



Update on Vaccine Supply

Strategic Advisory Group of Experts, Geneva

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BILL & MELINDA
GATES *foundation*



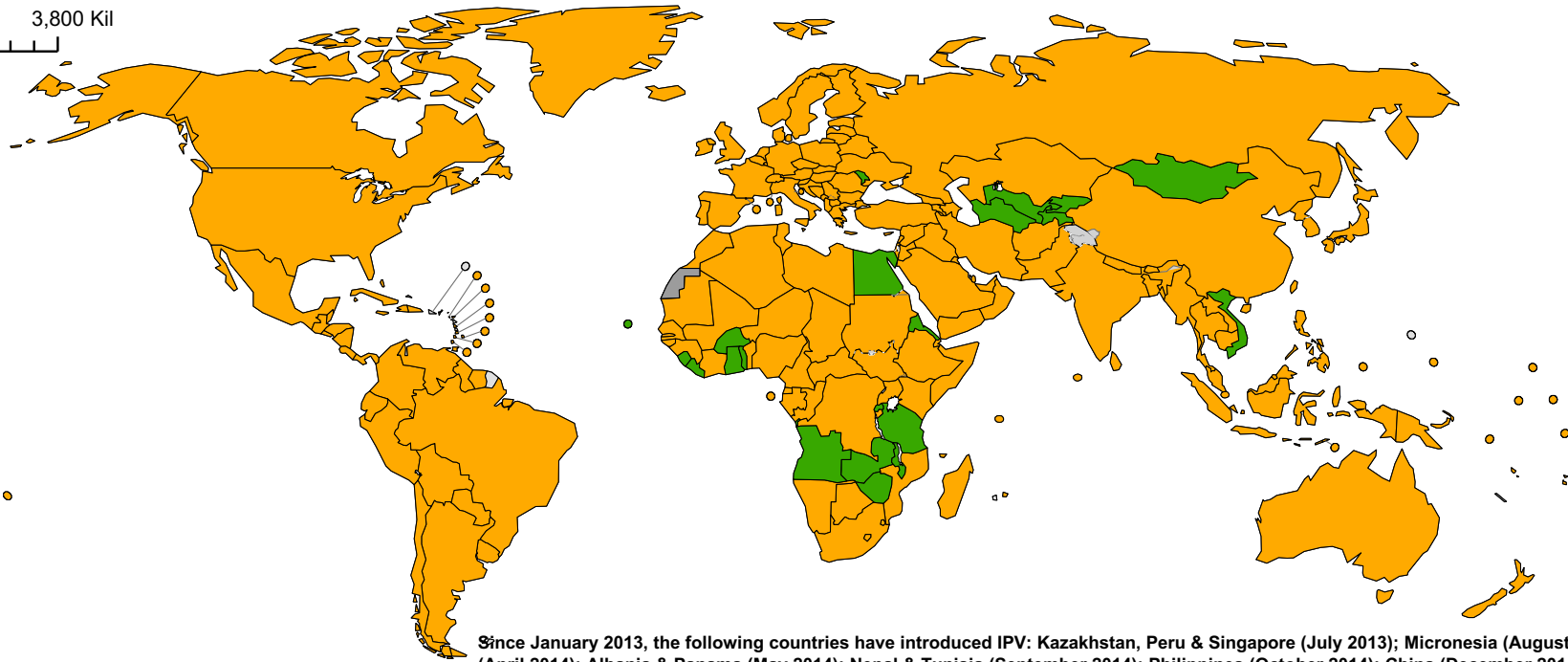
Overview of presentation

- **Status on IPV introduction and supply**
- **Update on OPV vaccine supply**
- **Update on mOPV2 vaccine supply**

Status on IPV introduction and supply

Countries using IPV vaccine to date and formal decision to introduce

0 950 1,900 3,800 Kil



- Introduced* to date (173 countries or 89%)
- Formal commitment to introduce in 2017-2018 (21 countries or 11%)
- Not available
- Not applicable

