



Polio Vaccine Supply Update

Independent Monitoring Board
May 2014

Outline

- Review of supply in 2013
- Update on supply in 2014
 - Update on IPV
- Risks and challenges
- Next steps

2013 Supply Situation: Lessons learnt

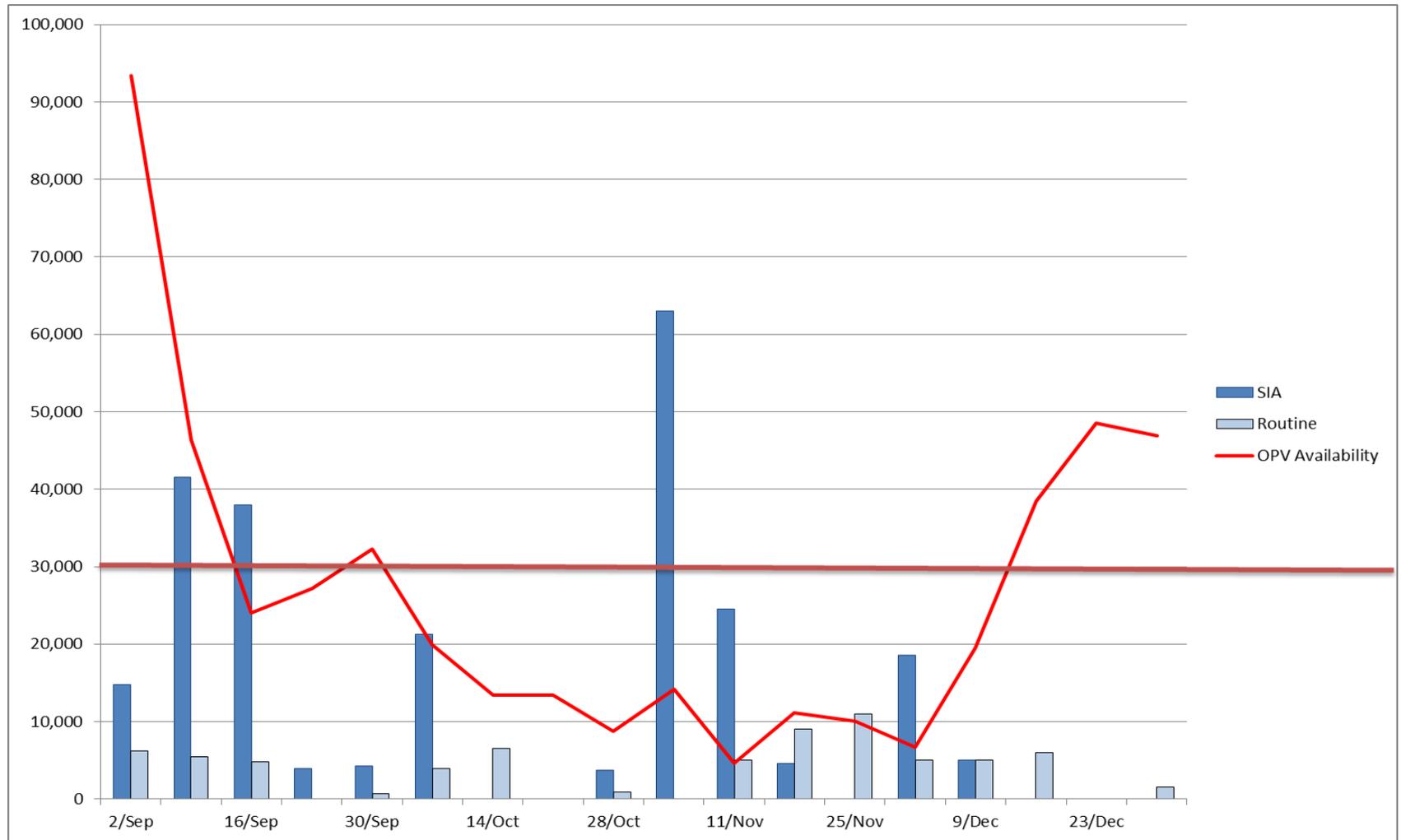


A highly constrained global Vaccine Supply Situation in 2013: Reasons

- **Delisting of two OPV suppliers** in 2012: reducing Q1 2013 availability
- **Delays in release of vaccine** from some suppliers in Q4 2013
- Originally forecasted **demands for 2013 were significantly lower**
*Increased number and scale of SIAs in endemic countries (**additional 160 md for Nigeria**)*
*Increased demand from regional outbreaks in Horn of Africa (**additional 20 million doses**) and Middle East (**24 million doses**)*

