



An update on IPV introduction and preparations for tOPV withdrawal

**On behalf of the Immunization Systems
Management Group**

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SAGE Meeting | October 2014 | Geneva**

Contents

1. IPV introduction update
2. Regulatory aspects and access to bOPV
3. Withdrawal of tOPV

IPV introduction: recent milestones

IPV launches in Tunisia and Nepal in September 2014

Total number of introductions to date: 7/126

Upcoming introductions: 3 in Q4 2014, 15 in Q1 2015

Financing for LMICs: discussions in
progress to resolve barriers

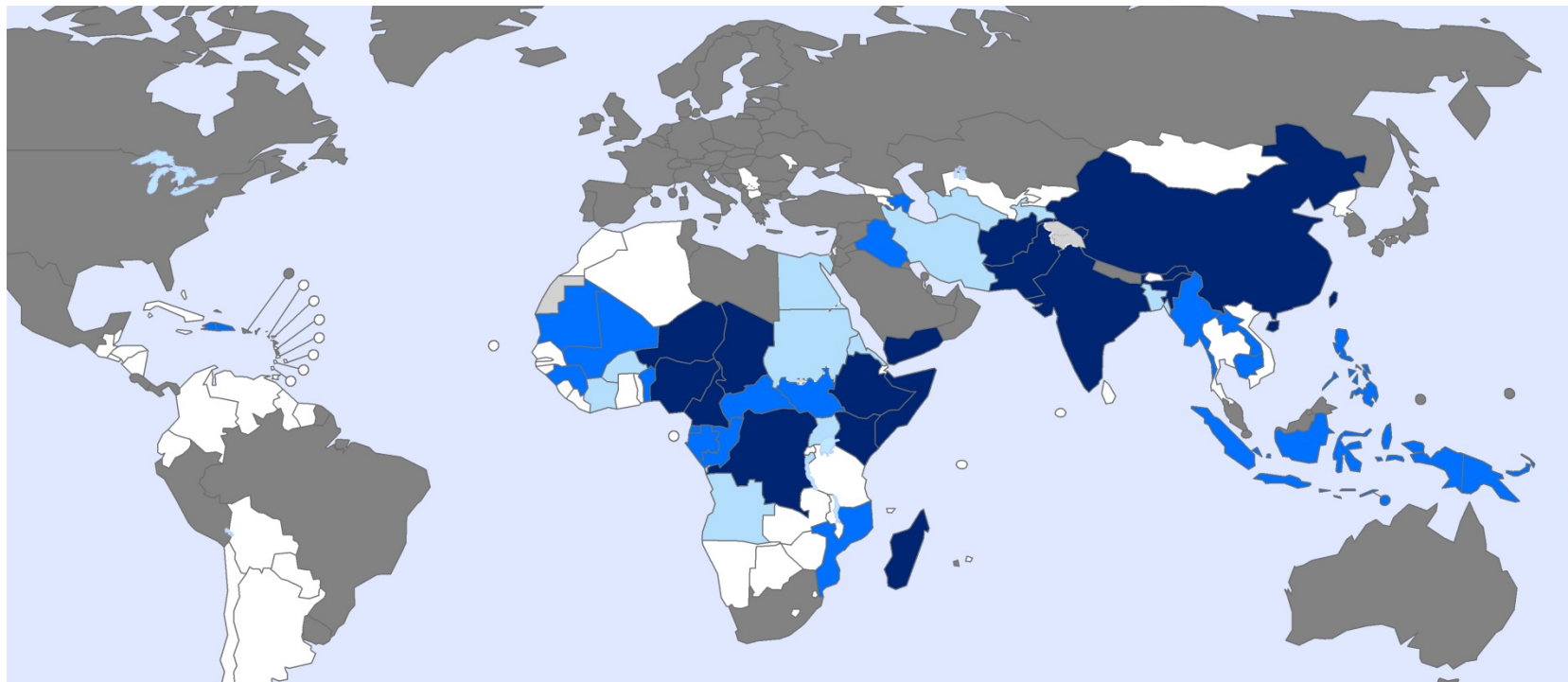
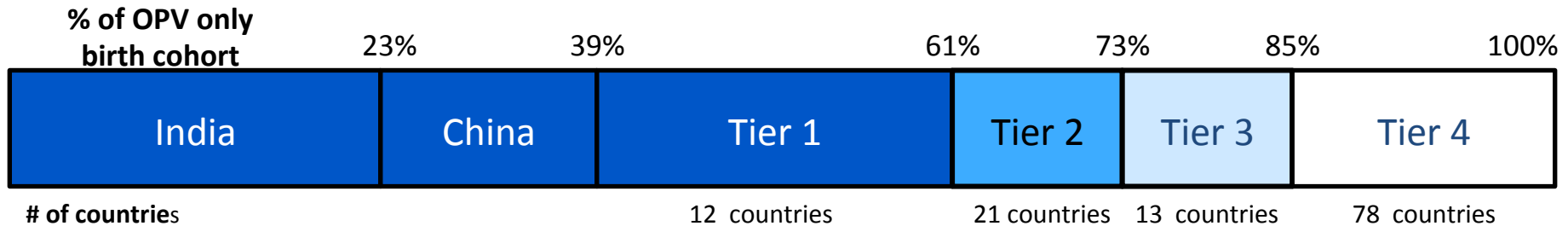
Communications: IPV training
materials for health workers and
many other resources published

