

POLIO ERADICATION AND POST-CERTIFICATION STRATEGY

PRE-BOARD MEETING
5 June 2018, Geneva



Agenda

Topic	Presenter
1. Polio eradication update	WHO <i>10 minutes</i>
2. IPV supply, demand and price outlook	Gavi <i>10 minutes</i>
3. Polio transition and post-certification	Gavi, WHO <i>10 minutes</i>
4. Discussion	<i>45 minutes</i>

1

POLIO ERADICATION UPDATE

Michel Zaffran

Director, Polio Eradication

POLIO | GLOBAL ERADICATION INITIATIVE

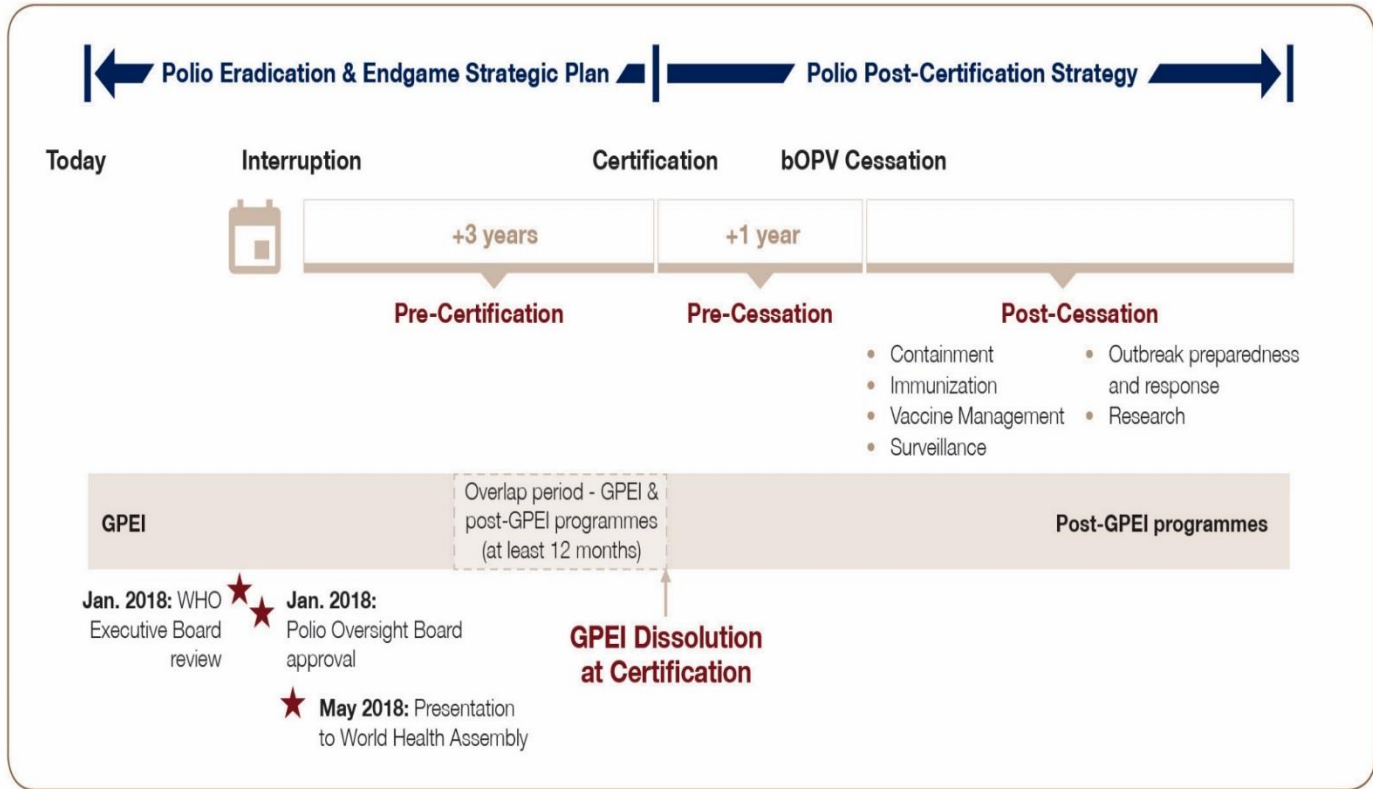
Polio Eradication – Global update

Gavi Pre Board Meeting , Geneva, 5 June 2018

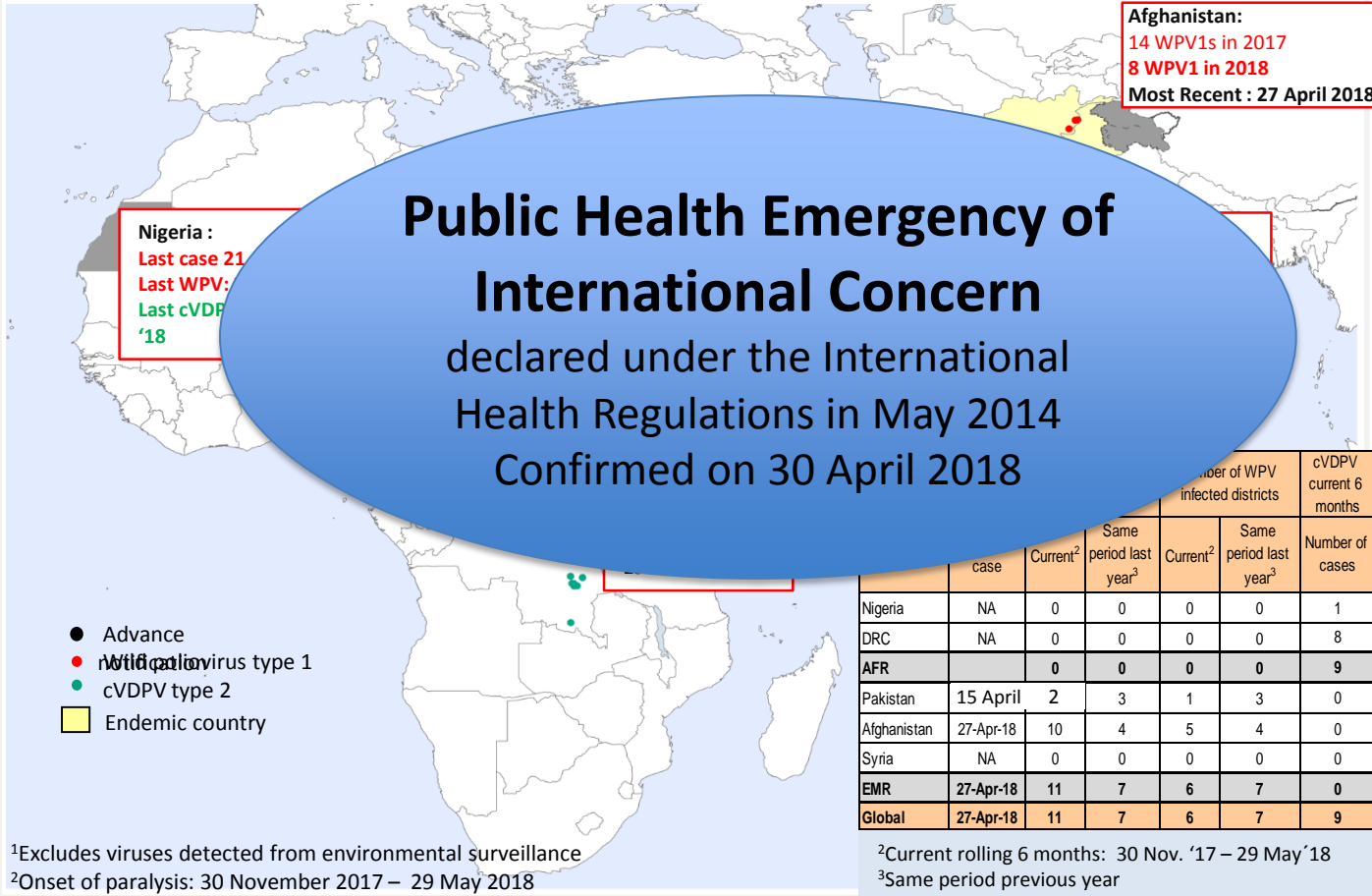
Michel Zaffran, Director, Polio Eradication