tOPV supply status as of Sept. 12, 2013

Source: Report to the IMB meeting, October 2013

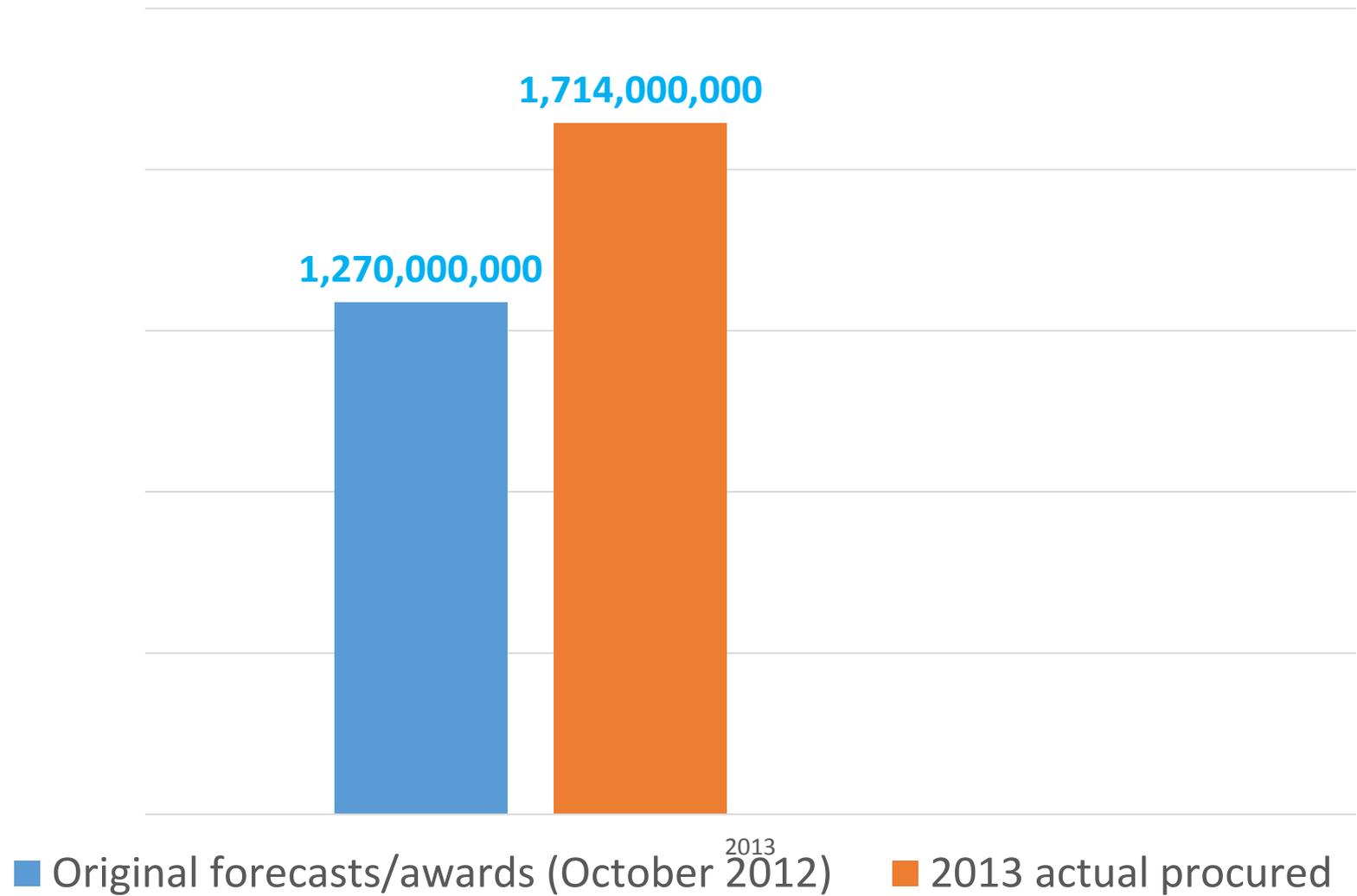


2013: Response to constrained supply situation

Mitigating measure: **Multiple increases in supply**