(<http://www.tinyurl.com/ipv-intro>)



*Right: Nepal launch
event and IPV poster*

Segmenting OPV-using countries according to level of risks of cVDPV2

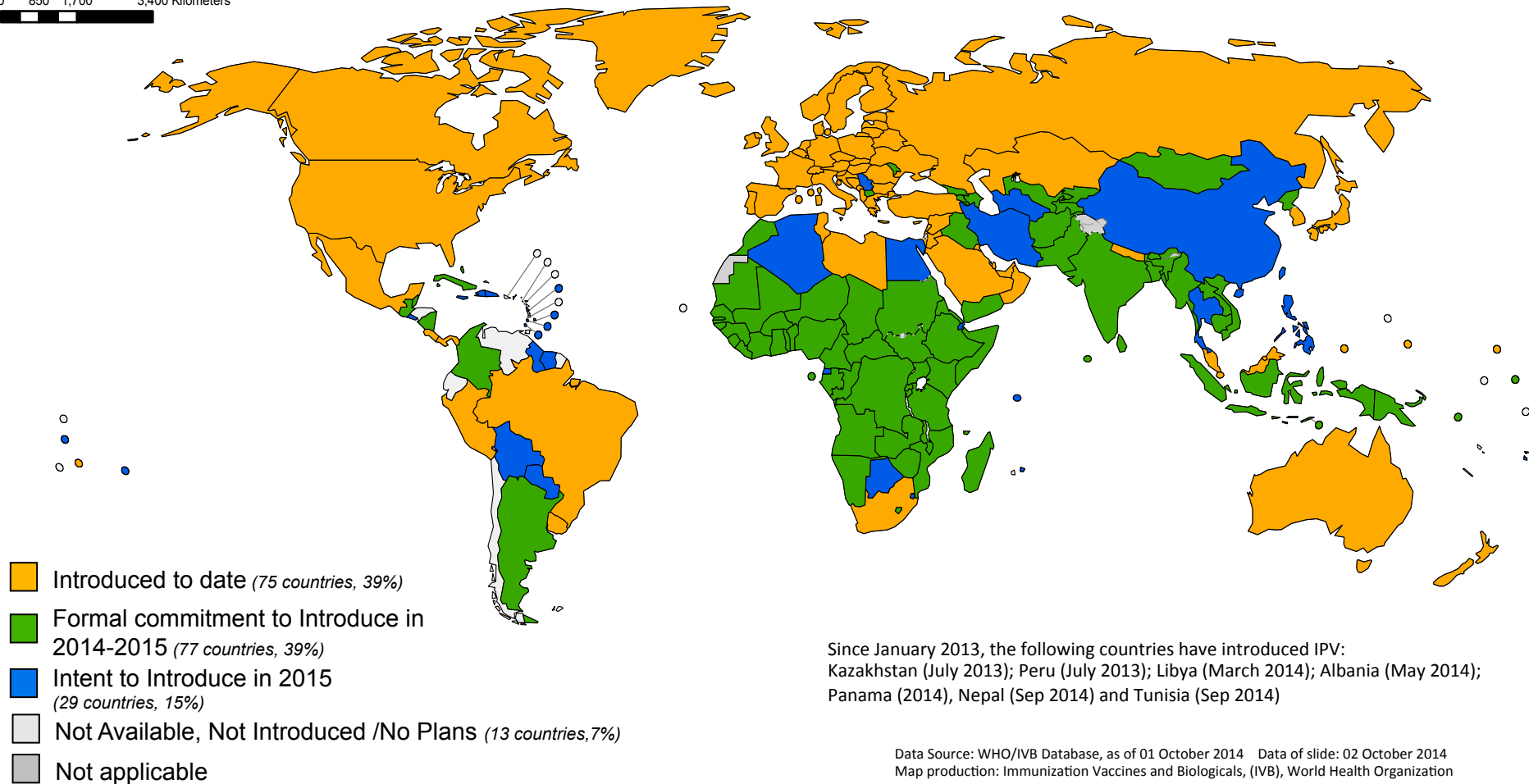


EPI

POLIO GLOBAL
ERADICATION
INITIATIVE

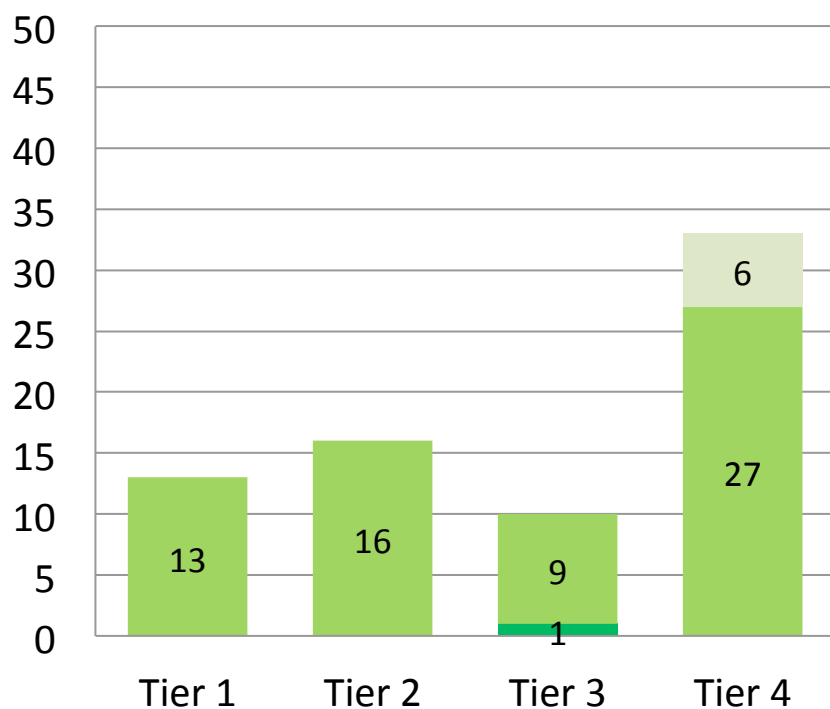
Countries using IPV vaccine to date and formal decision/intent to introduce

0 850 1,700 3,400 Kilometers



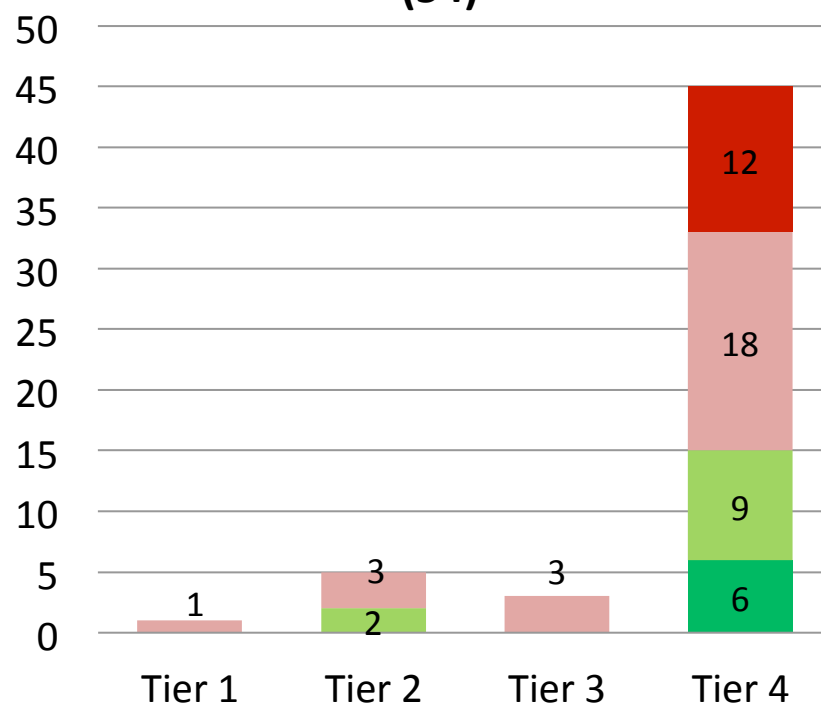
IPV decision update by Tier

Gavi Supported Countries (72)



■ Applied and Introduced ■ Applied ■ Planned

Non Gavi Supported Countries (54)

