



OPV type 2 withdrawal

Status of preparations

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On Behalf of the GPEI Immunization Systems Management Group

SAGE Meeting
Geneva, 20 October 2015

Criteria for assessing OPV2 withdrawal readiness (November 2013 SAGE)

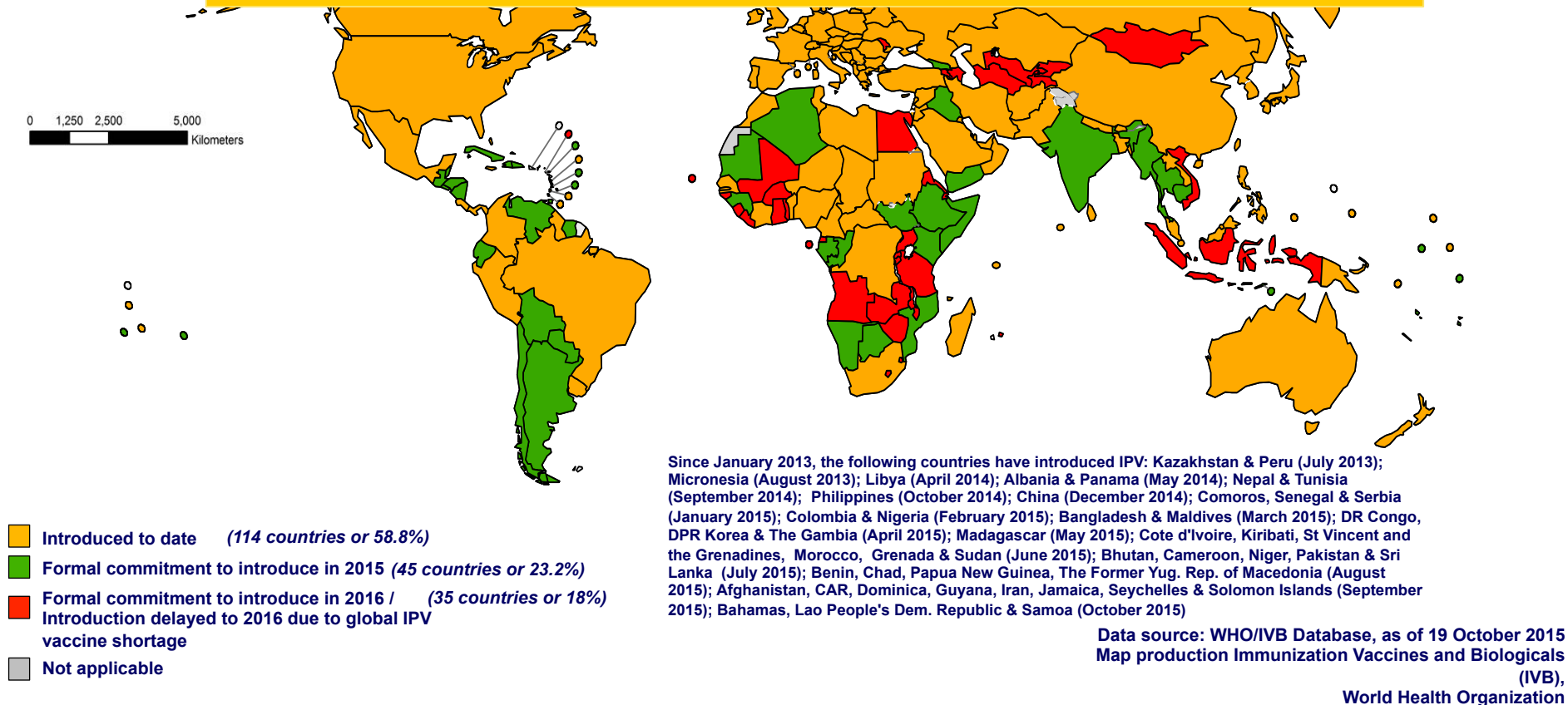
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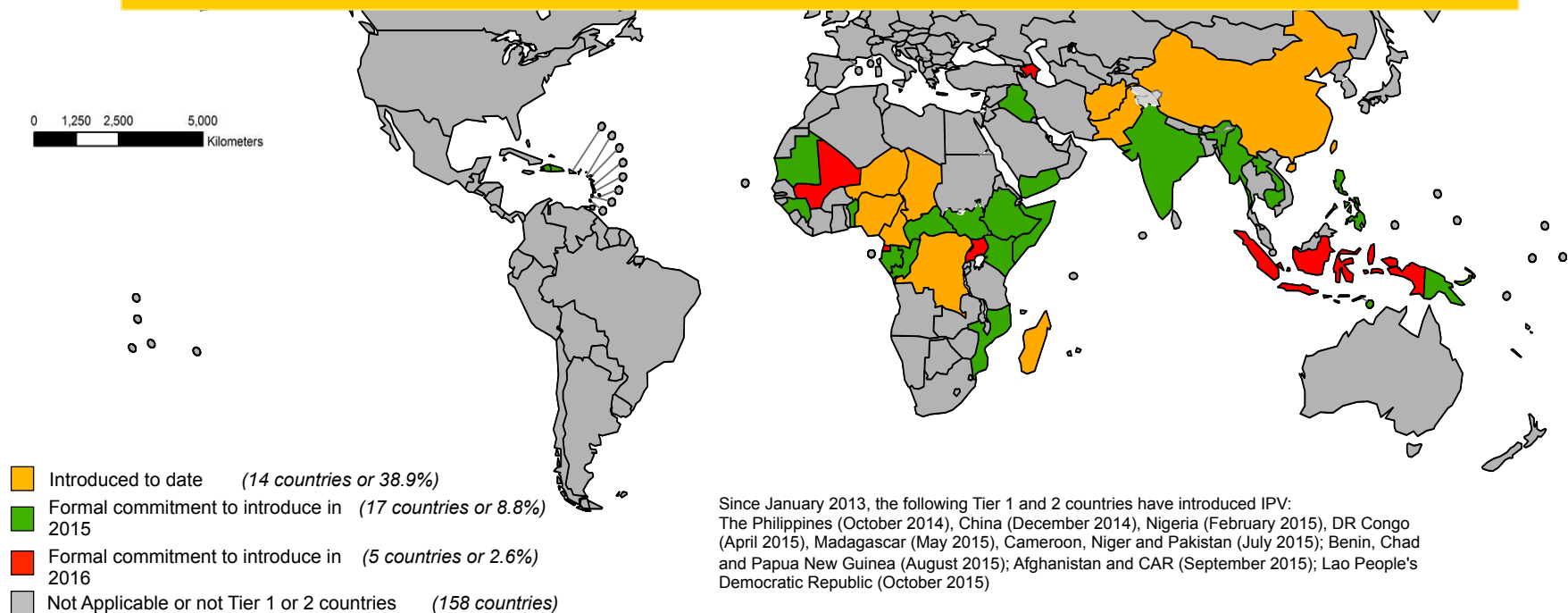
All countries have committed to introduce IPV

