

# **Report of the Polio WG Meeting**

## **04-05 September 2018**

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**World Health  
Organization**

# Polio WG: Objectives

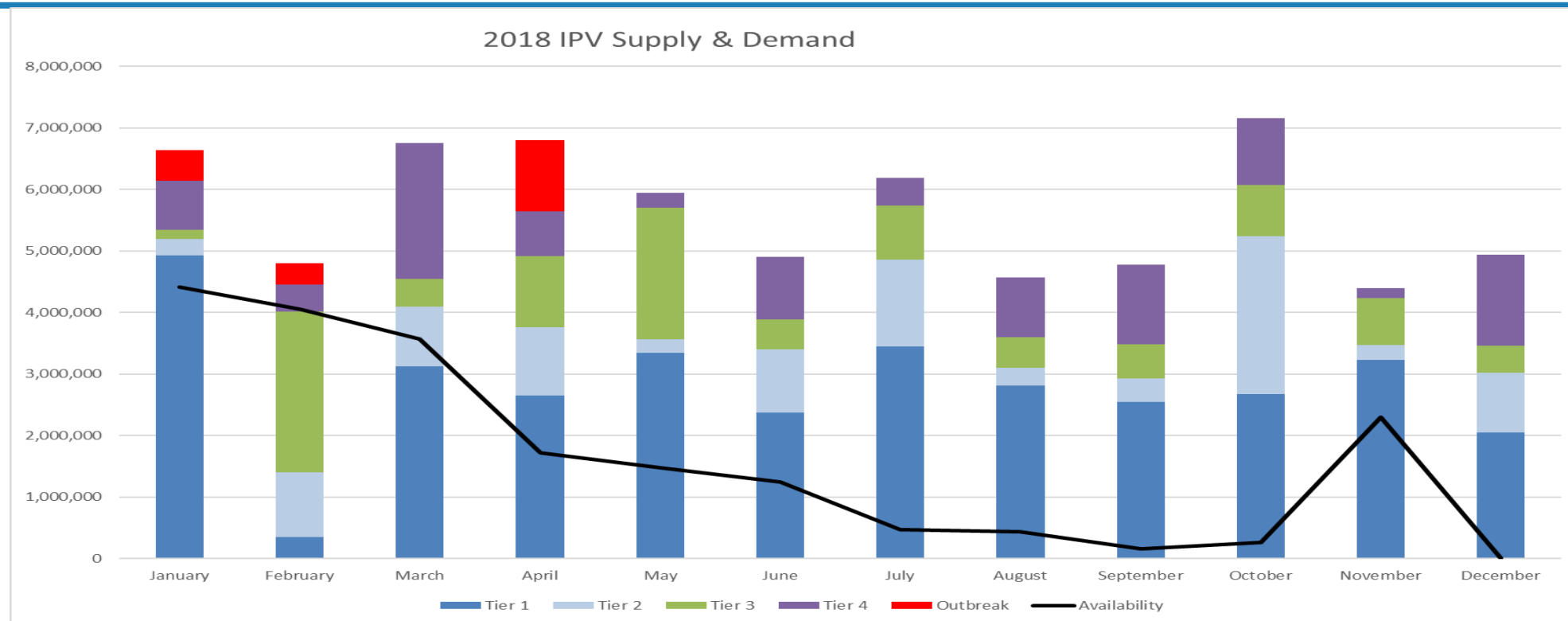
## To review

- GPEI program update and vaccine supply
- Options appraisal for certification of eradication
- “Readiness criteria” for bOPV withdrawal
- Containment Breach Protocol
- Scientific data and availability of Intra-Dermal devices
- Whole cell Pertussis Hexavalent vaccine landscape analysis
- Country-based risk assessment of poliovirus re-emergence

