Oral Polio Vaccine Supply Outlook

UNICEF Supply Division

September 2014

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Oral Polio Vaccine (OPV) Supply Outlook – September 2014

This update reports on anticipated OPV availability during 2H 2014 and 1Q 2015 for intensified polio eradication activities and highlights actions taken to meet country demand and Endgame strategic considerations.

1. Summary

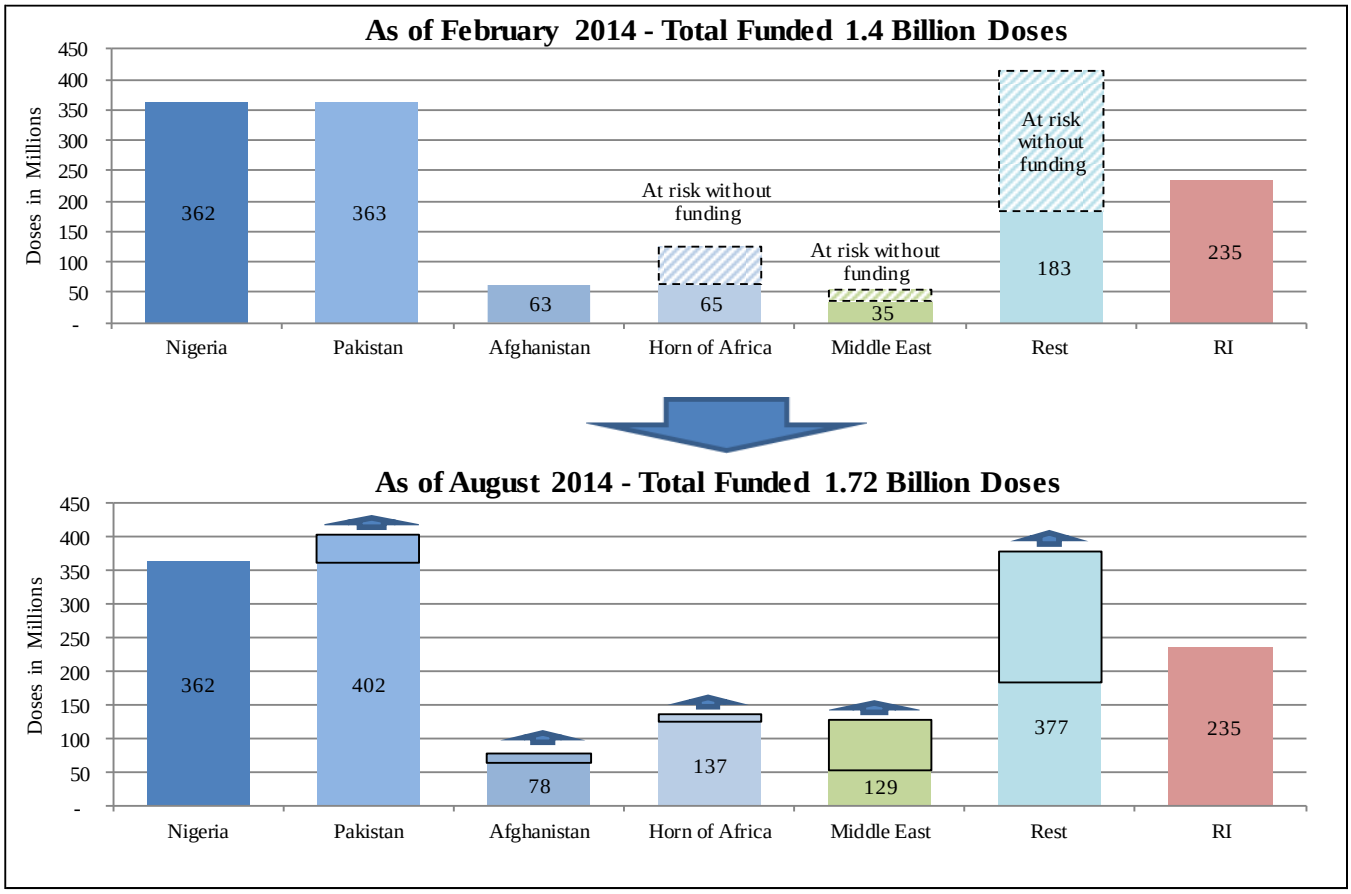
- 2014 funded OPV country requirements have increased to 1.75 billion from the previous 1.4 billion doses. The mobilisation of additional funding principally in May has reversed prior supressed demand due to funding shortfalls.
- Manufacturer supply has been maximised for 2014 through 1Q 2015 and should meet all planned country preventive supplementary and routine requirements. A carry-over of ~210 million doses is currently available to cover unplanned demand and ensure a carry-over to meet 1Q 2015 requirements. However, any additional demand materialising during the course of the year will draw on existing availability and could risk reducing supply to meet 1Q 2015 requirements.
- OPV procurement through UNICEF during 1H 2014 reached 909 million doses, split evenly between tOPV and bOPB. Regional demand in the Horn of Africa, Central Africa and the Middle East have increased on account of additional target population coverage and case response management.
- In line with the Global Polio Eradication Initiative (GPEI) Endgame Strategy Plan, UNICEF, partners and manufacturers are planning the type 2 cessation and the tOPV/bOPV switch to ensure adequate supply of both vaccines when needed for 2015-2017, and minimize tOPV overstock risk at country and global levels.