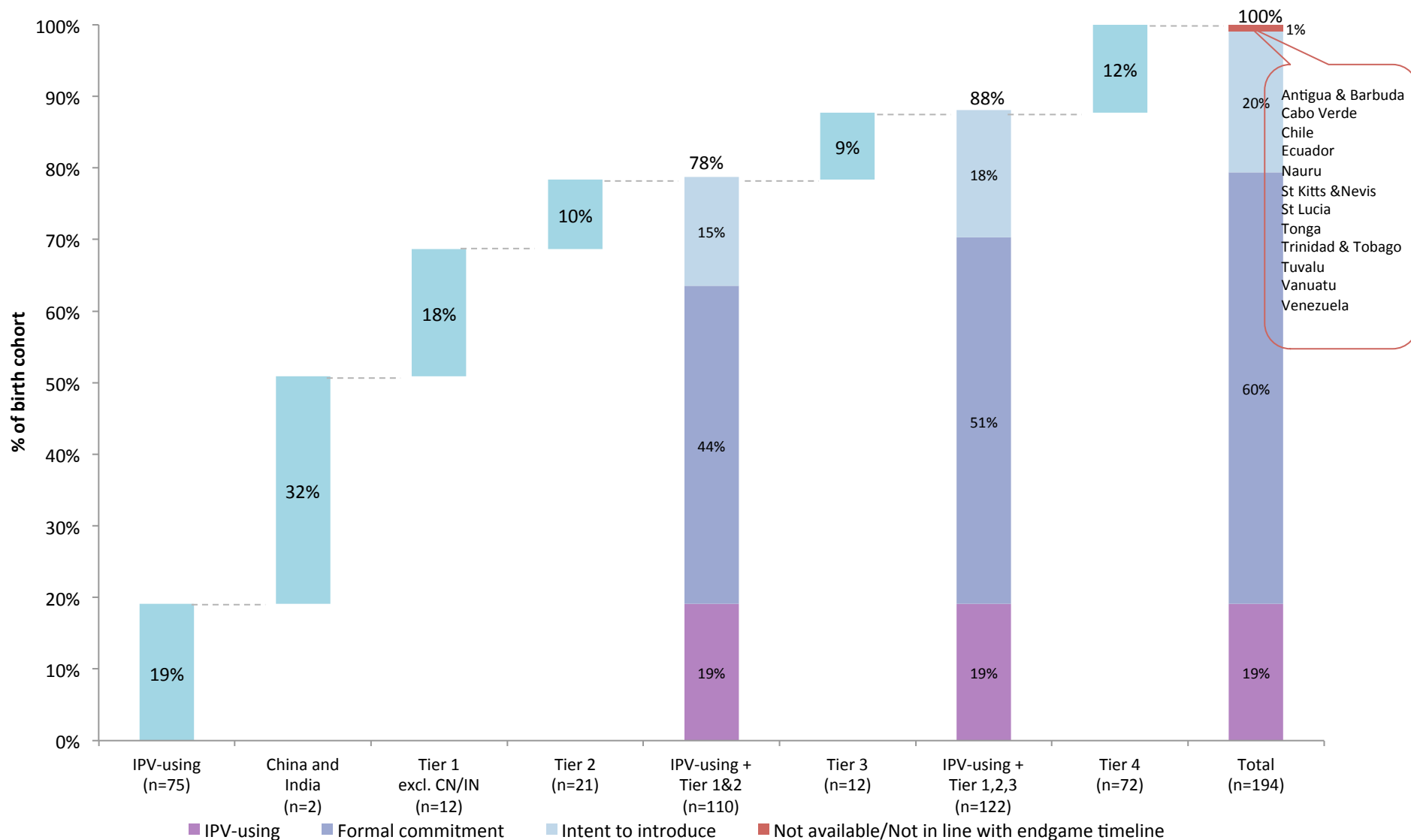


■ Introduced in Routine ■ Formally Committed
 ■ Intent to Introduce ■ No Information

Data Source: WHO/IVB Database, as of 14 October 2014 Data of slide: 14 October 2014
 Graph production: Immunization Vaccines and Biologicals, (IVB), World Health Organization

Overview of Global birth cohort by IPV status/tier

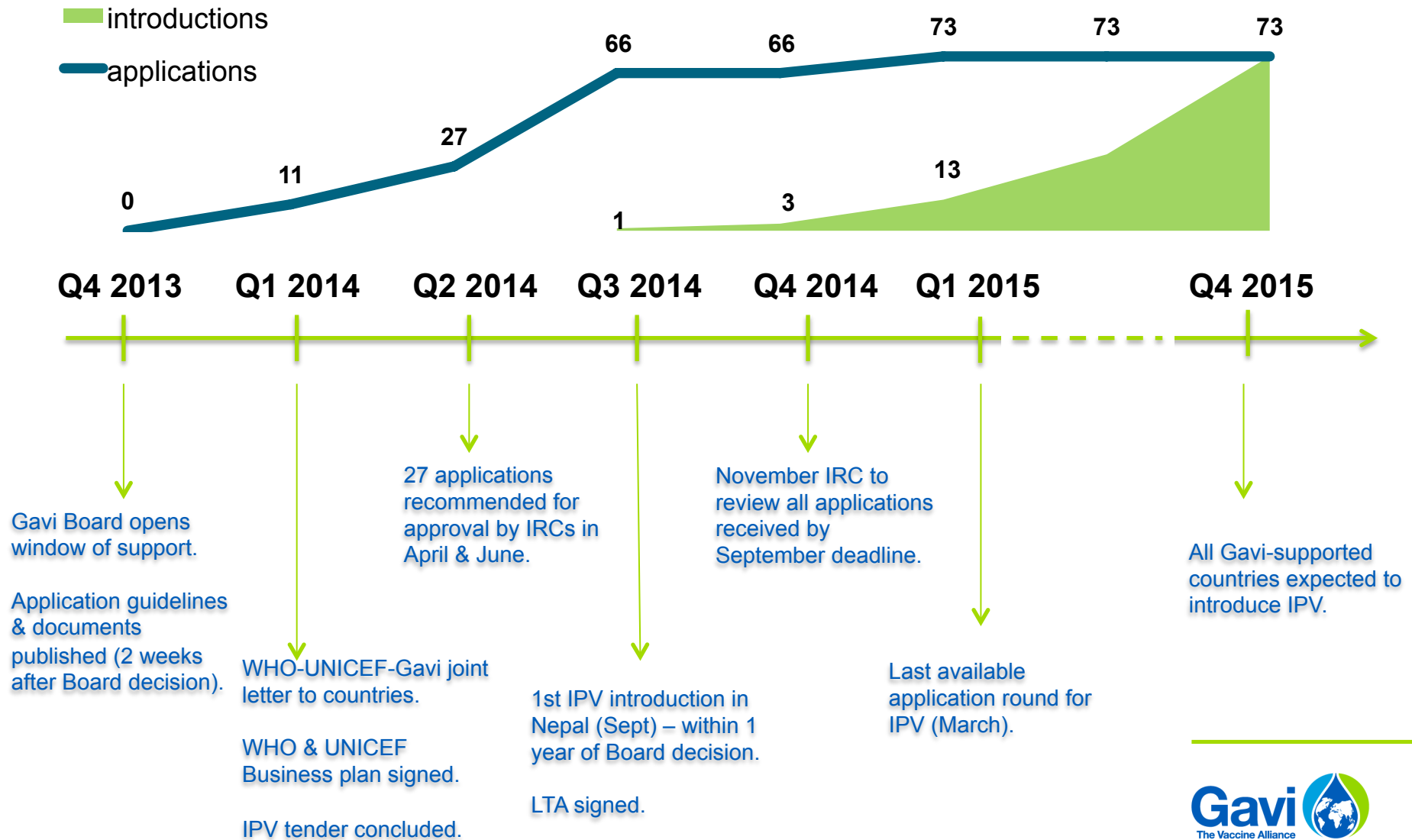
(100% = 138.7 million births in 2013)