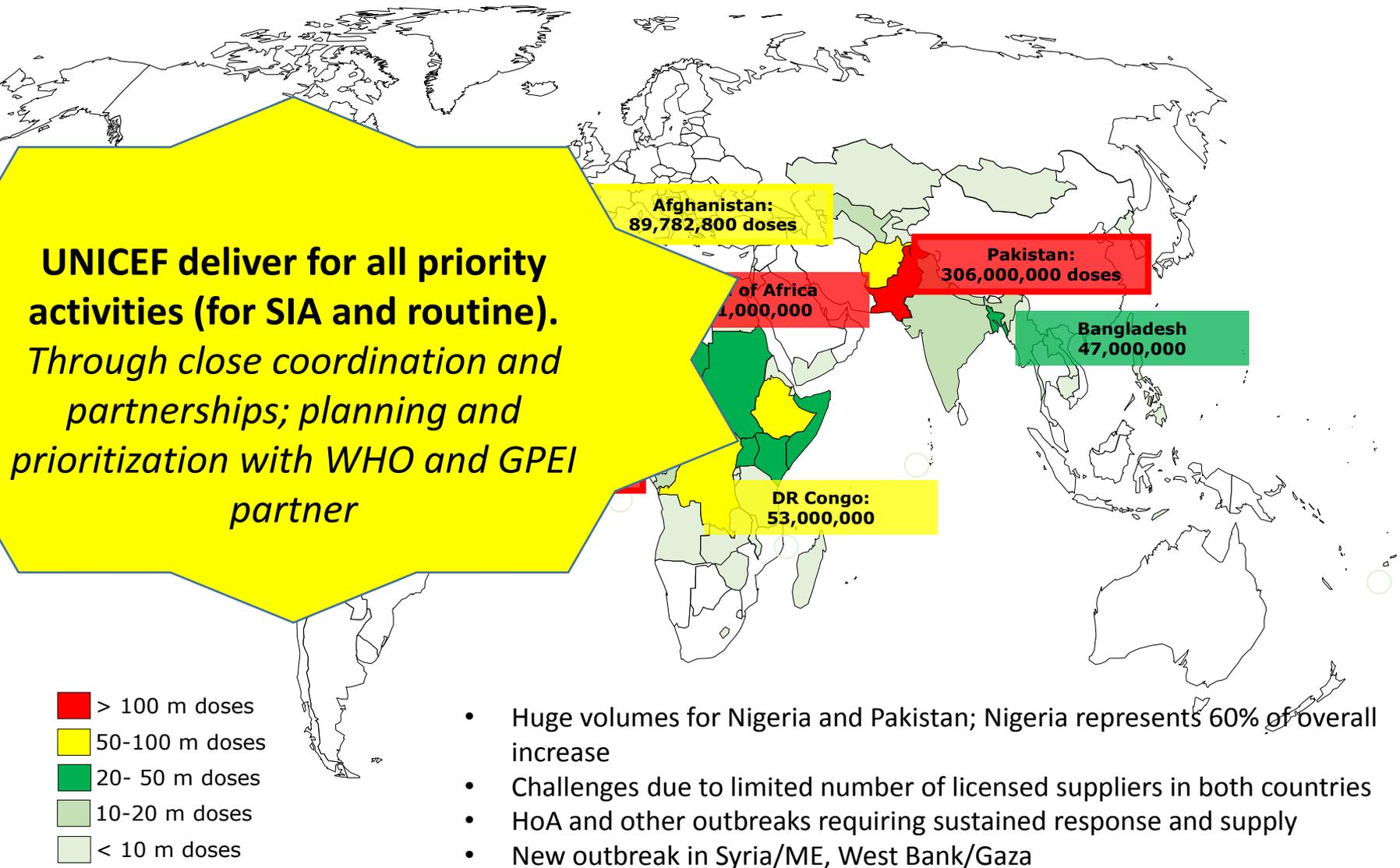
- Demands continued to grow resulted in **maximizing supplier capacity** through Q1 2014 (example: Middle East outbreak)
- All released **supply immediately shipped** for delivery: buffer compromised

