Polio eradication and endgame strategy

IPV supply, financing and introduction: An update

On behalf of IMG partners

Michel Zaffran
SAGE Meeting | April 2014 | Geneva
Setting the stage for IPV introduction

September 2013: GPEI donors commit to fund IPV implementation

September - October 2013: WHO regional committees

November 2013:
- SAGE recommendations on IPV introduction planning and schedule
- GAVI Board decision to support all GAVI countries
- Briefing of WHO representatives of OPV using countries

December 2013: GAVI application window opens

January 2014:
- Letter to Ministers of Health signed by heads of WHO, UNICEF and GAVI
- Letter of UNICEF Regional Directors to all country representatives

February-March 2014:
- UNICEF tender awarded and IPV prices made public
- EPI Managers’ meetings in Africa, Europe and Eastern Mediterranean regions, national workshops in Nigeria, Bangladesh, Nepal, etc.
Efforts to date

• Countries divided into ‘tiers’ based on criteria to identify risk following type 2 OPV withdrawal
• Mappings of all planned vaccine introductions to ensure no negative impact
• Analysis of country readiness, cold chain and demand forecasting
• Status assessments of regulatory environment and IPV registration
• Securing sufficient vaccine supply at affordable prices
• Communication on WHO recommendations and IPV pricing based on UNICEF tender outcomes
• Adapting the integrated RI-PEI framework in 10 focus countries
Tiers of OPV-using countries and birth cohort

<table>
<thead>
<tr>
<th>% of birth cohort</th>
<th>24%</th>
<th>38%</th>
<th>61%</th>
<th>72%</th>
<th>83%</th>
<th>100%</th>
</tr>
</thead>
<tbody>
<tr>
<td>India</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>China</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tier 1</td>
<td>12</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tier 2</td>
<td>19</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tier 3</td>
<td>14</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tier 4</td>
<td>77</td>
<td></td>
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</tbody>
</table>

# of countries:
- 12 countries (Tier 1)
- 19 countries (Tier 2)
- 14 countries (Tier 3)
- 77 countries (Tier 4)
## New vaccine introductions incl. IPV

### Updated date: March 2014

<table>
<thead>
<tr>
<th>Country</th>
<th>Penta</th>
<th>Pneumo</th>
<th>Rota</th>
<th>MSD</th>
<th>MR/MMR</th>
<th>HepB birth</th>
<th>HPV</th>
<th>IPV</th>
<th>YF</th>
<th>MenA</th>
<th>No. NV introduced by 2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Botswana</td>
<td>2009</td>
<td>2011</td>
<td>2000</td>
<td></td>
<td></td>
<td>2014</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Mauritius</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2015</td>
<td>1</td>
</tr>
<tr>
<td>Swaziland</td>
<td>2010</td>
<td>2008</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Seychelles</td>
<td></td>
<td>2008</td>
<td></td>
<td></td>
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<td>1</td>
</tr>
</tbody>
</table>

### Example from East & South AFRO:

- Close to 70 new vaccine introductions planned from 2014-17
- By end 2015, IPV will be introduced in all 21 countries
- 3 countries planning to introduce IPV in 2014 and 17 countries in 2015
Results of cold chain capacity analysis as of 26 March

- Capacity gaps quantified
- Follow up to confirm status and close gaps
- Review of existing plans to expand and improve capacity where needed
- Monitoring of next steps to be closely tracked

**Tier 1 Countries (n=13)**
- Somalia
- Afghanistan
- Ethiopia
- India

**Tier 2 Countries (n=14)**
- Indonesia
- CAR, South Sudan
- 4 countries: Haiti, Lao PDR, Mali, Mozambique
- 7 countries: Azerbaijan, Cambodia, Guinea, Mauritania, Myanmar, Papua New Guinea, Timor-Leste

- Sufficient Cold Chain Capacity
- Insufficient Cold Chain Capacity
- Unknown due to unrest
- Unknown
## Financial support to countries

