ZIMBABWE | 10 | 10 | 0 | 0 | 0 | 3.05 | 90.9 | 65 | 93.85 | 100 | 50 |
| AFRO | MAURITANIA | | | 18.18 | 0 | 20 | 3.48 | 79.3 | 233 | 39.91 | | 50 |
| WPRO | CHINA | 13 | 13 | 50 | 0 | 100 | 2 | 92.9 | 5 | 100 | 100 | 33.33 |
| EMRO | EGYPT | 9 | 11 | 0 | | 0 | 3.82 | 92.8 | 5095 | 88.2 | 100 | 100 |
| EMRO | DJIBOUTI | | | 25 | | 25 | 1.86 | 65.8 | 131 | 48.85 | | 100 |
| AFRO | BOTSWANA | 10 | 10 | 20 | | 20 | 2.77 | 82.5 | 201 | 65.67 | 100 | 100 |
| AFRO | GAMBIA | | | 0 | | 0 | 3.19 | 88.1 | 177 | 50.85 | | 100 |
| WPRO | MALAYSIA | 64 | 64 | 12.5 | | 12.5 | 2.17 | 79.6 | 1762 | 17.37 | 100 | 100 |
| EURO | UK | 6 | 6 | 50 | | 50 | | | 27 | 92.59 | 100 | 100 |
| EMRO | IRAN | | | 0 | | 0 | 4.16 | 96.9 | 381 | 96.59 | | 100 |
| AMRO | CANADA | | | 100 | | 100 | | | 2 | 100 | | 100 |
| AFRO | UGANDA | | | 0 | | 0 | 3.49 | 88.6 | 718 | 83.01 | | 100 |
| AFRO | MALAWI | | | 0 | | 0 | 2.81 | 79.7 | 709 | 57.26 | | 100 |