Vaccine Supply comparisons (OPV doses)*, 2013



**2013 actual procured based on Purchase orders made in 2013, and include approx. 150 delivery for January/February campaigns*

Delivered around 1.7 billion doses, 2013



Delivering for 2014 and beyond



PERISHABLE GOODS
MAY 15 1994 2200
CTN No. 33 OF 50
DRIVER FOR NOV 2010
KEEP AT ROOM TEMPERATURE
DEST - ETHIOPIA
SHOULD BE ARRIVED TO DESTINATION AT
MAX 7 X 24 HOURS



KEEP AT ROOM TEMPERATURE

Delivering for 2014 and beyond

- Additional **460 million OPV doses** awarded in November 2013 **for 2014**. Maximized existing supplier capacity.
- Awarded quantities determined by several **factors and assumptions**:
 - Endorsement by **EMG** to increase demand/buffer
 - **Lessons learnt**: Assumption that 2014 demand would equal or exceed 2013 demand; funding remains stable
 - **Increased demand assumptions for Nigeria** in line with 2013
 - **Pakistan based on Nov 2013 mapping**: assuming an additional 30 mds for routine needs
 - Added some additional unplanned demand (**~ 30 mds**) per quarter

Delivering for 2014 and beyond

Accounting for Q1 2015:

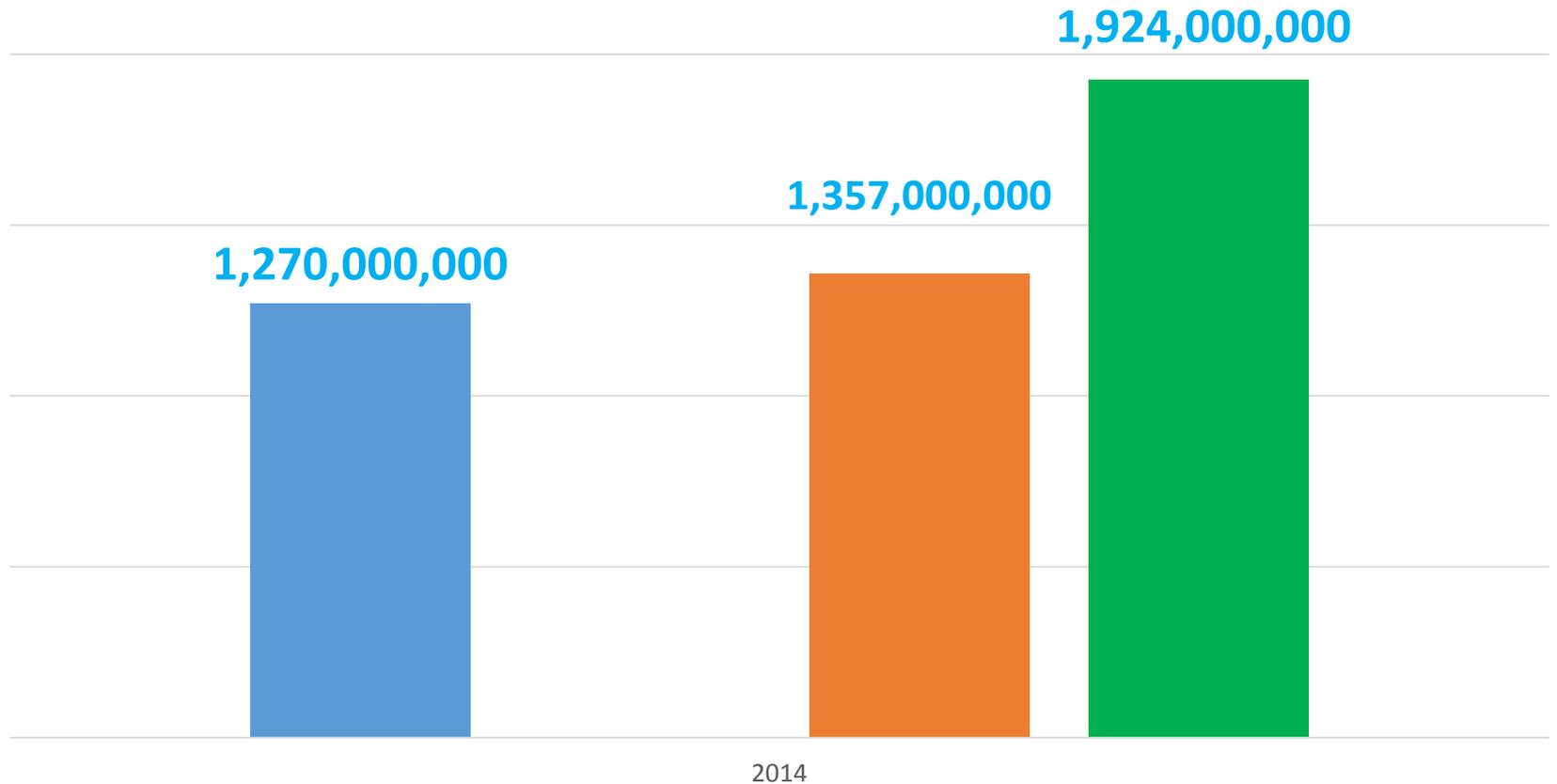
- Assumptions:

 - Demand requirements similar to **Q1 2014**

 - Almost **no carry over from Q4 2014**

- An additional award of **100 million doses** was awarded to one EU supplier to maximize capacity, of which 50 mds can be available in 1H

Vaccine Supply comparisons (OPV doses)*, 2014



- Original forecasts/awards (October 2012)
- 2014 forecasts based on Jan 2014 Calendar
- 2014 total supply (incl. addt'l awards)