Key reasons for progress

- **Effective partnership with Gavi, and across GPEI**
 - Most GAVI countries (66/72) have applied by September

Gavi support : A fast-track approach



Key reasons for progress

- **Effective partnership with Gavi, and across GPEI**
 - Most GAVI countries (66/72) have applied by September
- **High level advocacy**
 - Ensures IPV stays on the agenda
- **Regional leadership**
 - Across both WHO and UNICEF
- **Integration into EPI**
 - Building on strong base of new vaccine introduction experience
 - IPV introduction as part of routine immunization activities
- **Support to all at risk countries**
 - Financial and technical assistance to countries, including POB endorsed support to 16 priority non-Gavi countries

Mitigating remaining risks

- **RISK: IPV not licensed in all countries**
 - Use of revised collaborative procedure and Regional Joint dossier review meetings in October – November
- **RISK: IPV intro timelines not aligned across all WHO regions**
 - PAHO organizing regional meeting mid November to plan introductions
- **RISK: Middle income countries may not meet 2015 deadline**
 - Polio Oversight Board (POB) endorsement of exceptional time limited financial support mechanism for 16 non-Gavi countries
- **RISK: High impact countries delay introduction**
 - High level advocacy with China and India: Decision made but precise timeframe remains uncertain
- **RISK: Supply not sufficient to meet all country needs**
 - Work to define precise needs for SIAs use; prioritize high risk countries