46/126 countries have introduced since 1 January 2013
45 more countries will introduce in 2015
35 Countries will introduce in 2016



Tier 1 and 2 Countries using IPV vaccine and formal decision to introduce

14/35 Tier 1&2 countries have introduced IPV
17 Tier 1&2 Countries will introduce before the end of 2015
Uganda, Mali and Equatorial Guinea: February 2016
Azerbaijan and Indonesia : July 2016



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
Country Tier classification was updated on 15 October 2015

Data source: WHO/IVB Database, as of 19 October 2015,
based on 36 tier 1 & 2 countries
Map production Immunization Vaccines and Biologicals (IVB),
World Health Organization

IPV supply challenges

Many changes in availability since August 2014 :

- Both suppliers supply less than contracted quantities because of challenges with the scale up of production
 - 59% reduction of projected amount in 10 dose vials in 2015-2016
 - 46% reduction in 5 dose vials in 2015-2016
 - Interruption of supply of single dose vials through, at least Q1 2016
- Combination vaccines also in short supply globally
 - Pentavalent and Hexavalent aP based combination vaccines

Increased demand for SIAs in endemic countries

- 10.3 million doses in 2015
 - 1 million doses in Pakistan not yet used
 - 350,000 doses in Afghanistan not yet used

Reserve stock for outbreak response after the Switch

- 3.4 million doses : 1 million in June; 2.4 million in December

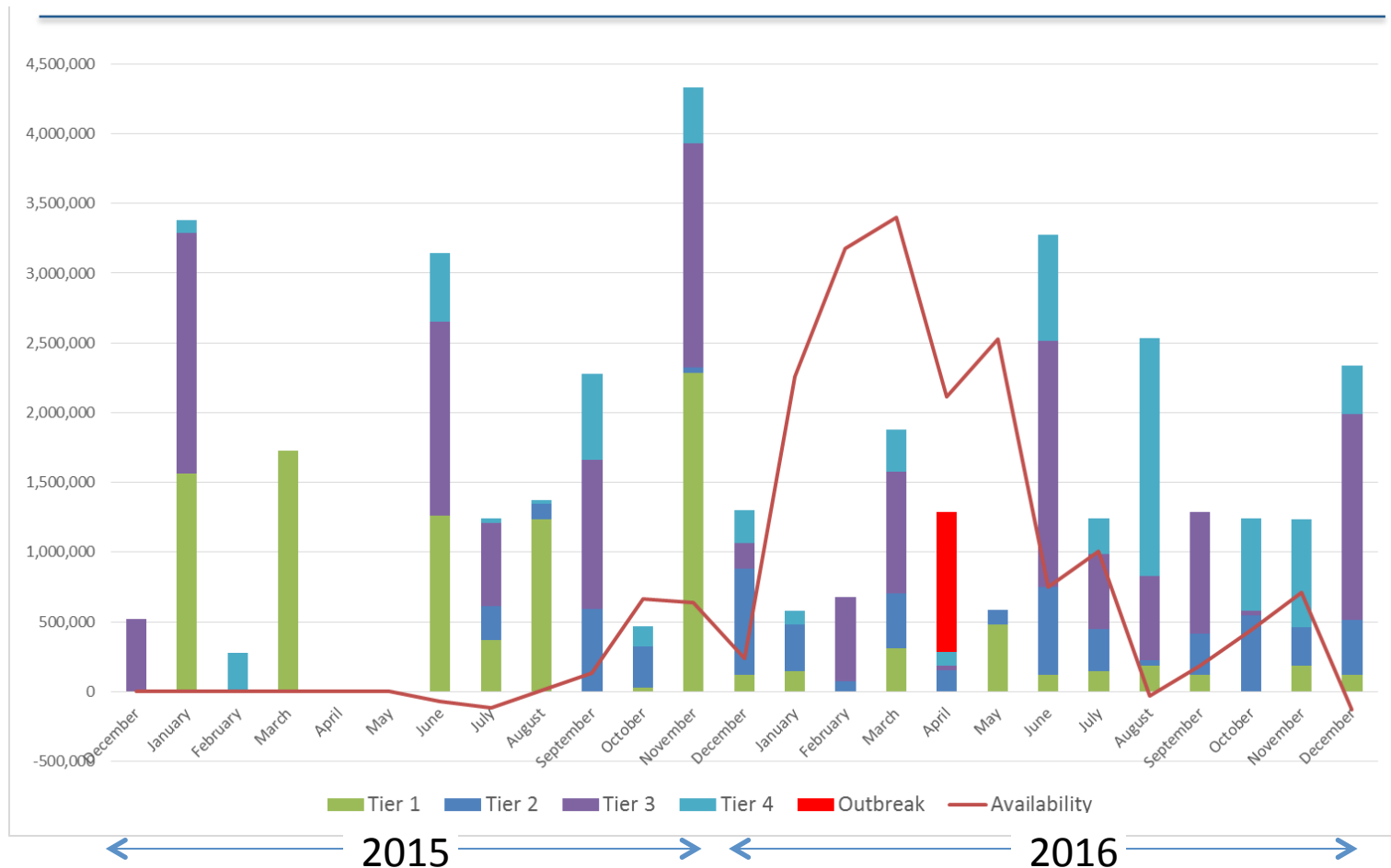
Reduced IPV availability

Principles for allocation

- All tier 1 & 2 countries introduce before the Switch
- IPV stock for outbreak response after the Switch is available in April (1 mio doses) and December 2016 (2.4 mio doses)
- Large countries will have change from 5 dose vials to 10 doses vials (e.g. India and Nigeria)
- Supply to a number of tier 3 & 4 countries delayed to July 2016.
- Some tier 3&4 countries may face stock-outs in before the Switch