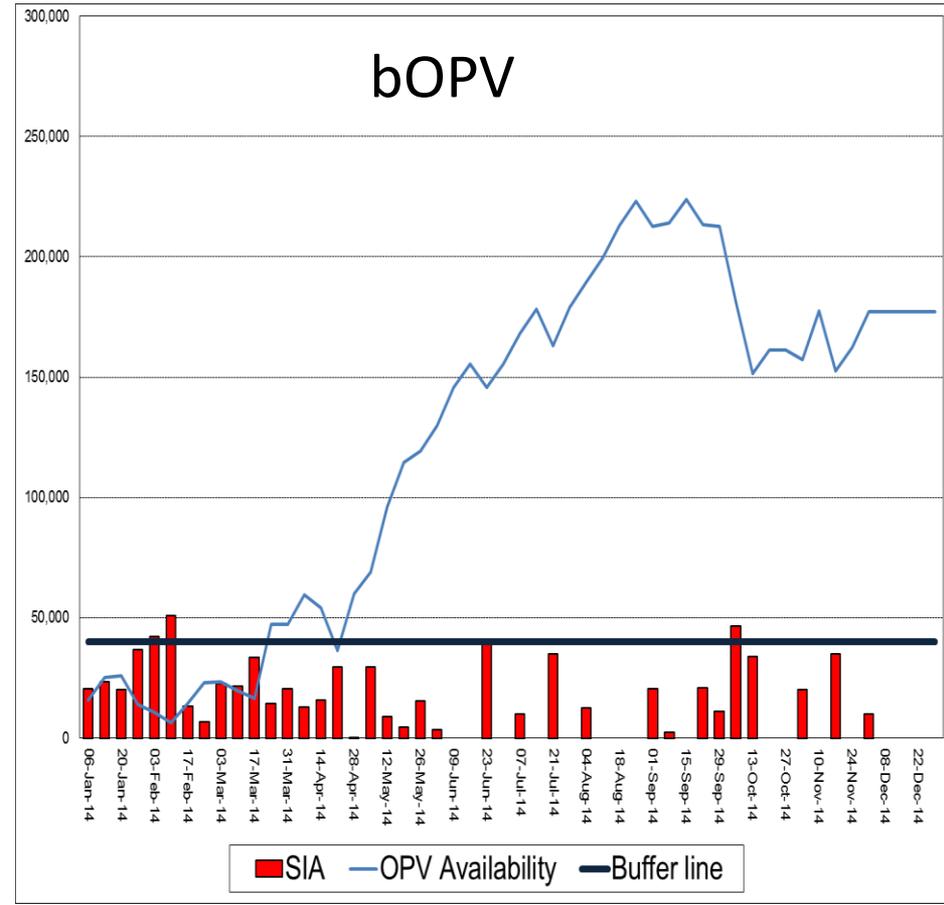
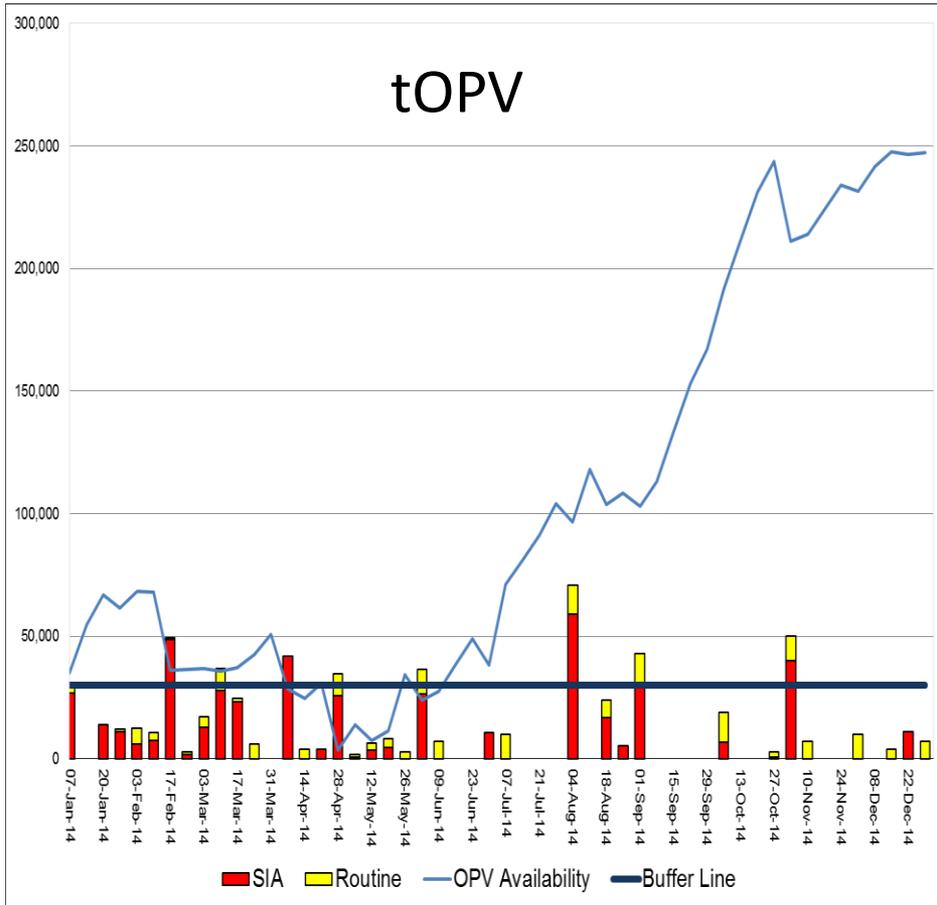
**2014 figures include orders made/to be made in 2014, and include delivery for large scale January/February campaigns*

