

# **Pre-requisites for the withdrawal of type 2 OPV**

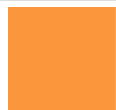
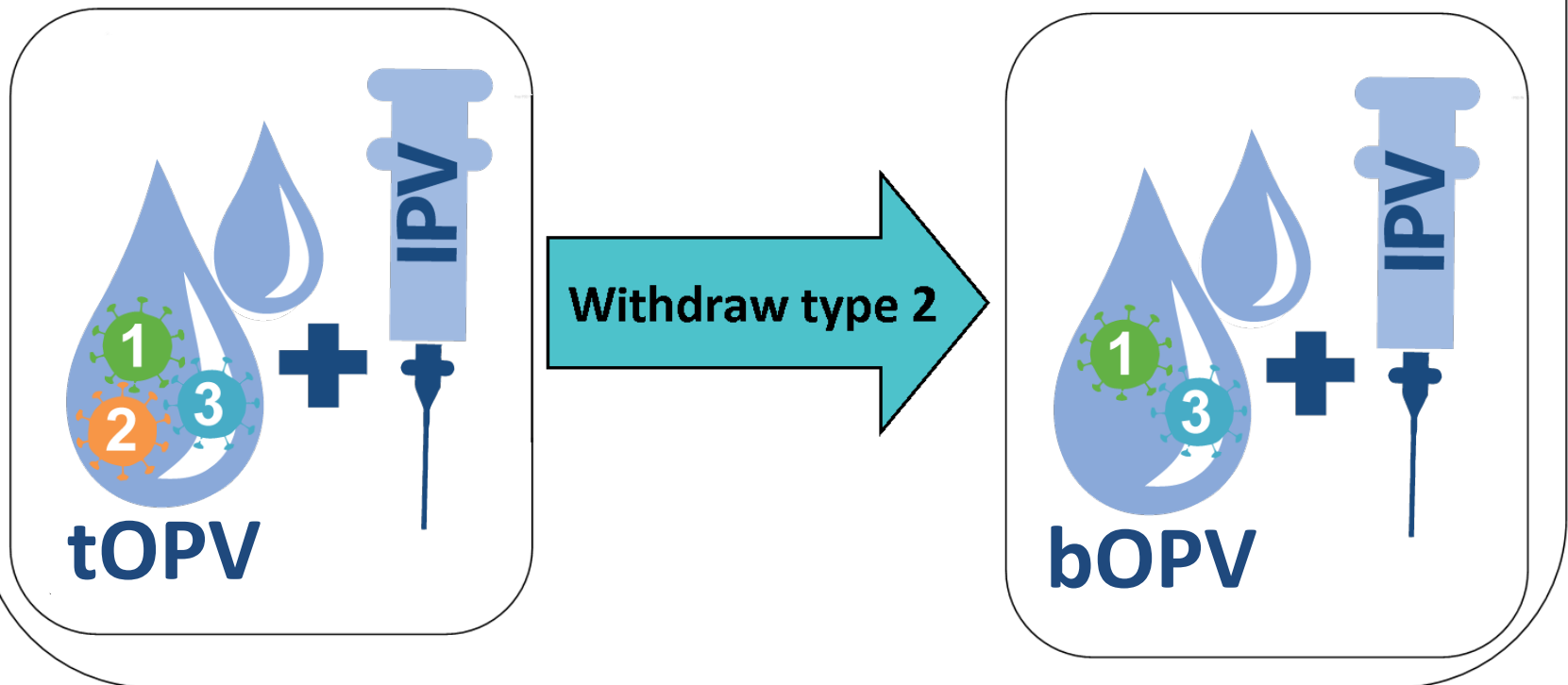
## **Report on progress**

Meeting of the Strategic Advisory Group of Experts  
Geneva, 14 April 2015

Michel Zaffran, WHO/EPI  
On behalf of the IMG

# Endgame Plan : Objective 2

OPV will be removed in a phased approach, beginning with the removal of type 2 poliovirus strain in a switch from tOPV to bOPV.



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# Criteria for assessing OPV2 withdrawal readiness (November 2013 SAGE)