* Including partial introduction in India

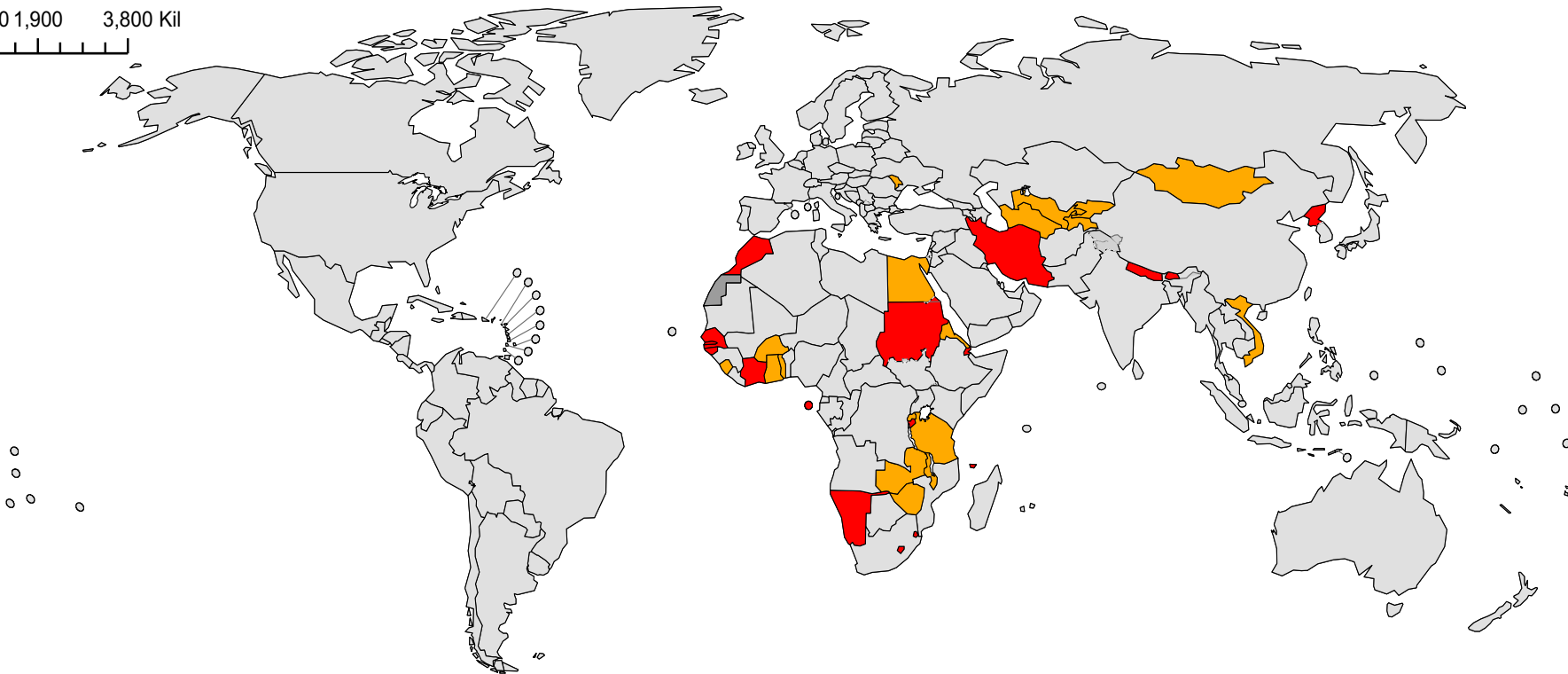
Since January 2013, the following countries have introduced IPV: Kazakhstan, Peru & Singapore (July 2013); Micronesia (August 2013); Libya (April 2014); Albania & Panama (May 2014); Nepal & Tunisia (September 2014); Philippines (October 2014); China (December 2014); Comoros, Senegal & Serbia (January 2015); Colombia & Nigeria (February 2015); Bangladesh & Maldives (March 2015); DR Congo, DPR Korea & The Gambia (April 2015); Madagascar (May 2015); Cote d'Ivoire, Grenada, Kiribati, Morocco, St Vincent and the Grenadines & Sudan (June 2015); Bhutan, Cameroon, Niger, Pakistan, Philippines & Sri Lanka (July 2015); Benin, Chad, Papua New Guinea, The Former Yug. Rep. of Macedonia (August 2015); Afghanistan, CAR, Dominica, Guyana, Iran, Jamaica, Seychelles & Solomon Islands (September 2015); Bahamas, Lao People's Dem Rep, Nauru, Samoa (October 2015); Antigua and Barbuda, Botswana, Burundi, Cook Islands, Guinea, India, Mauritania, Mauritius, Mozambique, Namibia, Nicaragua, St Lucia, Suriname, Tuvalu, Vanuatu & Yemen (November 2015); Algeria, Belize, Cambodia, Dominical Rep, Ecuador, Ethiopia, Fiji, Gabon, Georgia, Honduras, Kenya, Myanmar, Paraguay, St Kitts & Nevis, S. Sudan, Thailand, Tonga & Trinidad & Tobago (December 2015); Cuba, El Salvador, Guatemala, Haiti, Iraq & Venezuela (Bolivian Rep of) (January 2016); Azerbaijan, Bolivia & Timor-Leste (February 2016); Chile & Mali (March 2016); Argentina, Congo, Djibouti, Lesotho, Sao Tome & P., Uganda (April 2016); Armenia, Guinea-Bissau, Indonesia & Swaziland (July 2016); Eq. Guinea (August 2016)