**What does
OPV supply
situation look
like in 2014?**



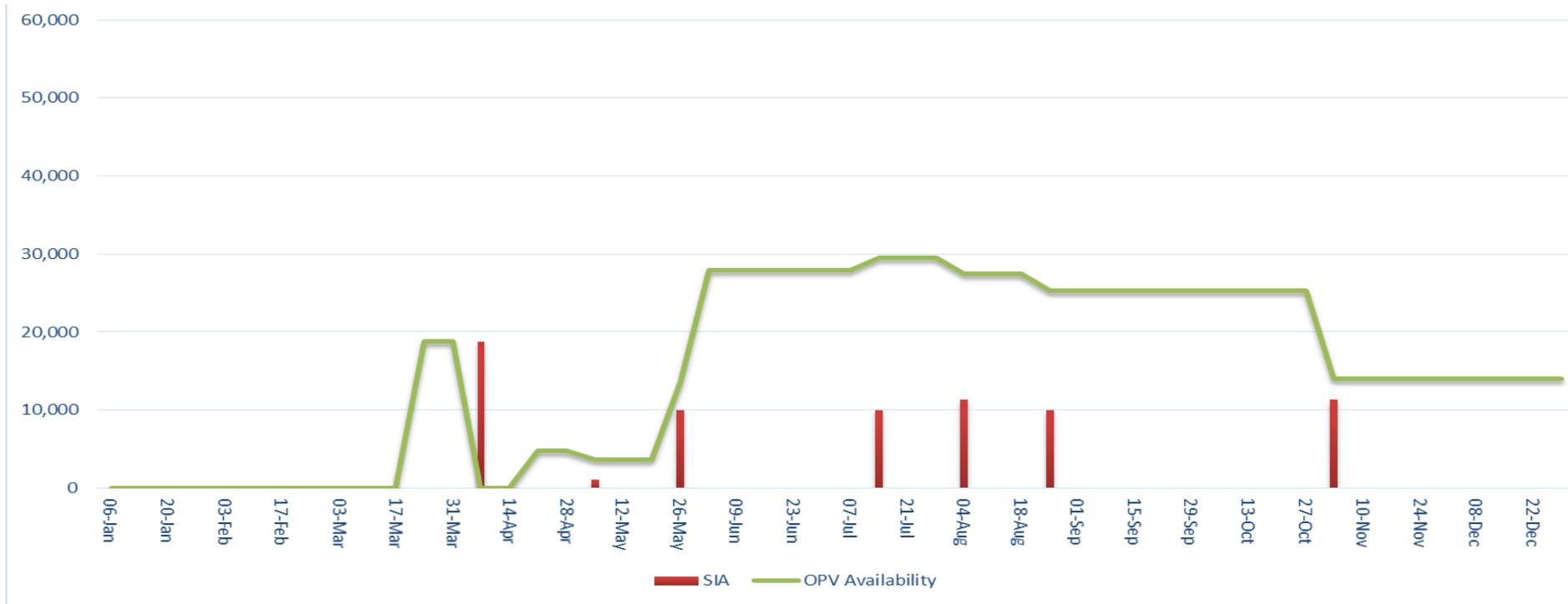
Vaccine supply for remainder of 2014 based on SIA calendar as of Jan 2014