# Progress towards eradication

- The WG noted the continued circulation of WPV and cVDPV
- WG emphasized what the program has achieved:
  - Limiting WPV1 circulation to active corridors between Afghanistan and Pakistan
  - Control of cVDPV2 outbreak in Syria
  - Reduction in number of inaccessible children in Nigeria
  - Expansion of environmental surveillance
- WG expressed concern about reaching children in countries with inaccessible areas
  - In Kandahar, Afghanistan 1.3 million children remained inaccessible in August 2018
- New GPEI strategic plan (2019-2023) presents an opportunity:
  - Help develop a primary healthcare system that can deliver high routine immunization coverage in the most vulnerable countries
  - Coordination and collaboration between GPEI, EPI, GAVI and other partners

# IPV supply & demand projections for 2018



**While routine requirements are fully met through UNICEF, other needs are not met:**  
**SIAs outside of endemics of around 3M doses (e.g. Syria and Ukraine for campaigns, Uganda and Rwanda for refugees)**  
**Catch up of around 43M doses (across 33 countries)**

# OPV Vaccine Supply Update

- Program needs to establish clear communication with vaccine manufacturers and develop a supply requirements plan, *especially if mOPV1 is to be reintroduced* into the program
- Countries receiving mOPV2 for outbreak response need better accountability
- Better systems need to be put in place for retrieving mOPV2 vials after SIAs

# Certification of eradication

## Options Appraisal Document

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- The Global Certification Commission (GCC) secretariat drafted an appraisal of 3 options for certification of global poliovirus eradication

### ***The main question is:***

- Whether to include cVDPVs in the requirements for certifying eradication of polio
- If cVDPVs are included – How to do so?

# Background - prior definitions

- 1988 WHA resolution calls for the “global eradication of poliomyelitis”, but specifically refers to WPV.
- WHA documents in 2012 and 2015 specifically highlighted WPV eradication and referred to cVDPV only in the context of heightened surveillance.
- 2015: GCC declaration that WPV2 had been eradicated worldwide did not consider the presence or absence of cVDPV2 (consistent with prior regional certifications).
- February 2018: GCC re-evaluated criteria for certification and recommended that the declaration of eradication of WPV should take into account the epidemiology of cVDPVs at that time.

# Certification of Eradication

## Core Assumptions

- ***Certification***: implies a high degree of certainty that specific criteria have been met; requires strict procedures (e.g. documentation process by every country, oversight and vetting by regions, and then by GCC) which provides high confidence that transmission has stopped.
- ***Validation of absence***: implies a lower level of certainty due to unknowns about transmission and/or substantial challenges to meeting certain criteria. Procedures are not yet determined but would be expected to be less rigorous than those required for certification.



# Proposed Options - 1A

- Certification of eradication is based on the interruption of transmission of WPV alone followed later by separate process to validate the absence of VDPVs

# Proposed Options - 1B

- Certification of eradication based on the interruption of WPV transmission, with consideration of the context of ongoing or recent cVDPV outbreaks, followed later by a separate process to validate the absence of VDPVs.
- *Proposed context at GCC meeting in Feb 2018:*
  - Consider all types of cVDPV: No detection of a persistent cVDPV2 outbreak from any population source in the previous 18\* months; and no detection of a cVDPV1 or 3 outbreak from in previous 6\* months.
- *Alternatively:*
  - Consider only types 1&3: No detection of a cVDPV1 or 3 outbreak from any population source in the previous 6\* months

\* time frame could be further discussed

# Proposed Options - 2

Certification of eradication in two stages:

- Stage 1 based on interruption of WPV transmission;
- Stage 2 based on evidence of no new VDPV emergence or circulation following OPV cessation.
- Stage 1 may or may not include consideration of VDPV status

***All the proposed options could include a sequential approach of first addressing certification of type 3 and then address type 1.***