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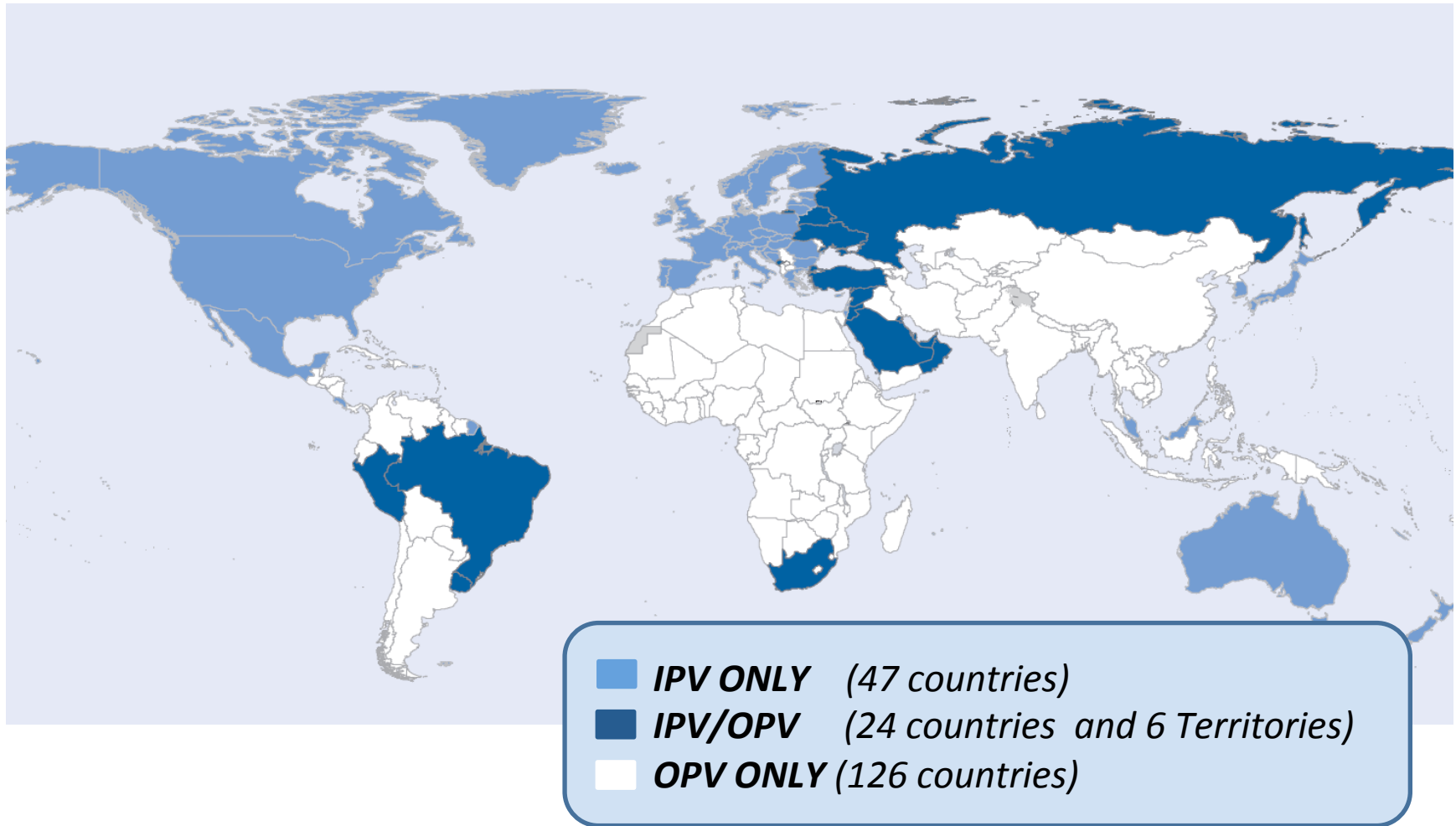
**Trigger for OPV2 withdrawal:** absence of 'persistent' cVDPV2s globally

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# January 2013 : 126 OPV-only using countries should introduce by the end of 2015

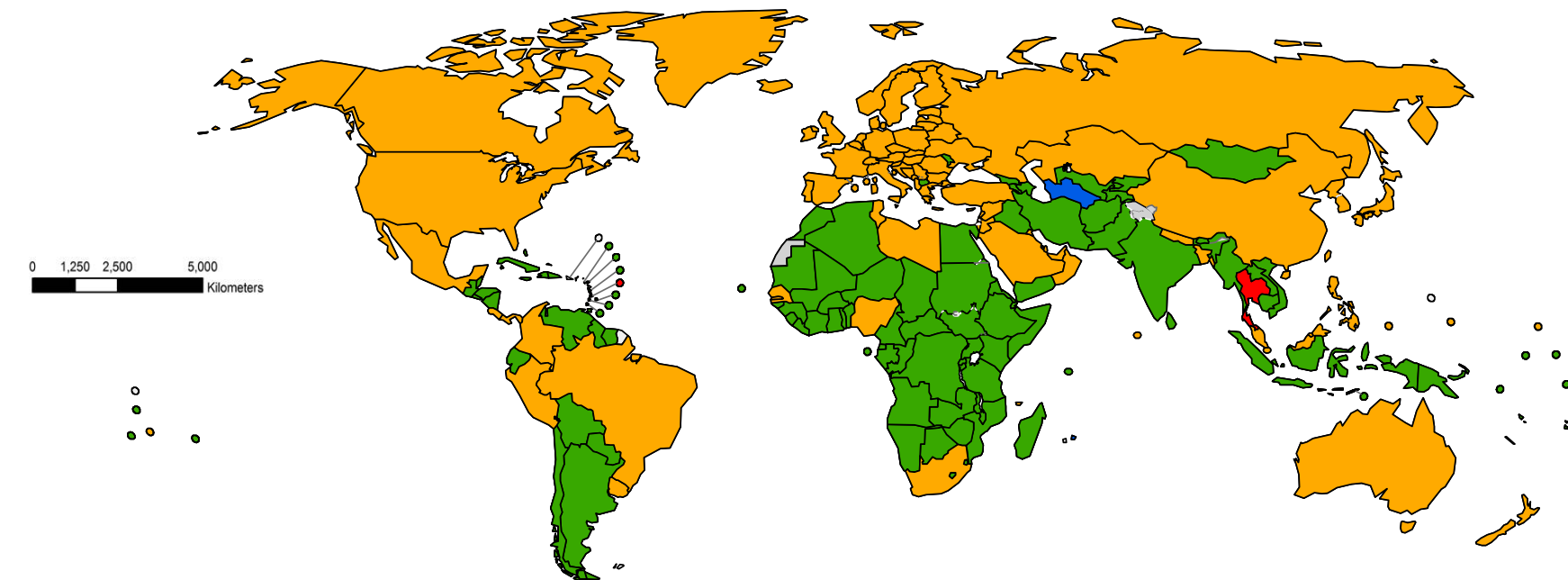


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# IPV Introduction status - April 2015

**18 introductions**  
**106 commitments/intents to introduce in 2015**



- Introduced to date (86 countries or 44%)
- Formal commitment to introduce in 2015 (104 countries or 54%)
- Intend to introduce in 2015 (2 countries or 1%)  
(Mauritius, Turkmenistan)
- Intend to introduce in 2016 (Thailand) (2 countries or 1%)  
Formal commitment to introduce in 2016 (Saint Lucia)
- Not Available
- Not applicable

Since January 2013, the following countries have introduced IPV:  
 Kazakhstan & Peru (July 2013); Libya (March 2014); Albania (May 2014); Panama (July 2014); Nepal (September 2014); Tunisia (September 2014); Philippines (October 2014); China (December 2014); Comoros (January 2015); Senegal (January 2015); Serbia (January 2015); Colombia (February 2015); Nigeria (February 2015); Bangladesh (March 2015); Maldives (March 2015); The Gambia (April 2015) and DPR Korea (April 2015)