2. January – August 2014

UNICEF's previous OPV Supply Updates[1] provide general market background and updates on 2013 and 1H 2014 demand. They describe actions UNICEF and partners took to mitigate previous supply constraints, including substantially increasing awards during 2013 and 2014. UNICEF OPV procurement during 1H 2014 reached 909 million doses versus an anticipated demand of 982 million doses (see Figure 2). Constrained OPV availability during 1H 2014 in addition to limited operational funding, reduced projections for funded demand to 1.4 billion doses. However, following recent additional resource mobilization, funded OPV demand increased to 2013 levels, and are projected to reach 1.72 billion doses for 2014 (Figure 1). Current manufacturing capacity has been maximised through 2014. Supply is sufficient to cover all country supplementary and routine requirements and currently provides a ~210 million dose carry-over for case response management and 1Q 2015 country requirements by year-end.

[1] UNICEF OPV Supply Updates: July 2013, November 2013 and February 2014.

Figure 1 2014 Projected Demand by Geography



Source: WHO / UNICEF Supply Division.

Table 1 Key Issues by Geography[2]

Nigeria	• Total SIA demand remains at 362 million doses. • The number of doses to be supplied per national campaign activities (NIDs) and sub-national campaign activities (SNIDs) were reduced from 35 million to 29 million doses on account of revised target population. • 2 NIDs and 7-8 SNIDs are anticipated during 2014.
Pakistan	• Total country demand has increased to 402 million doses and wastage rates have been reduced. • During 2014-to-date, Pakistan accounts for four times as many children paralysed by polio than the rest of the world combined.[3] Last year Pakistan accounted for 20% of cases globally. • 5 NIDs, 3-4 SNIDs and 9-10 Short Interval Additional Dose Strategy (SIADS) are anticipated during 2014. • 24 million doses for case management response preparedness are retained, of which 16.5 million have been delivered.
Afghanistan	• Total SIA demand increased to 78 million doses from 63 million as per the original 2014 plan on account of country need adjustments. • 8 million doses for case management response preparedness have been delivered to Afghanistan.

[2] Table 1 is based upon the latest estimates as of the note's publishing date, which are subject to change / update from WHO and countries.

[3] Global Polio Eradication Initiative, *Polio This Week*, WHO, Geneva, August 2014.

Horn of Africa	• Funded demand in the region increased to 137 million doses, from 65 million as of the last update on account of case management response. • 26 million doses are required on account of increased target population coverage in Kenya as part of the case management response required in Somalia. • A recent OPV case identified in Somalia will require case management response to continue.
Middle East	• Demand in the Middle East increased by 94 million doses as per the original 2014 plan to reach 129 million on account of case response management in Iraq, Egypt and Lebanon.
Remaining Global Demand	• The remaining planned global funded demand has decreased to 377 million doses compared to the 413 million, as per the original 2014 plan. • Despite a reduction of 36 million doses following country need adjustments, country requirements increased in a number of Central African countries, notably Cameroon, Congo and Gabon, on account of case management response and preparedness. • Case response management efforts have increased on account of OPV case detection in CAR and Equatorial Guinea.