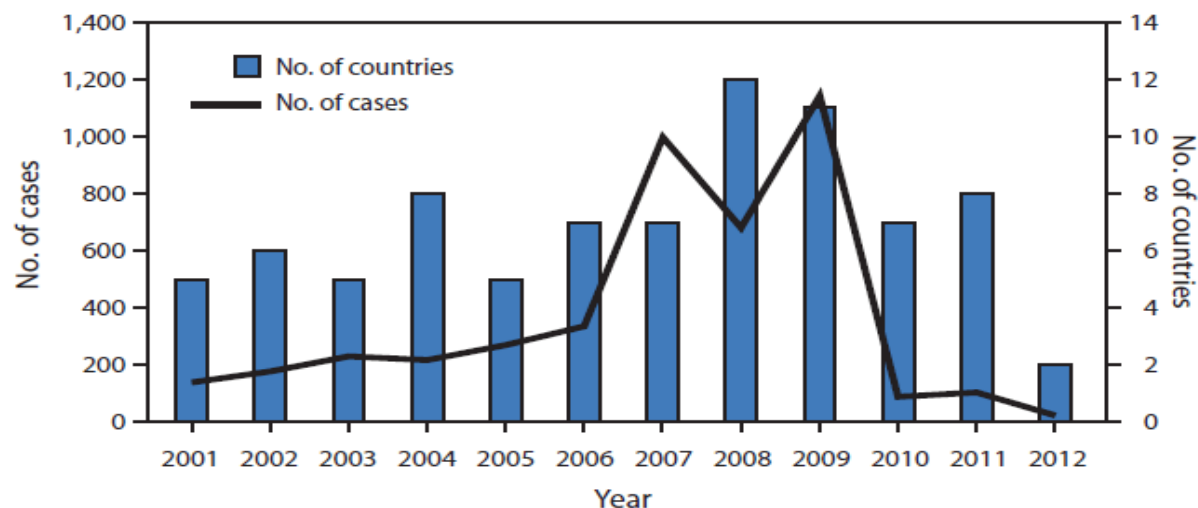
# Options appraisal: SAGE WG's Summary

- WG welcomed the options appraisal as a suitable tool for reviewing the criteria for certification of eradication of polioviruses.
- The WG agreed that the GCC should respond to the present circumstances acknowledging the challenge of certifying absence of cVDPVs in the development of eradication certification criteria. The “absence of cVDPVs” denotes that no VDPV is being transmitted anywhere, and that all VDPVs are under containment.
- WG provided input into the appraisal paper, with the chair of the GCC in attendance.
- The options will be reviewed by the GCC in October 2018.

# Certification of eradication

## Certification of WPV3 eradication prior to global certification

Reported WPV3 cases and countries, 2001-2012



- The GCC chair discussed the possibility of certification of WPV3 eradication as a trial run of final certification of polio eradication
- WG reviewed the pros & cons of certification of WPV3 ahead of WPV1
- *Epidemiological background:*
  - *No WPV3 has been detected since November 2012; since then >150K and 92K stool samples from AFP cases tested negative for WPV3 in AFRO and EMRO, respectively*

# Trigger and Readiness criteria for bOPV withdrawal

## Trigger:

- Certification of polio eradication

## Revised Readiness Criteria:

1. Adequate population immunity
2. No persistent cVDPV1 or cVDPV3 circulation
3. Sufficient IPV supply for all countries to adopt 2 IPV dose schedule

## Additional criteria for iVDPVs:

- Surveillance for PIDs established
- Therapeutic options for clearing infections among iVDPV available