Data source: WHO/IVB Database, as of 10 April 2015  
 Map production Immunization Vaccines and Biologicals (IVB),  
 World Health Organization

# Key reasons for progress

## Effective partnership with GAVI, and across GPEI

- All GAVI countries that have applied for IPV support (71) have
- 

## High level advocacy and Regional leadership

- 

## Integration into EPI

- 

- 

## Innovative approaches to speed up licensure

- joint reviews using expedited review procedure for PQ vaccines

## Support to countries

- 

-

# IPV: Remaining Challenges (1)

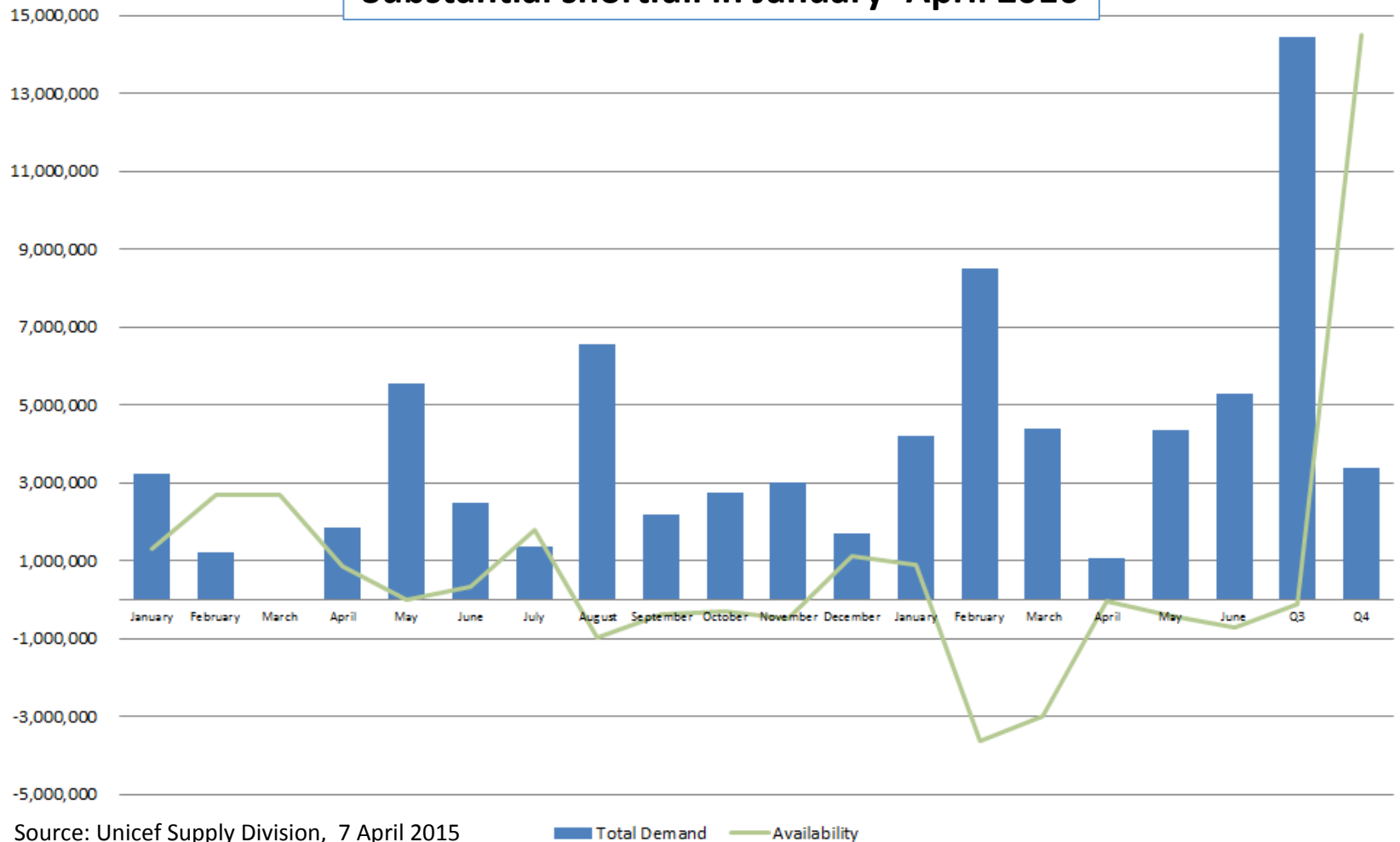
## 1. Tight IPV supply situation

- Both manufacturers will supply less than initially committed volumes in 2015 and 2016
- Pakistan and Nigeria planning more IPV SIAs for wild virus eradication purposes
- Need to delay planned introduction in most lower risk countries (tier 3 and 4) that have not yet introduced



# IPV Supply : 10 dose vials

Substantial shortfall in January- April 2016



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# 10 dose vial shortage : mitigating strategies

- Delay supply of buffer stock to countries
- High level discussions with companies to explore additional doses
- Exploring ways to accelerate local production in Indonesia
- Exploring existing stockpiles
- Confirming timing of IPV needs for SIAs in Pakistan
- Phased introduction in large countries (Pakistan, Indonesia, Ethiopia )
- Maximizing use of IPV licensed in India but not prequalified, for India programme

# IPV: Remaining Challenges (2)

## 2. Busy 2015 introduction schedule

- 41 countries planning introduction in Q4, including:
  - 4 countries in Tier 1 (India, Somalia, Ethiopia)
  - 5 countries in Tier 2 (Cambodia, Equatorial Guinea, Indonesia, Lao PDR and Guinea)
- Number will increase to 54
  - with countries that have to delay to accommodate limited supplies

