Global NITAG Network Meeting

Revised GPEI Strategy Timelines and Planning for bOPV Cessation

Chair: Mario Melgar

Presenters: Zubair Wadood (POL), Rocio Lopez Cavestany (POL), Alejandro Ramirez Gonzalez (IVB)

11 December 2024

Agenda Global NITAG Network Meeting

1. Welcome and Opening Remarks

Mario Melgar

2. Update on Polio Epidemiology, Immunization Coverage, and Surveillance

Rocio Lopez Cavestany

Alejandro Ramirez Gonzalez

3. Revised GPEI Strategy Timelines

Zubair Wadood

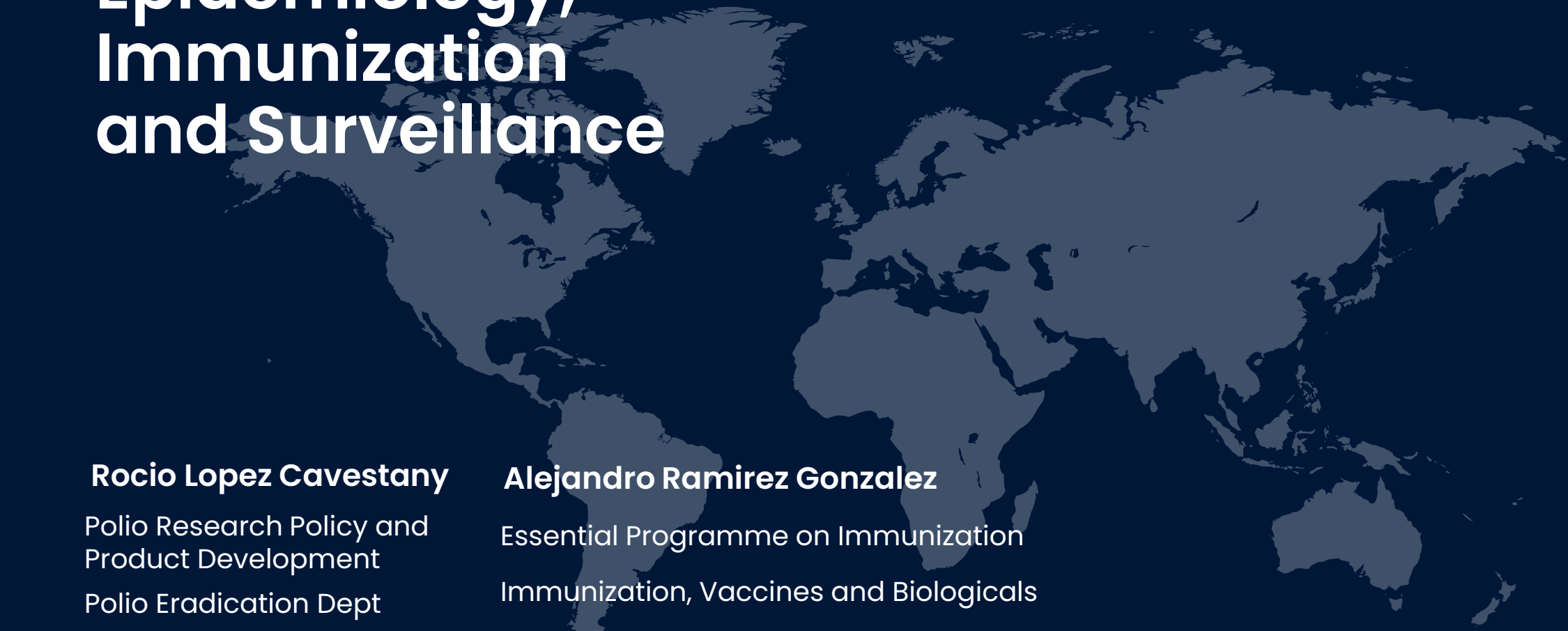
4. bOPV Cessation Policy Framework

Rocio Lopez Cavestany

5. Wrap up and closing

Mario Melgar

Status of Polio Epidemiology, Immunization and Surveillance



Rocio Lopez Cavestany

Polio Research Policy and Product Development

Polio Eradication Dept

WHO, HQ, Geneva

Alejandro Ramirez Gonzalez

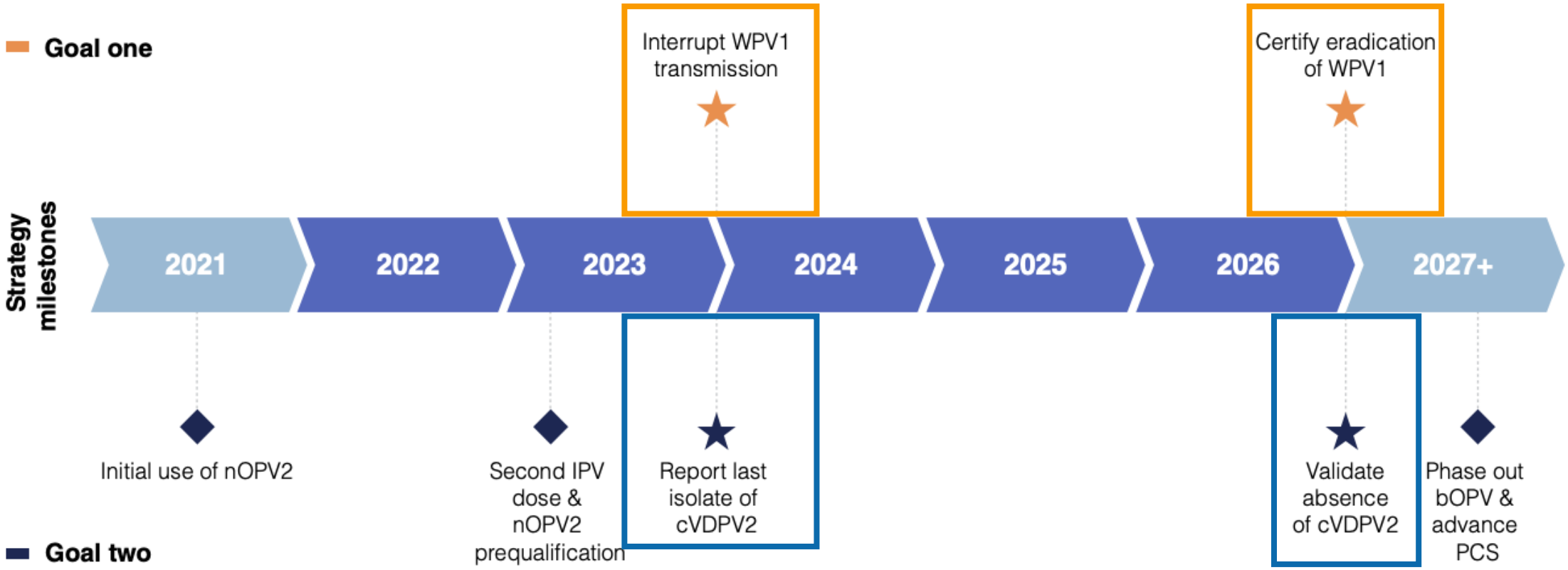
Essential Programme on Immunization

Immunization, Vaccines and Biologicals

WHO, HQ, Geneva

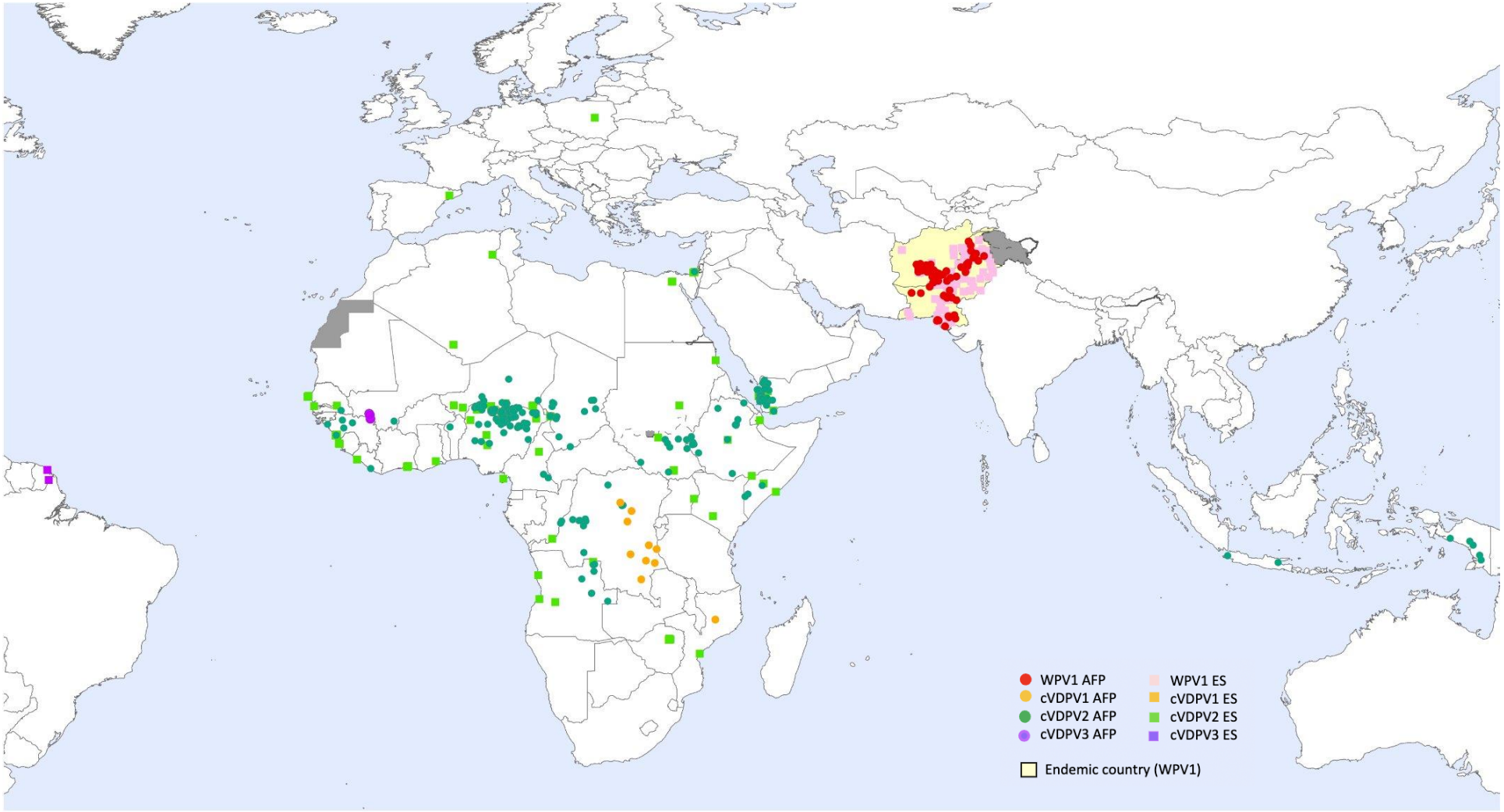
Polio Eradication Strategy 2022-2026