Eradication and Post Certification



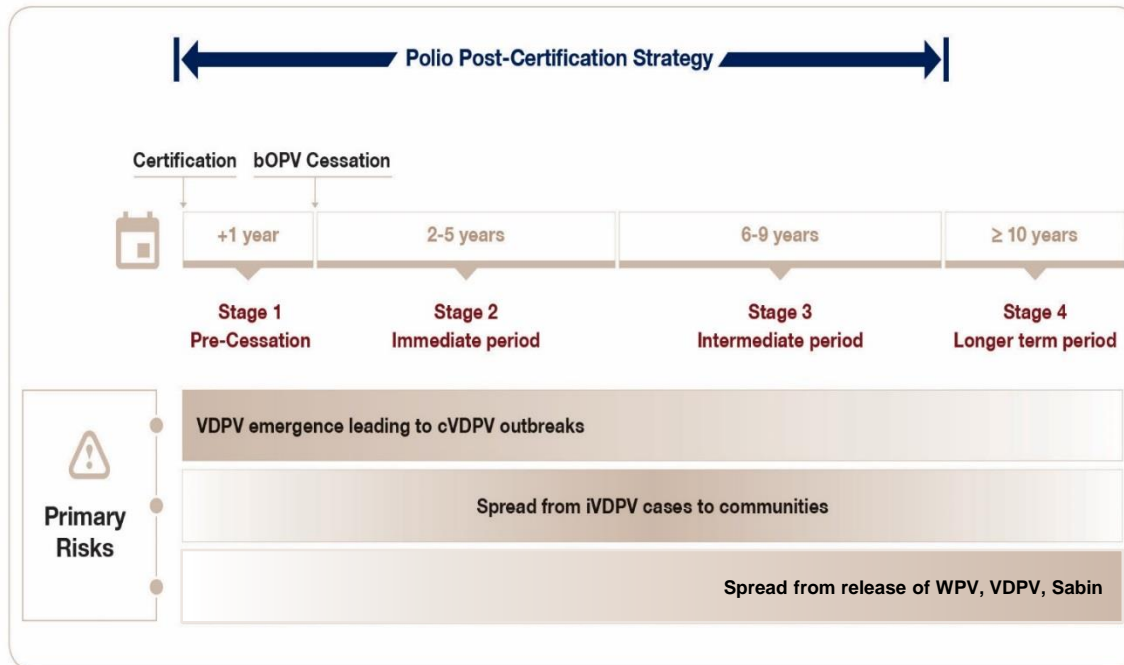
Global Wild Poliovirus & cVDPV Cases¹ (Past 6 Months²)



Risks from poliovirus after certification

Core PCS assumptions

- **Global eradication of all wild poliovirus** will be certified¹
- The **likelihood of poliovirus re-emergence will decrease** with time, but the **severity of the consequences will increase** with time
- Under the International Health Regulations (IHR), **detection of any poliovirus must be notified to WHO** and could require a prompt, globally coordinated response
- Future **governance, management, and coordinating structures** and processes will be in place when this strategy takes effect



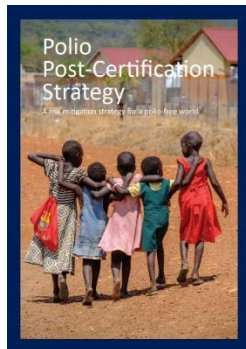
¹ A separate process will be undertaken by the Global Commission for the Certification of Poliomyelitis Eradication (GCC) and the Strategic Advisory Group of Experts on Immunization (SAGE) to determine the criteria and method to validate the absence of Vaccine derived poliovirus (VDPV) after global withdrawal of the bivalent oral poliovirus vaccine (bOPV).

Post-Certification Strategy (PCS) Summary

Polio Eradication and Endgame Strategic Plan (PEESP)¹

- 1 Poliovirus detection & interruption
- 2 OPV² withdrawal, IPV³ introduction, immunization system strengthening
- 3 Containment & global certification
- 4 Transition Planning

- Mainstream polio-essential functions to sustain global eradication
- Support country transition planning
- Capture lessons learned



Post-Certification Strategy (PCS)

Purpose: *Defines the technical standards for the polio-essential functions that will be needed to sustain a polio-free world.*