Challenges related to IPV introduction

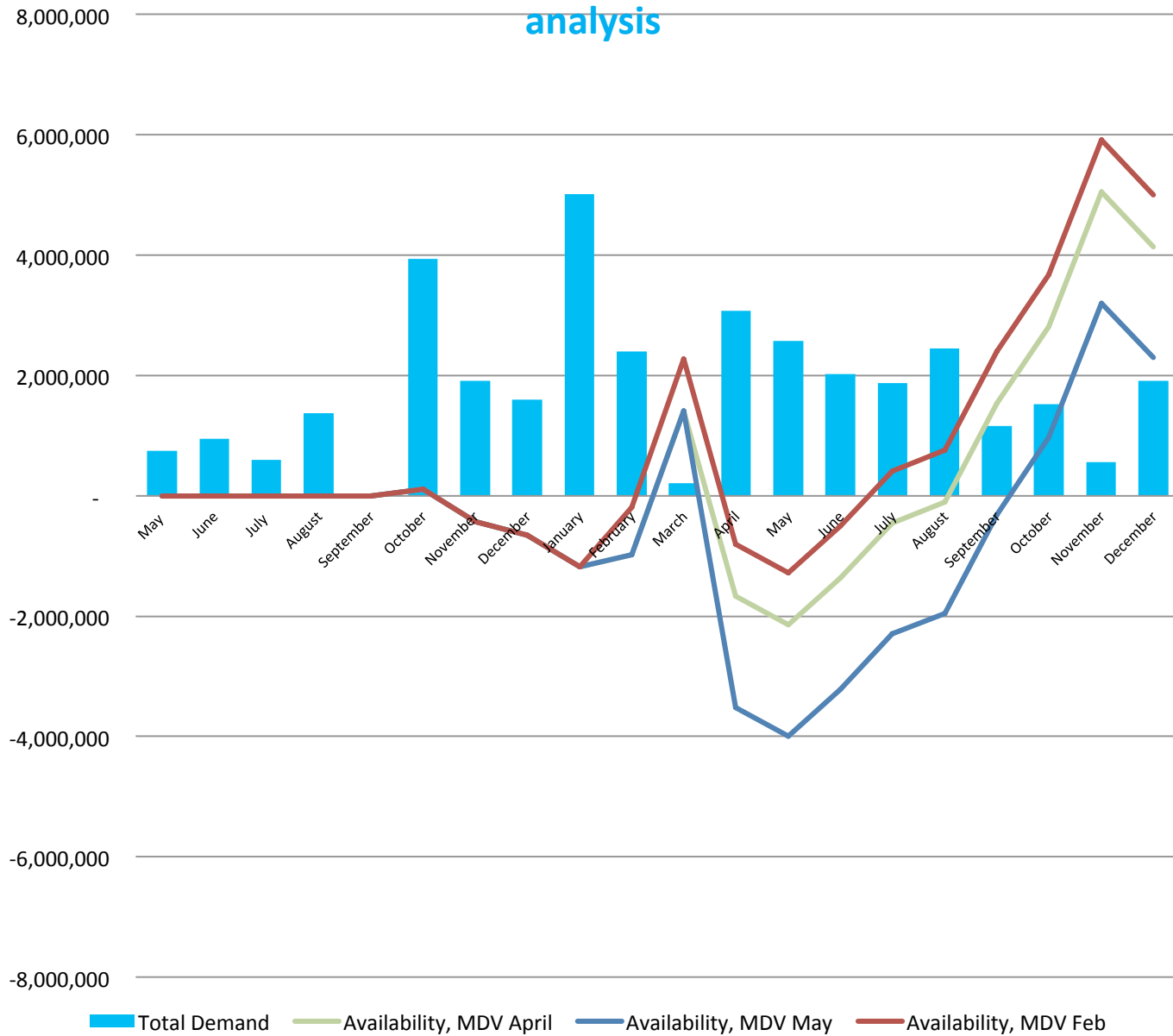
Constrained Supply of IPV for 2015

- Progress on Multi-dose vial policy for 28 days
 - WHO Approval/recommendation during Q4 2014
 - Production change: expected April 2015 (delay related to label changes and placement of VVM sticker)
 - Potential changes in expected wastage rates
 - 10 dose vials: from 50 to 20%