# 108 countries introducing IPV

## April to December 2015

| April     | May        | June                        | July          | August           | September          | October           | November     | December    |
|-----------|------------|-----------------------------|---------------|------------------|--------------------|-------------------|--------------|-------------|
| DPR Korea | Madagascar | Benin                       | Afghanistan   | Argentina        | CAR                | Antigua & Barbuda | Algeria      | Ecuador     |
| DR Congo  | Sudan      | Botswana                    | Angola        | Rwanda           | Djibouti           | Armenia           | Barbados     | El Salvador |
| Gambia    |            | Cameroon                    | Azerbaijan    | Macedonia        | Dominican Republic | Belize            | Burundi      | Georgia     |
| Morocco   |            | Chad                        | Bahamas       | Papua New Guinea | Ghana              | Bolivia           | Dominica     | Guatemala   |
| Nauru     |            | Cote d'Ivoire               | Bhutan        | Zimbabwe         | Iran               | Cambodia          | Suriname     | Guinea      |
|           |            | Grenada                     | Burkina Faso  |                  | Jamaica            | Cook Islands      | Turkmenistan | Kyrgyzstan  |
|           |            | Guyana                      | Cabo Verde    |                  | Liberia            | Cuba              | Zambia       | Paraguay    |
|           |            | Haiti                       | Chile         |                  | Seychelles         | Egypt             |              | Venezuela   |
|           |            | Kiribati                    | Congo         |                  | Solomon Islands    | Equatorial Guinea |              |             |
|           |            | Mali                        | Eritrea       |                  | South Sudan        | Ethiopia          |              |             |
|           |            | Namibia                     | Gabon         |                  | Swaziland          | Fiji              |              |             |
|           |            | Niger                       | Guinea-Bissau |                  | Tajikistan         | Honduras          |              |             |
|           |            | St Vincent & the Grenadines | Iraq          |                  | Timor-Leste        | India             |              |             |
|           |            | Sri Lanka                   | Kenya         |                  | Trinidad & Tobago  | Indonesia         |              |             |
|           |            | Togo                        | Malawi        |                  | Vanuatu            | Lao PDR           |              |             |
|           |            | Tuvalu                      | Mauritania    |                  |                    | Lesotho           |              |             |
|           |            | Tanzania                    | Mozambique    |                  |                    | Mongolia          |              |             |
|           |            |                             | Myanmar       |                  |                    | Nicaragua         |              |             |
|           |            |                             | Pakistan      |                  |                    | Moldova           |              |             |
|           |            |                             | Sierra Leone  |                  |                    | St Kitts & Nevis  |              |             |
|           |            |                             | Uganda        |                  |                    | Samoa             |              |             |
|           |            |                             | Uzbekistan    |                  |                    | Sao Tome Y        |              |             |
|           |            |                             |               |                  |                    | Principe          |              |             |
|           |            |                             |               |                  |                    | Somalia           |              |             |
|           |            |                             |               |                  |                    | Tonga             |              |             |
|           |            |                             |               |                  |                    | Viet Nam          |              |             |
| n= 5      | n= 2       | n= 17                       | n= 22         | n= 5             | n= 15              | 54                | n= 7         | n= 8        |

### Legend

Tier 1 countries Tier 2 countries Intent to introduce

Yemen and Mauritius are introducing in 2015 but no month of introduction available. Saint Lucia and Thailand are introducing in 2016.

Source: WHO/UNICEF database as at 10 April 2015

Tier 1 countries are countries with cVDPV2 transmission or cVDPV2 reported since 2000 & WPV endemic countries

Tier 2 countries are countries with cVDPV 1/3 since 2000 or large /medium size countries with DTP3 coverage <80% in the past 3 years as per WUENIC

# Criteria for assessing OPV2 withdrawal readiness (November 2013 SAGE)

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**Trigger for OPV2 withdrawal:** absence of 'persistent' cVDPV2s globally

# bOPV Licensing for Routine Vaccination

tOPV to bOPV

- bOPV label change to include routine vaccination is not yet available
- bOPV is a vaccine for interim use only (3-4 years)

## **WHA resolution:**

- The May 2015 resolution will urge countries to accept bOPV for use in routine programmes
  - On the basis of WHO-prequalification
  - While National registration is on-going
  - While National registration is on-going