| WHO Region | Country | IPV introduction date (Year-month) | IPV1 coverage 2016 (%) (WUENIC) | IPV1 coverage 2022 (%) (WUENIC) | Change in IPV1 coverage (%) (WUENIC) | DTP3 coverage 2016 (%) (WUENIC) | DTP3 coverage 2022 (%) (WUENIC) | Change in DTP3 coverage (%) (WUENIC) | Percent of health facilities monitored for tOPV | Total number of tOPV vials found | Potential inadvertent tOPV use (Y/N) |
|---|---|---|---|---|---|---|---|---|---|---|---|
| AFRO | DRC | 15-Apr | 54 | 68 | 14 | 70 | 65 | -5 | 28 | 87 908 | |
| AFRO | NIGERIA | 15-Feb | 52 | 62 | 10 | 53 | 62 | 9 | 12 | 3 553 693 | |
| EMRO | AFGHANISTAN | 15-Sep | 66 | 71 | 5 | 66 | 69 | 3 | | | |
| EMRO | YEMEN | 14-Nov | 61 | 72 | 11 | 71 | 74 | 3 | | | |
| AFRO | CHAD | 15-Aug | 41 | 61 | 20 | 41 | 60 | 19 | 24 | | |
| EMRO | PAKISTAN | 15-Jul | 56 | 90 | 34 | 75 | 85 | 10 | | | Y |
| AFRO | ANGOLA | 18-Jan | | 38 | | 59 | 42 | -17 | | | |
| AFRO | GUINEA | 15-Nov | 47 | 47 | 0 | 47 | 47 | 0 | 47 | | |
| AFRO | BURKINA FASO | 18-Jan | | 91 | | 91 | 91 | 0 | 12 | 21 502 | |
| EMRO | SYRIA | Jan-00 | 58 | 65 | 7 | 42 | 46 | 4 | | | |
| AFRO | COTE D IVOIRE | 15-Jun | 48 | 77 | 29 | 87 | 76 | -11 | 19 | 20 339 | |
| AFRO | MALI | 16-Mar | 54 | 77 | 23 | 76 | 77 | 1 | 28 | 137 000 | |
| AFRO | SOUTH SUDAN | 15-Dec | 34 | 67 | 33 | 45 | 73 | 28 | 67 | 37 882 | |
| AFRO | ETHIOPIA | 15-Dec | | 65 | | 66 | 65 | -1 | 50 | 77 252 | |
| EMRO | SUDAN | 15-Feb | 64 | 94 | 30 | 93 | 84 | -9 | | | |
| AFRO | NIGER | 15-Jul | 74 | 84 | 10 | 80 | 84 | 4 | 12 | 1 843 053 | |
| AFRO | CAR | 15-Sep | 44 | 44 | 0 | 42 | 42 | 0 | 48 | | |
| EMRO | SOMALIA | 15-Oct | | 42 | | 42 | 42 | 0 | | | |
| EURO | TAJIKISTAN | | | 97 | | 96 | 97 | 1 | | | |
| AFRO | GHANA | 18-Jan | | 99 | | 93 | 99 | 6 | 12 | 31 084 | |
| AFRO | BENIN | 15-Aug | 62 | 76 | 14 | 76 | 76 | 0 | 100 | | |
| AFRO | TOGO | 18-Jan | | 82 | | 82 | 82 | 0 | 29 | | |
| AFRO | SIERRA LEONE | 18-Jan | | 91 | | 84 | 91 | 7 | 11 | 78 477 | |
| AFRO | SENEGAL | 15-Jan | 72 | 88 | 16 | 93 | 88 | -5 | 16 | | |
| AFRO | CAMEROON | 15-Jul | 70 | 67 | -3 | 75 | 68 | -7 | 100 | 266 528 | |
| WPRO | PHILIPPINES | 15-Jul | 37 | 71 | 34 | 84 | 72 | -12 | 14 | 38 188 | |
| AFRO | KENYA | 15-Dec | 70 | 89 | 19 | 89 | 90 | 1 | 18 | 366 264 | |
| AFRO | MOZAMBIQUE | 15-Nov | 72 | 70 | -2 | 88 | 61 | -27 | 38 | 265 027 | |
| SEARO | INDONESIA | 16-Jul | 2 | 77 | 75 | 84 | 85 | 1 | | | |
| AFRO | CONGO | 16-Apr | 33 | 74 | 41 | 71 | 78 | 7 | 16 | 37 094 | |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| AFRO | ALGERIA | 15-Dec | 94 | 89 | -5 | 91 | 77 | -14 | | | |
| AFRO | LIBERIA | 18-Jan | | 71 | | 73 | 78 | 5 | 53 | 376 360 | |
| AFRO | ZAMBIA | 18-Jan | | 73 | | 95 | 82 | -13 | 12 | 28 560 | |
| AFRO | GUINEA-BISSAU | 16-Jul | 30 | 75 | 45 | 85 | 74 | -11 | 52 | 9 638 | |
| AFRO | BURUNDI | 15-Nov | 60 | 91 | 31 | 94 | 91 | -3 | | | |
| AFRO | TANZANIA | 18-Jan | | 88 | | 92 | 88 | -4 | 20 | 1 516 | |
| AFRO | ERITREA | 18-Jan | | 95 | | 95 | 95 | 0 | 25 | 22 860 | |
| EURO | UKRAINE | | 75 | 73 | -2 | 19 | 73 | 54 | | | |
| EURO | ISRAEL | | | | | | | | | | |
| AMRO | USA | | | | | | | | | | |
| AFRO | ZIMBABWE | 18-Jan | | 90 | | 90 | 90 | 0 | 10 | 4 295 | |
| AFRO | MAURITANIA | 15-Nov | 65 | 70 | 5 | 74 | 76 | 2 | 100 | 50 744 | |
| WPRO | CHINA | 14-Dec | | 99 | 99 | 99 | 99 | 0 | 0 | | |
| EMRO | EGYPT | 18-Jan | | 97 | | 95 | 97 | 2 | | | |
| EMRO | DJIBOUTI | 16-Apr | 46 | 59 | 13 | 68 | 59 | -9 | | | |
| AFRO | BOTSWANA | 15-Nov | 49 | 86 | 37 | 95 | 86 | -9 | 29 | 14 682 | |
| AFRO | GAMBIA | 15-Apr | 95 | 78 | -17 | 95 | 79 | -16 | 28 | | |
| WPRO | MALAYSIA | Jan-00 | 98 | 99 | 1 | 98 | 97 | -1 | | | |
| EURO | UK | | | | | | | | | | |
| EMRO | IRAN | 15-Aug | | 99 | | 99 | 99 | 0 | | | |
| AMRO | CANADA | | | | | | | | | | |
| AFRO | UGANDA | 16-Apr | 44 | 90 | 46 | 93 | 89 | -4 | 75 | 41 012 | |
| AFRO | MALAWI | 18-Jan | | 84 | | 84 | 86 | 2 | 10 | 12 848 | |