 - 5 dose vials: from 30 to 15%
- Planning and monitoring of introductions
 - Prioritizing and closely tracking country readiness to mitigate delays and maximize available stocks

Multiple injections

- Some resistance by countries to three injections at DTP3/penta3 contact

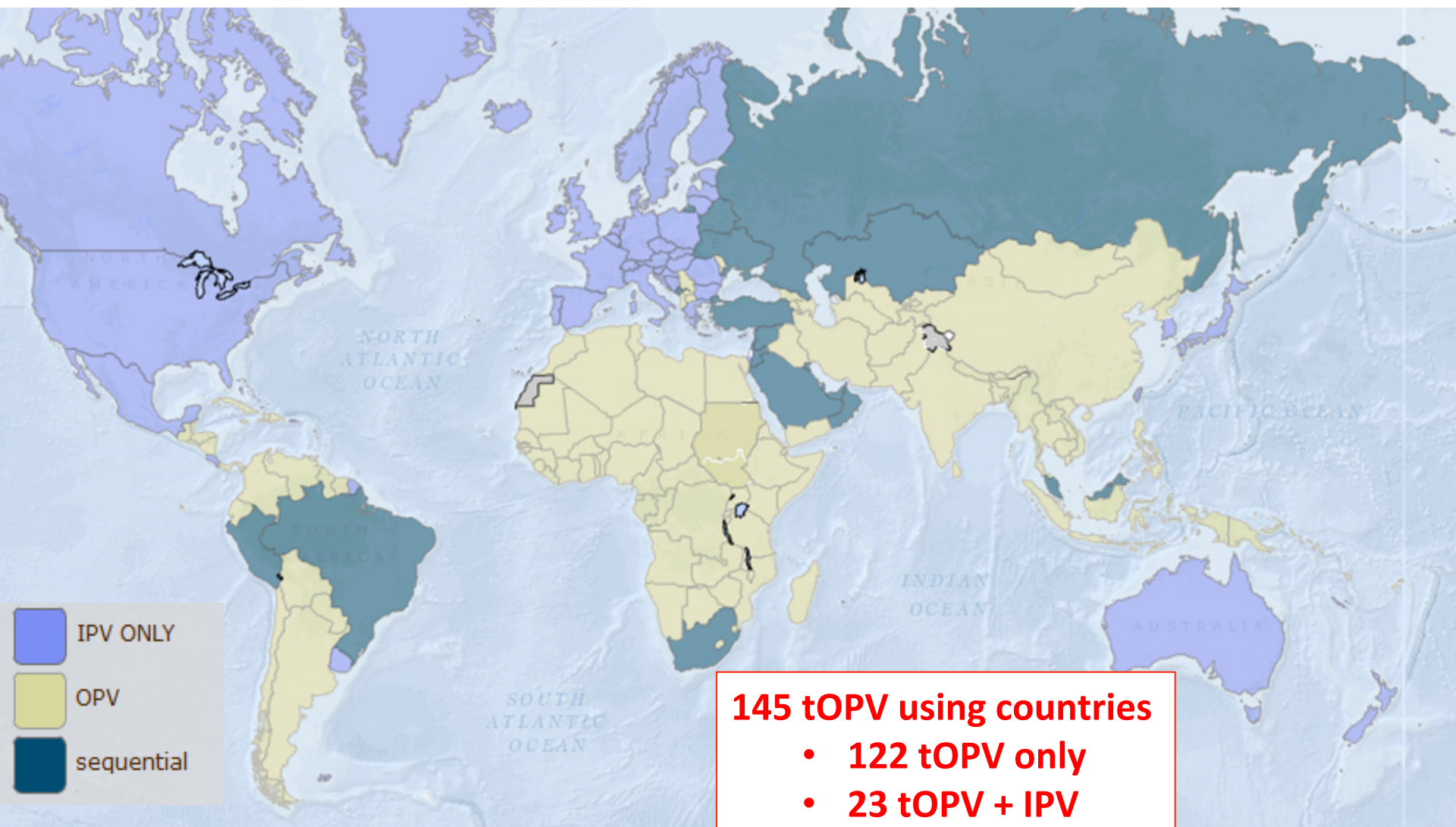
10 Dose Vial Presentation with MDVP, sensitivity analysis