The Vaccine Supply Task Team (VSTT), under the Eradication Management Group (EMG), comprised of WHO, UNICEF, Bill and Melinda Gates Foundation (BMGF) and Centers for Disease Control and Prevention (CDC), is monitoring OPV supply and demand for the short- and long-term requirements, taking into account supply availability, risks, funding and programmatic requirements. UNICEF 2015 awards remain at 1.120 billion doses and were reviewed during 2Q 2014. Subsequent quarterly reviews to be made during 3Q and 4Q 2014 will inform actions to be taken during 2H 2014 to meet 2015 country demand. A focus area of work for the VSTT will be to review the demand forecasts in preparation for the switch to bOPV. Potential factors which could affect availability are highlighted below (Table 2).

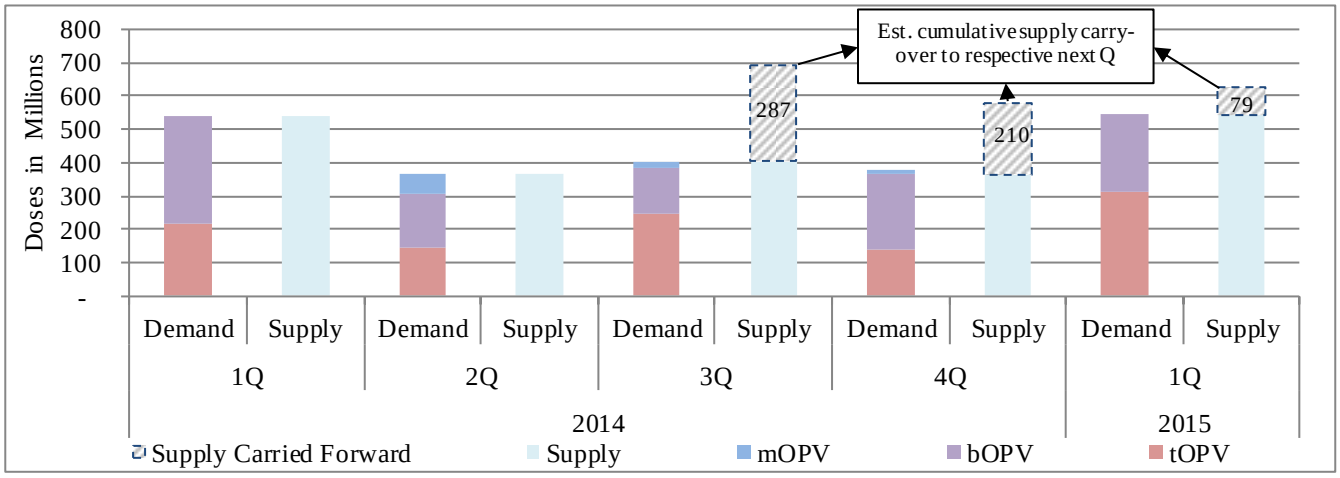
Table 2 OPV Availability Risk Factors to Supply

Issues	Considerations
Licensing Requirements	- Only two suppliers have bOPV and tOPV vaccines licensed in Pakistan and Middle Eastern countries and three manufacturers have products licensed in Nigeria. As both Pakistan and Nigeria take deliveries of ~40% of supply, a limited licensed supplier base can present challenges to ensure supply allocations. - Additional demand from Middle Eastern countries for OPV from the same supplier base is adding further pressure on supply allocations. - Nigeria has granted several ad hoc waivers to alternative suppliers. Pakistan should license additional OPV suppliers. A blanket waiver or an expedited review is required to license other suppliers to these countries.
Risks to Supply	- Countries should avoid requesting more vaccines than needed. In-country stock should be taken into account upon each request to ensure maximum availability to meet requests as it reduces availability to be used in other countries. - Any suspension of production will risk necessary flexibility in switching between bOPV and tOPV.

3. Supply and Capacity by Type

Figure 2 depicts current OPV availability and timing by OPV type. Supply for 2014 has been maximised through 1Q 2015 and should meet all currently planned country requirements for SIA and RI activities. Supply during 1Q and 2Q met demand, and 224 million doses were carried-over from 2Q to 3Q 2014. A carry-over of ~210 million doses is currently available for case management response and use for country requirements through 1Q 2015. However, any draw-down on the carry-over for case management response will reduce the quantities available for 1Q 2015 accordingly, which could result in later challenges for manufacturers to supply country requirements during 1Q 2015. One manufacturer has yet to confirm total availability for 1Q 2015.