# bOPV label change

## 3 manufacturers / fillers have applied for label change

Pasteur in November 2014

– Approval expected in France mid-2015

- GSK in March 2015

– Approval expected in Belgium mid-2015

- Panacea Biotec Ltd in March 2015

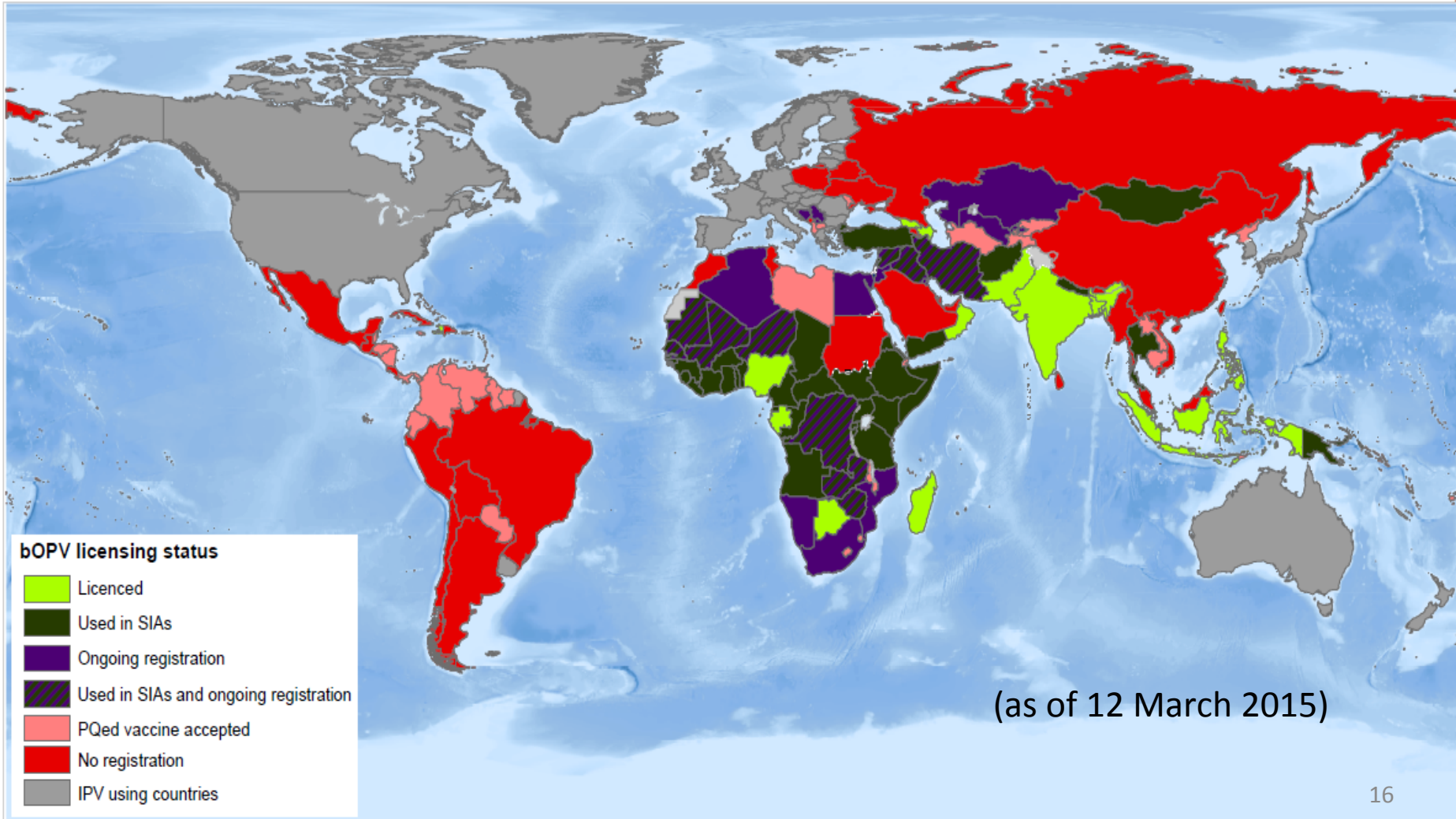
– approval expected in India before mid-2015

# Global bOPV Licensing Status

**GLOBAL BOPV LICENSING STATUS (INCLUDING PRE-QUALIFIED ACCEPTING COUNTRIES)**



MAP DATE: 12 March 2015,



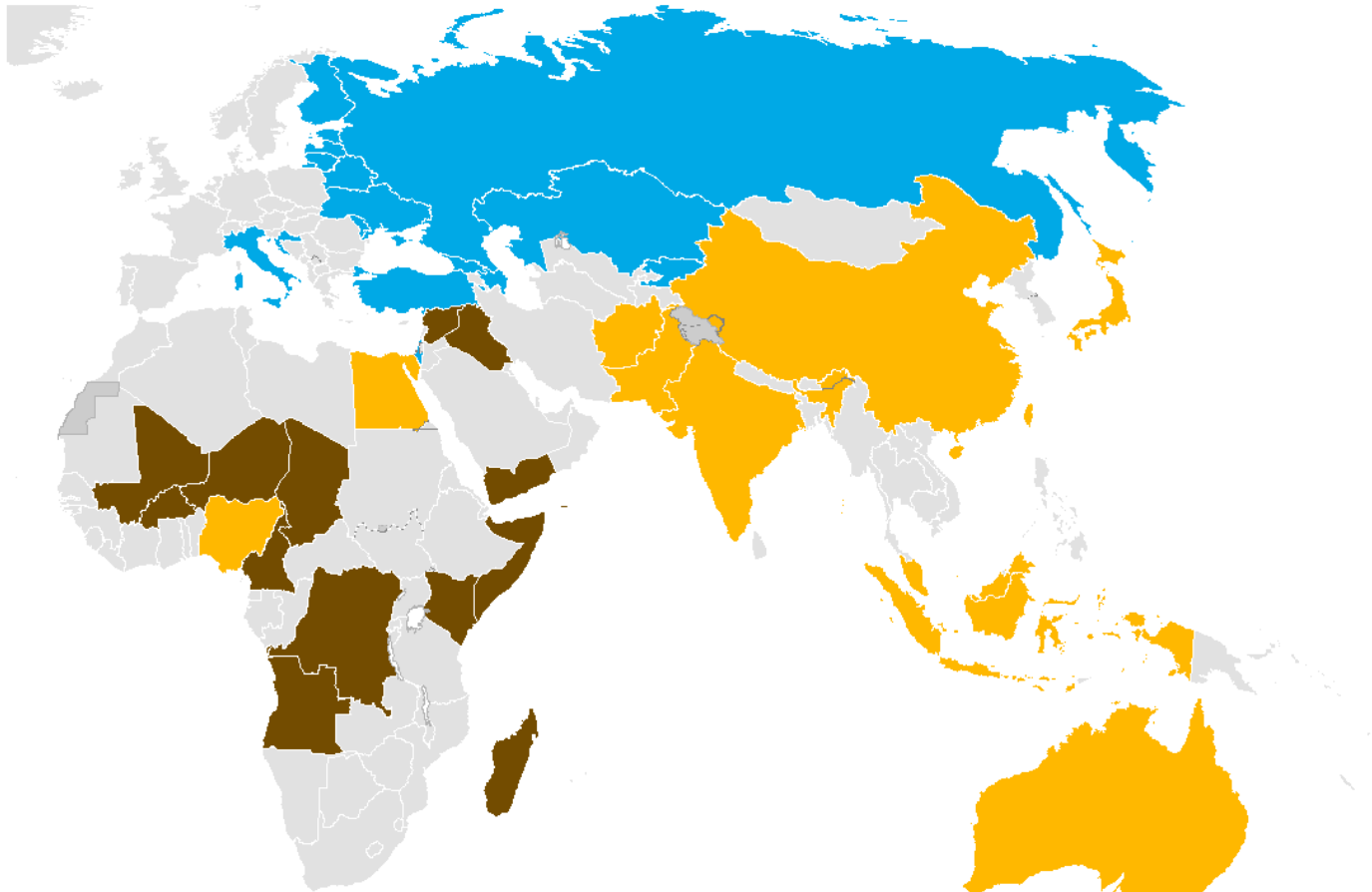


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# Environmental surveillance\* for polioviruses