Stress testing by Vaccine Supply Task Team shows supply is sufficient for significant increases in Q3/4 SIA schedule in 2014



Note: Availability is based on the production capacity of current manufacturers. If any manufacturer goes offline this year, the availability as outlined could be in jeopardy.

mOPV1 supply and demand through December 2014



- 87 mds of mOPV1 supply available in 2014; ~ 70 mds already allocated to Pakistan
- No more mOPV1 on contract; any additional mOPV1 for 2015 will require a reduction in either bOPV or tOPV for Q1 2015
- EMG reviewing mOPV1 requirements: with focus for Asia

Inactivated Polio Vaccine (IPV): an update



IPV for SIAs: supply update

- **Current IPV tender:** intended for **introduction in routine immunization requirements**
- Delays in IPV introduction plans in 2014 allows flexibility for **UNICEF to meet some IPV requirements for some SIA in endemic countries: 1,899,900 million IPV doses**
 - Week of 19th May 749,900 doses : EMG decided to allocate **200,000 for each** Nigeria & Pakistan.
 - Week of 16th June 400,000 doses
 - Week of 23rd June 750,000 doses
- For 2015, IPV priority is to cover demand for routine introduction; **No expectation for additional IPV for large scale SIAs unless RI demand changes** (e.g. due to delay in introductions or funding constraints)
- **Lead time for suppliers for IPV is significantly longer than for OPV**
 - 3-6 months for single and 5 dose vial (once WHO PQ'd)
 - ~9 months for IPV in 10 dose vials
 - Capacity expansion beyond current awards requires a 2 year lead time for 10 dose vials.
- If Program priorities change and SIA activities are required in addition to routine:
 - supply could be available only if there is **flexibility with routine requirements through buffer stock or number of shipments to countries**

Potential supply risks and challenges



Potential supply risks and challenges

2014-2015

- **Supplier-related risks** including batch failures, release delays, production stop, or delisting from WHO PQ.
- **Licensing requirements** for Pakistan, Nigeria and ME reduce flexibility: Need to increase base of licensed suppliers
- **International Health Regulation:** review potential supply implications?

Note: Changes in supply of one type of OPV will impact availability of the other types (mOPV, tOPV, bOPV).

2015-2017

- Risk of insufficient supply in medium term if additional awards not made **early**. Bulk production **lead time long** (18-24 months).
- Production capacity: Product transitions **require planning** with industry to secure production capacity.

Next steps:

For the OPV SIA calendar

- **Joint forecasting and supply planning with GPEI partners** scheduled for May:
 - Review supply and demand based on revised SIA calendar
 - Advise suppliers by end **May** on split by OPV type for remainder of 2014 and to award any additional supply
 - Review global demand and supply requirements for 2015-2017 to secure sufficient bulk by type
 - Review requirements for **mOPV**

Next steps (cont'd)

For the Switch:

- Planning for OPV2 withdrawal and tOPV/bOPV switch - ensuring sufficient supply of tOPV prior to the switch and bOPV in time for the switch
 - Firm up country plans to advise manufacturers of requirements for type 2 **by June**
 - Agree on requirements and timelines for filling of stockpile quantities and issue RFP in **May/June**
 - Coordination with industry: consultations, meetings
 - Development of a **strategy and guidelines**: operationalize the switch upstream

For IPV in SIAs

- Ensuring availability of IPV for potential SIAs in endemic countries and accelerated introduction of IPV into RI.
 - Decision on *allocation* of remaining available IPV in 2014
 - *Plans* for any 2015 additional IPV SIAs to estimate needs **by May**

Timely decision making by the programme will allow for proper planning

I thank
you



Securing Sufficient IPV Supply

