Oral Polio Vaccine Supply Outlook

UNICEF Supply Division

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This update reports on 2015 oral polio vaccine (OPV) supply and planning for intensified polio eradication activities prior the switch, confirmed for April 2016. It includes key OPV supply considerations for the Endgame Strategic Plan through 1Q 2016.

A more recent note covering OPV exists. Please visit http://www.unicef.org/supply/index_54214.html

1. Summary

- The Endgame Strategic Plan of the Global Polio Eradication Initiative (GPEI) requires the removal of all OPVs in the long-term, beginning with a switch from trivalent OPV (tOPV) to bivalent OPV (bOPV), removing type 2 (OPV2) from immunization programmes, know as “the switch”. In October 2015, WHO's Strategic Advisory Group of Experts on Immunization (SAGE) reconfirmed the withdrawal of OPV2, and the timing of the switch for April 2016. Following SAGE’s recommendation, UNICEF has started to place bOPV procurement orders (POs) for routine immunization (RI) requirements, for delivery from December 2015 through March 2016.

- GPEI partners, including UNICEF, the World Health Organization (WHO), vaccine suppliers, and countries, are currently planning for the switch. UNICEF’s main objectives are to adequately supply both products prior to the switch, and minimize tOPV overstock risk across countries and suppliers during and following the switch.

- UNICEF anticipates that bOPV supply availability will be sufficient to meet all RI requirements for the switch, including some additional buffer capacity to meet unplanned RI demand, and supplementary immunization activities (SIA) following the switch. UNICEF anticipates tOPV supply to be constrained throughout the period as a result of a short-term peak in demand and the cessation of production.

- UNICEF anticipates minimized tOPV wastage rates at country level following proactive UNICEF coordination and follow up on tOPV country orders since early 2015.

- UNICEF strongly advises countries to submit requests for bOPV as soon as possible to obtain cost estimates and to ensure funds are available at UNICEF by latest 11th January 2016, in order to ensure timely procurement and delivery for in-country distribution.

2. Background

UNICEF’s previous OPV Supply Updates¹ provide general market background and updates on previous supply availability and country requirements. They describe actions UNICEF and partners took to mitigate previous supply constraints, including substantial award increases during 2013 and 2014 to ensure sufficient supply.

The GPEI has made significant progress since 2014 towards meeting eradication Objective 1 (as defined in the Endgame Strategy). Nigeria has not reported any wild poliovirus (WPV) cases since July 2014. WHO subsequently removed Nigeria from the list of polio-endemic countries in September 2015,² and certified the global eradication of type 2 WPV (WPV2), following the last case in 1999. The Horn of Africa, the Middle East and Central Africa have not recorded any transmission of type 1 WPV (WPV1) during 2015, and no WPV1 cases outside of Pakistan and Afghanistan have occurred so far this year.

Objective 2 (as defined in the Endgame Strategy) requires the phased cessation of all OPVs to eliminate the risks of vaccine-associated paralytic polio (VAPP) and circulating vaccine-derived poliovirus (cVDPV). The first phase of OPV cessation is the withdrawal of OPV2 from all immunization programmes and a switch from tOPV to bOPV for routine and SIA use. WHO’s SAGE reconfirmed the switch for April 2016, to be implemented globally in a synchronized manner. The switch is an ambitious and unprecedented global undertaking for countries, suppliers, and GPEI partners. The planning for OPV2 withdrawal is already underway, and UNICEF is managing tOPV and bOPV supply allocations in close coordination with suppliers, taking into consideration the production lead times of 15 to 24 months from bulk to finished released vaccine. It further requires significant advanced coordination with countries to minimize the risk of excess tOPV stocks and delivery of bOPV in time for the switch.

3. **2015 Supply and Demand**

Compared to previous years, OPV supply availability through UNICEF has remained relatively stable and sufficient to meet all planned and unplanned demand since 2Q 2015, including for cVPDV outbreak responses in DR Congo, Guinea, Lao PDR, Madagascar, South Sudan, and Ukraine. This was due in part to additional supply capacity available from a supplier that recently secured WHO prequalification, despite the loss of capacity (equivalent to an estimated 140 million OPV doses) from another supplier that decommissioned a production facility.