5 dose vials (Bilthoven Biologicals)

19 tier 3&4 countries introduce after the Switch



Source: Unicef Supply Division, 13/09/15

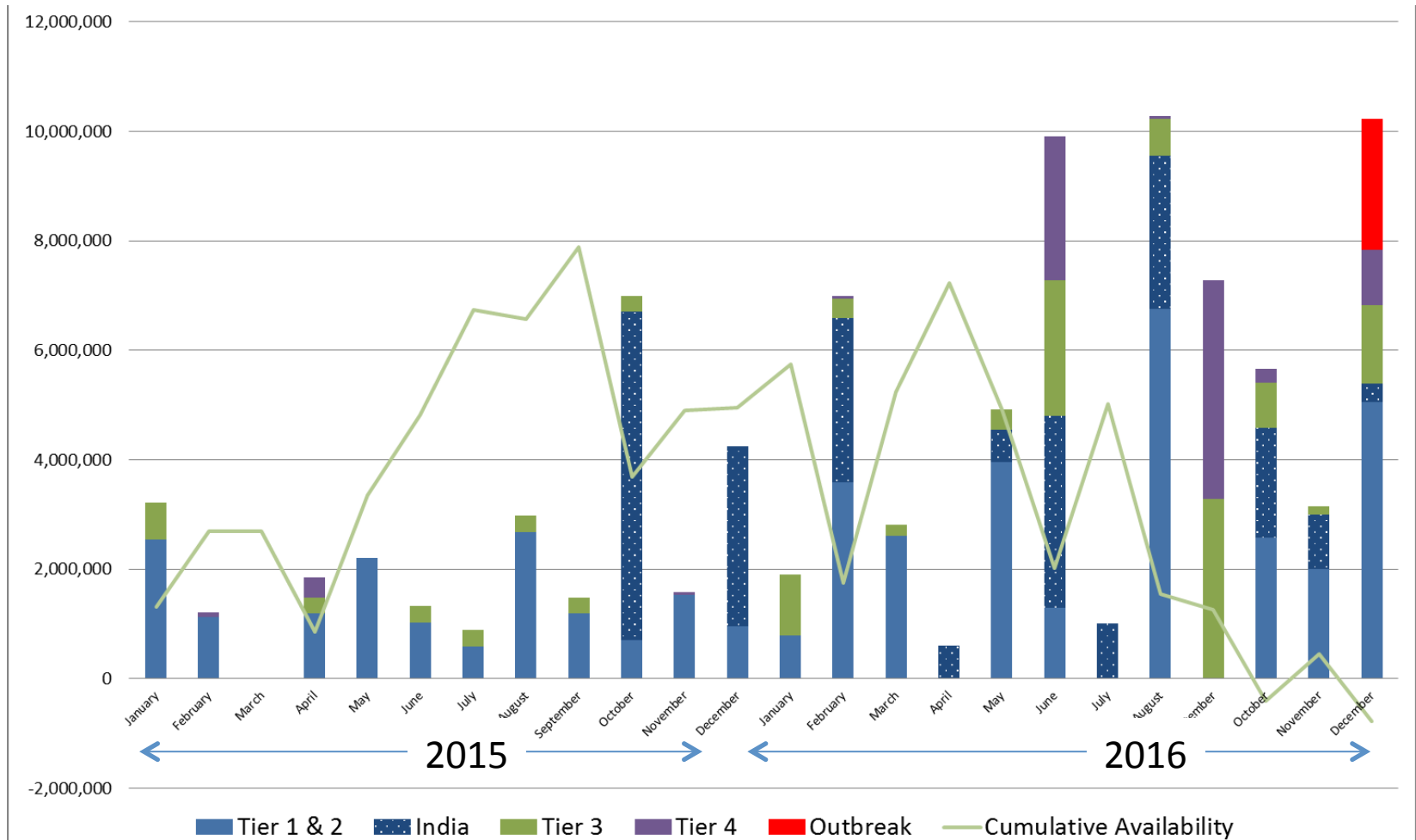


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10 dose vials (Sanofi)