*Off-Track for these two goals, strategy extension discussed in later slides



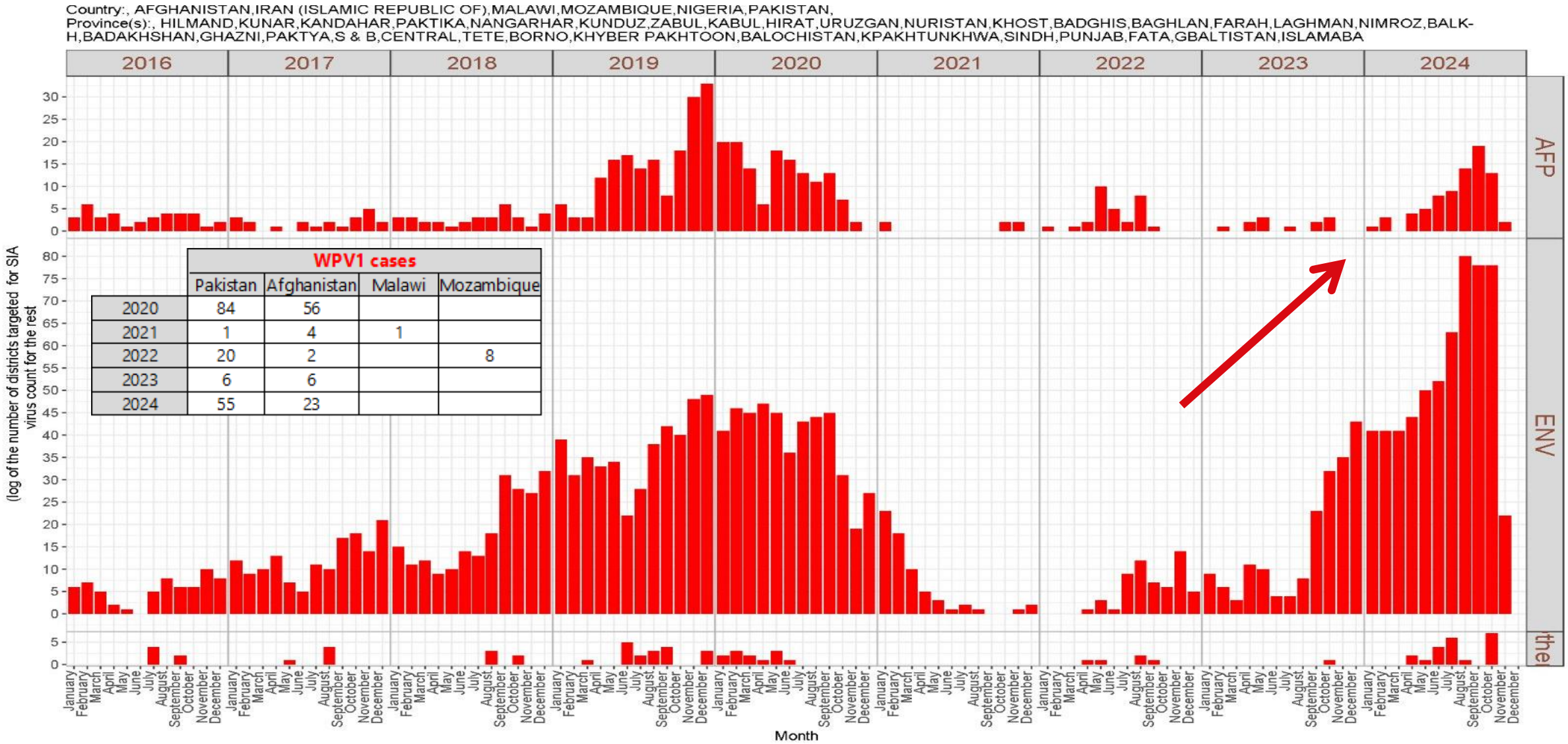
PCS = Post-Certification Strategy.
Source: WHO.

Progress Against Goals 1 and 2
Global WPV1 and cVDPV Isolates in 2024
(As of 26/11/24)



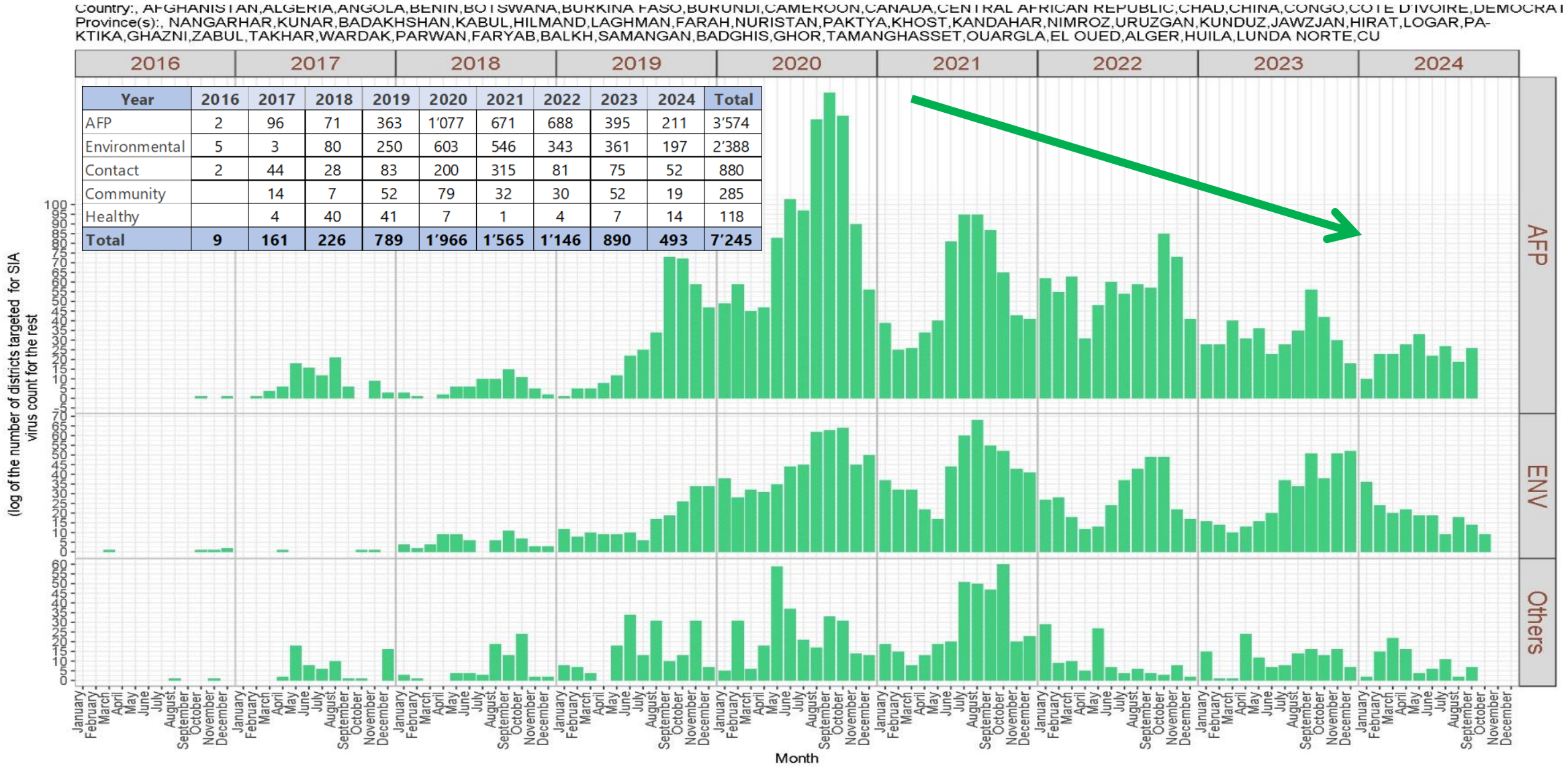
onset/collection date: 01 Jan – 26 Nov 2024, Data in WHO HQ as of 19/11/24

WPV1 Epi-curves January 2016 - November 2024
(As of 26/11/24)



WPV1 cases				
	Pakistan	Afghanistan	Malawi	Mozambique
2020	84	56		
2021	1	4	1	
2022	20	2		8
2023	6	6		
2024	55	23		

cVDPV2 Epi-curves January 2016 - November 2024
(As of 26/11/24)



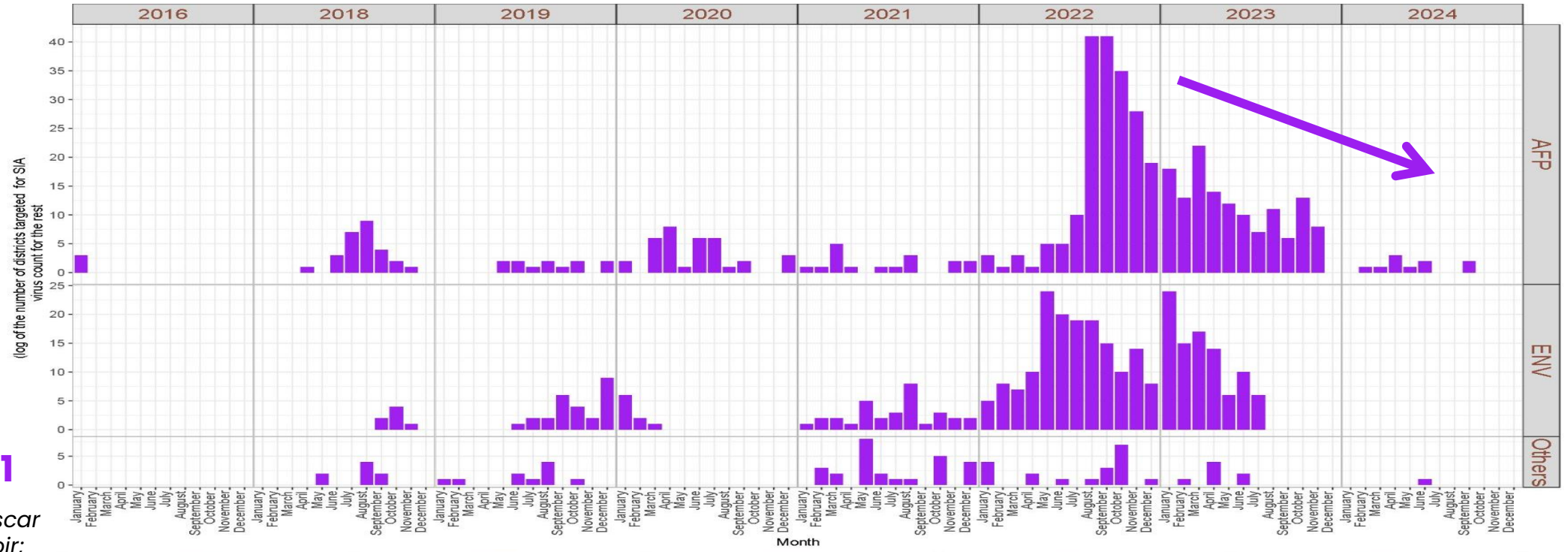
Year	2016	2017	2018	2019	2020	2021	2022	2023	2024	Total
AFP	2	96	71	363	1'077	671	688	395	211	3'574
Environmental	5	3	80	250	603	546	343	361	197	2'388
Contact	2	44	28	83	200	315	81	75	52	880
Community		14	7	52	79	32	30	52	19	285
Healthy		4	40	41	7	1	4	7	14	118
Total	**9**	**161**	**226**	**789**	**1'966**	**1'565**	**1'146**	**890**	**493**	**7'245**