- EUR: 15 countries Azerbaijan, Belarus, Georgia, Kyrgyzstan, Kazakhstan, Latvia, Lithuania, Republic of Moldova, Russian Federation, Turkey, Ukraine, Italy, Estonia, Finland and Croatia
- ES established by 2013 end: Afghanistan, Australia, China, Egypt, India, Indonesia, Israel, Malaysia, Nigeria, Japan and Pakistan
- ES to be established by end 2015: Angola, Burkina Faso, Cameroon, Kenya, Niger, Chad, DR Congo, Iraq, Madagascar, Mali and Yemen, Syria, and Somalia

\*No. of sample sites varies between countries; site selection is based on high-risk population, convenience and epidemiological evidence

# Preparation for mOPV2 Stockpile

poliovirus.

- Timely arrival for effective outbreak

issued for filling 100 million doses



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# Preparation for outbreak response



**Protocol for notification, risk assessment,  
and response following detection of  
poliovirus type 2 following globally-  
coordinated cessation of serotype 2-  
containing oral polio vaccine**

**(Draft version 14 October 2014)**

SAGE endorsed the type 2 response protocol (October 2014), including

- Detection
- Notification
- Risk assessment
- Response strategy and scope of response

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# Containment Strategy: Key Changes

## Major changes in eradication strategy since 2009 (when the initial GAP-III draft was published)

- Phased removal of WPV and Sabin virus (type 2 first)
- Universal IPV introduction
- Availability of mOPV2 stockpile

## Key updates in the containment strategy

- Phased containment of type 2 virus
  - Phase I : Global coordination for readiness **(by end 2015)**
  - Phase II : Global type 2 containment **(2016-2018)**
  - Phase III : Long-term containment **(Starting 2019)**
- **Phase II:** all type 2 poliovirus (both wild and Sabin) contained with primary and secondary safeguards.
- **Phase III:** Safeguards against wild poliovirus strengthened; Safeguards against Sabin remain as phase II



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# Phase I Implementation

- **Under GAPIII** : all Regions need to update inventories according to the revised phase I, and contain, transfer or destroy:
  - By end 2015 : WPV2 infectious and potentially infectious material including cVDPV2
  - By July 2016 (within 3 months of OPV2 withdrawal) : OPV2/Sabin2 strains
- **GAPIII implementation training**
  - Provided to Global Polio laboratories
  - Offered to vaccine manufacturers and national oversight bodies
- **Guidance (certification schemes) to be developed**
  - Assess compliance of essential poliovirus facilities with containment of type 2 provisions,
  - Provide manufacturers with the appropriate understanding of the requirements that must be met in order to obtain the desired containment certification (containment certification requirements)

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# Verification of the global eradication of wild poliovirus type 2

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## Following the Executive Board (January 2015)

- Member States requested by WHO ROs to confirm the absence of detection of WPV2
- In coordination with Regional Certification Commissions

**Global Certification Commission** will confirm the eradication of wild polio virus type 2 (Q3-2015).

## Following the Executive Board (January 2015)

- Member States requested by WHO ROs to confirm

# OPV type 2 withdrawal in practice

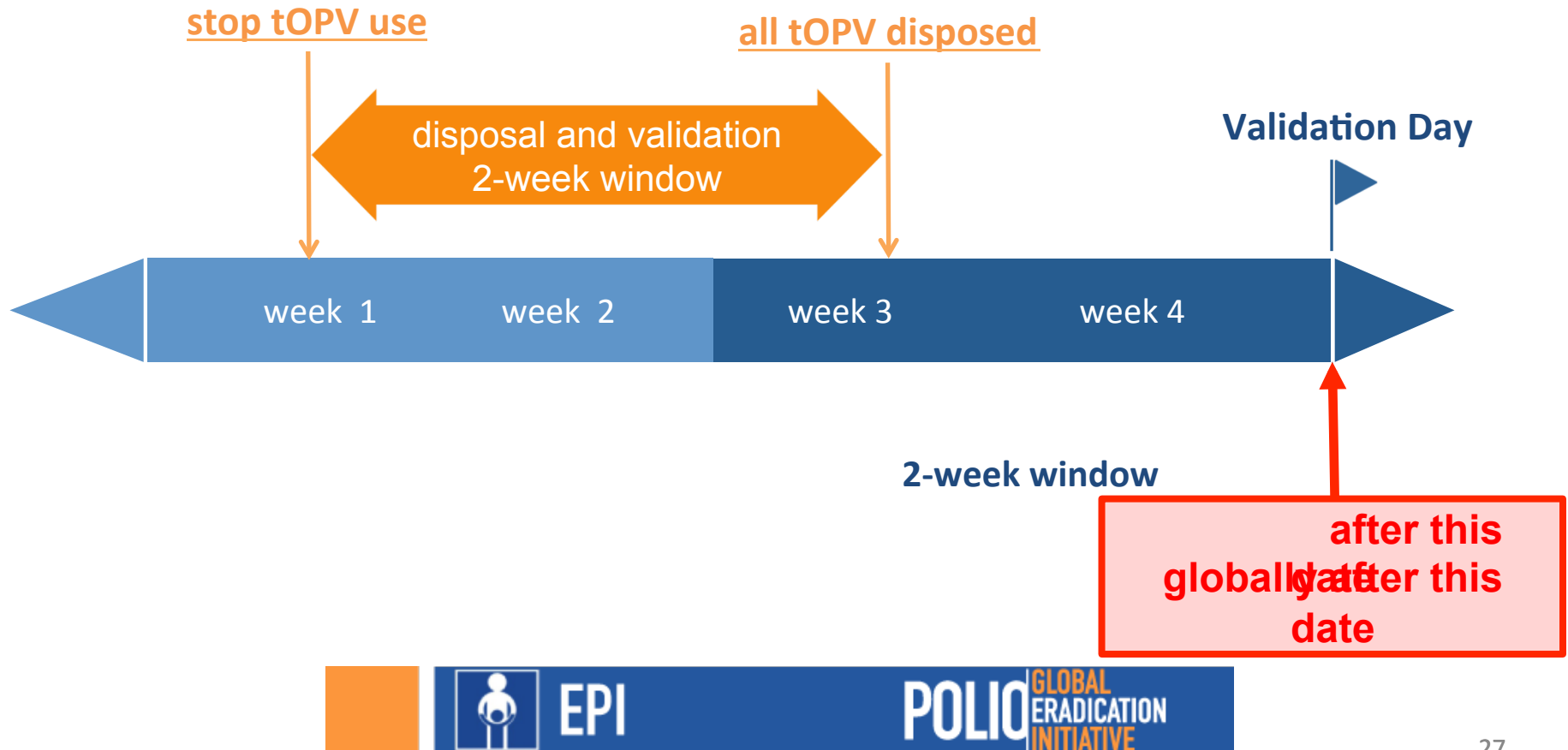
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## after the national switch date