PCS goals

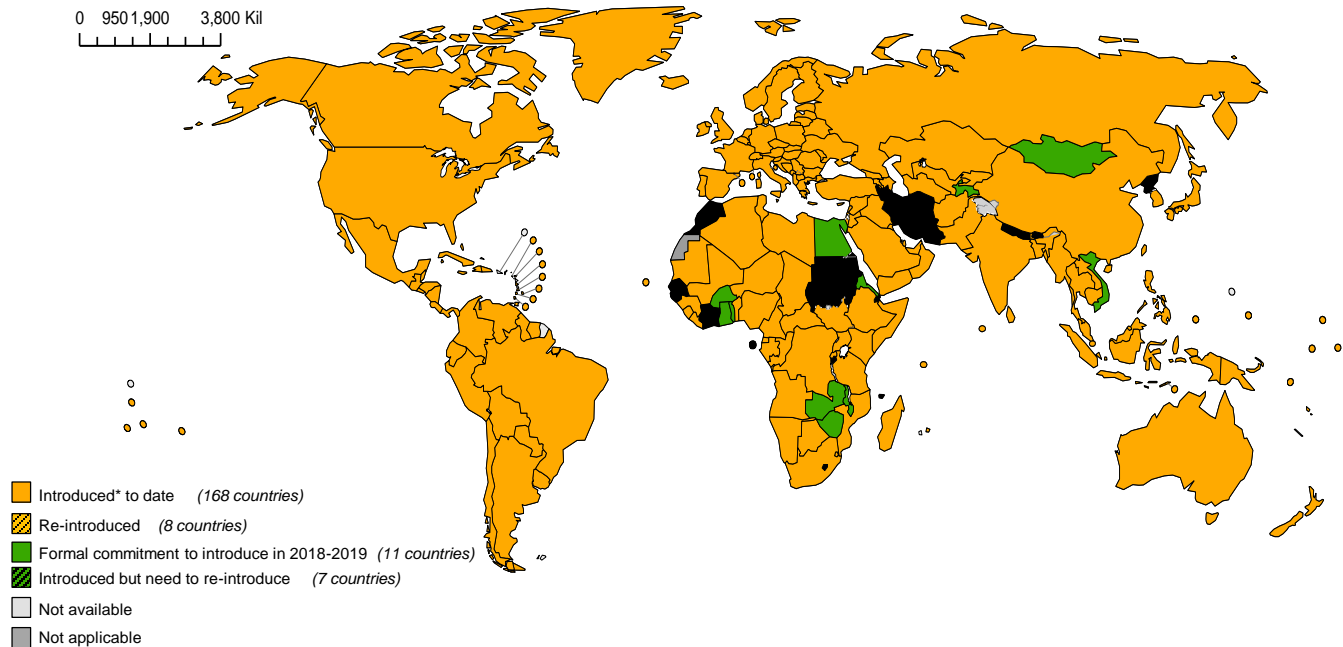
	Description
1 Contain Poliovirus Sources	Ensure potential sources of poliovirus are properly controlled or removed
2 Protect Populations	Withdraw OPV from use and immunize populations with IPV
3 Detect and Respond	Promptly detect any poliovirus reintroduction and rapidly respond to prevent transmission

Note: Research & Development is included in the PCS as a cross-cutting enabling function

IPV is a critical risk mitigation tool

- Risk of VDPV2 is highest in countries with large unvaccinated cohorts and low routine immunization coverage, and especially in those bordering cVDPV2 outbreaks.
- Countries holding polioviruses in laboratories, or producing IPV, are also at higher risk due to possible containment breach.
- IPV's primary role is to provide an immunity base to **reduce the risk of paralytic disease** in case of any exposure to type 2 poliovirus
 - Protect from paralysis
 - Aids rapid immunity build-up if an OPV campaign is implemented.

Countries using IPV vaccine to date and formal decision to introduce



34 million children missed must receive IPV

- **34 million children have not received IPV***
 - 20 Countries where introduction was delayed :
 - 16 Countries which were forced into stock out after introduction
- **SAGE recommends that countries plan catch up activities**
 - Catch up can be done with either fractional dose or full dose IPV, through routine visits or SIAs
- **cVDPV2 outbreaks highlight risks to countries with low coverage**
 - cDPV2 likelihood decreases over time, however impact increases significantly
 - With waning type 2 immunity, to stop the spread of cVDPV2 outbreaks, population immunity must be as high as possible