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 2016. All rights reserved.

Data source: WHO/IVB Database, as of 11 April 2017
Map production Immunization Vaccines and Biologicals (IVB),
World Health Organization

Countries with IPV supply disruptions

0 950 1,900 3,800 Kil



- Countries with delayed introduction (18 countries or 9.2%)
- Countries with delayed resupply (17 countries or 8.8%)
- Not available / Countries already introduced
- Not applicable

Data source: WHO/IVB Database, as of 11 April 2017
Map production Immunization Vaccines and Biologicals (IVB),
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Communication to countries

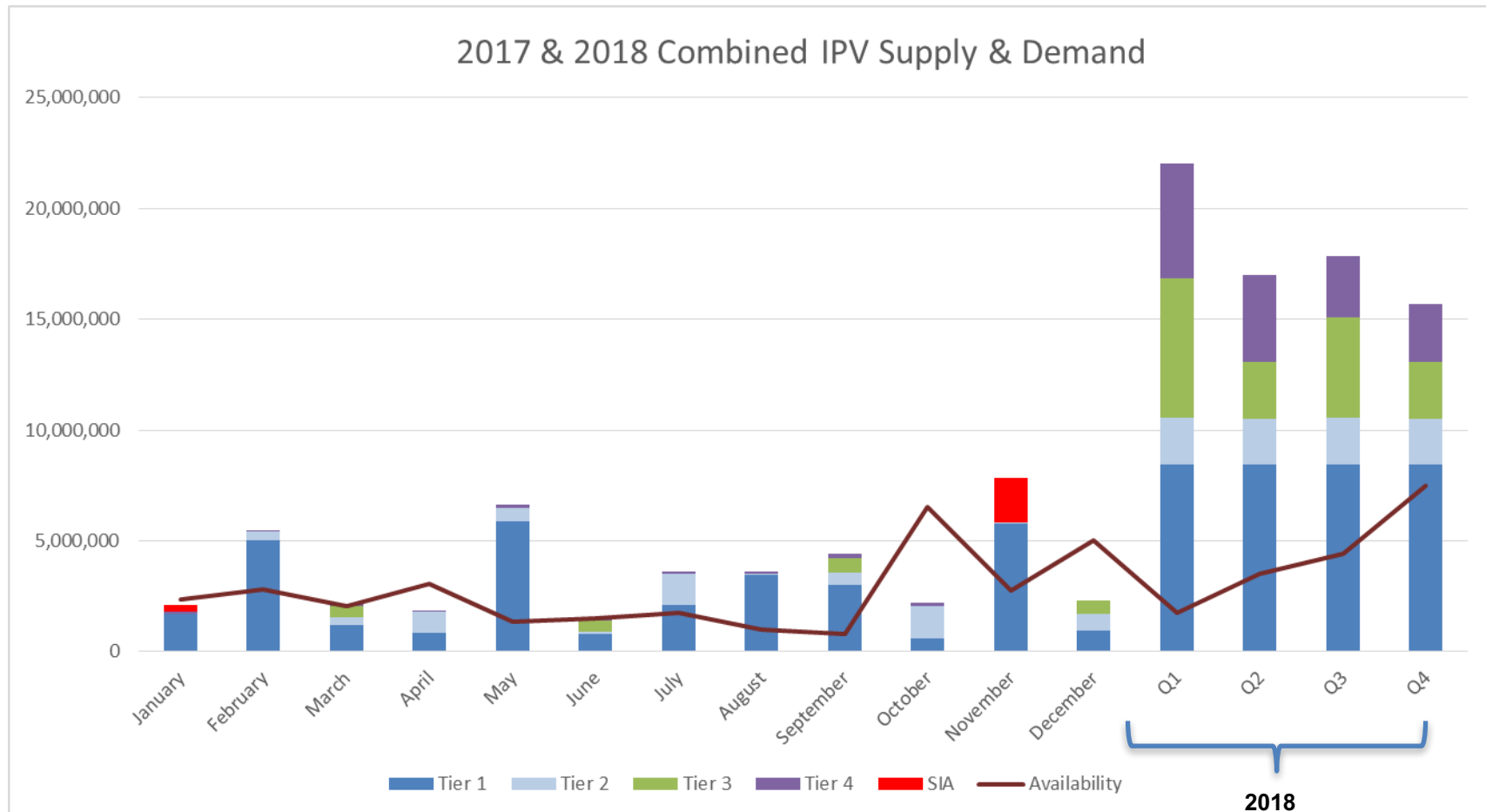
Tier 2 countries (15) are informed that...:

- 12 countries 'paused' in Q1 but all will receive supply in Q2. Due to the extremely tight supply situation, warned that there could be further interruptions throughout 2017;
- No guarantees for future deliveries and their shipment plans will be reviewed on a quarterly basis;
- Strongly encouraged to consider moving to fIPV routine with partner support to stretch supplies

Tier 3 and Tier 4 countries (35) are informed now that...:

- Due to the overall worsening supply situation it will not be possible to supply/resupply them in Q4 2017;
- Will be informed before October 2017 of when they can receive IPV in 2018 (need manufacturers' 2018 production schedule);
- Any country moving to fIPV will be prioritised and would be supplied as soon as adequate IPV becomes available

IPV situation 2017 & 2018 with these changes



- Current contracts expiring end of 2018
- Due to long production lead times, new tender to be issued in May

Fractional dose IPV implementation globally

- **Routine Immunization**
 - fIPV in RI rolled out nationally
 - India, Sri Lanka
 - Bangladesh planned for coming weeks
 - Additional SEAR countries might be interested in implementing fIPV
 - In March 2017, PAHO TAG recommended that 14 countries* begin preparations to implement a 2 dose fractional dose sequential schedule
- **Supplementary Immunization activities in small geographical areas**
 - India, Pakistan

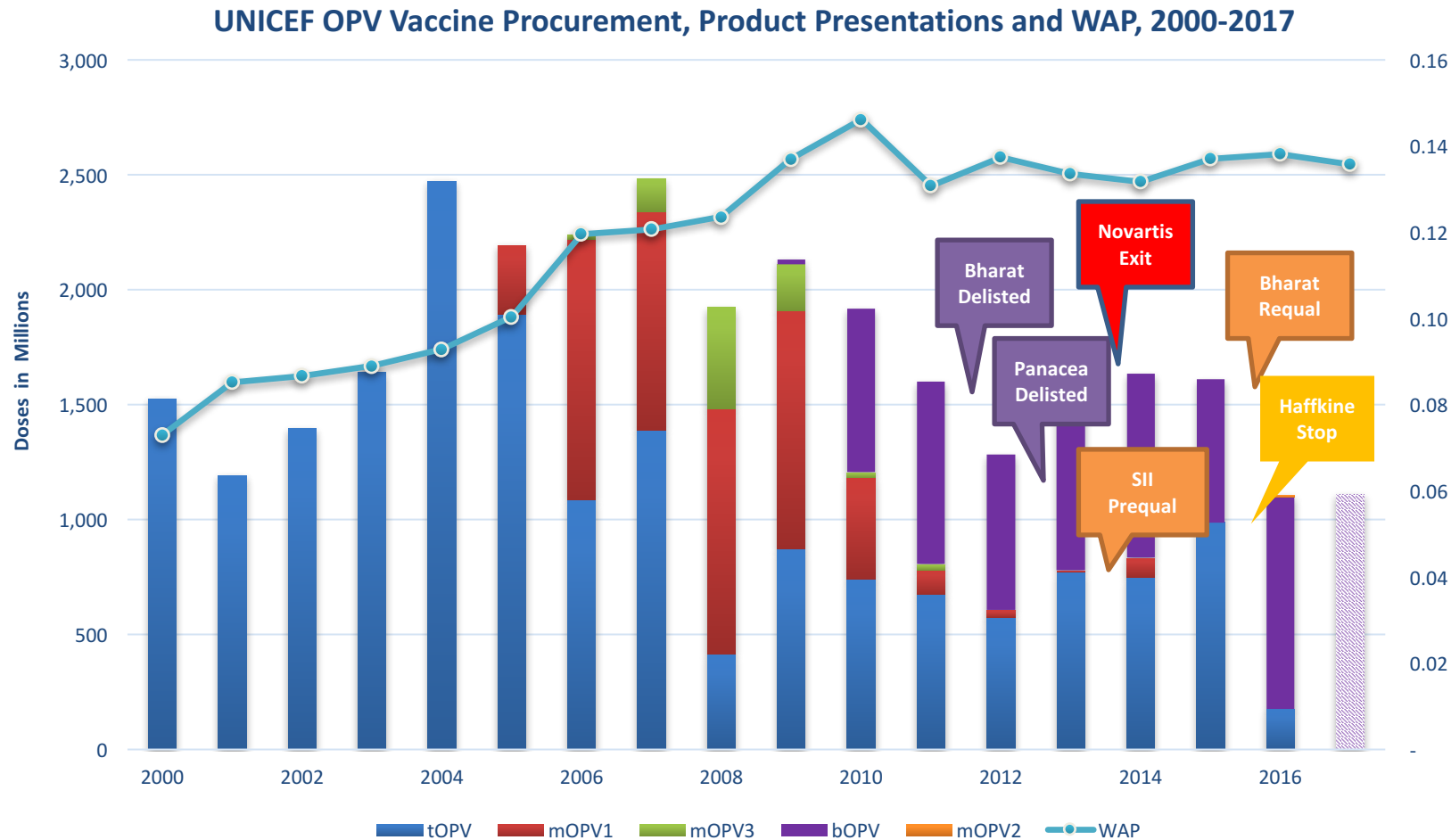
** Countries that administer more than 100,000 IPV doses per year and have the capacity to adequately train HCWs and supervise implementation: Argentina, Bolivia, Brazil, Chile, Colombia, Cuba, Ecuador, El Salvador, Honduras, Nicaragua, Paraguay, Peru, Uruguay and Venezuela*

Next Steps

- **In current environment, prioritise sustaining routine doses over SIA doses per SAGE recommendation**
- **Interface with supply on device availability**
 - Supply & procurement of 0.1 ml syringes for intradermal administration – may take around 6 months (tendering, production and delivery by sea)
 - New technologies still being explored
- **Collaborate with South East Asia on documenting fIPV experience to document learnings**
 - India, Sri Lanka
- **Re-review criteria on grading risk within the Tiers**
 - Reassess risk levels for post-switch world to take into account the length of time cohorts have been deprived of IPV, the recent emergences of type 2 events and the risk that iVDPVs could represent
 - Expected draft revision May 2017, to be endorsed by SAGE before end Q2 2017

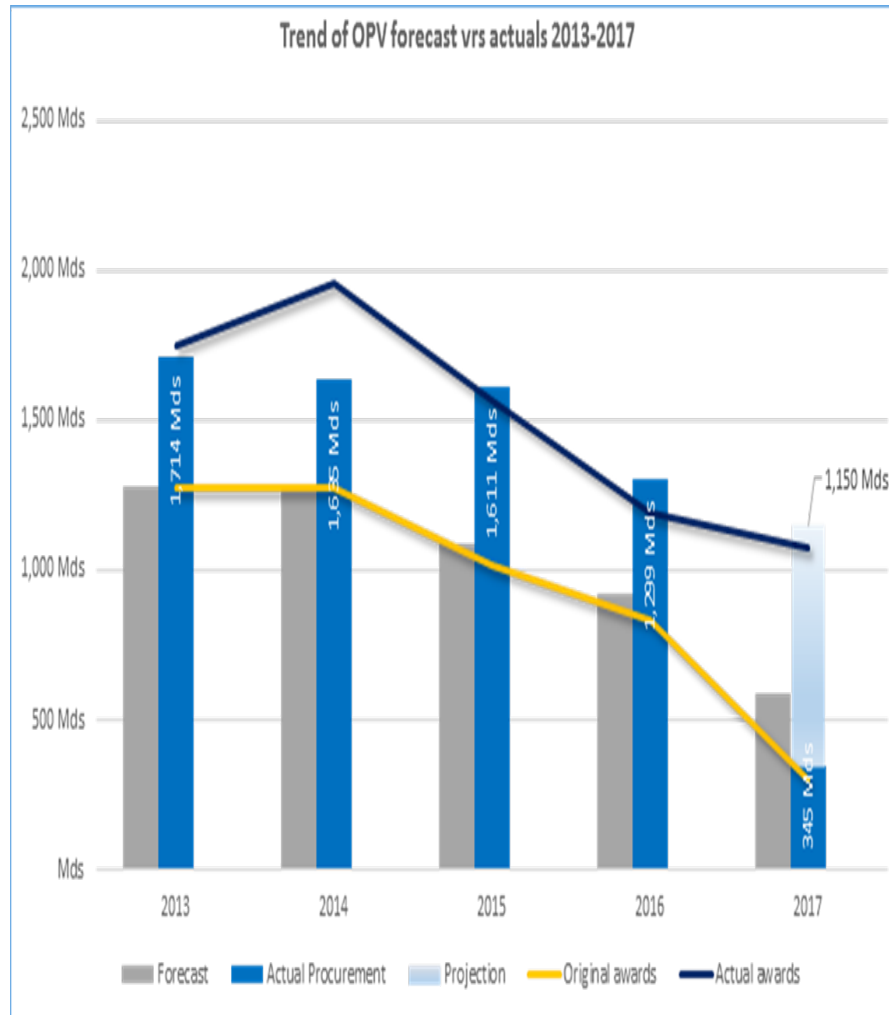
bOPV supply

Historic overview of UNICEF procurement including current tender period 2013-2017



- Two bulk vaccine producers have announced their planned market exits

Programmatic Demand Projections for past 10 years too low, requiring ad hoc procurement with short lead time



Awards 2013-2017

- 5.2Bds based on programme forecasts - leaving un-awarded quantities for 2017
- Following supply constraints in 2013, moving from awards based on forecasts to maximizing supply capacity (2013-2015)
- As of today, total awards of 7.7Bds – increased by 48%

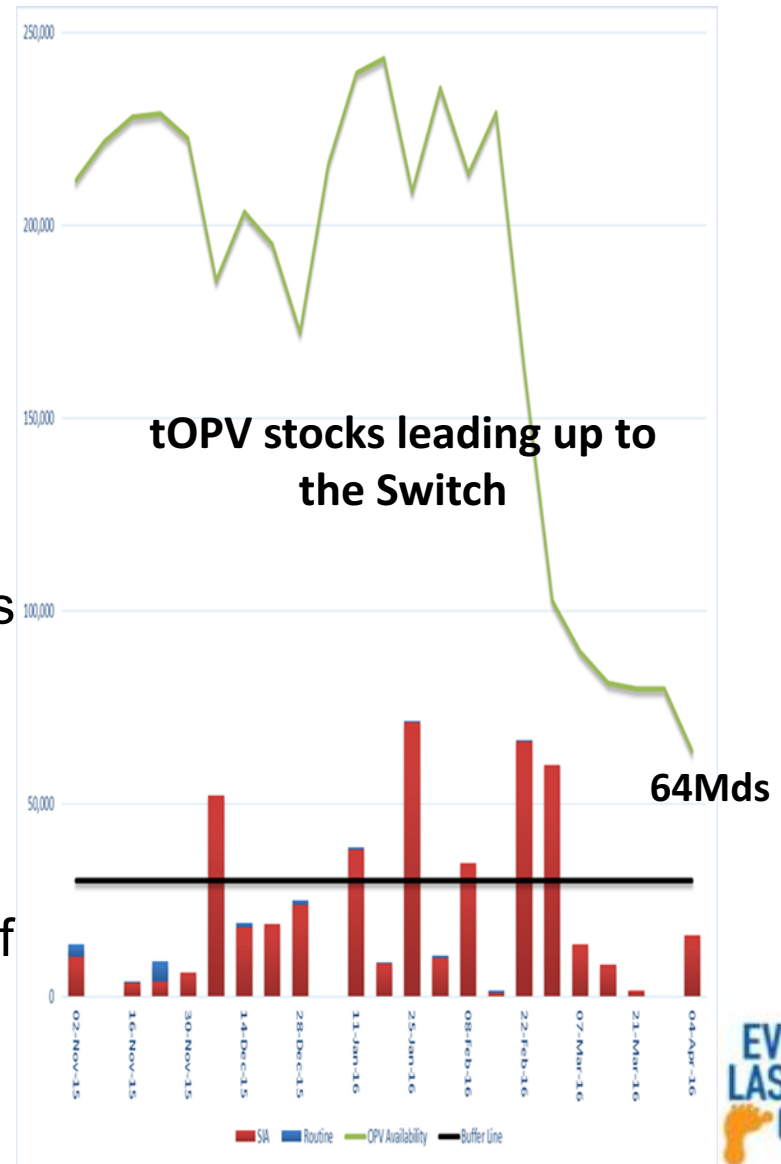
Lessons learned from tOPV Cessation

Planning starting 2014, increasing coordination and communication with industry to prepare