# Annex C: Brief biographies and conflict of interest for the Switch Evaluation Team and Sounding Board Members

## Switch Evaluation Team:

Natalia A Molodecky, PhD[1]
Roland W Sutter, MD, MPH&TM[2]

[1]Consultant, Task Force for Global Health (TFGH) Atlanta, Georgia, USA
[2]Consultant, Tamayo Federal Solutions (TFS), Virginia Beach, Virginia, USA

### Natalia A Molodecky, PhD

Dr. Natalia Molodecky is an infectious disease epidemiologist with more than a decade of technical, policy and operational field experience in the polio programme, including at the World Health Organization (WHO) Headquarters (HQ) in Geneva, WHO Eastern Mediterranean Regional Office (EMRO), WHO Pakistan and Imperial College London. Dr Molodecky holds a PhD in infectious disease epidemiology from Imperial College London, focusing on modelling WPV1 and cVDPV2 transmission in Pakistan and Afghanistan to inform eradication and outbreak control strategies. Most recently, Dr Molodecky provided technical and strategic support to WHO EMRO on risk of emergence and spread of cVDPV2 (including in Yemen, Sudan and Egypt) and WPV1 persistence in Pakistan and Afghanistan. Previously, Dr Molodecky advised WHO Pakistan and Afghanistan country programmes on the risks of poliovirus transmission in the context of the COVID-19 pandemic to inform the respective National strategies. In Pakistan, Dr Molodecky served as Senior Advisor and Coordinator for Risk Assessment and Decision Support (RADS) at Pakistan's National Emergency Operations Centre (NEOC), providing technical, strategic and operation advice and support to the NEOC leadership. During the 2019 cVDPV2 outbreak in Pakistan and Afghanistan, Dr Molodecky was Coordinator for RADS and modelled cVDPV2 transmission to guide outbreak response strategies. Prior to her time in Pakistan, Dr Molodecky spent over a decade working with the Research and Product Development (RAP) team at WHO-HQ and the Vaccine Epidemiology Research Group (VERG) at Imperial College London. While at WHO-HQ, she worked extensively on clinical trials and seroprevalence surveys, and provided technical and strategic support on cVDPV2 outbreaks globally, through risk assessments of emergence and spread of cVDPV2. At Imperial College London, her work focused on building statistical and mathematical models to predict risk of WPV1 and cVDPV2 transmission and determine optimal vaccination strategies.

Dr Molodecky was part of Imperial College London's VERG leading up to the global withdrawal of OPV2, conducting type-2 immunity estimates and projections in advance of the switch. She also worked on advising the Pakistan programme on the number of tOPV SIAs that would be required leading up to the switch, taking into account their ongoing WPV1 transmission and requirement for frequent bOPV campaigns. Moreover, as a member of the GPEI's Cessation Risk Task Team (CRTT), her work fed into decision-making around the switch.

Roland W Sutter, MD, MPH&TM

Dr Sutter received his medical and public health education and training in both Switzerland (Zurich University) and the United States (Tulane University). From 1980 to 1987, he worked as Regional Medical Officer for the International Organization for Migration (IOM) coordinating IOM´s health and medical support for refugees in South-East Asia (primarily "boat people"). This experience directed him into a public health career. From 1987 to 2002, Dr Sutter worked for the Centers for Disease Control and Prevention (CDC) in Atlanta, focusing on the epidemiology of vaccine-preventable diseases, and especially on polio eradication. His last position at CDC was Chief, Polio Eradication Branch, the organizational home for the polio eradication activities at CDC. In 2002, Dr. Sutter was assigned to the World Health Organization (WHO) in Geneva, Switzerland. His last position at WHO was Coordinator of Research, Policy, and Containment (RPC) for the Global Polio Eradication Initiative (GPEI), focusing on research and product development affecting the pre- and post- polio eradication era. Dr Sutter led the development of several new polio vaccines, including mOPV1, mOPV2, mOPV3, bOPV, and promoted Sabin-IPV. He has published extensively on polio, diphtheria, and tetanus, including >200 publications in peer-reviewed journals, >30 book chapters, and numerous reports in CDC's Mortality Morbidity Weekly Report (MMWR) and WHO's Weekly Epidemiologic Record (WER).

