POLIO ERADICATION AND POST-CERTIFICATION STRATEGY

PRE-BOARD MEETING
5 June 2018, Geneva
# Agenda

<table>
<thead>
<tr>
<th>Topic</th>
<th>Presenter</th>
<th>Time</th>
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<tbody>
<tr>
<td>1. Polio eradication update</td>
<td>WHO</td>
<td>10 minutes</td>
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<tr>
<td>2. IPV supply, demand and price outlook</td>
<td>Gavi</td>
<td>10 minutes</td>
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<tr>
<td>3. Polio transition and post-certification</td>
<td>Gavi, WHO</td>
<td>10 minutes</td>
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<tr>
<td>4. Discussion</td>
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<td>45 minutes</td>
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Polio Eradication – Global update
Gavi Pre Board Meeting, Geneva, 5 June 2018
Michel Zaffran, Director, Polio Eradication
Eradication and Post Certification

Polio Eradication & Endgame Strategic Plan | Polio Post-Certification Strategy

Today | Interruption | Certification | bOPV Cessation

Pre-Certification | Pre-Cessation | Post-Cessation

• Containment
• Immunization
• Vaccine Management
• Surveillance

• Outbreak preparedness and response
• Research

GPEI

Jan. 2018: WHO Executive Board review
Jan. 2018: Polio Oversight Board approval
May 2018: Presentation to World Health Assembly

Overlap period - GPEI & post-GPEI programmes (at least 12 months)

GPEI Dissolution at Certification

Post-GPEI programmes
Global Wild Poliovirus & cVDPV Cases¹ (Past 6 Months²)

Public Health Emergency of International Concern declared under the International Health Regulations in May 2014 Confirmed on 30 April 2018

¹Excludes viruses detected from environmental surveillance
²Onset of paralysis: 30 November 2017 – 29 May 2018

Data in WHO HQ as of 29 May 2018
Risks from poliovirus after certification

Core PCS assumptions

• **Global eradication of all wild poliovirus** will be certified\(^1\)

• 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

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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. OPV\(^2\) withdrawal, IPV\(^3\) 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.

<table>
<thead>
<tr>
<th>PCS goals</th>
<th>Description</th>
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<tbody>
<tr>
<td>1</td>
<td><strong>Contain Poliovirus Sources</strong></td>
</tr>
<tr>
<td>2</td>
<td><strong>Protect Populations</strong></td>
</tr>
<tr>
<td>3</td>
<td><strong>Detect and Respond</strong></td>
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Note: Research & Development is included in the PCS as a cross-cutting enabling function

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\(^1\) Post-Certification Strategy (PCS) Summary

\(^2\) OPV

\(^3\) IPV
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 breech.

- 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

- Introduced* to date (168 countries)
- Re-introduced (8 countries)
- Formal commitment to introduce in 2018-2019 (11 countries)
- Introduced but need to re-introduce (7 countries)
- Not available
- Not applicable

Map production Immunization Vaccines and Biologicals (IVB), World Health Organization

Data source: WHO/IVB Database, as of 16 May 2018
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

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

India: Phased switch to fIPV in RI (2016/Nov 2017)
Bangladesh: Introduced fIPV following programme interruption (Nov 2017)
Sri Lanka: Switched to fIPV to avoid programme interruption (summer 2016)
Nepal: Plans to introduce fIPV nationally following interruption (July 2018)
Sudan: Considering fIPV catch-up vaccination (campaigns)
Togo: Planning fIPV catch-up vaccination (campaigns)
Tanzania: Considering fIPV catch-up vaccination (campaigns)

PAHO (6 countries): TAG recommended that specific countries switch to fIPV
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
GAVI’S FUTURE ENGAGEMENT IN POLIO
IPV support post-2020 (VIS)

**Primary considerations**
- Global public good – Insurance policy
- Alignment with SAGE recommendations
- Balancing risk appetite and costs

**Country inclusion, eligibility**
- 70 countries (status quo)
- Tailored based on risk
- Standard eligibility + transition policy

**Country funding level**
- Fully funded (status quo);
- Tailored based on risk
- Standard co-financing policy

**Funding duration**
- 10 yrs from bOPV removal
- Tailored based on risk
- Standard eligibility + transition policy
- Until certification

**WAP Hexavalent**
- Primary series (i.e., pentavalent)

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

<table>
<thead>
<tr>
<th>Risk level</th>
<th>Countries</th>
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<tr>
<td>Endemic</td>
<td>Afghanistan, Nigeria, Pakistan</td>
</tr>
<tr>
<td>Very High</td>
<td>Chad, Somalia, South Sudan</td>
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<tr>
<td>High</td>
<td>DR Congo, Ethiopia, Sudan</td>
</tr>
<tr>
<td>Medium</td>
<td>Angola, Cameroon</td>
</tr>
<tr>
<td>Low</td>
<td>Bangladesh, India, Indonesia, Myanmar, Nepal, all low probability</td>
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- 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

<table>
<thead>
<tr>
<th>Function</th>
<th>Part of current activities</th>
<th>Comparative advantage</th>
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<tbody>
<tr>
<td>Strengthen immunization systems</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Ensure availability of affordable IPV</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Strengthened VPD surveillance and lab capacity</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Support for vaccine stockpiles (IPV and mOPVs)</td>
<td>---</td>
<td>✓</td>
</tr>
<tr>
<td>Strategies for sustained IPV use and financing</td>
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<td>✓</td>
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<tr>
<td>Polio surveillance – AFP and environmental</td>
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<tr>
<td>Containment of polioviruses</td>
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<tr>
<td>Polio outbreak preparedness, detection and response</td>
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Board Meeting
6-7 June 2018
THANK YOU