10 tier 3&4 countries introduce after the Switch



Source: Unicef Supply Division, 13/10/15



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51 countries introducing IPV by April 2016

Up to 30 countries only receive supplies in July 2016

Oct-15	Nov-15	Dec-15	Jan-16	After April-16
Kenya	Algeria	Belize	Equatorial Guinea	Angola
Nauru	Antigua and Barbuda	Bolivia	Mali	Armenia
Somalia	Argentina	Cambodia	Saint Kitts and Nevis	Azerbaijan
Tuvalu	Barbados	Ecuador	Uganda	Burkina Faso
	Botswana	El Salvador		Burundi
	Chile	Fiji		Cabo Verde
	Congo	Gabon		Djibouti
	Cook Islands	Georgia		Egypt
	Cuba	Guatemala		Eritrea
	Dominican Republic	Honduras		Ghana
	Ethiopia	Myanmar		Guinea-Bissau
	Guinea	Paraguay		Indonesia
	Haiti	Thailand		Kyrgyzstan
	India	Trinidad and Tobago		Lesotho
	Iraq	Venezuela		Liberia
	Mauritania			Malawi
	Mozambique			Mongolia
	Namibia			Rep. of Moldova
	Nicaragua			Rwanda
	Saint Lucia			Sao Tome & Principe
	South Sudan			Sierra Leone
	Suriname			Swaziland
	Timor-Leste			Tajikistan
	Tonga			Togo
	Vanuatu			Turkmenistan
	Yemen			United Rep. of Tanzania
				Uzbekistan
				Viet Nam
				Zambia
				Zimbabwe
4	26	15	4	30

Legend

Tier 1 countries

Tier 2 countries

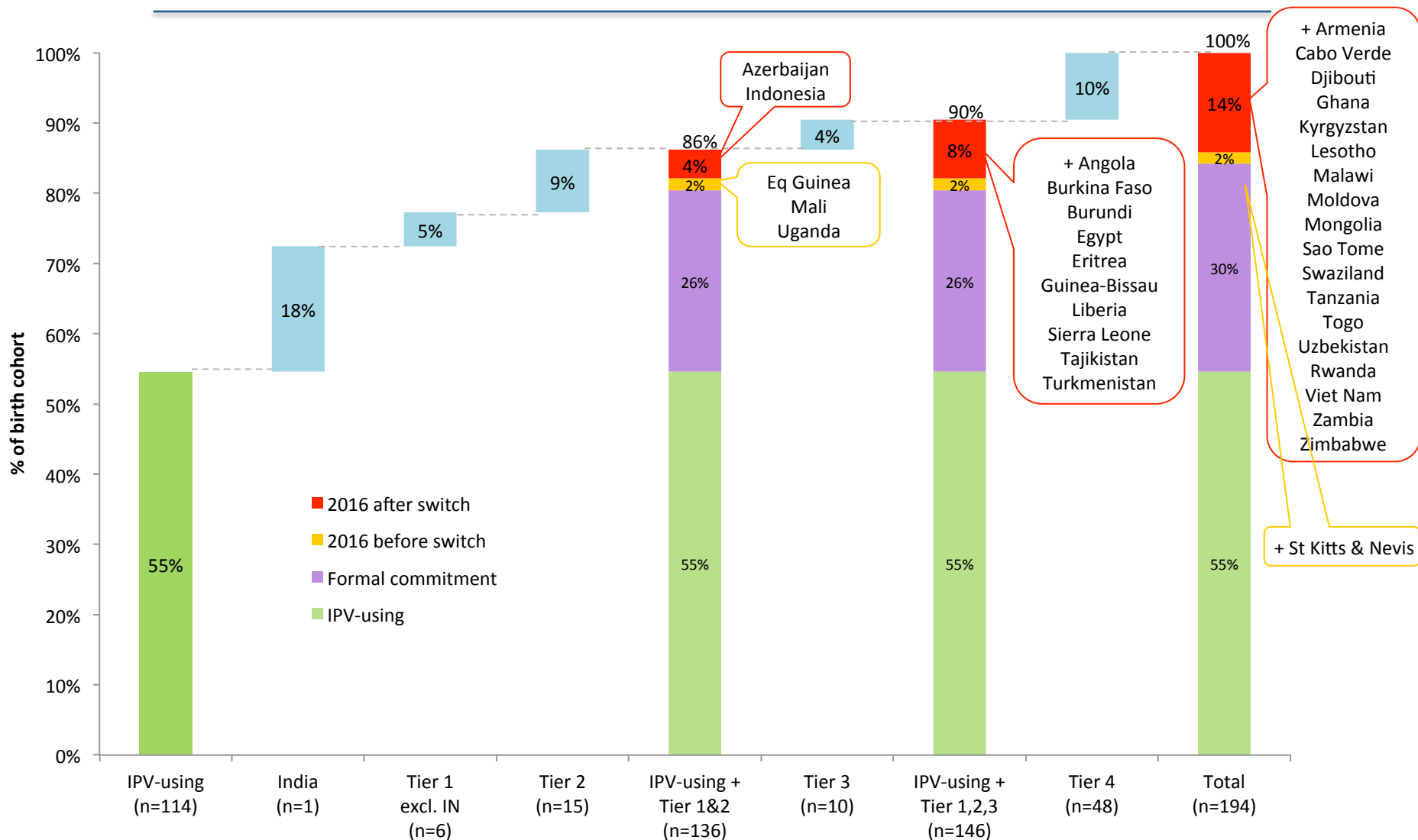
Small cohort countries could be supplied in March