Dr Sutter, as part of the Polio Eradication Department management team from 2002 to 2019, was responsible for policy development, including the withdrawal (i.e., Switch) of Sabin poliovirus type 2 from oral poliovirus vaccine (OPV2). In addition, Dr Sutter supervised the related WHO secretariats supporting the technical advisory groups (i.e., SAGE Polio Working Group, Polio Research Committee, Containment Advisory Group, and Sabin IPV Advisory Group).

Dr Sutter retired at the end of 2019 and has been consulting on COVID-19 and polio eradication-related issues.

## Sounding Board Members:

Walter A Orenstein, MD, DSc (Hon)
Dr John Sever
Dr Sunil Bahl
Prof J Peter Figueroa OJ, BSc, MBBS, DPH, PhD, FFPH
Professor Rose Gana Fomban Leke
Hiroyuki Shimizu, PhD
Dr Rana Muhammad Safdar

## Walter A. Orenstein, MD, DSc (Hon)

Walter A. Orenstein, MD, is currently a Professor Emeritus of Medicine, Epidemiology, Global Health, and Pediatrics at Emory University. From 2008 through 2011, Dr. Orenstein was Deputy Director for Immunization Programs at the Bill & Melinda Gates Foundation. His primary focus at the foundation had been on polio eradication, measles control, and improving routine immunization programs. Prior to 2004, Dr. Orenstein worked for 26 years in the Immunization Program at the Centers for Disease Control and Prevention. From 1988-2004, he was the Director of the United States Immunization Program. He is a former Assistant Surgeon General of the USPHS. Dr. Orenstein successfully developed, promoted, facilitated and expanded new vaccination strategies to enhance disease prevention.

Dr. Orenstein has authored and co-authored numerous books, journals and reviews. Dr. Orenstein co-edited Plotkin's Vaccines, 8th edition in 2024 – the leading textbook in the field. He is a past Chair of the WHO's Poliomyelitis Technical Consultative Group. He served as the Chair of the National Vaccine Advisory Committee (NVAC) from 2012 to 2016. He is also currently a member of the WHO's Strategic Advisory Group of Experts (SAGE) on Ebola Working Group. He is the former Chair of WHO's Immunization and Vaccines Related Implementation Research Advisory Committee (IVIR-AC). Between July 1, 2016 and June 30, 2018, Dr. Orenstein was the President of the National Foundation for Infectious Diseases (NFID). He is a Member of the National Academy of Medicine (2006-IOM); a Fellow of the American Association for the Advancement of Science (2018); a Fellow of the American Academy of Pediatrics (1980); as well as numerous other prestigious organizations.

Dr. Orenstein served as Chairman of the Technical Consultative Group on the Global Eradication of Poliomyelitis of the World Health Organization (WHO) from 1996 – 2004 and a member of the WHO SAGE (Strategic Advisory Group of Experts) Working Group on Polio Vaccine from September 2008 – 2020. He was Chairman of the WHO Immunization and Vaccines-related Implementation Research (IVIR-AC) from 2019 to 2024.

Dr. Orenstein's research focus has been on assessment of vaccine effectiveness in observational studies, methods to overcome vaccine hesitancy, ways to enhance uptake of recommended vaccines, and ways to facilitate polio eradication and sustain that eradication. In addition, Dr. Orenstein was a Principal Investigator for an NIH funded Center of Excellence for Influenza Research and Response (Emory CEIRR), with a focus on better understanding influenza pathogenesis and host response.

## Dr John Sever

Dr John Sever sadly passed away before the report was finalized. His legacy will live on in those committed to eradicating polio. A tribute to Dr John Sever is available at:

https://www.rotary.org/en/john-sever-champion-polio-eradication-dies

Excerpt from tribute below:

“John Sever, an infectious disease specialist and champion of Rotary’s polio eradication program, died on 25 April. He was 92.

A Rotary member since 1964, the Chicago, Illinois-born Sever worked for almost three decades as chief of the Infectious Diseases Branch at the National Institutes of Health. Later he served as a professor of pediatrics, obstetrics and gynecology, microbiology, immunology and tropical medicine at the George Washington University School of Medicine and Health Sciences. He published over 600 scientific papers in these fields.

On Sever's recommendation in 1979, Rotary would embark on its decades-long effort to eradicate polio globally, expanding what began as a vaccination campaign in the Philippines. Because of his expertise and advocacy, Sever served on the International PolioPlus Committee (IPPC) from its inception in 1994 and was a member and vice chair. His tireless efforts were instrumental in driving the global campaign to eradicate polio.”