**estimate based on UN population data*

Options for catching up missed children

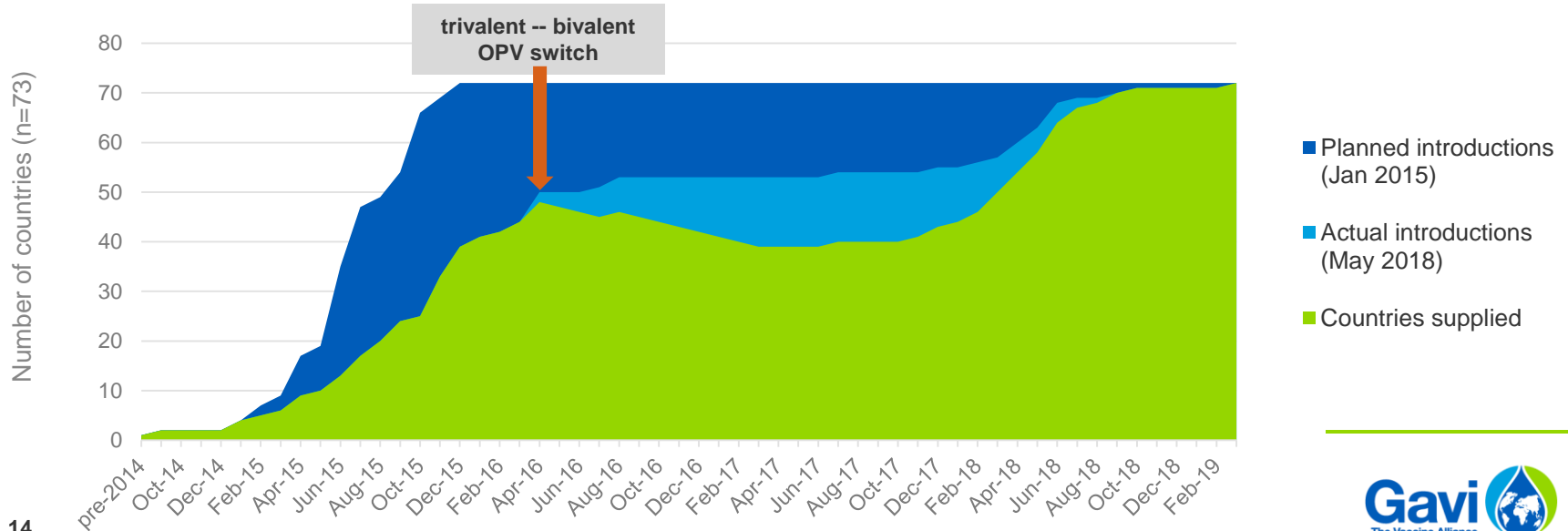
	Full dose in routine	fIPV SIAs
Timing	2019/2020. Full dose catch up can only occur in 2019/2020	2018. Can proceed now
High Coverage	Lengthy. Lengthy process due to non-targeted approach	Rapid. High coverage can be obtained rapidly
Protection	Adequate.	Better. 2 fractional doses offer better protection than one full dose
Impact on RI	Positive. Reinforces and supports RI program	Potential for disruption. May disrupt RI activities if not well planned
HCW confusion	No risk.	Minimal risk.
Cost	Higher cost.	Lower cost. Due to dose sparing, wastage and ability to proceed at 2018 prices