<table>
<thead>
<tr>
<th>Countries</th>
<th># Countries</th>
<th>Cohort</th>
<th>Financial support</th>
</tr>
</thead>
<tbody>
<tr>
<td>GAVI eligible (except India)</td>
<td>72</td>
<td>~55M</td>
<td>• Full support for vaccine costs (i.e. no co-financing)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Vaccine introduction grant of USD 0.80 per child</td>
</tr>
<tr>
<td>GAVI graduating countries</td>
<td>2</td>
<td>~44M</td>
<td>• Technical assistance</td>
</tr>
<tr>
<td>India</td>
<td>2</td>
<td>~44M</td>
<td>• Technical support</td>
</tr>
<tr>
<td>China</td>
<td>2</td>
<td>~44M</td>
<td>• Technical support</td>
</tr>
<tr>
<td>Lower-middle income countries</td>
<td>10</td>
<td>~6M</td>
<td>• Technical support</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Potential exceptional support for vaccine costs</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>(under development)</td>
</tr>
<tr>
<td>Middle income and higher income countries</td>
<td>42</td>
<td>~9M</td>
<td>• Technical support</td>
</tr>
<tr>
<td>TOTAL</td>
<td>126</td>
<td>~114m</td>
<td></td>
</tr>
</tbody>
</table>
Non-GAVI middle-income countries

Needs assessments in progress:
- IPV ability to pay model developed using existing information
- Willingness to pay survey under development to gather country data
- Collection of concerns from countries through regional and sub-regional meetings (e.g. technical support to decision-making, procurement, financing)

Options being explored (additional to regular TA) include:
- Credit lines/guarantees
- Funding vaccine for initial period of time
- One-off Introduction grant for start-up costs
- Subsidizing vaccine price

Based on analysis of actual country needs and feasibility of options, proposals will be discussed with GPEI donors.
IPV supply, presentations and pricing
IPV awards and demand aligned

- 1 dose presentations available in limited quantities throughout (3-1 mio.), more could become available from 2016 (but would reduce 5 dose supply)
- 10 dose available in high quantities starting from July 2014 (20-70-80 mio.)
- 5 dose presentation not yet prequalified by WHO (conditional award)
Lead times for ordering IPV

IPV is NOT OPV! Not available unless planned.

- **To anticipate 2014 Q4 introductions**, a ‘generic’ purchase order will be placed by UNICEF in coming weeks

- **Current lead time is up to 9 months** from order placement until vaccine can be delivered
  - 10 dose presentation: 9 months
  - 1 and 5 dose (when available): 3-6 months

- **For GAVI countries**, GAVI and UNICEF are working to reduce the lead time for the 10-dose, but this can only be done for known requirements that are confirmed

- **Non-GAVI countries** need to plan introduction based on these lead times. For stock management and replenishment of ongoing programmes, these timelines need to be built into reordering processes

- **UNICEF will confirm timing and availability per country**
## IPV prices for supply through UNICEF (2014-2018)

### Presentation | Supplier Name | IPV Price per Dose
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Single Dose</strong></td>
<td>Bilthoven Biologicals</td>
<td>$2.80 $2.80 $2.80 $2.80</td>
</tr>
<tr>
<td><strong>5 Dose</strong> (pending prequalification)</td>
<td>Bilthoven Biologicals/Serum Institute of India</td>
<td>$1.90 $1.90 $1.90 $1.90 $1.50-$1.90</td>
</tr>
<tr>
<td><strong>10 dose</strong></td>
<td>Sanofi Pasteur (73 GAVI supported countries)</td>
<td>€ 0.75 € 0.75 € 0.75 € 0.75 € 0.75</td>
</tr>
<tr>
<td></td>
<td>Sanofi Pasteur (tier 1)**</td>
<td>€ 1.49 € 1.49 € 1.49 € 1.49 € 1.49</td>
</tr>
<tr>
<td></td>
<td>Sanofi Pasteur (tier 2)**</td>
<td>€ 1.93 € 1.93 € 1.93 € 1.93 € 1.93</td>
</tr>
<tr>
<td></td>
<td>Sanofi Pasteur (tier 3)**</td>
<td>€ 2.40 € 2.40 € 2.40 € 2.40 € 2.40</td>
</tr>
</tbody>
</table>

