

UNICEF's Perspective: Polio Vaccine Supply for the Switch



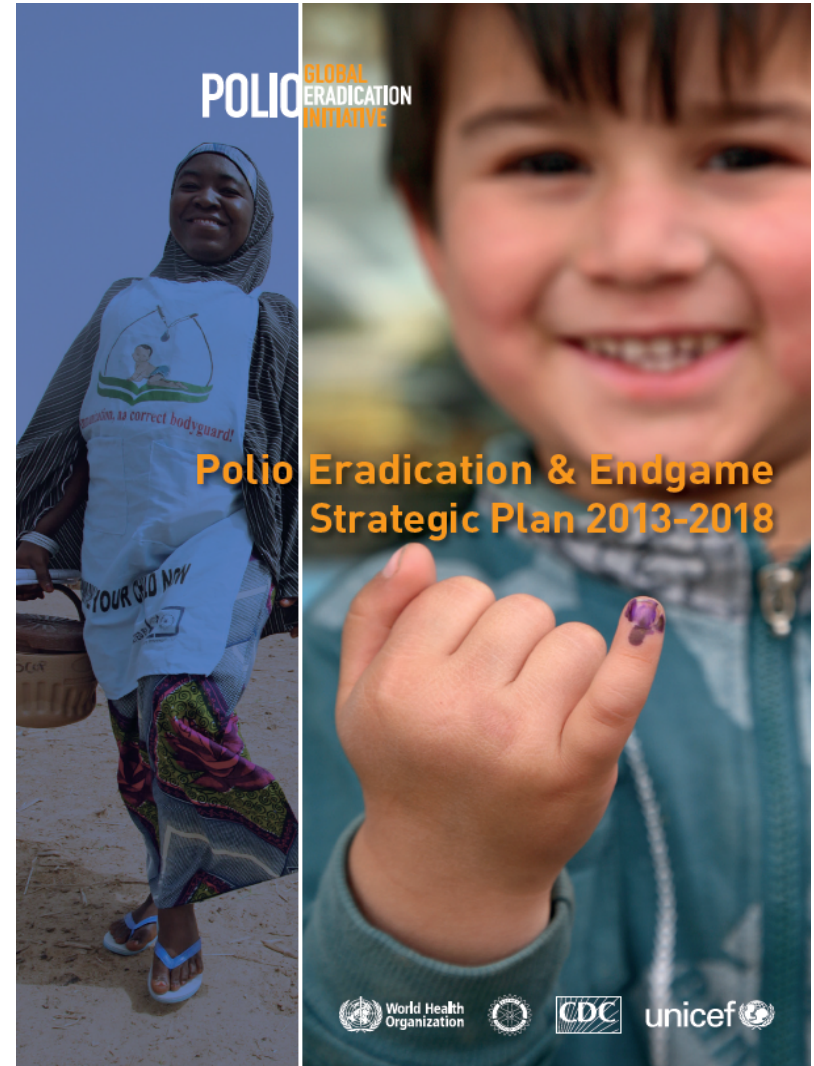
The Endgame Strategic Plan provided the Roadmap for the Switch and Changing Supply Needs

1. Detect and interrupt all poliovirus transmission

- Secure availability of **OPV (and IPV)** including urgent delivery of the appropriate type of OPV to stop WPV transmission and interrupt cVDPV outbreaks

2. Strengthen immunization systems and withdraw OPV

- Securing sufficient supply of **tOPV** and **bOPV** during the phased withdrawal of all OPVs starting with tOPV in April 2016
- **mOPV2** stockpile and response capacity
- At least 1 dose of affordable **IPV** available in OPV-only using countries



Planning for and Implementing tOPV Cessation: A (small scale) dry-run for OPV Withdrawal