2

IPV INTRODUCTIONS, SUPPLY AND PRICE OUTLOOK

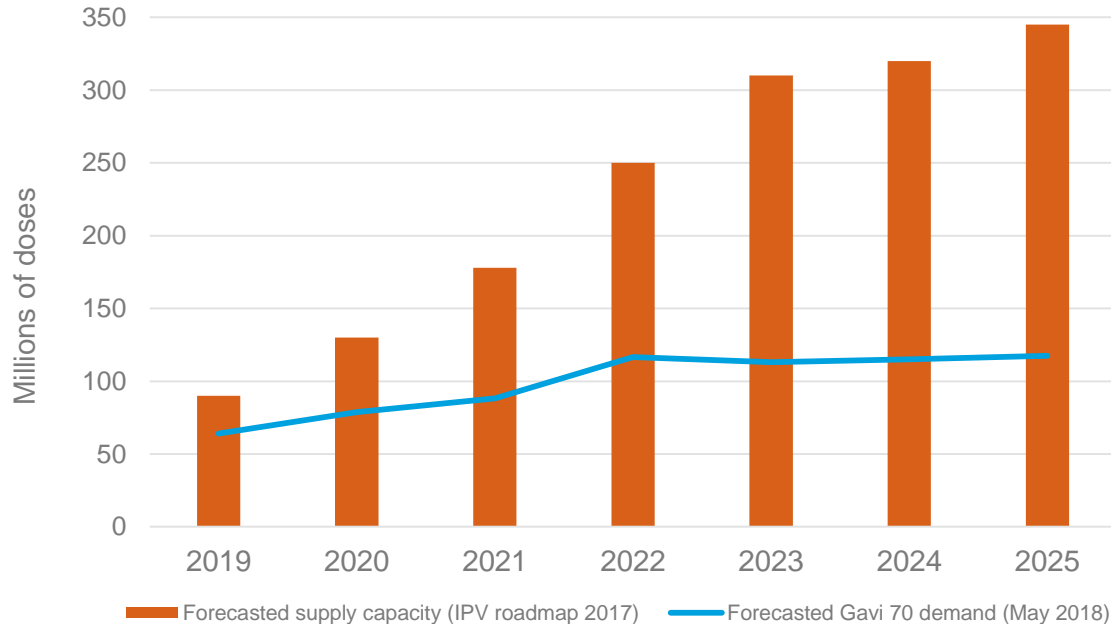
IPV introduction timeline

- Unprecedented introduction timelines for IPV introduction
- 70 Gavi eligible countries supported; India received one-time support
- 18 introductions delayed, 14 countries introduced and supply interrupted