- In routine, in campaigns and in trials/studies
  - Manufacturers will not supply any tOPV after the switch date

# Switch window example

April 2016 in a country



# Planning withdrawal at country level

## Switch protocol

- Discussion with countries during EPI managers meetings
- Dry –run of protocol in 3-4 countries by June
- Countries to develop Switch plan by September

## Technical Assistance

- WHO and Unicef Regional Offices
- Training of consultants and STOP teams

## Financing the effort

- Primarily country funding
- Additional level of support for high risk and LMI countries being estimated

## Intense communication effort

- High level communication by DG and UNICEF EXD to all MoH
- Briefing and technical materials to all WHO and UNICEF country offices

# Pre-requisites for OPV type 2 withdrawal : Summary

- **Substantial progress since November 2013 recommendations**
  - Good momentum for IPV introduction
  - Establishment of mOPV2 stockpile
  - Updates to GAP III
  - Global and regional planning for switch to bOPV
- **Significant remaining challenges require continued engagement of all actors**
  - Very tight IPV supply and busy Q4 introduction schedule
  - Licensure of bOPV by 156 countries
  - In-country planning for the Switch to bOPV
  - Implementation of containment

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**THE POLIO ERADICATION ENDGAME**  
BRIEF ON IPV INTRODUCTION, OPV WITHDRAWAL AND ROUTINE IMMUNIZATION STRENGTHENING

Under this endgame plan to achieve and sustain a polio-free world, the use of oral polio vaccine (OPV) must eventually be stopped worldwide, starting with OPV that contains type 2 poliovirus (OPV type 2). At least one dose of inactivated polio vaccine (IPV) must be introduced as a risk mitigation measure.

The steps involved are:

- By end 2015, introduce at least 1 dose of IPV into all routine immunization

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**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. In response, the endgame strategy. In response, the 2018 was developed.

The plan outlines a comprehensive approach to the elimination of all polio disease (both wild poliovirus and vaccine-derived poliovirus).

As one of its four major objectives, the plan outlines a comprehensive approach to the elimination of all polio disease (both wild poliovirus and vaccine-derived poliovirus).

**Why should countries introduce IPV?**  
Introducing IPV is a key element associated with OPV withdrawal.

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**PLANNING FOR IPV INTRODUCTION**  
Implementation Facts

globally, if no IPV is used, there will be a programmatic emergency for global public health. In response, the endgame strategy. In response, the 2018 was developed.

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World Health Organization

Health topics Data Media centre Publications Countries Programmes About WHO Search

**Immunization, Vaccines and Biologicals**

**IPV Introduction, OPV Withdrawal and Routine Immunization Strengthening**

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 Poliovirus Vaccine (IPV), withdrawal of Oral Polio Vaccine (OPV) and routine immunization strengthening.

The Strategic Plan was developed in response to the May 2012 World Health Assembly which declared the completion of poliovirus eradication to be a programmatic emergency for global public health. Under this plan to achieve and sustain a polio-free world, the use of OPV must eventually be stopped worldwide, starting with OPV containing type 2 poliovirus (OPV type 2). At least one dose of inactivated polio vaccine (IPV) must be introduced as a risk mitigation measure and to boost population immunity.

Recent News: IPV Introduction, OPV Withdrawal and Routine Immunization Strengthening; UNICEF awards IPV tender; New polio vaccine Position Paper

**Inactivated Polio Vaccine (IPV) Introduction and Oral Polio Vaccine (OPV) Withdrawal:**  
Rationale and Programmatic Implications for Objective 2 of The Polio Eradication and Endgame Strategic Plan

Immunization Systems Management Group (IMG)

**EPI** **POLIO** GLOBAL ERADICATION INITIATIVE Version date: February 10, 2014

**Reference documents :**  
[http://www.who.int/immunization/diseases/poliomyelitis/endgame\\_objective2/en/](http://www.who.int/immunization/diseases/poliomyelitis/endgame_objective2/en/)

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**IPV Administration and Multiple Vaccine Injections**

IPV should be administered at 14 weeks of age or the soonest following immunization visit. It should be given in addition to scheduled DTP3, OPV and other vaccine doses.

**Important facts:**

- IPV is a very safe and effective vaccine – and needed for the eradication of polio.
- It is safe to give multiple vaccine injections at one visit. Many countries successfully use this schedule.
- Multiple injections are better than spacing injections because they protect children, increase efficiency and lead to fewer overall vaccination visits.
- Concerns about multiple injections can be addressed through clear communication and pain reducing techniques.