cVDPV1 and cVDPV3 Epi-Curves

Data in WHO HQ
as of 26/11/24

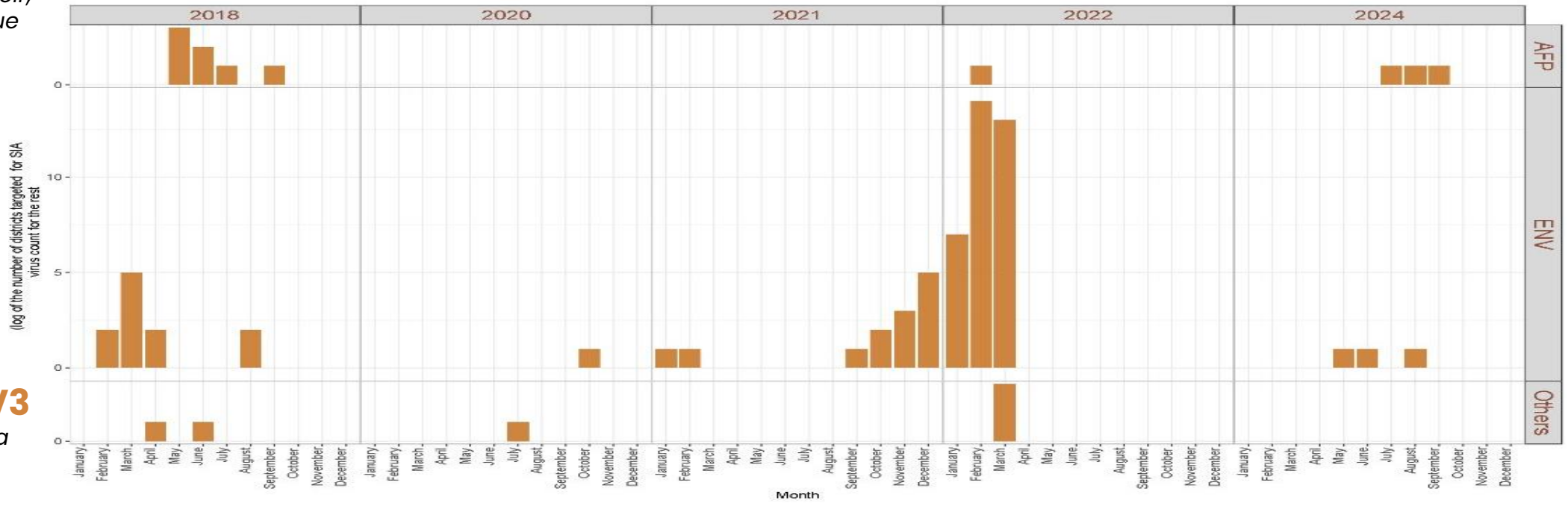
cVPDV1

Note: no cVPDV1 in Madagascar in 2024, core historic reservoir; cases in DRC in Mozambique



cVPDV3

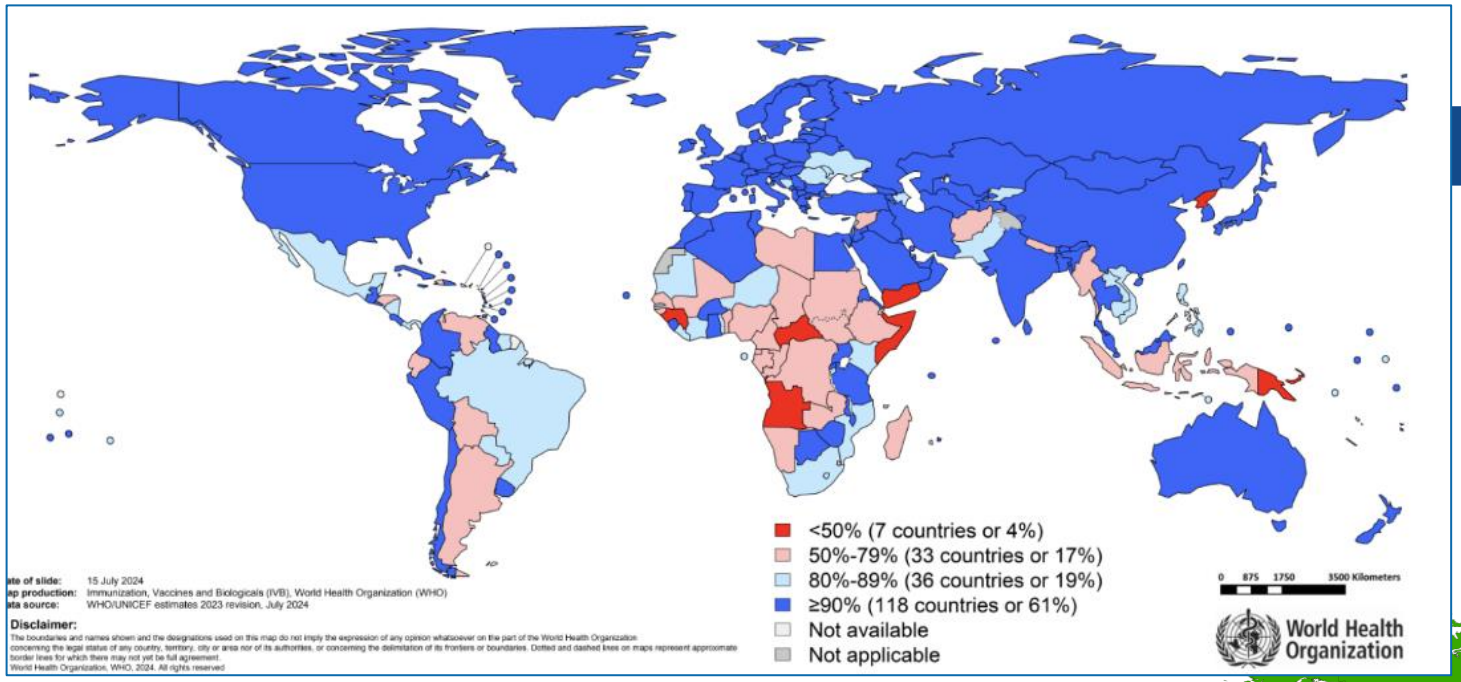
Note: recent cases in Guinea and Guyana positive ES



General characteristics of population/geographies of poliovirus outbreaks

- Persistently **low RI coverage**—higher proportion of under or unimmunized children—"Zero Dose communities"
- **Insecurity, conflicts and difficult to access population**
  - IDPs, Reach of the vaccination network to underserved high-risk mobile populations
  - Political instability
  - Multiple, competing, humanitarian emergencies
- **Operational and quality gaps**—persistently missed children

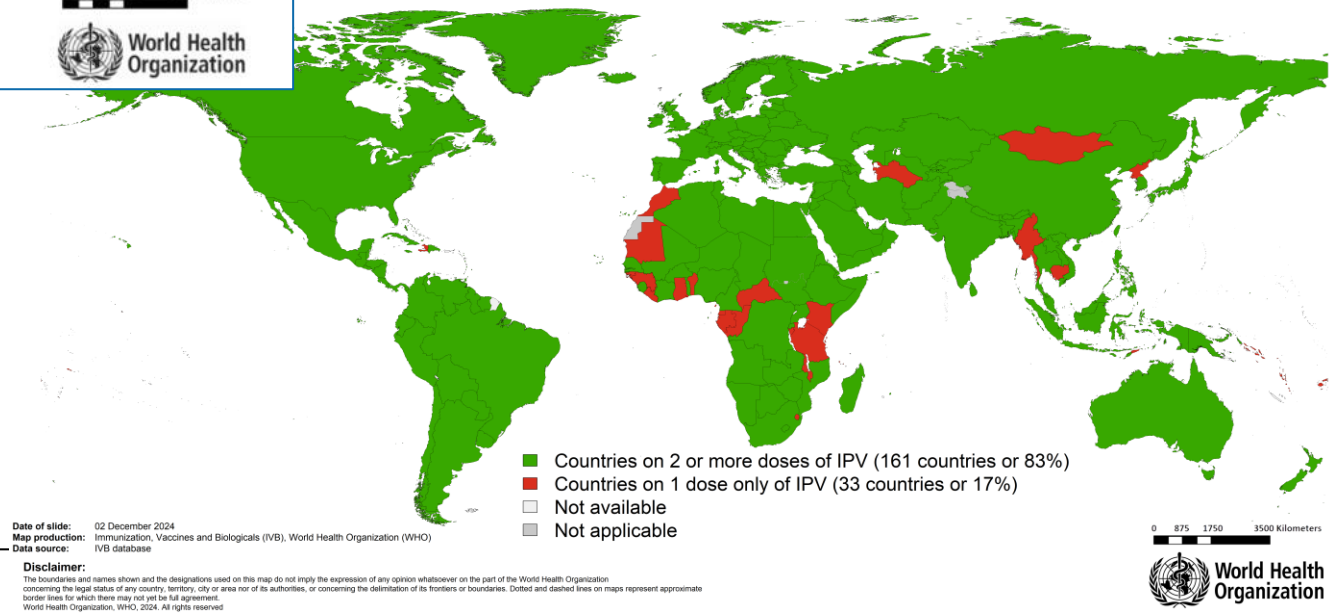
IPV in Routine Immunization



Immunization coverage with IPV1 in infants, 2023

Geographic distribution of IPV in immunization schedules, November 2024

- **33 countries** have yet to introduce a second dose of IPV – per SAGE recommendation and trigger for eventual bOPV cessation

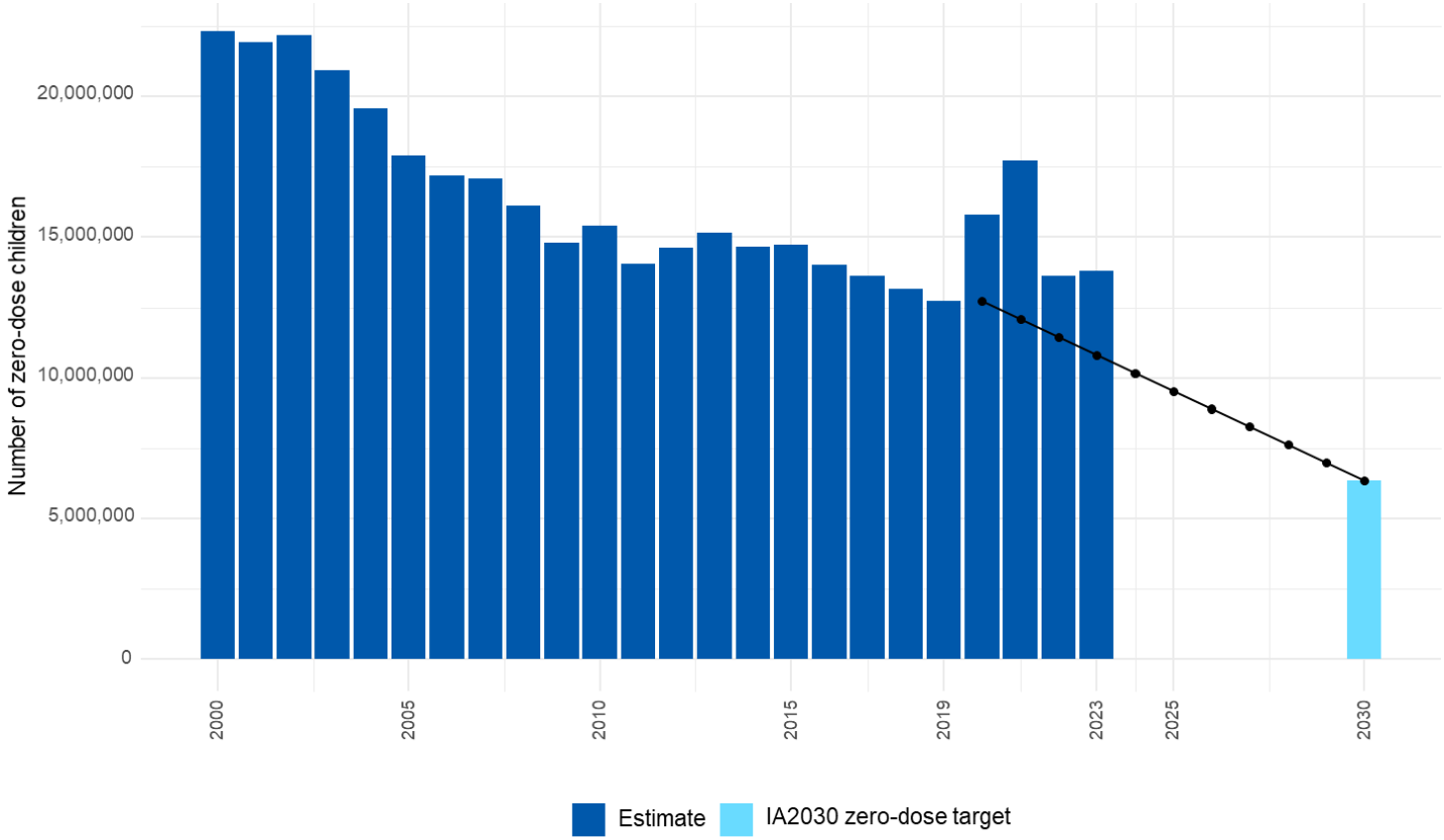


IPV coverage remains too low in countries with cVDPV circulation

Among OPV-using countries, countries with no cVDPV circulation show higher routine coverage with IPV1 and IPV2. In both groups of countries, IPV1 coverage is very similar to DTP3 coverage, which is generally administered during the same contact.