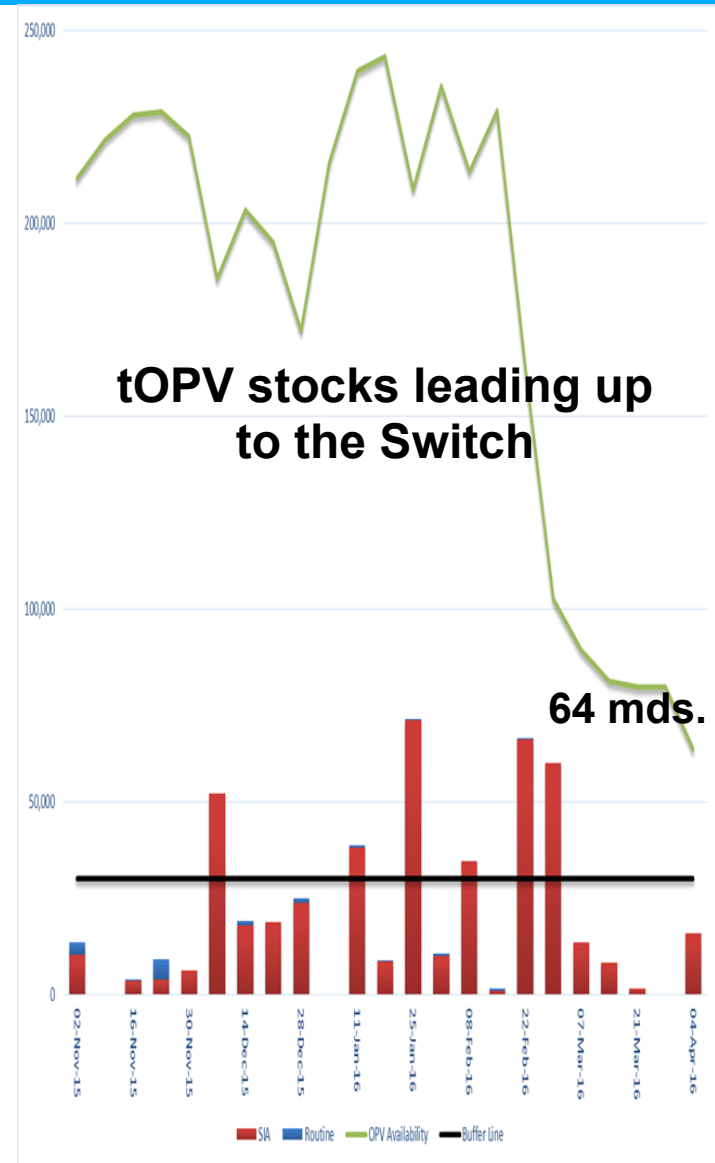
Planning starting 2014, increasing coordination and communication with industry to prepare

- 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

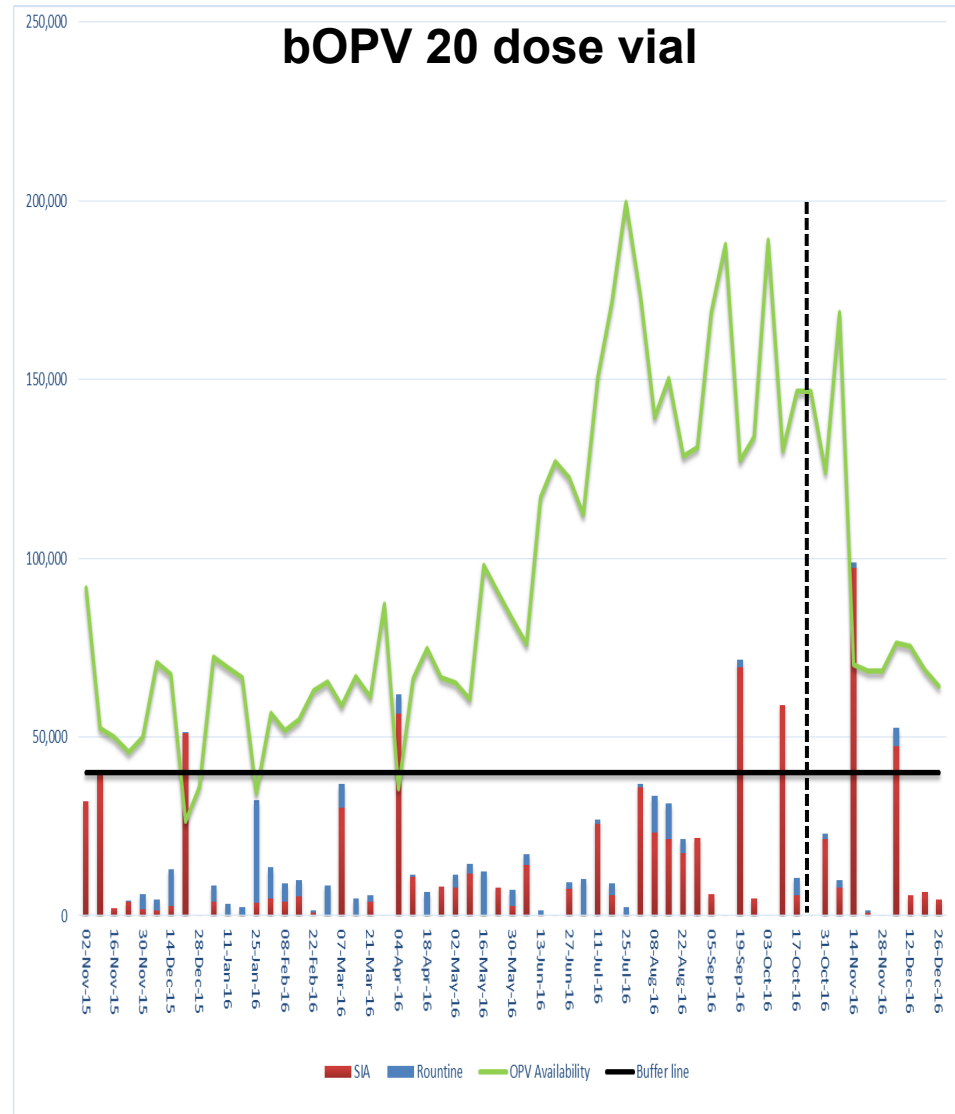
Residual stocks ~ 5% of total of 1.2 billion doses of tOPV 2015-2016