Mauritius is introducing in 2016 but no month of introduction available.

Source: WHO/UNICEF database as at 19 October 2015

IPV status and Global birth cohort

(100% = 136.1 million births in 2015*)



* United Nations, Department of Economic and Social Affairs, Population Division (2015). World Population Prospects: The 2015 Revision.



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IPV introduction / summary

Extraordinary commitment on the part of countries

- **All 126 OPV using countries** have committed to introduce at least one dose of IPV in their routine immunization programme before the Switch
- **44 countries** have introduced, of which 14 of the 35 countries at highest risk (tiers 1 & 2)
- **80 countries** have committed to introduce before the April 2016 Switch
- **Indonesia** will introduce in July 2016 and carry out a tOPV NID in March prior to the Switch

However short supply requires substantial adjustments

- **29 Tier 3&4 countries** can only be supplied in July 2016
 - Possibility that 7 small birth cohort countries be supplied in March
 - A small fraction of the birth cohort will be affected by 3-month gap



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Planning the Switch in countries

Switch Planning and Monitoring guidelines

- Developed by IMG sub group- available in English, French, Spanish
- Rolled out to countries during EPI managers meetings
- Countries requested to finalize plan by 30 September : **121/155 completed or underway**

Large countries status :

- **India:** Dry run conducted in June; Final stages of national switch planning; bOPV licensing data submitted
- **Nigeria:** National switch committee in place; Macro plan and draft budget available , being revised with ERC inputs
- **China:** Internal expert meeting held 25 August; National consultation conducted in September; bOPV licensing underway
- **Indonesia:** Formal confirmation of Switch in April ; National consultation completed 11-14 Aug. Switch guidelines drafted, licensing of bOPV is in progress,
- **Pakistan:** National workshop 7-9 Sept
- **Philippines:** Planning completed end August

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bOPV regulatory status

- **All 6 prequalified bOPV are licensed for use in routine immunization by their respective NRA**
 - label change for routine immunization will be facilitated by approvals issued in France, Belgium Indonesia and India
- **Current status of bOPV approval for routine use**
 - 122/148 countries do not represent a major concern:
 - 100 countries rely on WHO PQ, have registered bOPV for routine immunization or can introduce bOPV via waivers/tenders
 - An *additional* 22 countries have used bOPV in SIAs
 - 26 countries remain pending submission or under review
- **Countries that require focused attention**
 - China, Brazil and Mexico will license locally produced bOPV in due time
 - Bosnia/Herzegovina, Qatar and Rwanda do not yet have registration planned
 - Countries, having long review cycles are being tracked, e.g. Russia
 - Belarus , Kazakhstan accept product from Russia

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Surveillance

Plan for strengthening surveillance in high-risk countries

e.g. Central and West Africa, including Central African Republic, Gabon, Niger, Mali, Liberia, Guinea, and Sierra Leone.