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Polio vaccines used in routine immunization programs 2014



bOPV (types 1 + 3): Current Status

- First licensed, prequalified, and used in 2009, for campaign use (not to replace tOPV in routine programs)
- 5 bOPV producers licensed + prequalified, and 2 with national licensure
- bOPV introduced in Afghanistan in December 2009
- Over 4.5 billion doses used in 46 countries since 2009
- 8 national producers of tOPV are planning for bOPV production
- Sufficient production capacity for expanded global use (~900 million doses)

bOPV Routine Use: Requirements

- Regulatory approval in all OPV-using countries (n=145) by end of 2015
 - Modification of indication (label change)
 - Label restricts use for SIAs in endemic countries or for outbreak control
 - Additional clinical trial data
 - Clinical trials conducted in Bangladesh, India, Pakistan, Chile are or will be made available shortly to NRAs & manufacturers to apply for label change

bOPV Regulatory Activities: Ongoing Activities

- Mapping of regulatory pathways in 145 OPV-using countries
- Assist all bOPV manufacturers with label change
- Planning facilitation of timely licensing through joint review weeks
- **Exploring a new regulatory approach** : Possible World Health Assembly Resolution proposing to countries :
 - Acceptance for use in routine immunization programmes
 - In the unique context of Polio as a public health emergency
 - On the basis of the prequalification granted by WHO