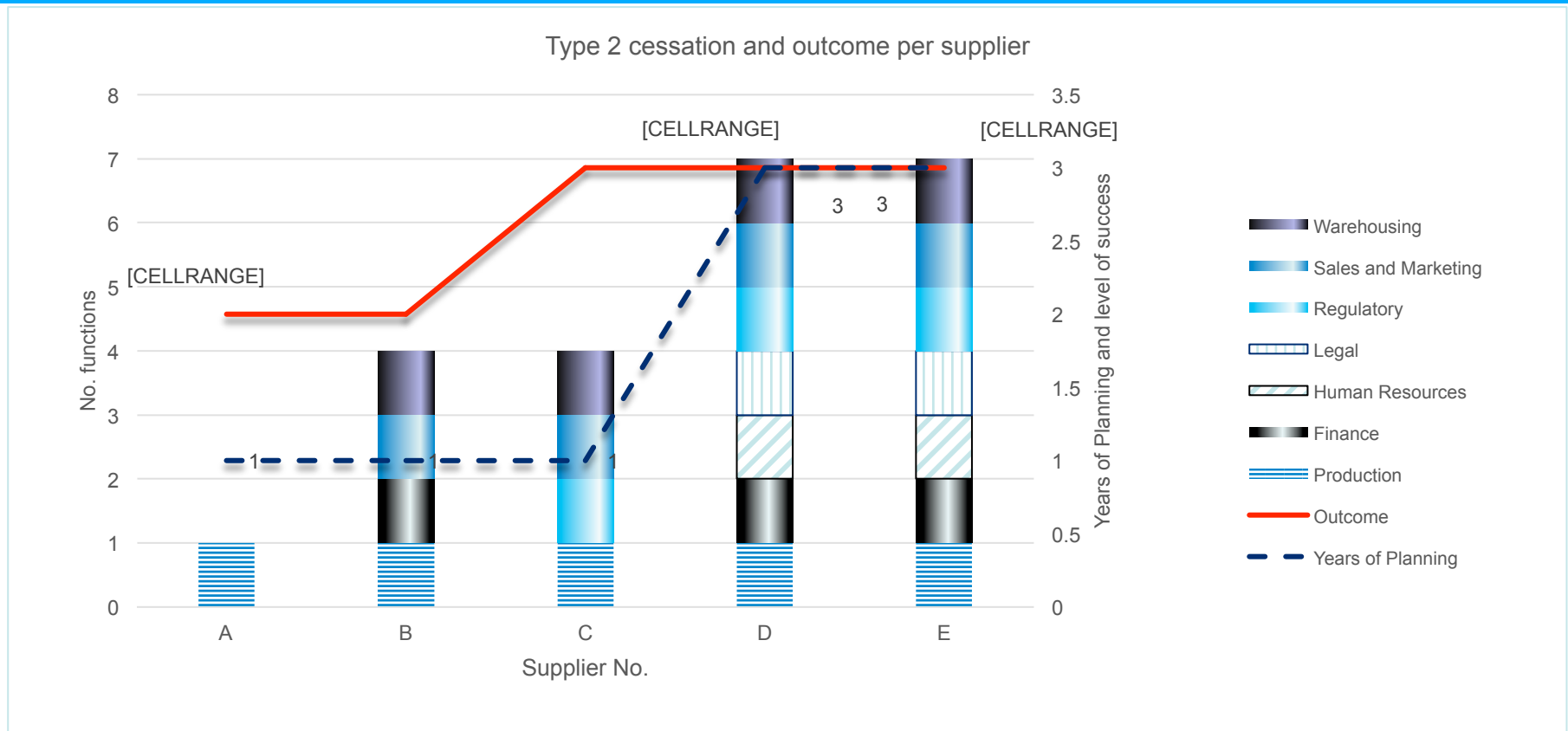
Securing Availability of OPV to stop WPV Transmission, interrupt cVDPV Outbreaks, and meet Routine needs