# Trigger and Readiness criteria for bOPV withdrawal

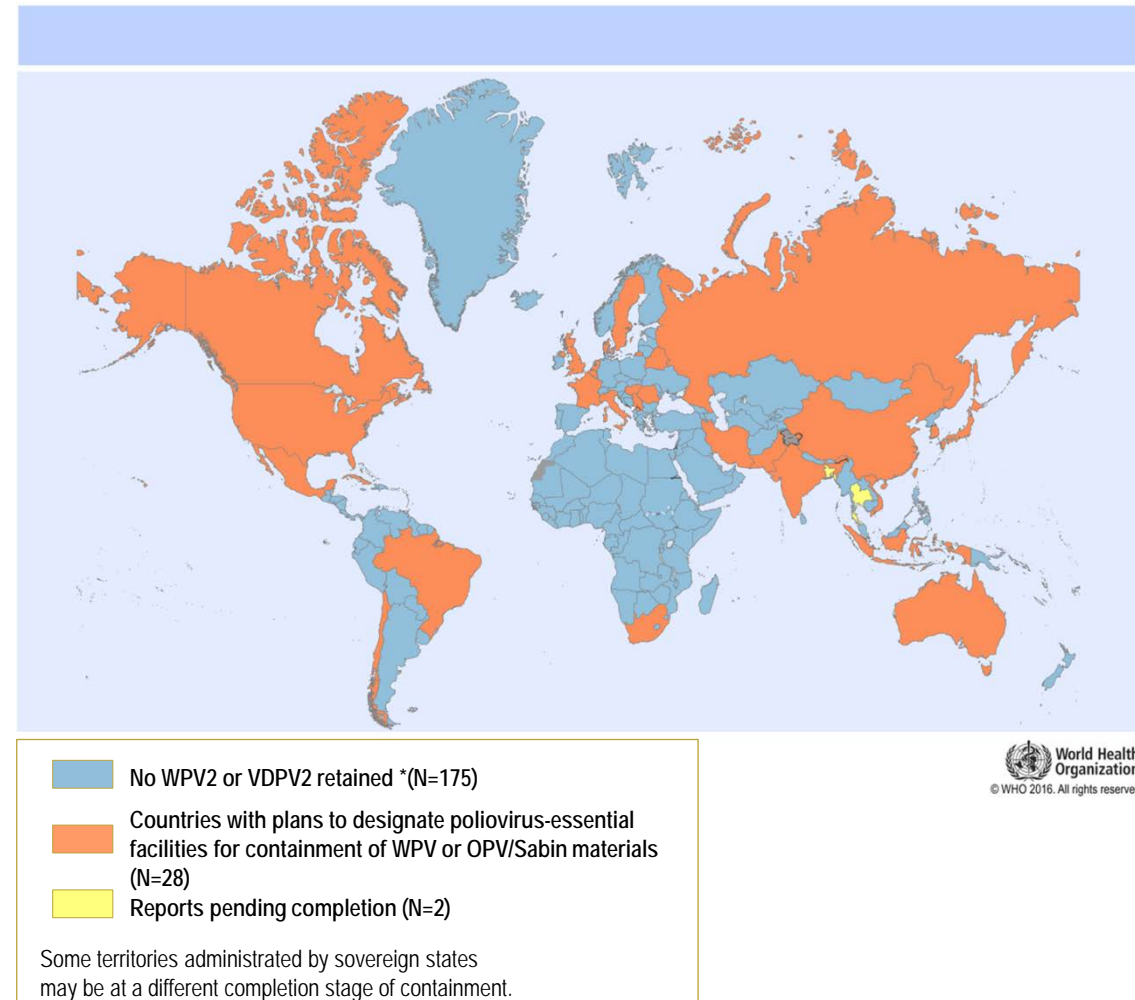
- The WG agreed with the revised readiness criteria and the need for additional criteria on iVDPV
- The WG agreed with the proposed timeline:
  - Plan to withdraw bOPV 6 - 18 months after certification “trigger point”
  - Start planning bOPV withdrawal in advance of certification
- The WG identified additional considerations:
  - Possible early certification of WPV3
  - Potential for step-wise, regional withdrawal of bOPV
- Next steps
  - Once decisions by GCC on certification requirements are final, SAGE WG will re-assess the readiness criteria

# Containment Breach Protocol

WG reviewed a draft of the protocol and suggested revisions

Guidelines for a public health response to a human exposure or infection related to a breach of poliovirus containment.

WG suggested that revised version is presented for endorsement at SAGE WG in early 2019.





# IPV Allocation Options for 2019-2020

## Supply & demand estimates 2019

Doses available after RI requirements are secured	
Realistic supply	71,650,000
Estimated RI requirement (UNICEF)	64,183,000
Availability after fulfilling RI	7,467,000

## Additional requirements above the RI quantities

- SIAs in endemic countries: 5.9 million doses
- Nigeria fIPV use in cVDPV2 response: 1.6 million full IPV doses (to cover ~7 million children)
- SIAs in outbreak countries/refugees: 3 million doses
- Catch up immunization: 42 million doses

What is the best use of the 7.5 million doses available in 2019?

# IPV Allocation Options for 2019-2020

- WG **agreed** the prioritization order for IPV allocation:
  1. Ensure that routine immunization needs in all countries are met.
  2. Ensure requests from endemic countries for SIAs to interrupt WPV.
  3. After these 2 requirements, excess doses should be allocated to populations that are IPV-unvaccinated since the switch, based on risk assessment.
- WG **recommended** countries provide periodic national and sub-national level reports of IPV stock, for routine immunisation and SIAs.
- WG recommended that a risk-ranking is conducted for ***refugee populations***
- Countries using fIPV should be prioritized for supply.

# Scientific data and availability of ID devices



**E008:** Auto-disable syringe for fixed dose immunization

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**PQS code:** E008/071

**Description:** Single Use auto-disable needle-free jet injector

**Manufacturer's reference:** PharmaJet® Tropis®

**Manufactured in:** United States

**Company:** PharmaJet Inc.

**Address:** 400 Corporate Crichel, Suite N, Golden, Colorado 80401 USA

**Telephone:** +1 888 900-4321

**Email:** [erin.spiegel@pharmajet.com](mailto:erin.spiegel@pharmajet.com)

**Web address:** <http://www.pharmajet.com>

Specifications		
Injector	Needle-free Syringe	Filling Adapter
Reference manufacturer: C503-10	Reference Manufacturer: C503-35: 10-up pouches, 100/box C503-36: 20-up pouches, 100/box	Reference manufacturer: C503-42: 1-up pouches, 100/box
Administration: ID	Nominal capacity and graduation: 0.1mL	Material of adaptor: Polycarbonate
Energy source: spring	Main materials of syringe: Polycarbonate	Compatibility only with the Tropis needle-free syringe
Life time cycles: 20,000	Prevented from reuse by: Plunger break before injection	Intended for one vial use for field filling of syringes
Inadvertent activation prevention feature	per unit: Primary packaging: blister packs: 1-up, 10-up or 20-up	Primary packaging: blister packs: 1-up
Warranty 2 years	Number of syringes per box: 100 units & 200 units, see Reference Manufacturer numbers above	Number of adapters per box: 100 units
The PharmaJet Tropis needle-free injection system is intended to deliver various medications and vaccines intradermally by means of narrow precise fluid stream, which penetrates the skin.		
Quality System Standard: ISO 13485		Product Standard: ISO 7886-3; ISO 21649, CE 556625
Comments:	Single-use auto-disable needle-free jet injector Note: Jet Injectors (single-use auto-disable needle-free syringe injectors) as medical devices (Class II) are regulated by National Regulatory Authorities. A Jet injector prequalified by the WHO PQS programme to deliver medications and vaccines is to be used according to label to deliver ONLY those medications and vaccines that have been approved by the relevant Authorities.	
Current PQS status:	pre-qualified: 04 June 2018	Valid until: May 2019

**Tropis is a WHO pre-qualified intradermal injector for IPV**

**Scientific data show that Tropis is safe and non-inferior to BCG Needle and Syringe in terms of ability to induce immune response**

# Scientific data and availability of ID devices



Injector – 0.1 mL ID

	Number Available by April 2019	Vaccinations possible by April 2019
Tropis Jet Injectors	5000	125,000,000
Syringes	5,000,000	5,000,000
Filling Adapters	1,000,000	5 to 10,000,000
IPV available in 2019 for Catch-up Campaigns from GPEI*	Scenario 1: 1.49 Million Scenario 2: 4.48 Million Scenario 3: 5.07 Million	7.45 million (fIPV) 22.4 million (fIPV) 25.35 million (fIPV)



Syringe – 0.1 mL Needle-free



Filling Adapter

Current procurement would allow for ~2.5 million children to receive 2 doses of fIPV for catch-up using Tropis