Tier 1 countries: Cape Verde, Egypt, Morocco, Palestine, Philippines, Samoa, Swaziland, Vanuatu
Tier 2 countries: Albania, Algeria, Fiji, Iran, Macedonia, Maldives, Namibia, Serbia, Thailand, Tonga, Tunisia, Turkmenistan
Tier 3 countries: Botswana, Gabon, Lebanon, Mauritius, Seychelles, Tuvalu

**Price and product information here:**
Conclusions for IPV supply

• Supply anticipated to be **sufficient to meet demand**
• Supply **available from mid 2014** to support early country introductions
  – Need to spread introductions and buffer stocks
• Available presentations 1 and 10 dose vials
  – Flexibility required from countries on preferred presentations to maximize introductions and utilization of available supply
• 5-dose presentation expected end Q3 or early Q4
  – From 2015 expect to meet all demand for 5 dose vials
• Substantial price reduction
• **No IPV containing combination** vaccines offered to UNICEF
  – Limited global supply (no availability of IPV/wP combinations)
Status of country planning and dialogue with countries
Themes from EPI Managers’ Meetings

Strong commitment to move forward within timelines

In spite of challenges and concerns:

• Managing programmatic implications within short timelines and with an already heavy workload
  – Numerous other priorities including other vaccine introductions
  – Cold chain capacity, social mobilization, communications
  – Timeliness of vaccine introduction grants

• Multiple injections at the same visit
  – Availability of combination vaccines

• Training of health workers:
  – A second vaccine against polio
Countries using IPV vaccine to date

Data Source: WHO/IVB Database, as at 28 March 2014
Map production: Immunization Vaccines and Biologicals (IVB), World Health Organization
Date of slide: 28 March 2014

- **Introduced to date**: 71 countries (37%)
- **Not Available, Not Introduced /No Plans**: 123 countries (63%)
- **Not applicable**

The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement. © WHO 2014. All rights reserved.
Countries using IPV and formal decision to introduce

A country will be considered as having made a formal decision when formal documentation of its decision to introduce IPV has been verified by the relevant WHO Regional Office.

Data Source: WHO/IVB Database, as at 28 March 2014 and Summary of POB indicators status as of 06 March 2014

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

Date of slide: 28 March 2014

1. Introduced to date (71 countries or 37%)
2. Introduction to occur in 2014 (3 countries or 2%)
3. Introduction to occur in 2015 (6 countries or 3%)
4. Not Available, Not Introduced /No Plans (114 countries or 59%)
5. Not applicable

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A country will be considered as having made a formal decision when formal documentation of its decision to introduce IPV has been verified by the relevant WHO Regional Office.

Data Source: WHO/IVB Database, as at 28 March 2014 and AFR/EUR/EMR EPI Managers Meetings in Feb/March 2014 and Summary of POB indicators status as of 06 March 2014

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

Date of slide: 28 March 2014
Main issues that could affect timelines

- **GAVI countries**
  - IRC meetings, recommendations, decision letters and release of introduction grant

- **Non GAVI tier 1-2 countries** (e.g. Philippines, Iraq, Gabon, Eq. Guinea)
  - Understanding what type of support is required and defining mechanisms

- **Key countries**: China, India, Thailand, Indonesia, Vietnam
  - Locking final decisions and timelines

- **PAHO countries**
  - April Working Group and TAG recommendations and next steps for countries of the Americas
Key next steps

- **Technical assistance** to countries for decision making and development of IPV introduction plans
  - **Dedicated focus** on Tier 1 and Tier 2 countries
  - **Consultants’ trainings** (Atlanta in March 2014, Brazzaville in April 2014)

- **Communication materials**
  - Introduction planning and roll out, health worker training kit

- **Deciding on possible financial support** to key middle income countries

- **World Health Assembly** report and Side Event for all OPV using countries

- Regular report on indicators to POB
  - IPV introduction and RI strengthening
Questions to SAGE

• Does SAGE concur that the IPV supply and financing situation (outcome of the UNICEF Tender) meet near term expectations and needs, and that they constitute a firm basis for meeting the set IPV introduction timelines?

• Does SAGE have advice for global, regional or national actions to further support the timely introduction of IPV by end-2015 as a central element of global readiness for OPV2 withdrawal?
THANK YOU!
MERCI!

For more information: