Polio eradication and Endgame strategy

IPV introduction
Strategy and Status

12th WHO/UNICEF consultation with OPV/IPV manufacturers and National Regulatory Authorities

Geneva
10 October 2013
## Current status

<table>
<thead>
<tr>
<th>IPV-OPV using</th>
<th># Countries</th>
</tr>
</thead>
<tbody>
<tr>
<td>OPV only</td>
<td>124 (2)</td>
</tr>
<tr>
<td>(Announced future introduction)</td>
<td></td>
</tr>
<tr>
<td>IPV</td>
<td>50</td>
</tr>
<tr>
<td>Sequential</td>
<td>20</td>
</tr>
<tr>
<td>Total</td>
<td>194</td>
</tr>
</tbody>
</table>
Polio Eradication Governance

World Health Assembly

- Objective 1: Independent Monitoring Board (IMB)
- Objective 2: Advisory Group of Experts (SAGE)
- Objective 3: Global Certification Commission (GCC)

Polio Oversight Board (POB)

Polio Partners Group (PPG)

Polio Steering Committee (PSC)

- Eradication Mgmt. Group (EMG)
- Imm Systems Mgmt. Group (IMG)*
- Polio Advocacy Group (PAG)
- Finance Working Group (FWG)

WHO Secretariat
Coordination of Strategic Plan Objective 2
- Immunization Systems Management Group (IMG) -

*Five work streams:*

- Implementation (readiness, supply & demand)
- Regulatory
- Financing
- Communications
- Routine immunization Strengthening
One joint-work plan guides activities across organisations
Coordination and accountability

**GAVI**
- GAVI Alliance Board
  - CEO and GAVI ET
    - SG Mgt groups (e.g. VIMT, SG2)

**Leadership alignment**
- GAVI CEO ↔ WHO ADG

**Operational integration**
- IMG Sub-groups:
  - Communications
  - Implementation
    - Financing
    - Regulatory
    - Routine immunization

**GPEI**
- Polio Oversight Board
  - Polio Steering Committee
    - Mgt groups (e.g. IMG, FWG, PAG)

Key:
- Oversight
- Executive Management
- Program Management
Coordination of Strategic Plan Objective 2
- Immunization Systems Management Group (IMG) -

*Five work streams:*

- Implementation (readiness, supply & demand)
- Regulatory
- Financing
- Communications
- Routine immunization Strengthening
Implementation work stream

Lead* : WHO/EPI and GAVI secretariat

Objective:
Ensure all OPV using countries have access to information, technical and financial support to introduce IPV and switch from tOPV to bOPV.

Status:
• Countries tiered according to level of risk
• Initial demand forecast developed
• Readiness assessment (product registration, supply chain)
• Policy dialogue with countries initiated (e.g. Regional Committees, Technical Advisory Groups, Key countries)
• Communication strategy
• Strategies for GAVI and Non GAVI countries

*This group operates as a joint subgroup of the IMG and the Vaccine Implementation Management Team, which helps coordinate new vaccine introduction through the GAVI Alliance
1. Tiering of countries
Rationale

Role of IPV

• Prevent poliomyelitis in IPV vaccinated individuals exposed to vaccine-derived poliovirus type-2 (VDPV2)
• Prime populations to improve the response to monovalent OPV type-2 (mOPV2) or an additional dose of IPV in the event of a type 2 polio outbreak
• Accelerate wild poliovirus eradication in remaining endemic countries by boosting immunity to wild poliovirus types 1 and 3

Strategy

• IPV introduction is a risk mitigation strategy,
• Criteria established to identify countries at highest risk following OPV2 cessation
  – cVDPV2 outbreak
  – Importations
• Prioritize communication, technical assistance and advocacy efforts

Support all OPV countries to introduce at least one dose of IPV by 2015
Criteria for tiering countries

Tier 1- Top Priority
• Countries with evidence of ongoing cVDPV2 transmission or cVDPV2 reported since 2000
  – cVDPV2 outbreak is the primary risk following OPV2 cessation
• WPV endemic countries
  – Potential for IPV to accelerate wild poliovirus eradication by boosting immunity to wild poliovirus types 1 and 3.

Tier 2- Second Highest priority
• Countries with any history of cVDPVs (types 1 and 3) since 2000
  – Risk factors for VDPV outbreaks are similar for all VDPV serotypes
• Countries that have repeatedly reported routine immunization coverage estimates of less than 80% over the past three years
  – Persistent low routine immunization coverage is the most important predictor of VDPV emergence
Tier 3:
• Countries sharing a border with Tier 1 countries that have reported WPV since 2003
  – Predicted future risk of cVDPV2 importations, based on trends for importation of wild virus
• Countries that have experienced a WPV importation since 2011.
  – Any WPV importation since 2011 (when India eradicated polio) reflects current risk of importation from remaining endemic countries.

Tier 4
• All other remaining OPV only using countries
Possible country tier for IPV introduction based on endemic status, history of cVDPV emergence, recent DTP3 coverage, and PV importation risk

**Legend:**
- **Countries that use at least one dose of IPV in the routine immunization schedule**
- **Tier 1:** WPV Endemic countries OR countries that have reported cVDPV2 since 2000
- **Tier 2:** Countries who have reported a cVDPV/cVDPV3 since 2000 OR large/medium sized countries with DTP3 coverage < 80% in 2009, 2010, and 2011 (as per WUNIC)
- **Tier 3:** Large/medium countries adjacent to Tier 1 countries that have reported WPV since 2003 OR countries that experienced a WPV importation since 2011*
- **Tier 4:** All other OPV only using countries

**Data Sources:**
- Admin. Boundaries: World Health Organization
- Base Map: ESR
- Map Production: Public Health Information and Geographic Information Systems (GIS)
- Large/Medium Countries: Countries with birth cohort greater than 20,000 live births per year as per UNDP estimate for 2015
  *Including environmental data

**Map Scale (A3):** 1:100,000,000
1 cm = 1,000 km

Datum: WGS 1984
Unit: Degree

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. borders. Omitted and distorted lines on maps represent approximate border lines for which there may not be full agreement.
<table>
<thead>
<tr>
<th>Tier</th>
<th>#</th>
<th>OPV Using Birth Cohort</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tier 1</td>
<td>14</td>
<td>61% 24% 14%</td>
<td>WPV Endemic OR cVDPV2 since 2000</td>
</tr>
<tr>
<td>India</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>China</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tier 2</td>
<td>19</td>
<td>11%</td>
<td>cVDPV1/cVDPV3 since 2000 OR DTP3 coverage &lt;80% in 2009, 2010, 2011</td>
</tr>
<tr>
<td>Tier 3</td>
<td>14</td>
<td>11%</td>
<td>Adjacent to Tier 1 countries with WPV since 2003 OR WPV Importation since 2011 (includes environmental data)</td>
</tr>
<tr>
<td>Tier 4</td>
<td>77</td>
<td>17%</td>
<td>All other countries</td>
</tr>
<tr>
<td>Total</td>
<td>124</td>
<td>100%</td>
<td></td>
</tr>
</tbody>
</table>
2. Demand Forecast
Scenarios represent an initial view into demand:


Both scenarios are ambitious, representing an unprecedented scale-up, requiring effective and clear communications with countries, streamlined financing, technical assistance and procurement processes.

Forecasts generated through global-level discussions with partners and preliminary discussions with some large countries; future iterations to be refined and validated with country input.

Dose calculated based on assumption that coverage will match DTP3 within 12 months after introduction, except for large countries where introduction spans over two years.
Initial IPV demand forecast

Line: Scenario 1*

Bars: Scenario 2*

*Scenario 1 = “Ideal”; Scenario 2 = “Endgame timelines”
3. Readiness
Impact of IPV on cold chain capacity is limited, however
- many countries systems are already stressed
- Other new vaccines introduction is an opportunity to address system limitations
## IPV and other introductions (examples)

<table>
<thead>
<tr>
<th>Country</th>
<th>2014 (# of introductions)</th>
<th>2015 (# of introductions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Afghanistan</td>
<td>(1) IPV</td>
<td>(1)</td>
</tr>
<tr>
<td>Angola</td>
<td>(2)</td>
<td>(1) IPV</td>
</tr>
<tr>
<td>Bangladesh</td>
<td>(3) 2+ IPV</td>
<td>(1)</td>
</tr>
<tr>
<td>Cameroon</td>
<td>(2)</td>
<td>(3) 2+ IPV</td>
</tr>
<tr>
<td>Congo, DR</td>
<td></td>
<td>(2) 1+IPV</td>
</tr>
<tr>
<td>Ethiopia</td>
<td>(1)</td>
<td>(1) IPV</td>
</tr>
<tr>
<td>Ghana</td>
<td>(1) IPV</td>
<td>(2)</td>
</tr>
<tr>
<td>Indonesia</td>
<td></td>
<td>(1) IPV</td>
</tr>
<tr>
<td>Kenya</td>
<td>(2) 1+IPV</td>
<td>(3)</td>
</tr>
<tr>
<td>Madagascar</td>
<td>(2) 1+ IPV</td>
<td>(1)</td>
</tr>
</tbody>
</table>
WHO Member States
194

IPV only using Countries
50
- Andorra
- Australia
- Austria
- Bahamas
- Belgium
- Bosnia and Herzegovina
- Brunei Darussalam
- Bulgaria
- Canada
- Costa Rica
- Croatia
- Cyprus
- Czech Republic
- Denmark
- Estonia
- Finland
- France
- Germany
- Greece
- Hungary
- Iceland
- Ireland
- Israel
- Italy
- Japan
- Latvia
- Lithuania
- Luxembourg
- Malta
- Mexico
- Monaco
- Netherlands
- New Zealand
- Niue
- Norway
- Palau
- Poland
- Portugal
- Republic of Korea
- Romania
- San Marino
- Slovakia
- United Kingdom
- United States of America
- Uruguay
- Singapore
- Slovenia
- Spain
- Sweden
- Switzerland

Sequential Schedules
20
- Bahrain
- Belarus
- Brazil
- Jordan
- Kazakhstan
- Kuwait
- Lebanon
- Malaysia
- Marshall Islands
- Micronesia
- Montenegro
- Oman
- Qatar
- Russia
- Saudi Arabia
- Turkey
- Ukraine
- United Arab Emirates
- South Africa
- Syria

Mostly OPV using Countries
124
- Argentina
- Bolivia
- Chile
- Colombia
- Ecuador
- Georgia
- Georgia
- Greece
- Iraq
- Jordan
- Kazakhstan
- Kuwait
- Lebanon
- Malaysia
- Marshall Islands
- Micronesia
- Montenegro
- Oman
- Qatar
- Russia
- Saudi Arabia
- Syria
- Algeria
- Angola
- Benin
- Burundi
- Cameroon
- Chad
- Equatorial Guinea
- Guinea
- Eritrea
- Iran
- Iraq
- Jordan
- Kazakhstan
- Kuwait
- Lebanon
- Malaysia
- Marshall Islands
- Micronesia
- Montenegro
- Oman
- Qatar
- Russia
- Saudi Arabia
- Syria

Tier 1
14
- China
- India
- Kenya
- Nigeria

Tier 2
19
- Afghanistan
- Cameroon
- Chad
- DRC
- Ethiopia
- Madagascar
- Niger
- Pakistan
- Somalia
- Yemen

Tier 3
14
- Bangladesh
- Benin
- Burkina Faso
- Côte d’Ivoire
- Egypt
- Nepal
- Sudan
- Tajikistan
- Turkmenistan
- Uganda

Tier 4
76
- Argentina
- Bolivia
- Chile
- Colombia
- Ecuador
- Georgia
- Georgia
- Ghana
- Guinea
- Guyana
- Haiti
- India
- Indonesia
- Iraq
- Jordan
- Kazakhstan
- Kuwait
- Lebanon
- Malaysia
- Marshall Islands
- Micronesia
- Montenegro
- Oman
- Qatar
- Russia
- Saudi Arabia
- Turkey
- United Arab Emirates
- South Africa
- Syria
- Algeria
- Angola
- Benin
- Burundi
- Cameroon
- Chad
- Equatorial Guinea
- Guinea
- Eritrea
- Iran
- Iraq
- Jordan
- Kazakhstan
- Kuwait
- Lebanon
- Malaysia
- Marshall Islands
- Micronesia
- Montenegro
- Oman
- Qatar
- Russia
- Saudi Arabia
- Syria

No Standalone
59
- Algeria
- Antigua and Barbuda
- Armenia
- Argentina
- Azerbaijan
- Benin
- Burkina Faso
- Burundi
- Cameroon
- Chad
- China
- Colombia
- Denmark
- Dominican Republic
- Eritrea
- Equatorial Guinea
- Georgia
- Ghana
- Guinea
- Guyana
- Haiti
- Honduras
- Iraq
- Israel
- Jordan
- Kazakhstan
- Korea (North)
- Korea (South)
- Kuwait
- Lebanon
- Luxembourg
- Malaysia
- Marshall Islands
- Micronesia
- Montenegro
- Oman
- Qatar
- Russia
- Saudi Arabia
- Senegal
- Sierra Leone
- Singapore
- Sudan
- Tajikistan
- Tanzania
- Turkey
- Ukraine
- United Arab Emirates
- Uruguay
- Uzbekistan
- Viet Nam
- Yemen

* Sabin IPV
** Still uses OPV in National Campaigns
*** OPV Booster after 5 yrs
4. Communication
Technical Communication work stream

**Leads:** UNICEF and WHO

- All stakeholders have access to updated policy information
- Comprehensive stakeholder advocacy strategy
- Technical guidance and quality assurance on communication activities for endgame strategies

**Status**

- Frequently Asked Questions documents circulated to regions and partners
- Website established on the WHO Immunization site
- Information kit for countries under-development
Frequently Asked Questions

PLANNING FOR IPV INTRODUCTION

Frequently asked questions (FAQs)

In May 2012 the World Health Assembly declared the completion of poliovirus eradication to be a programmatic emergency for global public health and called for a comprehensive polio endgame response, the Polio Eradication and Endgame Strategic Plan 2013-2018 was developed.

The plan outlines a comprehensive approach for completing eradication including the elimination disease (both wild and vaccine-related).

As one of its four major objectives, the plan calls on countries to strengthen routine immunization at least 1 dose of Inactivated Polio Vaccine (IPV) into routine immunization schedules in Polio Vaccine (OPV) in a phased manner, starting with type 2-containing OPV. This sheet provides guidance on the introduction of IPV and the switch from trivalent OPV (tOPV) to bivalent OPV (bOPV).

Why should countries introduce IPV?

Introducing IPV is a key element of the endgame plan and global readiness to manage risk associated with OPV2 cessation. The endgame plan calls for the introduction of IPV in all using countries by the end of 2015. The primary role of IPV will be to maintain immunity to polio virus while removing OPV2 globally. More specifically, IPV needs to be introduced following reasons:

- To reduce risks. Once OPV2 is withdrawn globally, IPV will help fill the immunity gap against type 2 polio virus should it be reintroduced. A region with IPV would have a lower risk of re-emergence or re-exposure to wild or derived type 2 polio virus.
- To interrupt transmission in the case of outbreaks. Should monovalent OPV2 needed to control an outbreak, the immunity levels needed to stop transmission easier to reach with IPV compared to use of mOPV2 in a completely unimmunized population. Thus introducing IPV now could facilitate future outbreak control.

What steps will be necessary to introduce IPV?

Once the decision to introduce IPV has been made by the national authorities, the first step in IPV introduction will be for the GPEI, GAVI Alliance and other immunization partners to support national authorities to develop annual integrated action plans for strengthening immunization services in the countries that need it most. Details will be elaborated and a model workplan with milestones and timelines finalized by the end of 2013. Within this framework, focus will be on the following four areas:

- Program management - including use of accountability frameworks, data management, evidence-based planning, training and supply management;
- Microplanning - including population mapping, harmonization of routine immunization schedules with polio SIA microplans to enable more complete session planning, vaccine supply management and cold-chain logistics;
- Advocacy and communication - including top-level advocacy, engagement of local community leaders and household-level outreach.
- Immunization delivery - monitoring of immunization sessions, local community coverage and vaccine acceptance, social mobilization efforts, availability of health workers, vaccine delivery and other immunization logistics and overall quality and impact of services.

How are the timelines for IPV introduction so tight? How will countries achieve introduction targets in such a short period?

Recently we achieved the lowest level of wild polio cases in history. With the prospect of eradicating WPV transmission realistic and achievable in the near-term, aggressive timelines are required to avoid missing this window of opportunity.

Planning for IPV Introduction FAQ | September 2013
IPV Introduction and OPV2 Cessation

This site provides information on objective 2 of the Polio Eradication and Endgame Strategic Plan. It contains the rationale for and resources related to the introduction of Inactivated Poliomyelitis Vaccine (IPV) and cessation of bivalent Oral Polio Vaccine (bOPV).

The site has 5 areas:

LEARN

Understand the rationale behind objective 2 including IPV introduction, OPV cessation and routine immunization strengthening.

PLAN

Plan for IPV introduction including scheduling and financing.

IMMUNIZE

About the Inactivated Poliovirus Vaccine (IPV) including presentation options and safety.

MONITOR

Access the repository to monitor the global status of IPV introduction.

TOOLBOX

Information pack and technical materials for IPV introduction.
5. Strategies for GAVI and non GAVI countries
Roles in procurement processes

GAVI Countries (Joint)
- Donors
- GAVI
  - UNICEF SD or PAHO - for IPV procurement (then onto IPV suppliers)
  - Countries – if procure directly per GAVI policy

Non-GAVI Countries (Coordinated)
- Donors
- UNICEF SD/PAHO
  - IPV suppliers – for procurement through UNICEF SD/PAHO
  - Countries – for those that procure directly*

*Final funding flows for directly (self) procuring countries, if applicable, to be determined
GAVI policy exceptions to align with the Endgame

GAVI mission, strategic goals and policies generally well aligned with supporting IPV; Some important recommended policy exceptions to support Endgame plans

- **Eligibility:** GAVI 73 countries
- **Application window:** Until June 2015 with introduction targeted within 1 year of approval. Window to remain open if need arises
- **Duration of support:** Full support until 2024, possible review in 2018 for graduating countries
- **Immunisation cover filter:** 70% DTP coverage filter does not apply
- **Co-financing:** Exception to co-financing
- **Introduction grant:** GAVI73 countries eligible

Donor Meeting with GAVI and GPEI 10 September 2013
6. Budget
# IPV budget summary and major assumptions 2014-2018

<table>
<thead>
<tr>
<th>Category</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccine costs (GAVI countries)</td>
<td>$230M to $294M</td>
</tr>
<tr>
<td>Introduction grants (GAVI countries)</td>
<td>$36M to $41M</td>
</tr>
<tr>
<td>GPEI Subsidies (Non-GAVI countries)</td>
<td>$22M to $54M</td>
</tr>
<tr>
<td>Tech. support &amp; partner costs*</td>
<td>$40M to $60M</td>
</tr>
<tr>
<td><strong>TOTAL COSTS:</strong></td>
<td><strong>$328M to $449M</strong></td>
</tr>
</tbody>
</table>

**Major Assumptions**
- tiered pricing of vaccines (range encompassing $1/dose for GAVI)
- introduction grants for GAVI countries only
- tiered subsidies for non-GAVI countries
- India and China self-finance
7. Some risks to a successful introduction of IPV
Risks to IPV introduction and mitigation activities

1. **Timing of country decision**
   
   *Need for clarity on:*
   
   – Price of the vaccine - short and long term
   – Financing /Subsidizing mechanisms - for GAVI & Non GAVI countries

2. **Delay to introduce post-decision**
   
   *Need for technical assistance to support:*
   
   – Licensing of IPV by NRAs
   – Assessment of supply system /cold chain readiness and necessary upgrades

3. **All countries introduce over a short time period**
   
   – Build sufficient capacity for Technical Assistance, including a cadre of well trained consultants
   – Close interaction with industry to ensure adequate and timely supplies of vaccines and AD syringes
Thank You!

12th WHO/UNICEF consultation with OPV/IPV manufacturers and National Regulatory Authorities

Geneva

10 October 2013