- capacity building and refresher training;
- strengthening of active surveillance;
- expansion of environmental surveillance;
- programme reviews.

Specific plans to manage surveillance in difficult-to-access areas

e.g. South Sudan, Somalia, Nigeria, Lake Chad, Afghanistan, Middle East)

- engaging NGOs;
- increasing field staff presence;
- conducting contact sampling and stool surveys;
- focusing on high risk-mobile populations;
- growing the networks of community informants.

Outbreak detection and response protocol

Endorsed by SAGE in October 2014.

Protocol being updated to reflect :

- New VDPV2 definition to enhance sensitivity;
- Wider use of IPV in outbreak response;
- Expansion of the scope of the immunization response.

To be reviewed after one year of the Switch.

mOPV2 stockpile

Global stockpile to respond to type 2 polio outbreaks following withdrawal

- Operational framework approved by the SAGE in October 2014.
- Framework updated (new VDPV2 classification, new approach for type 2 outbreak response.)

Status

- Stockpile of 50 million in finished product available by March 2016
- Additional 50 million doses to be available by July 2016
- 3.2 million doses of IPV reserved for use after the switch.

National stockpiles

GPEI will identify countries that decide to establish national mOPV2 stockpiles

- ensure authorities are fully aware of commitments under WHA 68.3
- storage under appropriate containment
- use of mOPV2 only after authorization by the Director General of WHO.

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Containment of type 2 poliovirus: goal

Goal: prevent transmission of PV2 from facilities to people

Phase I: *Reduce the number of facilities containing PV2:*

- ☠ Destroy unneeded PV2
 - WPV2 by end-2015
 - Sabin2 by July 2016
- ☠ Designate poliovirus-essential facilities for needed PV2

Phase II: *Reduce risk in remaining facilities:*

- ☠ Ensure appropriate containment of PV2 in poliovirus-essential facilities

Phase I: Global progress (WPV2)

AMRO, EURO, SEARO, WPRO

- ☢ All countries completed inventories in the past → *formal updates from all countries expected end-2015*
- ☢ Considering PV-essential facilities designations: **≥42**

AFRO & EMRO

- ☢ 15/47 (AFRO) and 18/21 (EMRO) countries completed inventory in the past → *formal statements from all countries expected end-2015*
- ☢ Considering PV-essential facilities designations: **1**

Strategies to ensure timely completion of Phase I:

- ❖ Major communication drive immediately after SAGE: inform & engage all stakeholders (scientific journals, etc.)
- ❖ High level advocacy with countries at risk of lagging behind
- ❖ Deployment of consultants to African countries to complete Phase I
- ❖ Closely monitor the progress towards completion of Phase I
- ❖ Outreach to facilities that do not actively work with Polio Virus
- ❖ Expand these actions in 2016 for Sabin2 specific requirements

Phase II: Appropriate containment of PV2 in poliovirus-essential facilities

Expect:

- ⚠ Poliovirus-essential facility: implement GAPIII (Annex 2/3)
- ⚠ Hosting country: certify PV-essential facilities against GAPIII
 - Nominate National Authorities for Containment (NACs)
 - Develop regulatory framework for containment.
- ⚠ Facilities that do not actively work with polio virus: implement GAPIII
 - No storage of PV2. Containment certification not required