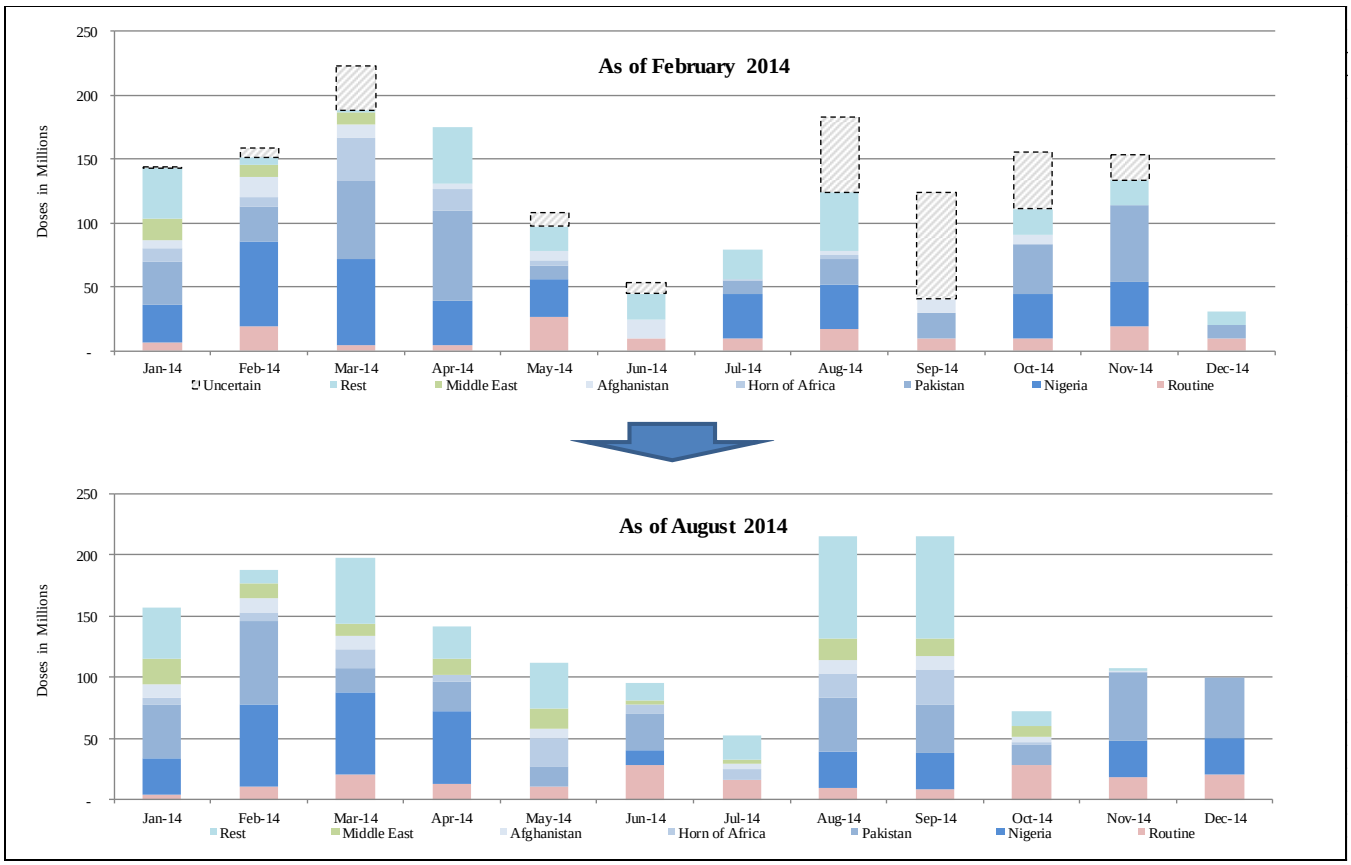
Figure 2 2014-1Q 2015 UNICEF OPV Cumulative Supply Availability (and Timing) versus Demand



Source: UNICEF Supply Division.