**What are the advantages?**

- Protects infants when they need it most
- More convenient for the caregiver
- Better to experience one moment of pain, rather than on two separate occasions

**How to administer multiple injections with IPV:**

- IPV is administered by intramuscular injection (IM) in a dose of 0.5 ml into the outer part of the thigh.
- First, IPV and PCV injections should be given in one thigh, with injection sites separated by at least 2 cm. The **penicillin** injection should be given in the other thigh.
- IPV can be administered to prematurely born infants and children with immunodeficiencies.

**How to minimize pain during vaccination:**

- Have the child sit up or the caregiver hold an infant. Encourage breastfeeding mothers to breastfeed their infants during vaccination.
- Stroke the skin or apply pressure close to the injection site before and during injection.
- Perform intramuscular injections rapidly, without aspiration, for appropriate vaccines.

**How to address concerns from parents and caregivers about:**

|   |   |
|---|---|
| <b>Safety of multiple injections</b>            | It is safe for your child to receive multiple injections at once.                                       |
| <b>Pain associated with multiple injections</b> | It is better for the child to experience one brief moment of discomfort than pain on two separate days. |

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**Multiple Injections: Acceptability and Safety**

Protecting infants as soon as possible

Version date: May 2014

**Contents**

- Background and WHO recommendations
- IPV safety
- Case studies: South Africa and Brazil
- Tips for health workers on giving multiple injections
- Frequently asked questions

This document is intended to support decision-making and planning at a national level, particularly in relation to scheduling of inactivated Polio Vaccines (IPV) and related questions on multiple injections.

**Multiple Vaccine Injections**  
Safety and Acceptability of Multiple Vaccine Injections, including with Inactivated Polio Vaccine

Immunization Systems Management Group (IMG)

**EPI** **POLIO** GLOBAL ERADICATION INITIATIVE Version date: May 2014

23 April 2014

# Thank You !

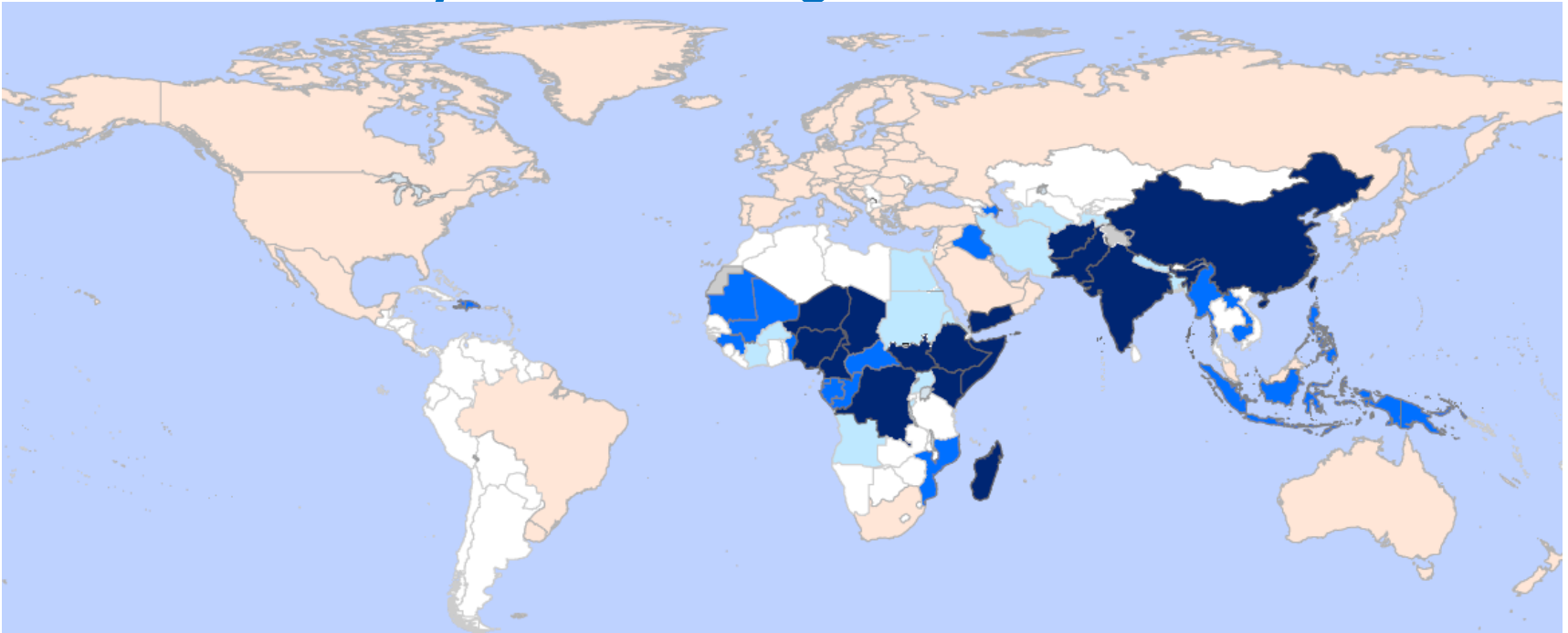


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# Country Tiers to manage IPV introductions



|               |  | # of countries | % of OPV birth cohort                        |
|---------------|--|----------------|--|
| <b>Tier 1</b> | <div></div> WPV endemic countries OR countries that have reported a cVDPV2 since 2000 <sup>1</sup>   | 15             | 60%<br>(38% attributable to India and China) |
| <b>Tier 2</b> | <div></div> Countries who have reported a cVDPV1/cVDPV3 since 2000 <sup>1</sup><br>OR large/medium <sup>2</sup> sized countries with DTP3 coverage <80% in 2009, 2010, 2011 as per WUNIC | 20             | 12%  |
| <b>Tier 3</b> | <div></div> Large/medium <sup>2</sup> countries adjacent to Tier 1 countries that reported WPV since 2003 OR countries that have experienced a WPV Importation since 2011                | 13             | 12%  |
| <b>Tier 4</b> | <div></div> All other OPV only using countries   | 78             | 16%  |