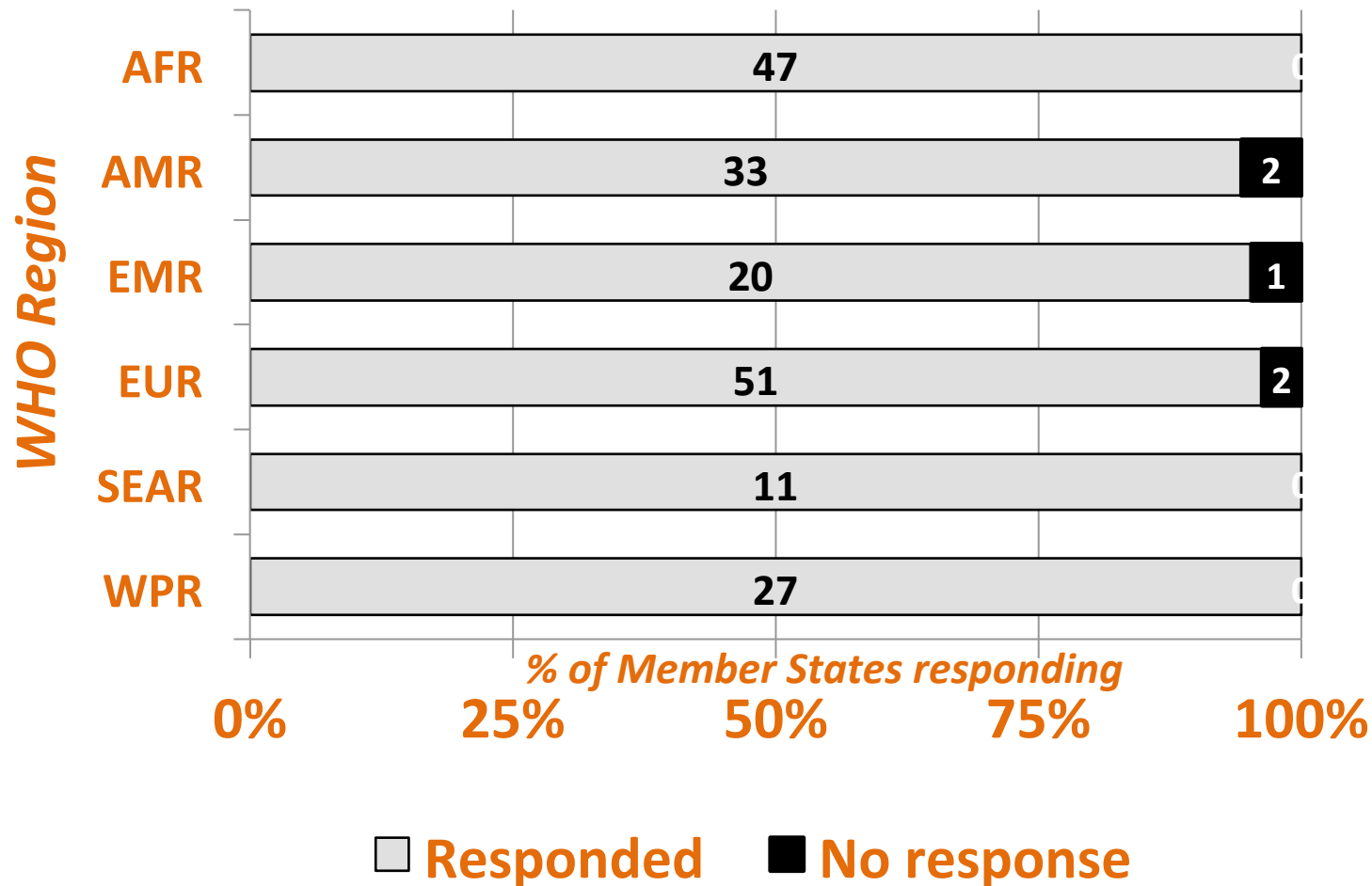
WHO provides support to:

- ⚠ Implement containment
- ⚠ Certify facilities against GAPIII
- ⚠ Address interim containment measures where full GAPIII compliance is not available yet

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Verification of the global eradication of WPV2: responses from 194 WHO Member States, by Region



Declaration on WPV2, Bali, September 2015

- The GCC concluded that indigenous wild poliovirus type 2 (WPV2) has been eradicated worldwide.
- The last WPV2 was reported from Aligarh district, northern India, in 1999.
- The GCC declared the eradication of WPV2 on the basis of :
 - formal documentation on ‘last WPV2 detection’ (if ever) submitted by 189 of 194 WHO Member States;
 - additional data from the global poliovirus laboratory network; and
 - the absence of WPV2 in > 2 million stool samples tested by the global lab network since 1999.



Thank you/Merci