# Scientific data and availability of ID devices

- WG agreed the performance and pre-qualification of Tropis device is an exciting development which could have applicability to other antigens.
- WG suggested more implementation experience both in routine and campaign settings
- WG recommended review by the Immunization Practice Advisory Committee (IPAC)

# Gavi's post-2020 IPV considerations

## wP-hexavalent supplier landscapes

One manufacturer has a licensed wP-Hexavalent vaccine and four others have products in development. Substantial supply availability to UNICEF expected from 2023

Manufacturer	Hexavalent Development Phase	PQ Date (Gavi Estimation)	Long-term Maximum Hexa Capacity (Doses)	wP-Pentavalent	IPV
Panacea	Marketed in India	2020	20-40M	✓	X
Manufacturer A	Phase II – completed	2022	30M-50M	✓	✓
Manufacturer B	Phase I – completed	2022-2023	30M-50M	✓	✓
Manufacturer C	Phase I – started	2022-2023	100M-150M	✓	✓
Manufacturer D	Preclinical	2024	30M-50M	✓	X



- Panacea relies on IPV supply from Bilthoven Biologicals, one of the two current prequalified manufacturers awarded by UNICEF
- Other manufacturers have mentioned their interest in pursuing development of wP-Hexavalent



# Gavi's post-2020 IPV considerations

## Risk of poliovirus re-emergence by country (2021-25)

	LOW INCOME COUNTRIES	LOWER MIDDLE INCOME COUNTRIES			UPPER MIDDLE INCOME COUNTRIES
	Initial self financing	Preparatory transition	Accelerated transition	Fully Self financing	Fully Self financing
High Risk	Afghanistan	Benin	Cameroon	Angola	
	Burkina Faso	Guinea	Côte d'Ivoire	Congo, Rep.	
	CAR	Mauritania	Djibouti	Indonesia	
	Chad		Kenya	India	
	Congo DRC		Nigeria	Papua New Guinea	
	Ethiopia		Pakistan	Ukraine	
	Guinea Bissau				
	Haiti				
	Liberia				
	Madagascar				
	Mali				
	Mozambique				
	Niger				
	Somalia				
	South Sudan				
	Uganda				
	Yemen				
Medium Risk	Burundi	Cambodia	Bangladesh	Bolivia	
	Comoros	Myanmar	Sudan	Timor Leste	
	Gambia	Nepal			
	Malawi	Tanzania			
	Sierra Leone	Zambia			
		Zimbabwe			
Low risk	Korea DPR	Eritrea	Ghana	Bhutan	Armenia
	Rwanda	Kyrgyz Rep		Georgia	Azerbaijan
	Togo	Lesotho		Honduras	Cuba
		Senegal		Kiribati	Guyana
		Tajikistan		Moldova	
				Mongolia	
				Nicaragua	
				Sri Lanka	
				Uzbekistan	
				Vietnam	

# Gavi's post-2020 IPV considerations

- The WG welcomed progress with wP-hexavalent vaccine and increasing options for IPV delivery into routine immunisation schedules.
- WG was comfortable with the risk assessment and suggested that the model should be periodically evaluated and updated.
- The **WG expressed concern** over the group of middle-income countries that are assessed as having a high-risk for polio re-emergence but are in Gavi-transition or fully-self-financing groups.



# Summary of Main WG Recommendations and Considerations

1. The new strategic plan 2019 - 2023 on polio eradication is an opportunity to strengthen coordination between GPEI, EPI, GAVI and other partners towards developing primary healthcare systems that can deliver high routine immunization coverage in the most vulnerable countries.
2. SAGE WG recommends to strengthen the accountability of management of mOPV2 vials after SIAs.
3. WG welcomed the certification options appraisal as a suitable tool for reviewing the criteria for certification of eradication of polioviruses.
4. Given IPV supply constraints, countries must be more accountable for IPV and need to provide periodic national and sub-national level reports of IPV stock, for both routine immunization and SIAs.