This is not an issue specific to IPV, but rather reflective of system strength in those countries, as shown by similar DTP3 coverage.

The global estimate of Zero-Dose children is off-track to achieve IA2030 goals



Source: WHO/UNICEF Estimates of National Immunization Coverage, 2023 revision.

Note: The Immunization Agenda 2030 (IA2030) calls on all countries to reduce the number of zero dose children in 2019 by half by 2030. Dark blue bars are the estimated number of zero-dose children in 2000-2030, light blue bar is the target number of zero-dose children by 2030. Line shows trajectory the country needs to be on, and points show annual goals to meet the target by 2030,assuming a linear decline.

- A key goal of the Immunization Agenda 2030 (IA2030) is to reduce the number of zero-dose children by half by 2030.
- Actual achievements show that the 2022 estimate (14.3 million) of zero-dose children is still slightly above 2019 (12.9 million) levels. I.e. global coverage has not fully recovered from pandemic disruptions and is not yet on track to achieve that target.

Since the Polio Oversight Board approved the Integration approach in Oct. 2023, Integration efforts have focused on 4 key areas

Campaign-based

Coordinated health system strengthening activities

Primary Integration Activities

1 Plusses

Products (i.e., hand soap, clean water) provided to communities as part of polio campaigns to address a basic need, build trust, and incentivize vaccination

2 Co-Delivery & Multi-Antigen Campaigns

Part of planned campaigns where OPV is added to other antigens or vice versa (i.e., measles, typhoid, Vitamin A deficiency, deworming)

3 Routine Immunization Strengthening

Coordination with Gavi & EPI on zero dose agenda, SBC activities, global efforts (i.e., Big Catch Up (BCU))

4 Integrated Service Delivery

Collaboration with civil society organizations and humanitarian aid groups to provide polio vaccines as part of primary healthcare services to otherwise inaccessible communities

Differentiated Approach

Primary focus in outbreak countries for Q1-Q2 2024, given lack of visibility over campaign schedules

Increased focus as campaign visibility improves

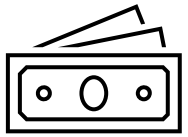
Key focus in CG, Endemics & BCU countries

Key focus in CG & Endemics

Hexavalent vaccine

- Whole cell pertussis hexavalent prequalified by WHO in March 2024 and available for Gavi support since December 2023
- This vaccine is expected to:
  - **deliver protection against the six diseases more efficiently and cost-effectively**
  - **reduce programmatic challenges associated with multiple injections,** among other anticipated programmatic benefits
- One product currently prequalified; additional products are expected to be prequalified in 2026 and 2027
- Supply availability will be gradual and driven by supply in the early years of the hexavalent program
- Demand snapshot
  - Approved: Mauritania, Indonesia, Madagascar, Burundi, Senegal, NW Syria
  - Interest to apply: Mozambique, Uzbekistan, Moldova, Zimbabwe, Uganda, Pakistan, Malawi
- Interest in non-Gavi countries
  - Turkmenistan (MIC) plans introduction in January 2025

Main considerations for switching to hexavalent



Feasibility and financial implications (including savings)

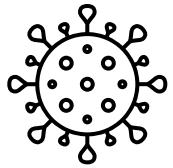
Vaccine costs for the hexavalent 4-dose series may be higher than for the current 3-dose pentavalent + 2-dose IPV , but important to consider programmatic benefits
- fewer injections
- reduced workload
- cost savings from delivery & dry supplies

10-dose presentation

Hexavalent vaccine is currently only available to Gavi-eligible countries in a 10-dose presentation. Countries using the 1-dose presentation of pentavalent vaccine should consider the implications of using 10-dose vials (cold chain, open-vial wastage)

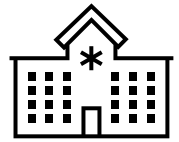
Planning and implementation logistics

Countries will need to switch from pentavalent to hexavalent; phase out of standalone IPV; and introduce a hexavalent booster during the 2YL contact (for most countries)



Introduction of a second dose of IPV (IPV2)

WHO recommends that countries introduce IPV2; those that have not done so yet are encouraged to introduce hexavalent or IPV2 as a matter of urgency



Programmatic shifts to a second year of life (2YL) contact

Tailored interventions, such as training and communications, will be necessary to ensure uptake and high coverage of the fourth hexavalent dose

Hexavalent resources

Hexavalent vaccine programme information

Summary of programme information

Gavi support guidelines

General Gavi guidelines

Gavi Programme Funding Guidelines

Gavi Vaccine Funding Guidelines


Vaccine Funding Guidelines

37

3.4 Hexavalent vaccine

→ SWITCH TO HEXAVALENT (FROM PENTAVALENT AND INACTIVATED POLIO VACCINE) IN ROUTINE SCHEDULE

Vaccine-specific mandatory application attachments

☐ Hexavalent switch form

Access full library of Gavi guidelines

Detailed product profiles

Programme overview

Countries eligible for Gavi support can apply to switch to whole-cell pertussis (wP) hexavalent (hexavalent) vaccine. This is a six-in-one vaccine that combines the pentavalent vaccine (diphtheria, tetanus, whole-cell pertussis, hepatitis B and haemophilus influenzae type b) with the inactivated polio vaccine (IPV).

The hexavalent vaccine is expected to help countries deliver protection against all six diseases more efficiently and cost-effectively and reduce programme barriers due to multiple injections – among other anticipated programmatic benefits.

Countries can continue using pentavalent and IPV or choose to switch to hexavalent. Gavi partners can assist countries to assess the financial, logistical and programmatic implications of a switch to hexavalent to determine which option is most suitable for their context.

Countries will need to continue using bivalent oral polio vaccine (bOPV) in their routine immunisation until global cessation. Hexavalent contains IPV but not bOPV, and both are needed.

Hexavalent switch form

Available in English and French


Gavi

Vaccine Switch Request Form

version as of April 2023

(For HPV and MCV switches, please use HPV- and MCV-specific switch request forms)

Please use this form to send Gavi the necessary information to review your country's request to switch to a different vaccine product, presentation, schedule or use. Fill in the light blue fields. For definitions and requirements, please consult the Gavi guidelines for vaccine optimisation.

Gavi Optimisation and Switch Guidelir

For multiple switch requests submitted in parallel, please use separate forms, one for each switch request. Please use the exact same vaccine product and presentations description as provided in Gavi's Detailed Product Profiles list.

Country name	Switch from	Switch to	Planned switch date	Switch grant requested
.....	.....	.....	(DD/MM/YYY)	Yes ☐ No ☐

1. Checklist for submission

To process this request, Gavi requires your country to fill out the following sections and provide the necessary documents:

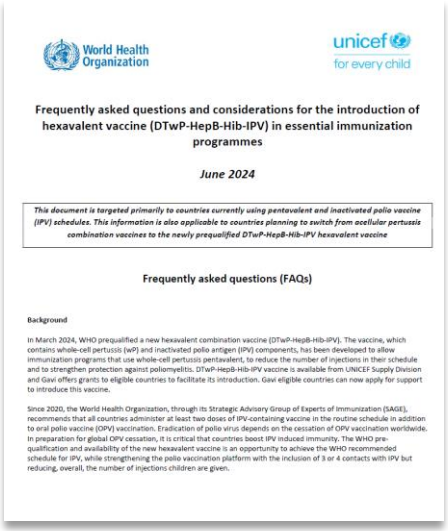
1. **Signature of Ministry of Health**[1] (necessary for all requests, see at the end of this form) ☐
2. **Switch impact assessment** (necessary for all requests, see next page on this form) ☐
3. If required[2]: supportive **NITAG recommendation** or **ICC endorsement** (minutes of a meeting endorsing the switch decision) ☐
4. If this switch increases the country's co-financing financial costs:[3] **signature of Ministry of Finance** ☐
5. If a switch grant (SG) is requested: **Budget**[4] in the Gavi template ☐

Note: Requests will not be reviewed unless complete.

Policy/Technical documents

Polio Vaccines: WHO Position Paper -June 2022

FAQs for the introduction of hexavalent vaccine (DTwP-HepB-Hib-IPV) in essential immunization programmes (available in English, French and Portuguese)


World Health Organization

unicef for every child

Frequently asked questions and considerations for the introduction of hexavalent vaccine (DTwP-HepB-Hib-IPV) in essential immunization programmes

June 2024

This document is targeted primarily to countries currently using pentavalent and inactivated polio vaccine (IPV) schedules. This information is also applicable to countries planning to switch from acellular pertussis combination vaccines to the newly prequalified DTwP-HepB-Hib-IPV hexavalent vaccine

Frequently asked questions (FAQs)

Background

In March 2024, WHO prequalified a new hexavalent combination vaccine (DTwP-HepB-Hib-IPV). The vaccine, which contains whole-cell pertussis (wP) and inactivated polio antigen (IPV) components, has been developed to allow immunization programs that use whole-cell pertussis pentavalent, to reduce the number of injections in their schedule and to strengthen protection against poliomyelitis. DTwP-HepB-Hib-IPV vaccine is available from UNICEF Supply Division and Gavi offers grants to eligible countries to facilitate its introduction. Gavi eligible countries can now apply for support to introduce this vaccine.

Since 2020, the World Health Organization, through its Strategic Advisory Group of Experts of Immunization (SAGE), recommends that all countries administer at least two doses of IPV-containing vaccine in the routine schedule in addition to oral polio vaccine (OPV) vaccination. Eradication of polio virus depends on the cessation of OPV vaccination worldwide. In preparation for global OPV cessation, it is critical that countries boost IPV induced immunity. The WHO pre-qualification and availability of the new hexavalent vaccine is an opportunity to achieve the WHO recommended schedule for IPV, while strengthening the polio vaccination platform with the inclusion of 3 or 4 contacts with IPV but reducing, overall, the number of injections children are given.

Revised Global Polio Eradication Initiative Strategy Timeline

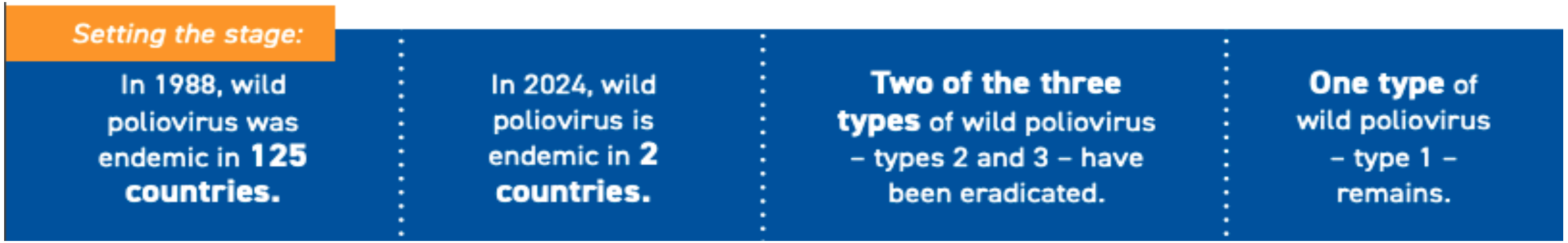
Zubair Wadood

Surveillance, Lab., Certification

Polio Eradication Dept

WHO, HQ, Geneva

Goal 1: Interrupt and Eradicate WPV1 in the final endemic countries



In recent years, the GPEI has struggled to operate amid a perfect storm of conditions in Afghanistan and Pakistan. Some of these challenges are within the programme's control and will be addressed directly to improve performance (i.e. programmatic), and others are outside of the programme's control but must be accounted for in activities (i.e. contextual).

Poliovirus Epidemiological Overview – Endemics: 2023-2024

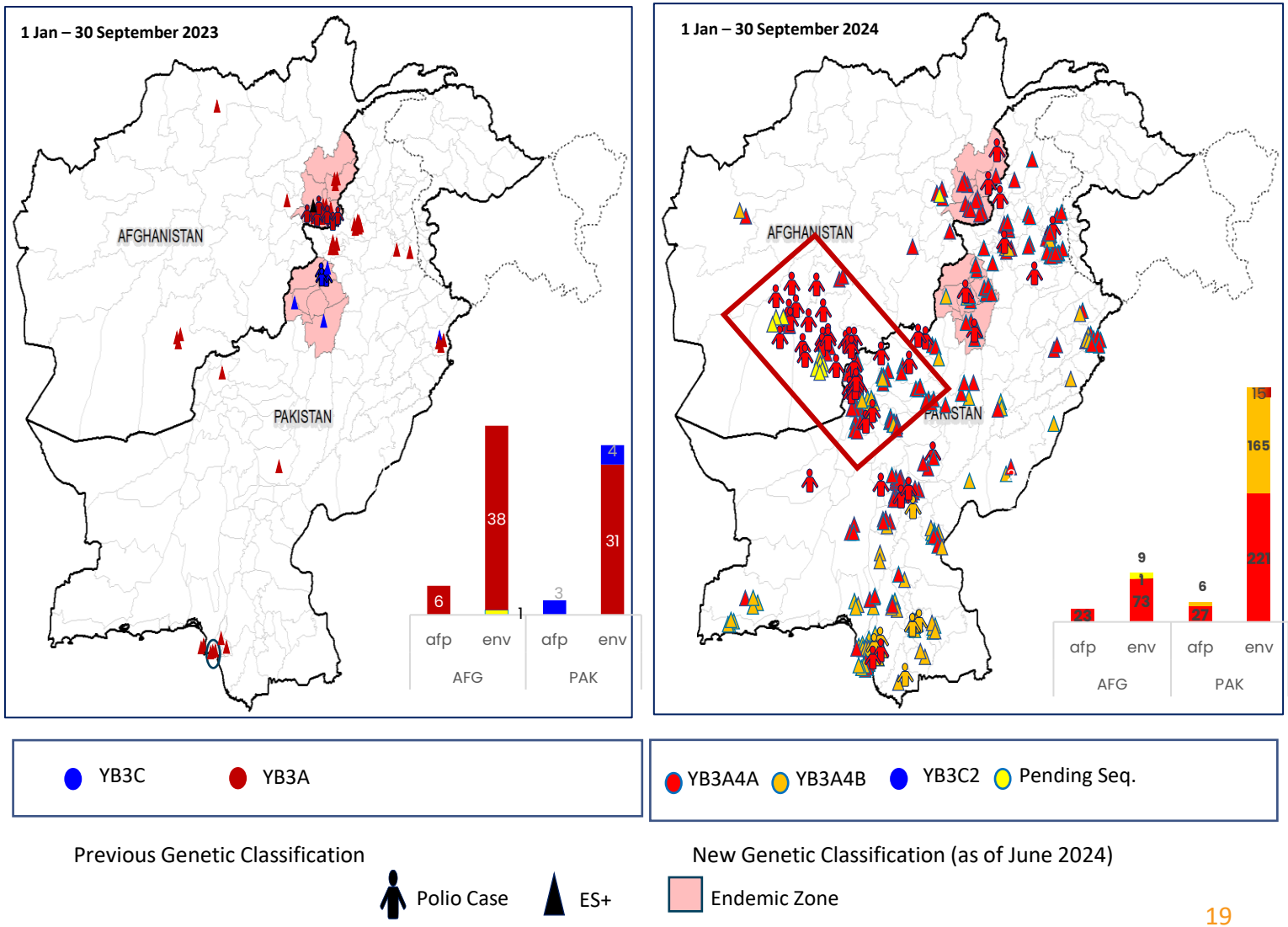
Risk of re-established transmission in the historic reservoirs
(Quetta-Kandahar Block, Peshawar-Nangarhar and Karachi)

The genetic diversity of detected WPV1 isolates is reducing.

Pakistan-Afghanistan—main challenges

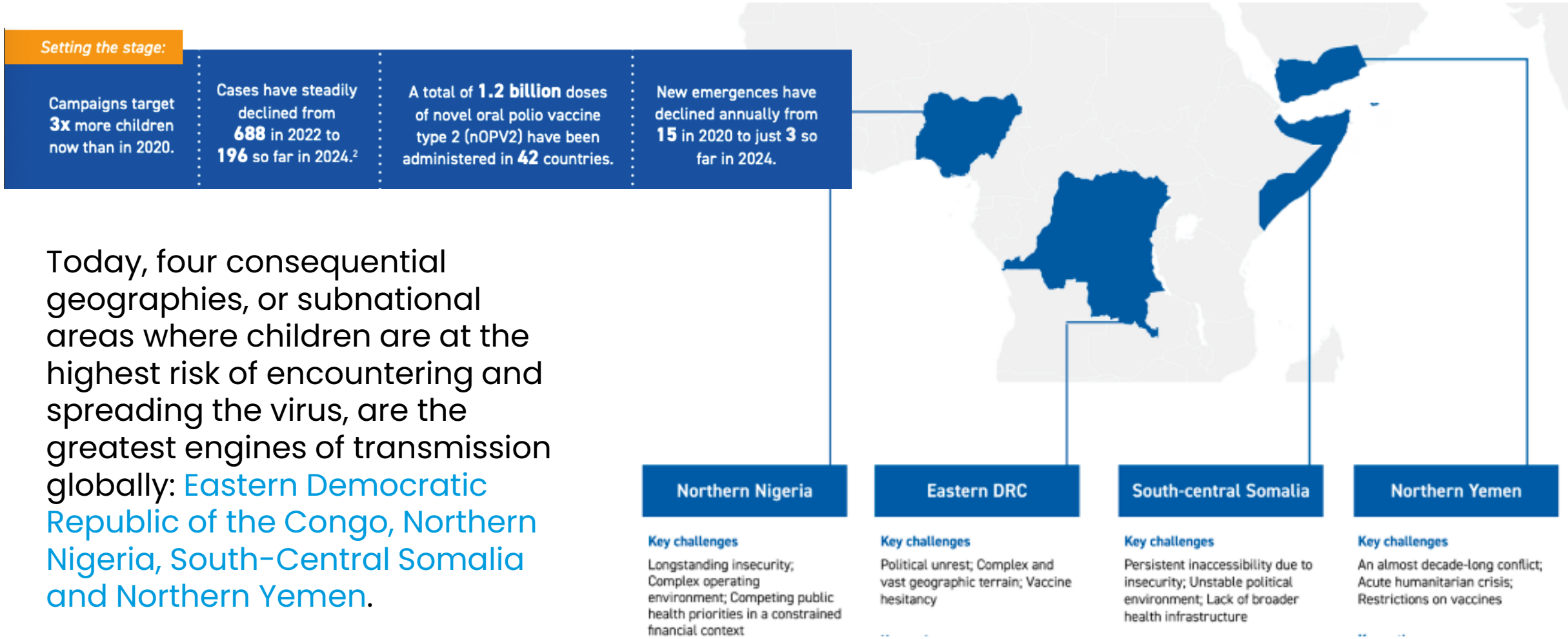
- Increasing insecurity, attacks on frontline workers and community boycotts in parts of KP and Balochistan provinces of Pakistan

- Southern region of Afghanistan—house-house campaign not allowed for almost 5 years (more than one million reported missed), September campaign is postponed



Goal 2: Stop and prevent type 2 variant poliovirus outbreaks

Fig. 3: Consequential geography snapshots



Today, four consequential geographies, or subnational areas where children are at the highest risk of encountering and spreading the virus, are the greatest engines of transmission globally: Eastern Democratic Republic of the Congo, Northern Nigeria, South-Central Somalia and Northern Yemen.

Poliovirus Epidemiological Overview – Africa: 2023-2024

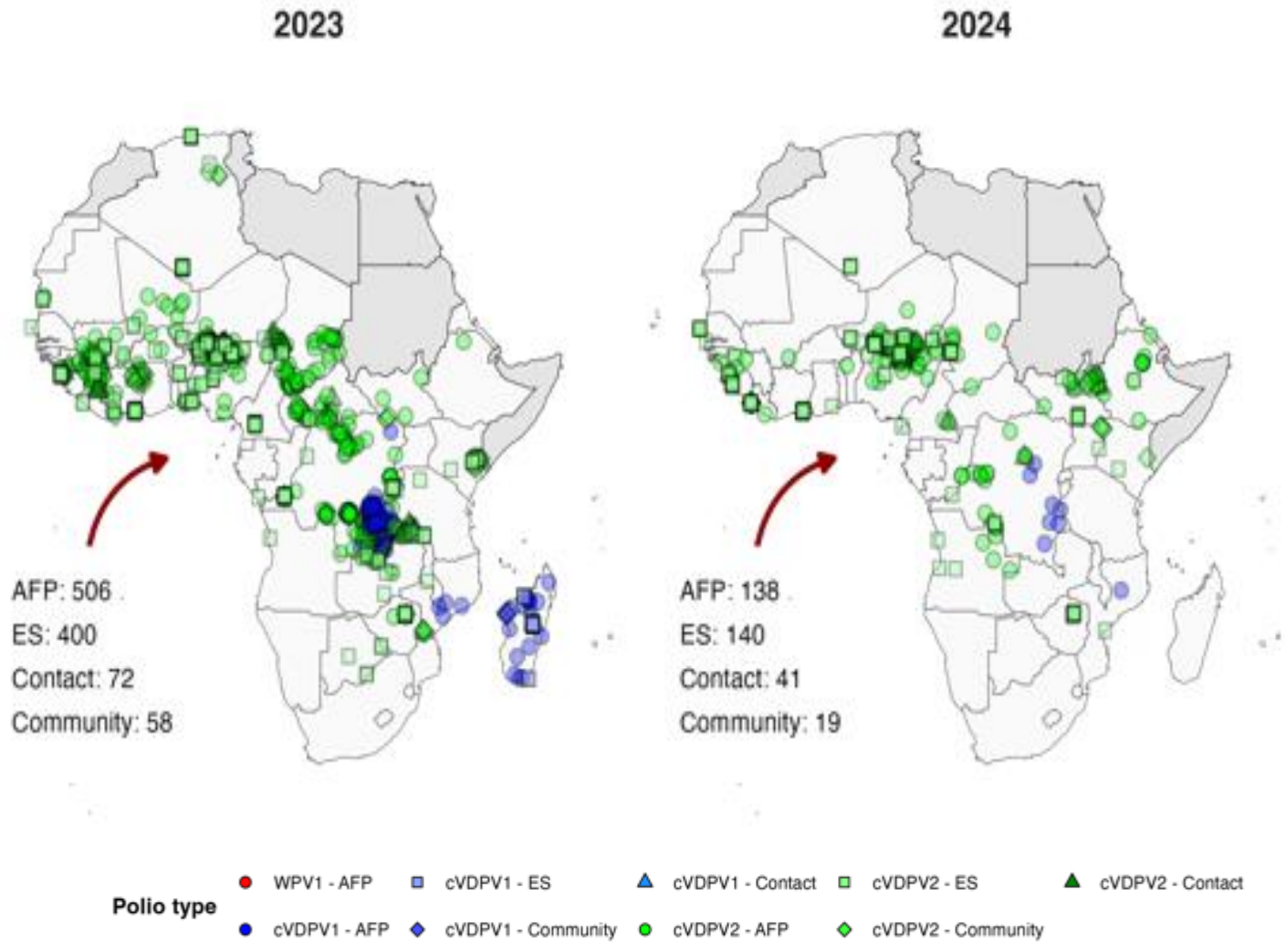
No cVDPV1 reported from Madagascar since last 12 months; cVDPV1 not reported from Mozambique since May 2024

cVDPV2 outbreaks continue in multiple countries—mostly Lake Chad Basin Countries, particularly North Nigeria

Progress in DR Congo but co-circulation (VDPV1 and 2) continues in East

North Nigeria and Eastern DRC continue as the core reservoirs

cVDPV2 transmission in Horn of Africa (mostly Ethiopia)



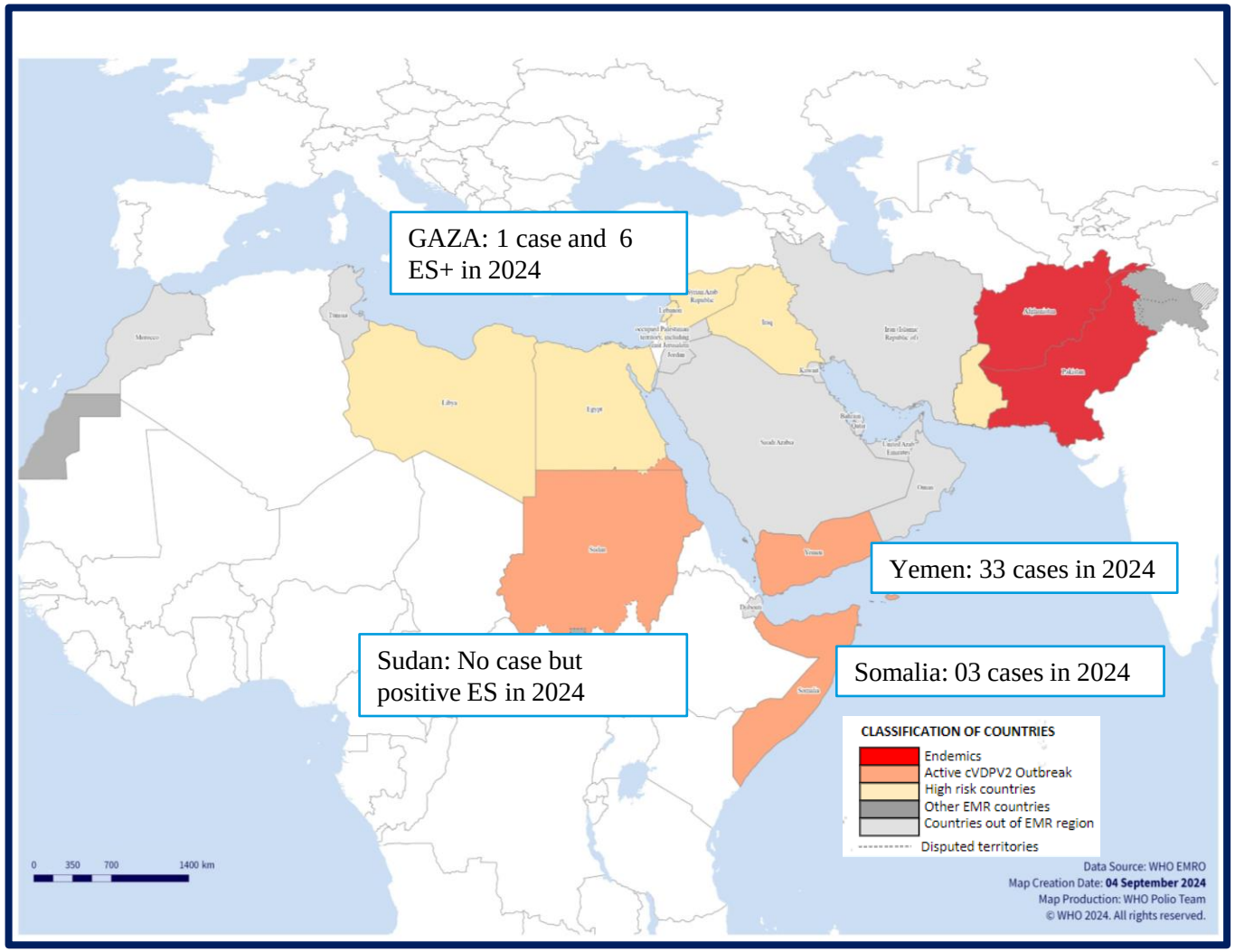
Poliovirus Epidemiological Overview – EMRO: 2023-2024

Large outbreak of cVDPV2 in North Yemen and South-Central Somalia.

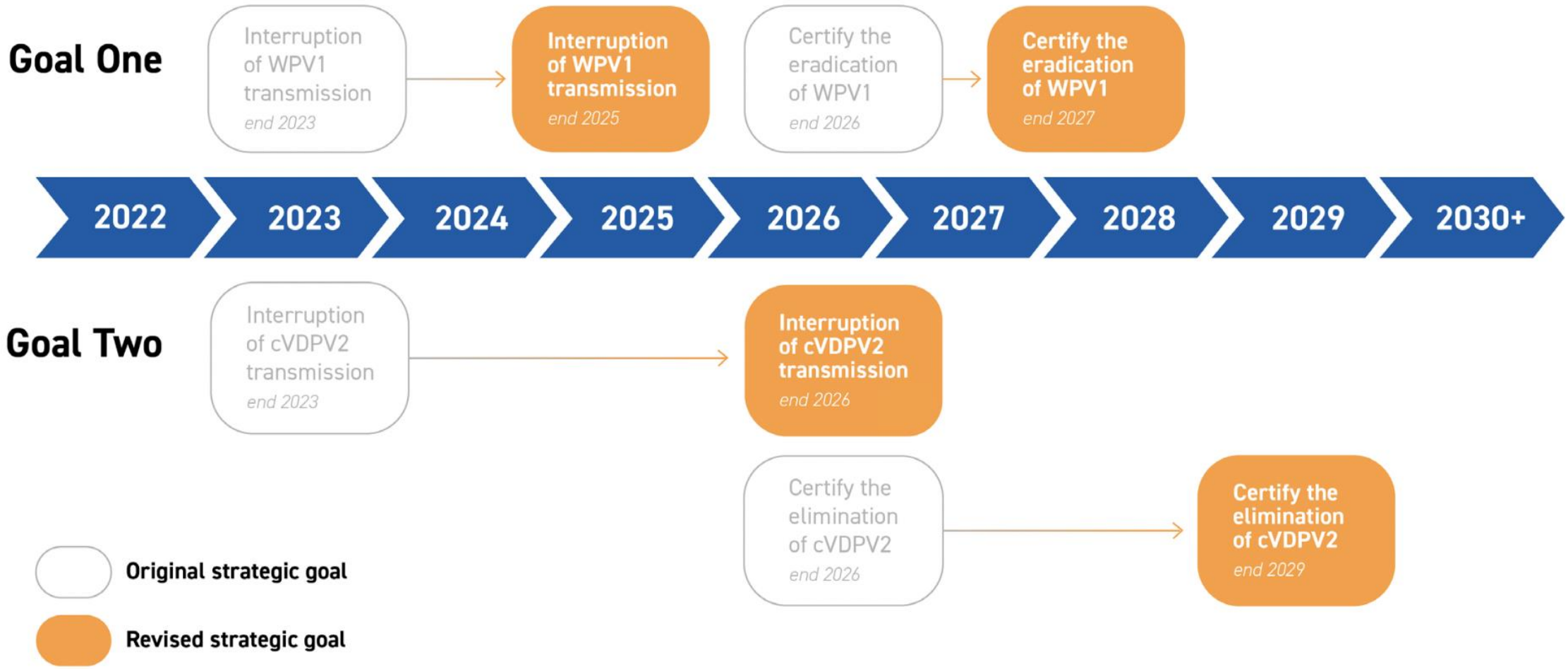
Very concerning new outbreak in Gaza with risk of spread—challenge to mount quality response.

Active conflict in Yemen and Gaza, inaccessibility and insecurity in Somalia

Progress in Sudan but situation remains fragile.

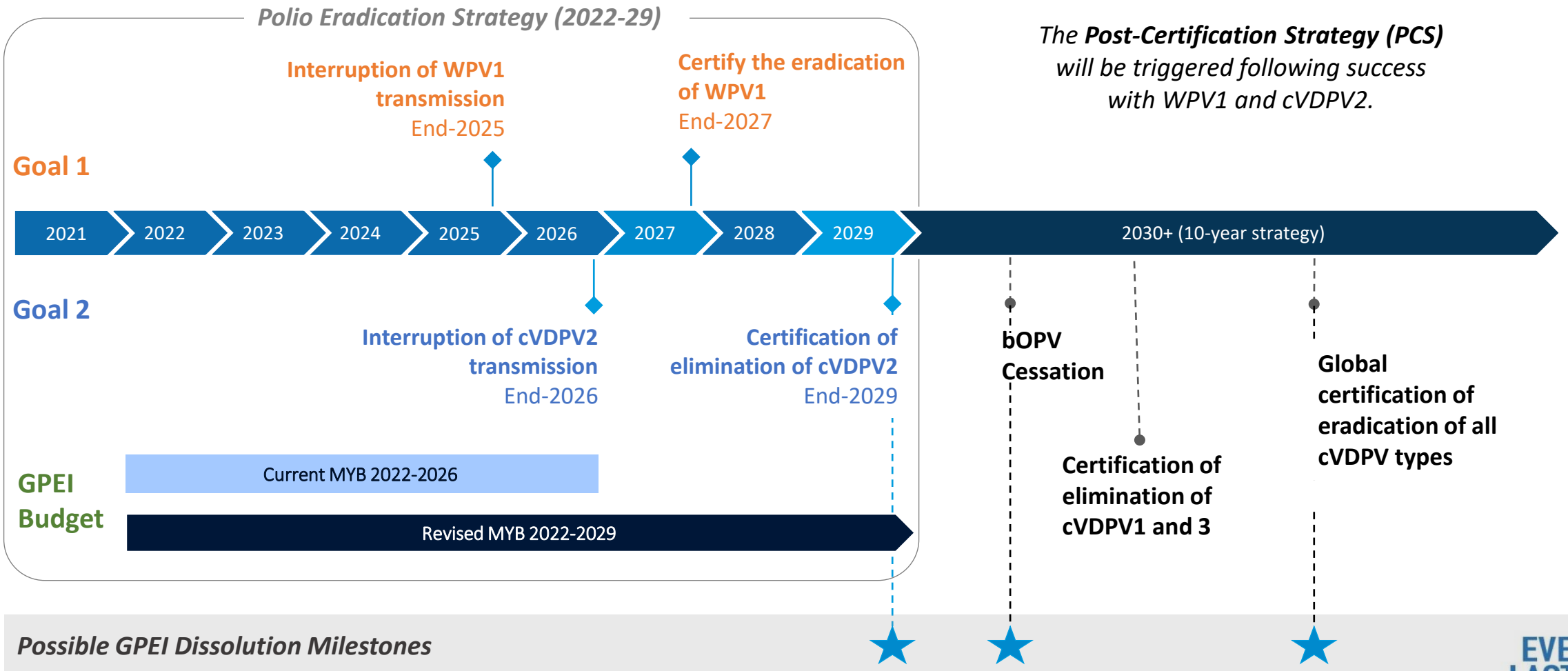


Global Polio Eradication Strategy Extension 2022-26 to 2029



https://polioeradication.org/wp-content/uploads/2024/11/GPEI-Strategy-extension-20241113.pdf

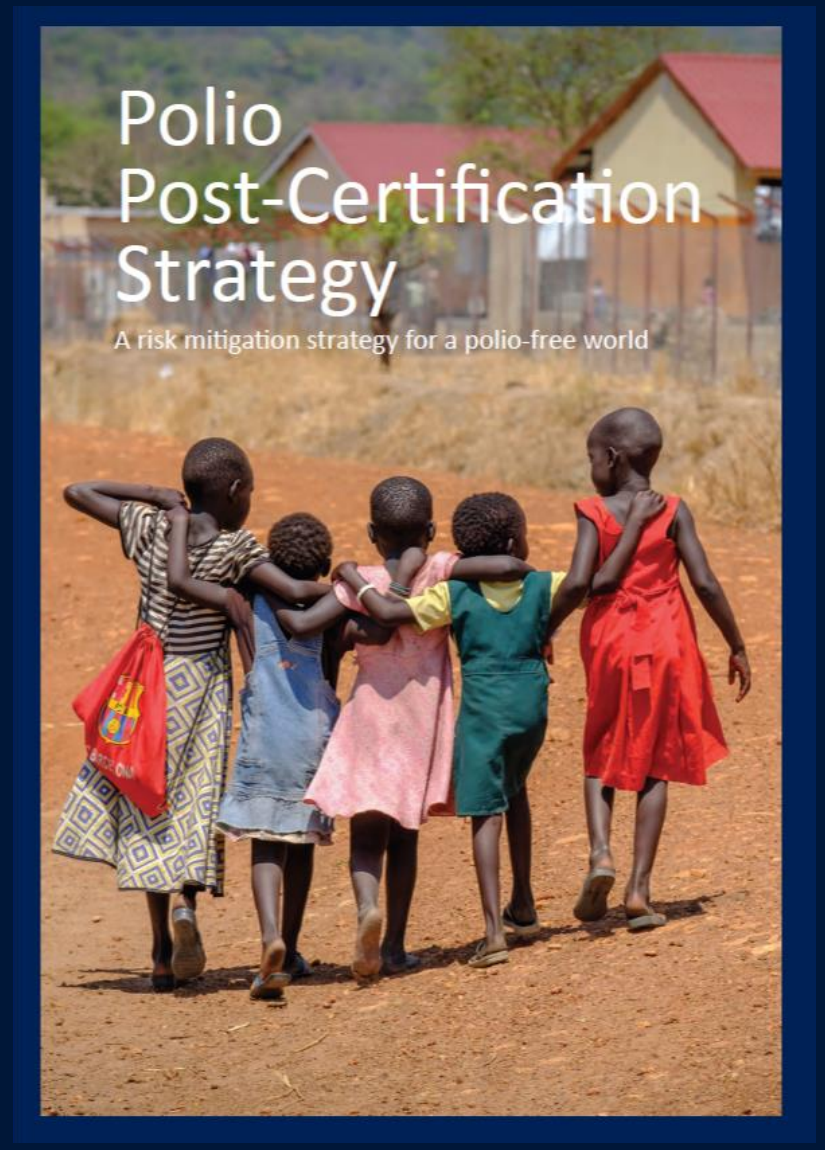
Eradication Strategy & Post-Certification Strategy Timelines



*The **Post-Certification Strategy (PCS)** will be triggered following success with WPV1 and cVDPV2.*

*Note: certification of elimination of cVDPV1 and cVDPV3 will be prior to global certification

bOPV Cessation Policy Framework



Rocio Lopez Cavestany

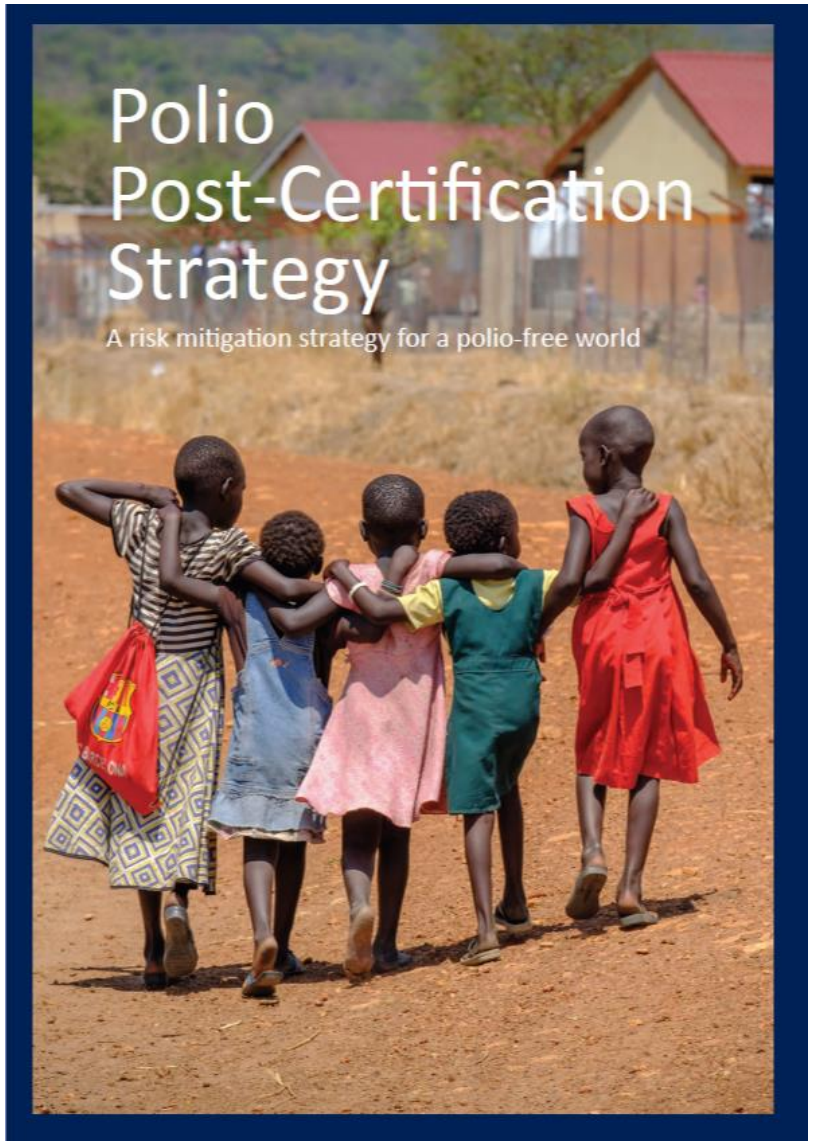
Polio Research Policy and Product Development

Polio Eradication Dept

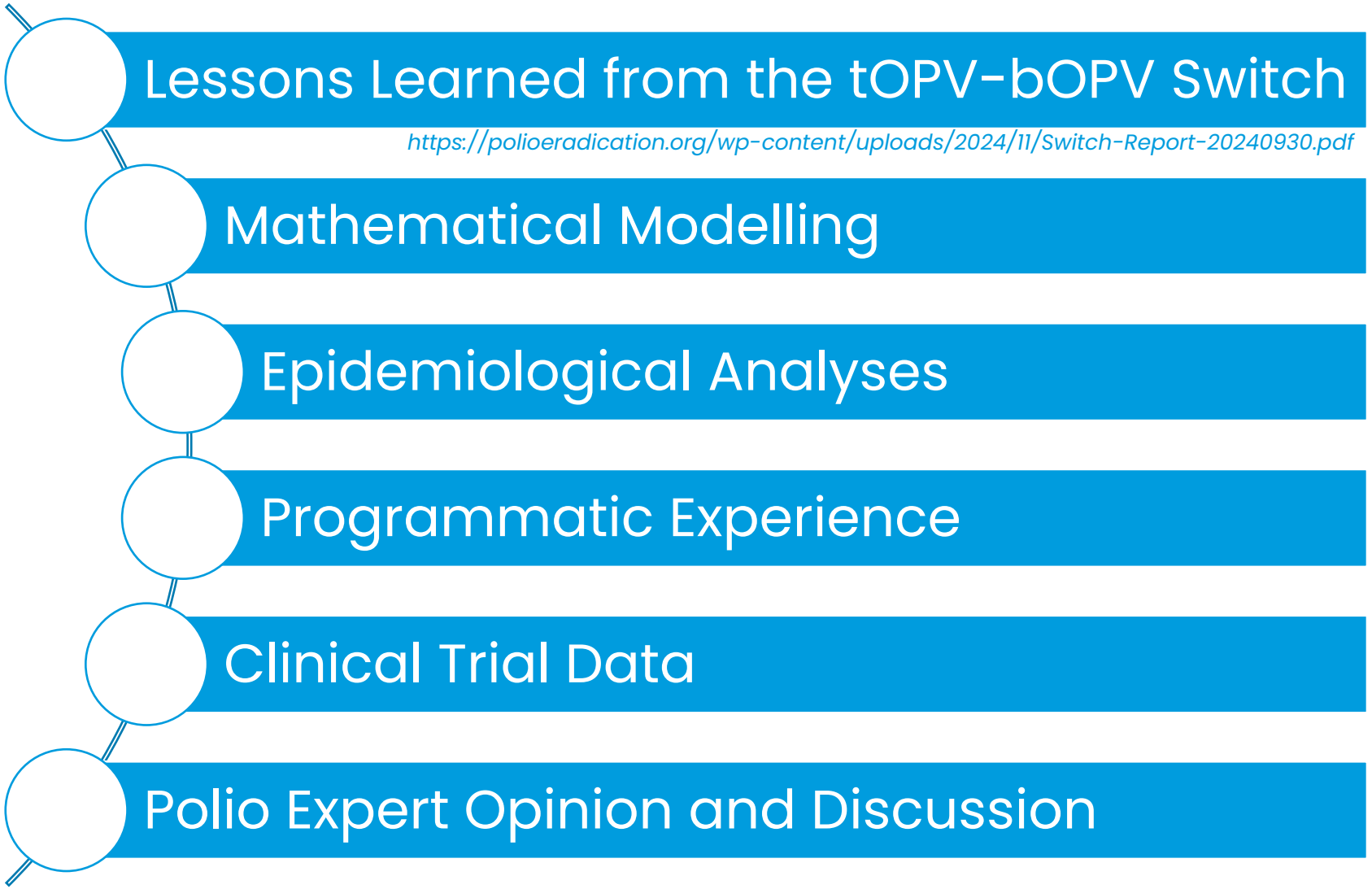
WHO, HQ, Geneva

Background: bOPV Cessation

- bOPV Cessation is a **globally synchronized withdrawal of bOPV** from routine immunization (all countries will become IPV-only using countries); **under current projections, anticipated in 2030.**
- To achieve global polio eradication, poliovirus must be removed from populations everywhere, including the Sabin viruses contained in the oral poliovirus vaccine (OPV).
- The bOPV Cessation Team (BOCeT) was created by GPEI's Strategic Committee in Jan 2023 to coordinate planning for bOPV cessation



Inputs to bOPV Cessation Planning



Initial BOCeT membership includes polio experts and involvement from GPEI partners and key stakeholders including:

- WHO, BMGF, PATH, Imperial College London, KidRisk, UNICEF, CDC, Gavi, LSHTM

Next steps to expand engagement to include Regional participation

bOPV Cessation Policy Framework: Nomenclature

1. GUIDING PRINCIPLES

*Definition: A basic idea or rule that explains or controls how something happens; ethical imperative – **first, do no harm***

Status: broadly agreed upon by SAGE in March 2024

2. TRIGGERS

Definition: Non-negotiable conditions that MUST be fulfilled prior to cessation

Status: broadly agreed upon by SAGE in September 2024

3. ENABLERS OF SUCCESS

Definition: requirements that, if achieved, will minimize the risk of cessation failure

Status: Ongoing.