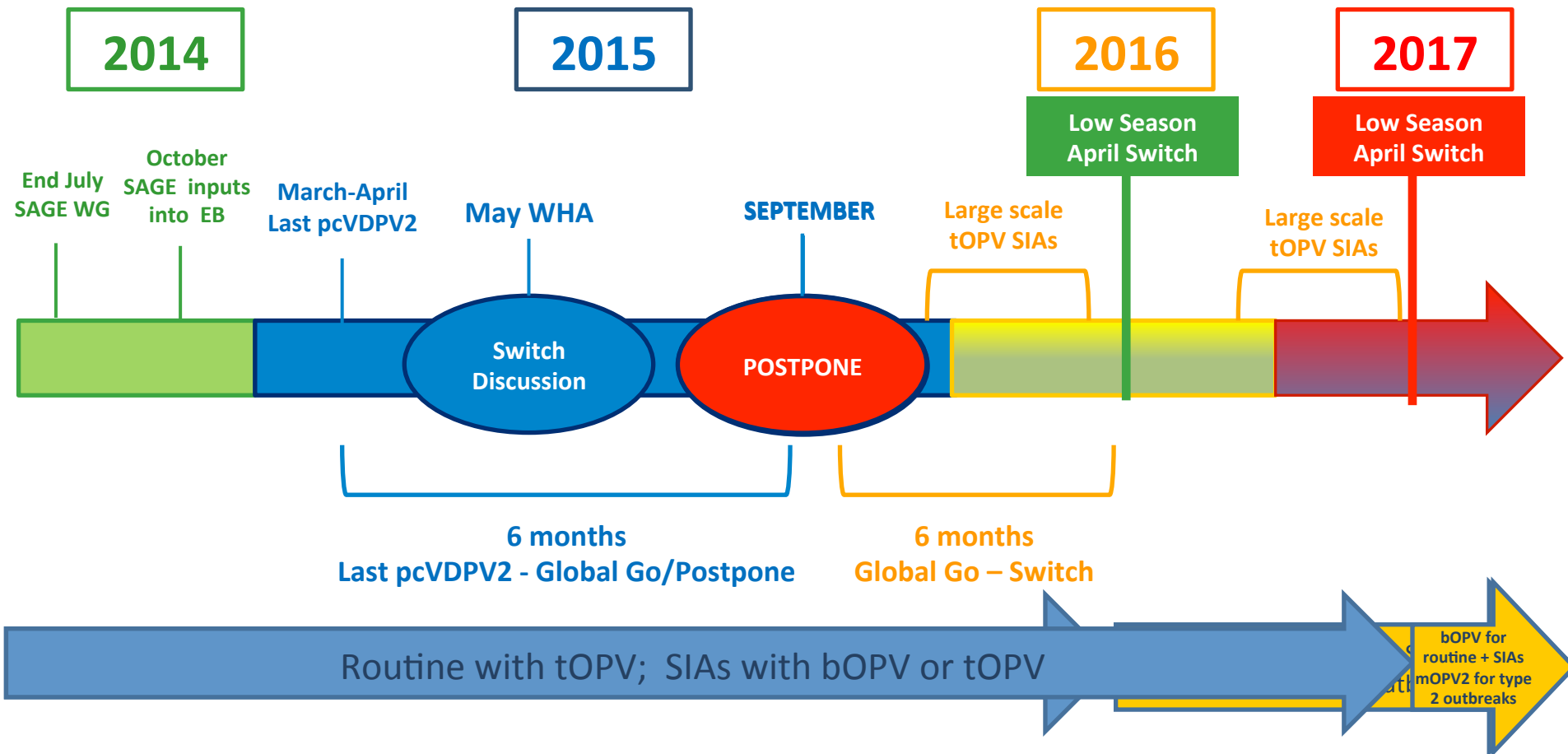
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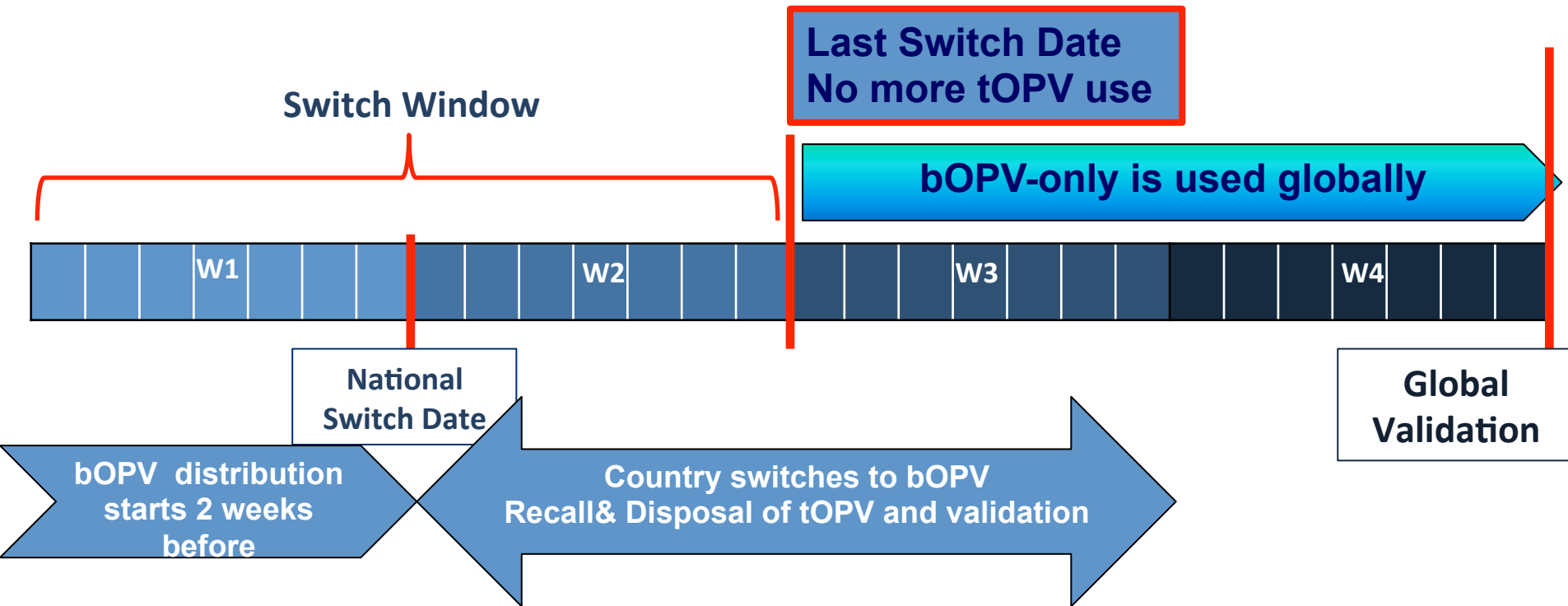
Planning for tOPV withdrawal

- **Complete replacement of tOPV by bOPV**
 - In 145 tOPV using countries : 122 with tOPV and 23 with tOPV/IPV schedules
- **Globally Synchronized over a 2 week period (dates tbd)**
 - Within these 2 week window, all countries switch on one day (national switch date)
 - Countries choose the day according to their plan
- **Recall – destruction – Validation**
 - During the 2 weeks following the national switch date
- **No use of any tOPV after the national switch date**
 - RI, SIAs, trials/studies
- **Manufacturers will not supply** any tOPV after the switch date

Timeframe for the Switch to bOPV



Example at country level (April 2016)



Next steps

- **Switch implementation working group**
 - Under IMG implementation subgroup
- **High level communications** with regions and countries from Q1 2015 to drive planning
- **Switch Protocol**
 - Step-by-step guideline
 - Dissemination and regional trainings
 - Work closely with UNICEF SD, particularly for coordination of implementation and supply strategies
 - Country pilot exercises

THANK YOU!
MERCI!



For more information:

http://www.who.int/immunization/diseases/poliomyelitis/inactivated_polio_vaccine/en/