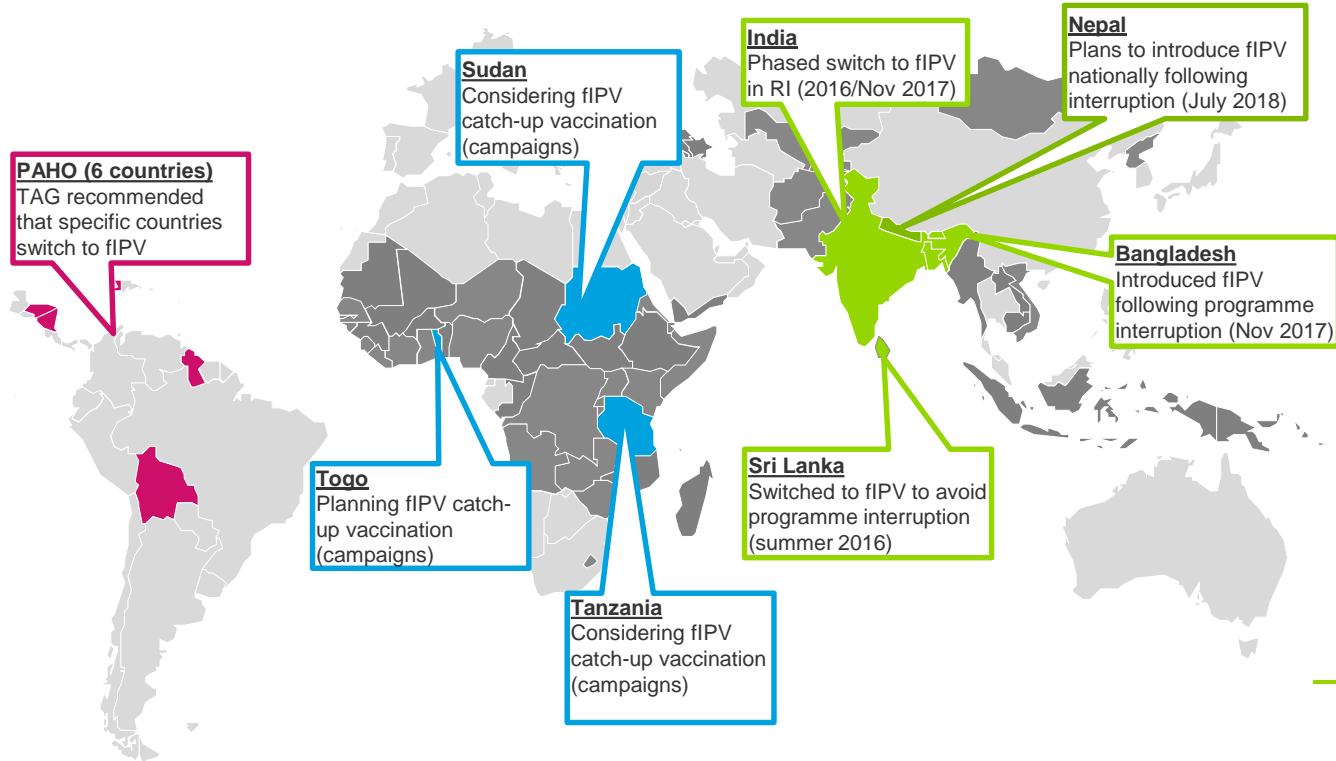
Global IPV capacity and price evolution

Forecasted supply vs. demand, 2019-25



- Recent UNICEF tender for 2019-2022 results in immediate price increase of 60% - 140%
 - India is facing a ~ US\$ 14 million per year IPV cost increase
- Price expected to reach levels similar to 2018 towards the end of the tender period
- Vaccination of missed cohorts and move to recommended 2-dose schedule as supply becomes available

Fractional IPV (fIPV) use in countries



wP Hexavalent vaccine timelines and approach

- **Recommendation to include wP Hexavalent in current VIS investment case**
- **wP Hexavalent to be compared to:**
 - Penta and IPV post-2020 standalone in primary series
 - DTwP and pentavalent for 1st booster dose
- **Board to decide in November 2018 whether to support wP Hexa in Gavi's vaccine portfolio**

***NB:** development of the standalone IPV remains the main priority for Gavi Alliance as part of the effort to eradicate polio, and any Hexavalent development should not adversely impact the availability of IPV standalone vaccines*

Hexavalent WG:

- WHO, UNICEF, BMGF and Gavi Secretariat

Objectives:

- Analyse the potential value of wP Hexa in context of Gavi support to polio eradication
- Describe the decision pathways required for Gavi to support Hexa
- Integrate programmatic, financial and supply analysis into VIS

3

GAVI'S FUTURE ENGAGEMENT IN POLIO

IPV support post-2020 (VIS)

Primary considerations



Funding levers

Country inclusion, eligibility	Country funding level	Funding duration	wP Hexavalent
<ul style="list-style-type: none">• 70 countries (<i>status quo</i>)• Tailored based on risk• Standard eligibility + transition policy	<ul style="list-style-type: none">• Fully funded (<i>status quo</i>);• Tailored based on risk• Standard co-financing policy	<ul style="list-style-type: none">• 10 yrs from bOPV removal• Tailored based on risk• Standard eligibility + transition policy• Until certification	<ul style="list-style-type: none">• Primary series (i.e., pentavalent)

Programme factors

Year of certification	Supply	Dosing, vax schedule	Duration of use	Price
2021	Sufficient for 2 dose schedule	2 full or fractional doses	10 years	WAP informed by recent tender

IPV support post-2020 (VIS)

Questions for discussion

Polio eradication is a global public good and continued use of IPV is necessary to achieve and secure this goal.

- Q1:** *Understanding that the risk of poliovirus re-emergence increases if countries discontinue use of IPV in EPI, how should the risk of programme discontinuation be weighed against the principle of country financing?*
- Q2:** *What should be the nature of Gavi's commitment to this effort – scope of countries, financing levels and duration?*

Broader engagement in polio eradication:

Polio transition

Risk level	Countries
Endemic	Afghanistan, Nigeria, Pakistan
Very High	Chad, Somalia, South Sudan
High	DR Congo, Ethiopia, Sudan
Medium	Angola, Cameroon
Low	Bangladesh, India, Indonesia, Myanmar, Nepal, all low probability

- Limited risk to Gavi in most countries
- Six fragile countries considered high-risk
- JAs increasingly being leveraged to determine immunization-critical functions and capacities for time-limited bridging support

Broader engagement in polio eradication: *Post Certification*

Post-Certification Strategy (PCS) developed

WHO draft strategic action plan presented to WHA

Essential polio functions

	Part of current activities	Comparative advantage
• Strengthen immunization systems	✓	✓
• Ensure availability of affordable IPV	✓	✓
• Strengthened VPD surveillance and lab capacity	✓	✓
• Support for vaccine stockpiles (IPV and mOPVs)	---	✓
• Strategies for sustained IPV use and financing	---	✓
• Polio surveillance – AFP and environmental	---	---
• Containment of polioviruses	---	---
• Polio outbreak preparedness, detection and response	---	---

THANK YOU



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