Key achievements 2016

- A total of 650Mds OPV (tOPV and bOPV) delivered December 2015-March 2016
- Timely roll out of bOPV for Routine Immunization in +75 countries before the Switch (3 delayed)
- Ability to meet 200Mds requirement for Nigeria outbreak through supplier flexibility and response capacity
- Additional awards of 805Mds bOPV for delivery in 2017



UNICEF Suppliers rate the tOPV Cessation somewhat-to-very successful from a Business Perspective



- A strategic approach to the tOPV cessation involving senior management
- Positive assessments: Longer term planning and more functions involved
- Actual procurement within an acceptable margin of deviation to forecast
- Warehouse capacity and meeting delivery timelines in the run up to the Switch was a challenge for 3 out of 5 manufacturers

Lessons Learned from tOPV Cessation and Guidance provided by Suppliers

- **Careful planning and close collaboration** between Program and suppliers can facilitate a successful market cessation!
- To the extent possible, address Program and suppliers **uncertainties up-front to** ensure transparency, with appropriate risk mitigation (e.g. co-sharing of financial risks – ensuring buffer capacity for supply)
- Guidance from industry:
 - **Involve suppliers from early stages** of decision making to ensure awareness and caution on supply realities
 - Early communication to allow for **integration into suppliers strategy** (production and industrial investment timelines)
 - **Establish channel and forum** between Program and suppliers for addressing concerns and resolve issues as they materialize

OPV stockpile

mOPV 2 Stockpile and Response Capacity as a Prerequisite for The Switch

- 2009: Tender for monovalent bulks type 1, 2 and 3 for stockpiling, awards for 1.1 billion doses
- 2015: Tender for conversion of monovalent bulks into finished product

Global stockpiles under UNICEF/GPEI contracts

Vaccine type, mio. ds	Bulk	Naked vials	Finished product
mOPV1	300	0	0
mOPV2	369	50	65
mOPV3	300	0	0
Total	969	50	65

- 14 million doses delivered May-October to respond to 3 outbreaks (2xNigeria, 1xPakistan)

GPEI stockpile strategy under revision Q4 2016

IPV

Inactivated Polio Vaccine in the Context of the Switch

SAGE recommendation April 2013

- All 126 OPV using countries to introduce at least one dose of IPV 6 months prior to the Switch