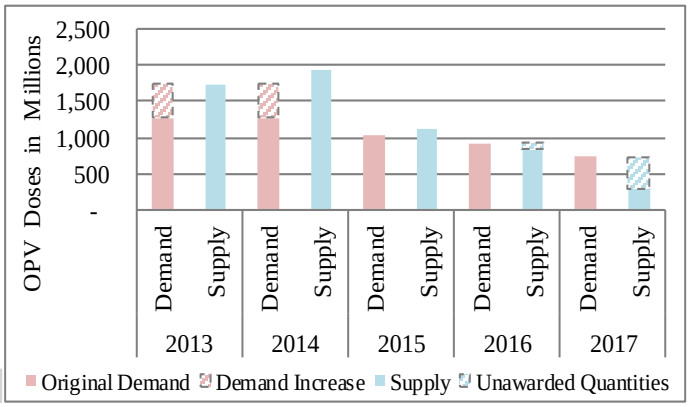
Figure 3 describes the changes to planned monthly deliveries on account of additional funding resources and funded activities which were postponed or reduced at the start of the year pending additional funding. These activities were denoted as "Uncertain". Major increases to supply can be noted during August and September 2014 on account of additional available funding.

Figure 3 2014 UNICEF OPV Monthly Delivery and Forecast



Source: UNICEF Supply Division.

Figure 4 2013-2017 UNICEF OPV Demand and Supply



Source: UNICEF Supply Division.

2013 and 2014 demand increased by 40% each year respectively from their original estimates (Figure 4). Current 2015-2017 demand and supply are based on 2012 tender assumptions and subject to GPEI Endgame Strategy progress, including eradication of WPV type 1 in Pakistan, Afghanistan and Nigeria; OPV type 2 cessation and the switch from tOPV to bOPV review. Country demand analysis for 2015 OPV requirements needs to be finalised by end-3Q / beginning 4Q 2014 in order to ensure sufficient supply availability.

4. Endgame Actions for 2015-2017

In line with the GPEI Endgame Strategy, UNICEF and GPEI have started planning the requirements to meet the goals for OPV type 2 cessation and the switch from tOPV to bOPV. In order to minimize the risk of any shortages in supply of all antigens and to ensure a smooth product transition in all OPV-using countries procuring through UNICEF, critical areas of activity are required over the next quarter to meet the objectives of a smooth transition as follows (Table 3):

Table 3 Endgame Strategy Considerations

Aspects	Considerations
Coordination with industry	- A bilateral consultation was held with two bulk manufacturers and WHO to ensure a timeline alignment for the switch timelines, production requirements and regulatory issues. This was a first of multiple consultations with industry anticipated during 2014.
Implementation	- A supply strategy to implement and operationalize the type 2 cessation and switch to bOPV will be required to ensure a smooth procurement transition and delivery between products.
Planning for OPV bulk stockpile	- A key requirement for type 2 cessation is monovalent bulk stock availability and filled mOPV2 product. UNICEF has contracts with 2 bulk manufacturers to ensure access to all three OPV strains bulk through 2018. Bulk stocks are expected to be produced by 2015. - A key criteria for the type 2 cessation is case management response capacity in case of bOPV case detection. UNICEF will issue a tender to ensure mOPV2 100 million doses availability prior to the switch in line with the Endgame strategic objectives.

Information related to the Endgame strategy and forecasting will materialise after meetings and consultation with Industry to be held during 3Q 2014.

5. Issues / Challenges

- 2015 bOPV and tOPV requirements need to be planned and concluded as soon as possible in order to ensure sufficient availability. For mOPV, a minimum nine-months production lead-time is required.
- The licensing requirements for OPV in certain endemic and high-risk countries continues to be a concern, particularly for bOPV.

- Future increases in supply capacity are in part dependent upon anticipated WHO prequalification of de-listed manufacturers and sufficient access of fillers to OPV bulk ingredient.

6. Steps Forward

- UNICEF and partners will continue to review and map all vaccine requirements for 2H 2014 and 1Q 2015. UNICEF will work with manufacturers to manage supply and demand to avoid any overstock.
- Identifying additional funding sources to support operations will be critical to ensuring activities that have been postponed or temporarily deferred are re-scheduled during 2H 2014.
- UNICEF will work with partners to plan for the switch from tOPV to bOPV and ensure sufficient tOPV buffer.
- RI requirements remain a priority. However, UNICEF may request flexibility on shipment timing for countries with sufficient stock at the central level in order to meet urgent country routine and campaign requirements as governed by supply availability.
- UNICEF anticipates the actions taken to date will ensure increased tOPV/bOPV carry-over supply during 1H 2015and will secure emergency response capacity to polio outbreaks.
- UNICEF and partners will support WHO's efforts to continue to encourage countries to license or grant temporary import waivers to WHO prequalified manufacturers with a capacity to supply OPV.

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