- Full transparency, but limited visibility on switch timelines and demand

Implementation 2015-2016

- Supplier concerns increasing: Financial risks related to bulk procurement and tOPV residual stocks – mitigation: equal and high utilization of supply arrangements (95%); partial compensation
- Program concerns increasing: Sufficiency of supply – mitigation: small physical stockpile established; additional awards Q4 2015



Procurement Objectives addressing Key Risks

1. **Sustain sufficient supply of bOPV to meet demand through polio eradication and bOPV cessation**
 - To secure the sustained, uninterrupted supply of vaccine of to meet planned programmatic requirements through eradication and final OPV cessation
 - To secure sufficiently-sized buffer of supply to meet unplanned demand associated with outbreak response, and intensification of activities as defined by the Program
 - To secure the sustained, uninterrupted supply of polio vaccine in the event of delayed eradication and OPV cessation

Procurement Objectives addressing Key Risks

2. To guide the cessation of the OPV market in a responsible manner while maintaining affordability

- To minimize risk of early market exits of manufacturers in the event of a delayed eradication and cessation, given the demand uncertainties for the outer years of tender
- To minimize risk of financial loss due to residual stocks with manufacturers associated with uncertainty in timelines and demand to balance affordability and market uncertainties

Bivalent OPV (bOPV) Vaccine Supply: 2018 through to cessation

- **Tender issued 30 December 2016, closed 17 February 2017 for 3.2-5.2 billion doses over the period of 2018 to 2022**
 - Proposals currently under evaluation including with input from a Procurement Advisory Group
 - Plan to present to the Strategy Committee (and POB, upon request) the supply risk mitigation options, recommended approach and budget requirement following review and assessment (anticipated in May)
 - Offered supply capacity is sufficient to meet demand, but in case of delay beyond 2018 in interruption of WPV transmission, high dependence on one bulk supplier

- **In order to develop the qualified estimate of the necessary bOPV buffer stocks for 2018 and beyond**
 - i) Modelers requested to provide their perspective on bOPV buffer stock requirements for triangulation; and
 - ii) UNICEF aims to provide a proposal for buffer stocks as part of the total supply risk mitigation package to be presented to GPEI before awards, based on supply capacity offered under the bOPV tender.