## Dr Sunil Bahl

Dr Sunil Bahl is a public health specialist from India with more than 25 years’ experience in the development and implementation of policies and strategies aimed at improving immunization coverage and controlling/eliminating vaccine preventable diseases.

Dr Bahl recently retired as the Adviser to the Regional Director of the World Health Organization (WHO) South-East Asia Region. Prior to this he held various positions in the Immunization and Vaccine Development Unit of the Communicable Disease department of the South-East Asia Regional Office of WHO. While serving as the Coordinator/Team Leader for Immunization and Vaccine Development, Regional Adviser for Accelerated Disease Control, and Medical Officer for Polio Eradication in the WHO South-East Asia Regional Office, Dr Bahl provided strategic leadership and oversight to the immunization and vaccine-preventable disease programs, including the planning and operationalization of the polio endgame strategy in the Region.

Dr. Bahl's significant contributions to the realm of polio eradication span over two and a half decades. He was a part of the team that played a central role in leveraging data derived from polio surveillance, monitoring and research to conceptualize and implement evidence-based innovative policies and interventions in India. These initiatives proved instrumental in surmounting programmatic challenges in the country and culminated in the achievement and certification of polio elimination in the South-East Asia Region of WHO.

## Prof J Peter Figueroa OJ, BSc, MBBS, DPH, PhD, FFPH

Dr Peter Figueroa is Professor of Public Health, Epidemiology and HIV/AIDS at The University of the West Indies, Mona, Jamaica where he led the development of a Doctor of Public Health program. He was National Epidemiologist in Jamaica, led the National HIV/STI Program from its outset in 1986 until 2008 and served as Chief Medical Officer from 1997–2002. He was a member of WHO's Strategic Advisory Group of Experts on Immunization from 2009–2015 and is chair of PAHO's Technical Advisory Group on Immunization since 2014. He was Rapporteur, WHO Technical Consultation Group on the Global Eradication of Poliomyelitis 1996-2004, and a member of WHO SAGE Working Group on Polio from 2010-2020 including Chair 2014-2015 and Co-chair 2018-2020. He has published widely on communicable diseases and public health including 190 peer reviewed papers and 3 books. He has received many awards for his work including the Order of Jamaica in 2008 and in 2019 a WHO award for Leadership in Global Health.

## Professor Rose Gana Fomban Leke

Emeritus Professor Rose Gana Fomban Leke is Professor of Immunology and Parasitology, Fellow of the Cameroon Academy of Sciences CAS, The African Academy of Science AAS, and The World Academy of Science, TWAS. Until March 2013, Head of Department at the Faculty of Medicine and Biomedical Sciences, University of Yaounde 1, and Director of the Biotechnology Centre. Chair of the Board of Directors of the National Medical Research Institute, IMPM, Vice President of the Scientific Committee of Cameroon First Lady's Research Centre (CIRCB). Invited as the 2014 Aggrey-Fraser-Guggisberg Memorial Lecturer at the University of Ghana, and awarded the Doctor Honoris Causa (DSc).

In 2011, one of six women who received the African Union Kwame Nkrumah Scientific Award for Women, and received the 2012 award for Excellence in Science from The Cameroon Professional Society. Elected International Honorary Fellow of the American Society of Tropical Medicine and Hygiene ASTMH in 2015. She is a member of the Canada Gairdner Foundation Global Health Award Advisory Committee.

Elected one of nine women as HEROINE OF HEALTH 2018 and celebrated in Geneva on May 20th, 2018 in the presence of the Director General World Health Organization, the Regional Director WHO/AFRO, and the Cameroon Minister of Health. On November 23, 2018, she was crowned by the Cameroon Medical Council as QUEEN MOTHER OF THE CAMEROONIAN MEDICAL COMMUNITY FORBES AFRICA April/May 2021 Edition named her as ICON #24.
December 2022 at the Conference on Public Health in Africa in Kigali, Rwanda, she received a Lifetime achievement award: Achievement in Global Health Leadership, by the AU and Africa CDC February 2023, appointed Chair of the Independent Review Committee (IRC) of the GAVI Alliance Received October 14 in Berlin the 2023 Virchow Prize for Global Health

Executive Director of the Cameroon Coalition against malaria, and Chair of the Multilateral Initiative in Malaria (MIM) Secretariat. She was President of the Federation of African

Immunological Societies, a Council member of the International Union of Immunological Societies for two terms.