Discussed with SAGE in fall 2024, pre-cessation SIA modelling framework for country risk-tiering endorsed, pending continued discussion.

Guiding principles for bOPV Cessation
Endorsed by SAGE in March 2024

1. Risks of failure to control cVDPVs following bOPV cessation are similar to those following tOPV-bOPV switch in 2016;

2. Preparation and implementation of bOPV cessation must follow **'first do no harm' principle**; at all cost we must strive to avoid that cessation results in thousands of children paralyzed with cVDPV as was the case after tOPV to bOPV switch;

3. It is preferable to delay cessation and be fully prepared then implement cessation hastily, risking failure;

4. GPEI leadership must acknowledge that planning and implementation of bOPV cessation will require considerable program commitment, financial resources and partner engagement

Triggers for bOPV Cessation

Endorsed by SAGE in September 2024

1. Certification of eradication of WPV1 by the Global Certification Commission (GCC)
2. Certification of elimination of cVDPV2 by GCC as proof that OPV cessation is possible.
3. No persistent (circulation > 6 months) cVDPV 1 and 3 outbreaks in the previous 24-month period at the time of the decision to proceed with bOPV cessation.
4. Available stockpiles of type-specific OPV (novel or Sabin) in sufficient quantity.
5. All countries have established at least a 2-dose IPV schedule in RI (per WHO recommendations) for a minimum 2-year duration.
   - In places where IPV coverage is considered suboptimal (IPV2<80%), a risk-tiered approach for pre-cessation supplementary immunization activities with bOPV and/or IPV will be used to further boost immunity

Enablers of Success for bOPV Cessation

Ongoing BOCeT and SAGE discussion

1. **High population immunity**
   - SAGE October 2024: Endorsed modelling framework for country risk-tiering to plan pre-cessation SIAs. Pending continued discussion in SAGE March 2025.

2. **Sufficient vaccines**

3. **Verified absence of cVDPVs and sensitive poliovirus surveillance pre and post cessation**

4. **Outbreak response capacity**

Recent SAGE recommendations on IPV use in Routine Immunization

SAGE March 2024:

"SAGE reiterated that **only countries at low risk of polio** (as designated by each WHO region) that have attained high routine immunization coverage with at least 2 IPV doses should consider transitioning to IPV only schedules ahead of planned synchronized bOPV cessation"

SAGE September 2024:

There are some countries that could consider already moving to IPV-only schedules based on per country factors. **The SAGE WG is building a risk criteria framework to determine eligible countries that could safely transition to an IPV only schedule** which will be presented in the March 2025 SAGE meeting.

No new recommendation is issued at the moment.

Conclusion

- **WHO is available to support and provide guidance to NITAGs on all items below**

- **The revised GPEI strategy extends Goal 1 and 2 timelines**
  - WPV1 interruption of transmission end 2025; certification of eradication end 2027
  - cVDPV2 interruption of transmission end 2026; certification of elimination end 2029
- **Support MOH in Vaccine Transitions**
  - Assist Ministries of Health in assessing readiness and applying for Hexavalent vaccines or transitioning to IPV-only schedules.
- **Enhance Surveillance Quality**
  - Provide technical and operational support to improve AFP and environmental surveillance systems for timely detection and response to poliovirus.
- **Strengthen Routine Immunization Integration**
  - Collaborate with MOH to link polio eradication strategies with initiatives to increase routine OPV/IPV immunization and catch-up vaccination coverage.
- **Facilitate Planning for bOPV Cessation**
  - Work with countries to develop and implement risk mitigation strategies and cessation plans in alignment with global timelines.
- **Prioritize High-Risk Areas**
  - Support the identification and targeted interventions in high-risk or underserved areas to close immunity gaps.

Global NITAG Network Meeting

Revised GPEI Strategy Timelines and Planning for bOPV Cessation

Chair: Mario Melgar

Polio Session Lead: Diana Chang-Blanc (IVB)

Presenters: Zubair Wadood (POL), Rocio Lopez Cavestany (POL), Alejandro Ramirez-Gonzalez (IVB)

11 December 2024

Thank you

Extra Slides for Discussion

Recent SAGE recommendations on IPV use in Outbreak Response (1/2): for IPV-only countries

NOTE: SAGE WG continue to support use of OPV for outbreak response as a primary tool because of its ability to elicit mucosal immunity.

SAGE October 2022:

On the basis of the findings of this review, **SAGE concluded that countries with exclusive IPV vaccination and a high level of sanitation and hygiene may opt to conduct a timely initial outbreak response with IPV only.**

This option is recommended if poliovirus transmission is confined to a well-defined population group or geographical area. SAGE emphasized that poliovirus transmission should be monitored, including through enhanced environmental surveillance, and if transmission persists, an OPV response should be considered.

SAGE outlined key considerations for the choice of vaccine and the shift from an initial IPV-only to an OPV response. The most important factors are the spread and scale of the outbreak. Transmission confined to a subpopulation or geographical area allows an IPV-only response. Widespread transmission in the general population warrants an OPV response. SAGE also outlined additional considerations to be included in the risk assessment.

The review showed that many countries using only IPV do not have updated polio outbreak response plans. SAGE urged countries to update or develop national polio outbreak response plans in line with existing recommendations, with advice from their national immunization technical advisory group (NITAG).

Recent SAGE recommendations on IPV use in Outbreak Response (2/2): for OPV+IPV countries

NOTE: SAGE WG continue to support use of OPV for outbreak response as a primary tool because of its ability to elicit mucosal immunity.

SAGE June 2023:

"...in areas where transmission continues after 2 or more OPV campaigns, an additional IPV (full or fractional dose) campaign (together with OPV whenever possible) should be conducted to enhance individual level protection and reduce transmission by enhancing mucosal immunity..."

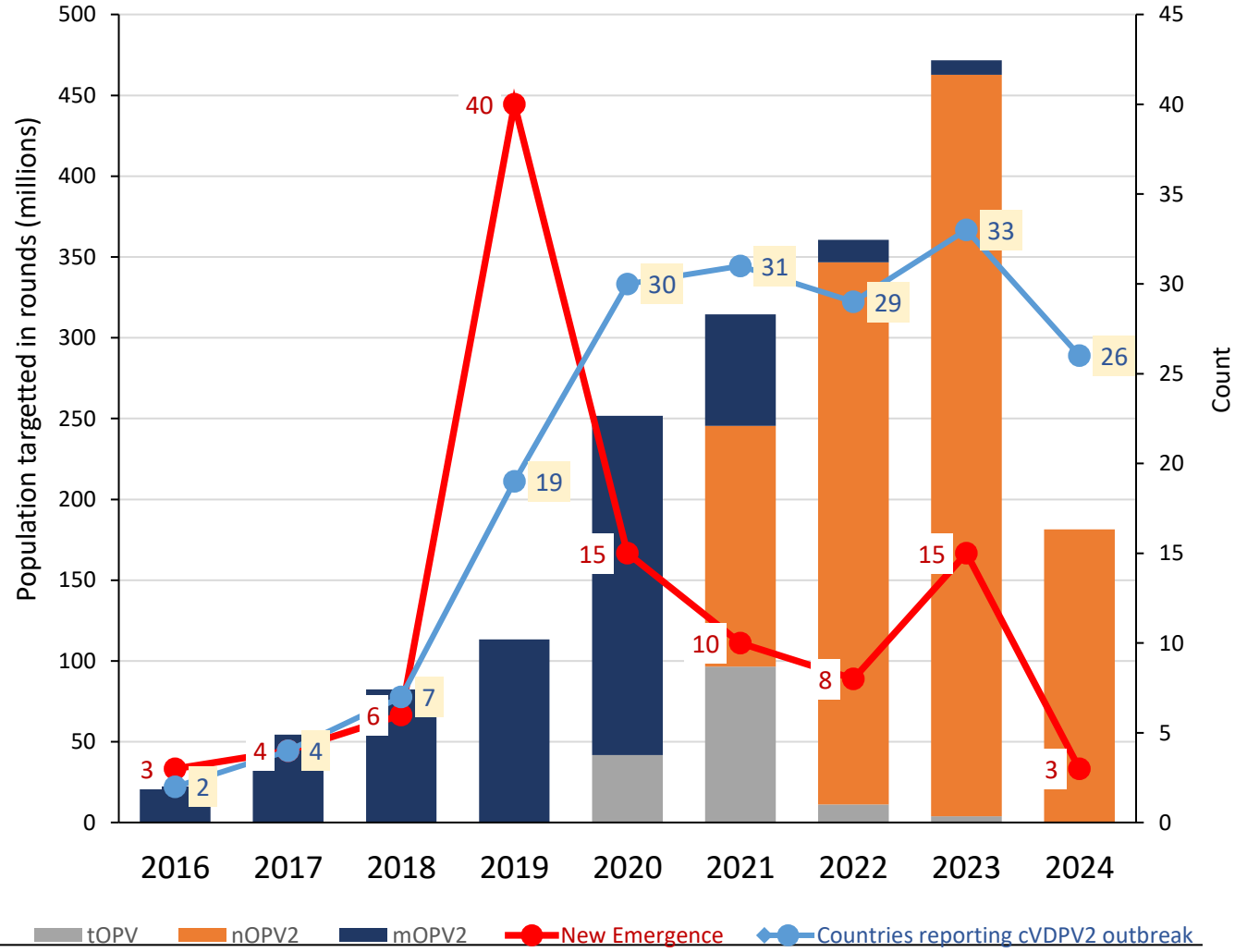
SAGE September 2024:

SAGE WG continue to support the use of OPV for outbreak response as a primary tool. If logistically possible and emphasizing a timely response, OPV + IPV initial response should be considered in certain settings (i.e., conflict, weakened health infrastructures, high levels of malnutrition and chronic enteric infections).

If timeliness of outbreak response will be affected, the initial response should not be delayed, and IPV can be added in subsequent rounds.

Type 2 containing oral polio vaccines (OPVs) utilized and trend of new outbreaks May 2016-2024*

- Shift from Sabin to a more genetically stable **novel OPV2 (nOPV2).**
- More than 1 billion doses of nOPV2 used for outbreak response
- Decline in new emergences of cVDPV2 following use of nOPV2
- Q1 and Q2 2024 implementation was impacted by supply disruption. BioFarma supply resumed and BioE is now prequalified.



Gaza polio outbreak response

Two rounds
of vaccination campaign using nOPV2
R1: **1 Sep. 2024**
R2: **Oct. 2024** (Four weeks after end of R1)

640,500 children
under 10 years of age in all 5 governorates

Campaign modality
Fixed sites, Outreach and **Mobile teams** for 7 days (5 + 2 days for mop-up) in 3 phases

Microplan
Flexible to adapt to further security deterioration and associated population displacements.

*nOPV2- novel Oral Polio Vaccine Type 2

Vaccines: 1.6 million doses of nOPV2 released for over 640,500 children

Cold chain – over 650 sets of fridges, freezers, cold boxes and vaccine carriers

SBC + awareness activities: Building trust, community engagement, mass media, misinformation management

Coordination WHO, UNICEF and UNRWA along with partners continue support to the MoH

First vaccination campaign 1-12 Sept reached 558,963 children (87% of the estimated target of 640,000 children)