mOPV stockpile

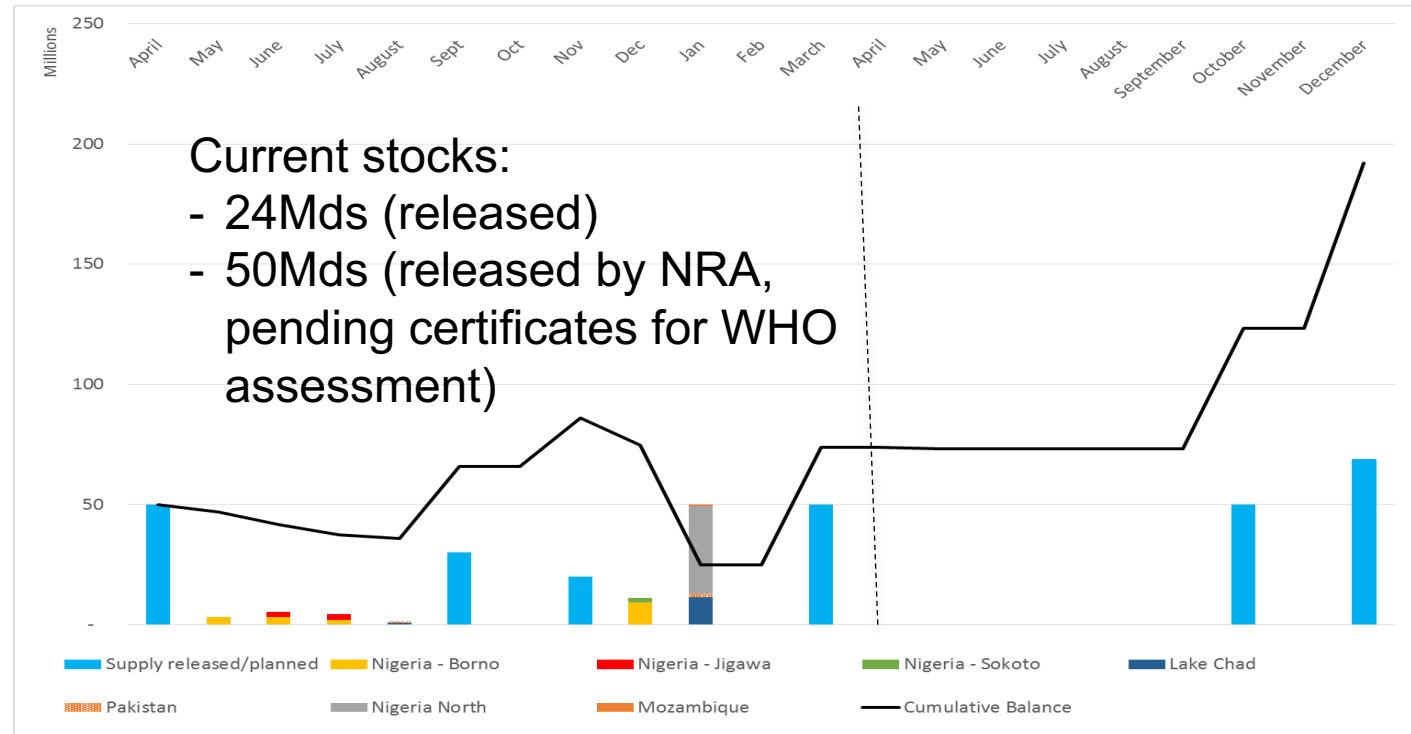
mOPV2 stockpile: Rationale and overview

- Based on bulk stockpiles of monovalent OPV bulks established in 2009 in preparation for OPV cessation
- Finished product stockpile set up 2015/2016 to respond to any type 2 outbreaks/events following tOPV withdrawal
- Global stockpile of finished product, managed through GPEI Advisory Group, release for use upon approval by WHO Director-General
- Careful vaccine handling and stock management needed to avoid re-introduction of type 2 viruses
- Growing importance given IPV shortage
- Demand to-date has exceeded estimates

mOPV2 Stockpile: Update after 11 Months

Current situation

- To date, 76Mds out of 100Mds that are in the stockpile have been used
- 119Mds on order, depleting type 2 bulk from one supplier
- Original stockpile budget/plans were for 138Mds in 2016-2017



Why?

- Frequency of detection somewhat above model predictions
- Responses outside of the agreed planning parameters based on Protocol (0.5+2.3Mds vs average 4.5Mds)

Looking ahead

- Risk of depletion of mOPV2 stockpile before October delivery?
- Use of +70Mds in Nigeria/Lake-Chad areas – risks of new VDPVs?

Using the lessons learned to rethink the GPEI Polio Stockpiles

Cross functional Polio Stockpile Working Group established to consult with other groups before reporting to Strategy Committee in mid-2017

Questions under discussion:

- How many doses should we have of each vaccine, and how should we set the parameters? How to balance financial and technical requirements...
- What are the likely requirements for bulk vs finished product?
 - mOPV2 finished product requirements (bulk already depleted with one supplier – contracting for conversion of bulk to finished product with 2nd supplier in progress)
 - Requirements for mOPV1 and mOPV3
- Implications of IPV supply on stockpile requirements (and OPV cessation)
- Number and types of suppliers:
 - Bulk manufacturers?
 - Fillers?
 - GAP III implications?

Conclusion

- **IPV**

- Continues to be constrained through 2017 and 2018, requiring close monitoring to continually balance demand with available supply
- Countries in Tier 3 and 4 will be further risk-tiered
- Countries interested in shifting to fractional IPV will be supported and prioritized to do so

- **OPV**

- Vaccine supply currently sufficient, but with increasing risks in case of further delays due to market exits by bulk suppliers
- Increasing reliance on a single bulk supplier

- **mOPV stockpiles**

- For post cessation currently under review by GPEI, including for mOPV2 to ensure sufficient capacity for outbreak response for a polio free world

Thank you