She has served and still serves as a consultant on many committees for the World Health Organization (WHO): the Malaria Policy Advisory Committee (MPAC), The Malaria Elimination Oversight Committee. She has been Chair of the African Regional Commission for the Certification of the Eradication of Poliomyelitis (ARCC) since 1999, and read the declaration on August 25 2020, to announce Africa free from the Wild Polio Virus. She is one of the six members of the Global Certification Commission (GCC), the member for the African Region.
She has been a member and Chair of the African Advisory Committee for Health Research (AACHR), a member of the Global ACHR, a Board member of the Global Forum for Health Research, and since 2013 serves on the WHO Emergency Committee for Polio eradication.
She has served as Vice-Chair of first Technical Evaluation Reference group (TERG) of the Global Fund, and awarded a Plaque of Honour. She was Chair of the DSMB Azithromycin-chloroquine clinical trial. Also was a member of the Scientific Advisory Group (SAG) for Ebola vaccine trials in Guinea.

Her research interest: Immunology of parasitic infections, particularly Malaria. With a keen interest in Global Health and Health Systems Strengthening. She has been very effective in training the next generation of scientists, MDs, MSc, PhD, national and international, and continues to do so through the HIGHER WOMEN CONSORTIUM CAMEROON, a holistic mentoring program, one of her very successful initiatives. This consortium has had much impact in mentorship of young scientists and researchers and has reached secondary and primary schools.

Hiroyuki Shimizu, PhD

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Dr. Hiroyuki Shimizu is the senior researcher of the National Institute of Infectious Diseases (NIID), Tokyo, Japan. I had been serving as the Chief of the Laboratory of Enteroviruses of the Department of Virology II, NIID, is functioning as a WHO WPRO Global Specialized Polio Laboratory for global polio eradication. The laboratory is also responsible for virus isolation/identification and development of new diagnosis methods of polio- and enteroviruses as a WHO Collaborating Center. The major focus of my research has been laboratory diagnosis, molecular epidemiology, molecular pathogenesis of poliomyelitis and enterovirus infections, and genetic and phenotypic characterization of vaccine-derived polioviruses to establish future polio immunization strategies. I am currently serving as the Committee Member of the "National Committee for the Certification of Poliomyelitis Eradication of Japan", organized by the Ministry of Health, Labour and Welfare, Japan, and conducting poliovirus containment activities for poliovirus-essential facilities as a national audit team member.

## Dr. Rana Muhammad Safdar

Dr. Rana Muhammad Safdar is currently serving as the Lead Strategic Advisor to US CDC in Pakistan. In an illustrious public health career spanning over a period of 3 decades, he remained actively engaged in strategizing, planning and implementing disease prevention and control interventions at different levels ranging from a Medical Officer in Basic Health Unit to the top national assignment of the Director General Health to the Government of Pakistan.

As a Field Epidemiologist with specializations in emerging infectious disease epidemiology and Health Metrics & Evaluation, Dr. Rana had the opportunity to lead all national priority disease control programs in the country including EPI, Polio Eradication, Prevention & Control of Viral Hepatitis as well as HIV/AIDS, TB, and Malaria. With his principal assignment of the Chief of the Field Epidemiology & Disease Surveillance Division at NIH Pakistan, he also served as the National Focal Point for IHR. His national contributions include conceptualizing and executing a national Network of Emergency Operations Centres (EOCs) for Polio eradication. In the same capacity, he had successfully contained the aggressive VDPV2 epidemic that struck Pakistan in 2019.

When the pandemic struck Pakistan, as the Coordinator of the National Emergency Operations Centre and National Manager, Expanded Programme on Immunization, Dr. Rana led the process of development and implementation of national COVID-19 surveillance and response system encompassing issuance of daily situation reports and conducting risk assessments that formed basis of all critical decision making at the National Command Operations Center, National Immunization Management System, National Health Helpline 1122 etc. In parallel, he also led negotiations with GAVI enabling Pakistan to benefit from donation of almost 110 million doses of COVID-19 vaccine from COVAX and also represented Pakistan in World Health Assembly during 2021 and 2022. Sharing his varied experience, Dr. Rana continues to benefit global health as part of the Committee constituted by WHO to review the amendments in IHR-2005. Moreover, he is also currently serving as member of the WHO's Strategic & Technical Advisory Group on Infectious Hazards of Pandemic Potential (STAG-IH).