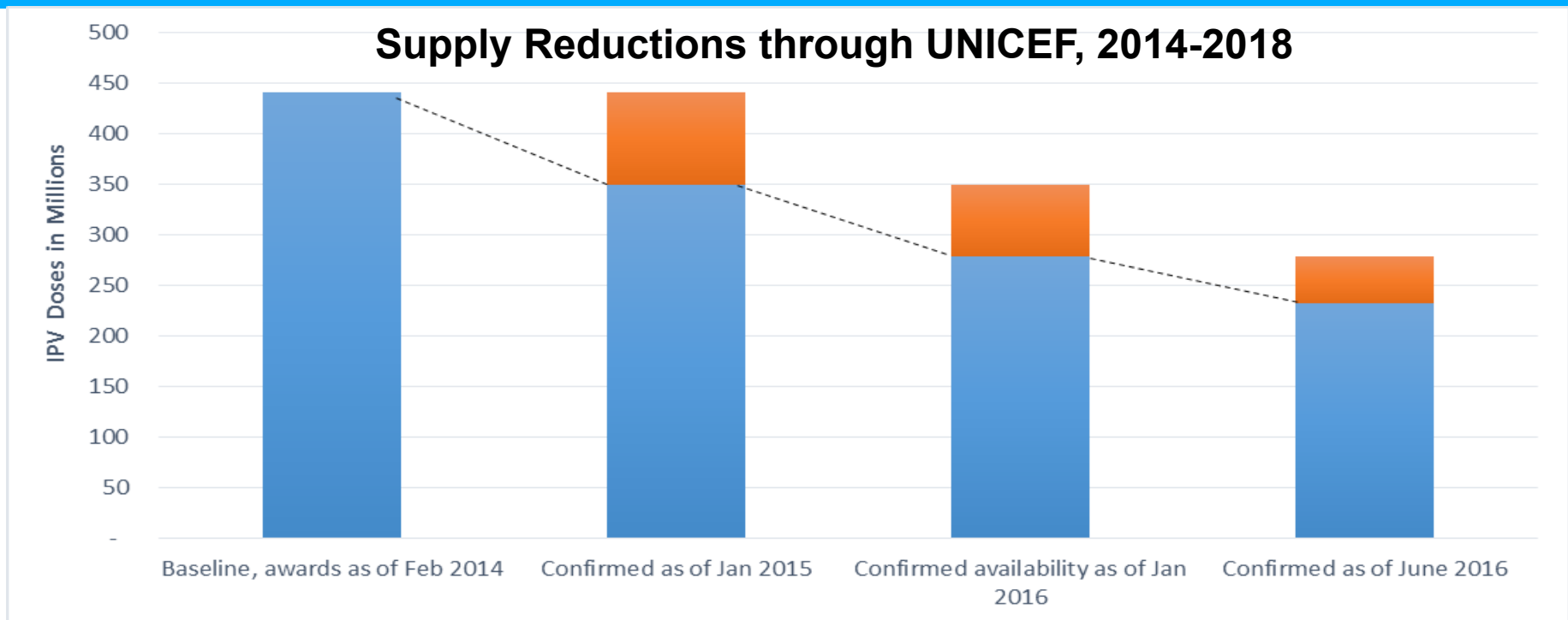
Rationale for IPV

- Minimize the occurrence of paralytic disease from type 2 VDPV post switch **due to priming of immune system**
- Tender issued October 2013 leading to awards of 441 million doses, expected to fully meet projected demand

SAGE recommendation October 2016

- Explore options to mitigate supply shortages (fIPV, new products)
- Catch up of IPV vaccinations – when supply becomes available
- Decisions on post cessation schedule and duration of vaccinations to be provided October 2017

Supply Evolution from early 2014 to October 2016: From 'Comfortable' to 'Crisis Management'



Due to **delays in manufacturer's scaling up** due to insufficient bulk

Unplanned production stops and repeated delays; delays in restart after maintenance; planned installation and validation of new equipment; break down of equipment, delayed release of vaccines (bulk and finished products); technical issues

No buffer stocks at different steps of production, leading to direct impact on supplies of any delays or reductions in released quantities

Applied Principles for Allocating the IPV Supply

The Polio Oversight Board, which is made up of the heads of agencies of GPEI partners agreed to the following (April 2016):

- 1. Ensure adequate IPV supply to meet current and future needs of Afghanistan, Pakistan to ensure interruption of WPV transmission**
- 2. Sustain use of IPV in routine immunization programme in highest risk countries (Tier 1 and Tier 2)**
- 3. Ensure sufficient quantities of IPV are available for outbreak response post-Switch.**
- 4. Provide clarity to Tier 3 and 4 countries regarding supply availability so they can adequately plan**

Further Reductions of 8 Million Doses communicated over the past three Weeks, requiring further Prioritisation

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- 2. Sustain use of IPV in routine immunization programme in highest risk countries (Tier 1 and Tier 2) likely delay to some countries**
- 3. Ensure sufficient quantities of IPV are available for outbreak response post-Switch – currently no supply for outbreak**
- 4. Provide clarity to Tier 3 and 4 countries regarding supply availability so they can adequately plan – around 49 countries currently not receiving supplies**

Polio Vaccine Supply in Context of the Switch, and Way Forward

Overall, a successful switch considering

- **tOPV market cessation**
- **bOPV introductions in routine programmes**
- **mOPV2 stockpile established**

IPV supply continues to be constrained with no prospect of improvement until 2018/2019; and few options for mitigation

bOPV tender in progress

- **To be issued in coming weeks to secure supply through to cessation (2021-2022)**
- **Consultation via webinar with industry prior to issuance of tender**
- **Supply to start from January 2018**

Thank you