Figure 1 compares SIA OPV demand by type between 2014 and 2015 covering specified regions and endemic or previously endemic countries. It includes the aforementioned countries affected by recent cVDPV outbreaks. tOPV and bOPV have almost exclusively been used since 2014. mOPV1 use in Pakistan and Afghanistan was for programmatic considerations, and is no longer offered by UNICEF at this time. OPV procurement volumes for non-endemic and non-outbreak countries throughout the rest of the world (“Rest”) reduced by 45% on account of meeting programme goals.

**Figure 1** UNICEF Actual and Planned SIA OPV 2014 and 2015 Demand Comparison by Country/Specified Regions

Source: UNICEF Supply Division.
Figure 2 UNICEF Actual and Planned RI OPV 2014 and 2015 Demand Comparison

![Graph showing UNICEF Actual and Planned RI OPV 2014 and 2015 Demand Comparison](image)

The reduction in 2015 RI volume is due to close monitoring of tOPV deliveries to avoid overstock risk in preparation for the switch. The GPEI’s Eradication and Outbreak Management Group (EOMG) comprised of the Bill and Melinda Gates Foundation (BMGF), Rotary International, UNICEF, the United States Centers for Disease Control and Prevention (CDC) and WHO, monitors OPV supply and manages short- and long-term demand requirements. Based on the EOMG assessment, OPV supply will continue to be sufficient to meet all RI requirements, and current EOMG approved SIAs, through end-2015.

Source: UNICEF Supply Division.

UNICEF anticipates a projected carry over of approximately 200 million doses into 1Q 2016 on account of the build-up of supply in preparation for 1Q 2016 OPV SIA demand. Any further increases in demand during 2015 will reduce supply availability for 1Q 2016 and pre-switch activities.

Figure 3 describes UNICEF’s annual OPV procurement by type, per year, over the past five years (2010-2015), leading up to the switch.

Figure 3 UNICEF OPV Procurement Evolution by Vaccine Type 2010-2015

![Graph showing UNICEF OPV Procurement Evolution by Vaccine Type 2010-2015](image)

Source: UNICEF Supply Division.

4. 1Q 2016 Supply and Demand for the Switch

- GPEI has increased its focus on targeted countries and regions where it deems populations require an immunity boost with tOPV, mostly delivered via SIAs, prior to the switch. Concurrently, GPEI is continuing with efforts to eradicate WPV1 in Pakistan and Afghanistan, and preventing future outbreaks in Nigeria.
UNICEF anticipates high demand in 1Q 2016, mainly because of the planned pre-switch tOPV SIAs to boost immunity among certain populations. These SIAs were planned in response to recent outbreaks of cVDPV in a number of countries (i.e. DR Congo, Guinea, Lao PDR, Madagascar, South Sudan and Ukraine).

The total OPV supply requirements to meet the estimated 1Q 2016 demand is 540 million doses, of which approximately 460 million will be for tOPV (Figure 4). The quantity of doses suppliers must deliver in one quarter is extremely high and unprecedented. It may require suppliers to allocate extraordinary resources to handle the manufacturing and logistical requirements to ensure timely delivery. To address this, UNICEF is requesting additional tOPV supply from suppliers to meet the increased demand prior to the switch.

Figure 4 UNICEF 1Q 2016 OPV Demand Forecast in Preparation for the Switch Compared to 1Q 2015

In addition to this, the creation of a global mOPV2 stockpile by end-March 2016, prior to the switch, accounts for an additional requirement of 50 million doses in production capacity.

Any doses delayed for delivery to March 2016 for the switch may come too late for planned campaigns and risk being wasted. An intensified SIA calendar for pre-switch tOPV immunity boosting campaigns, and supply requirements for the routine introduction of bOPV, in approximately 70 countries procuring through UNICEF, account for the need.

• UNICEF anticipates tOPV supply will be constrained though February 2016, considering that tOPV production is in its final stages for 1Q 2016 requirements, the recent cVDPV outbreaks and updated outbreak protocols, resulting in additional outbreak response requirements.

• To meet overall demand, UNICEF has maximized supplier capacity in 2015, and ensured continued supplier OPV production through 2015 to ensure sufficient supply for the high-anticipated demand during 1Q 2016.

• In addition, the EOMG confirmed the need for an additional 70-million tOPV doses to respond to additional SIA requirements or outbreak response prior to the switch.

5. OPV Supply Issues and Challenges

Supply availability currently exceeds demand as suppliers continue to produce at maximum capacity, in excess of current monthly requirements to ensure sufficient carry over availability for 1Q 2016 peak demand. However, suppliers warn that this is now resulting in large amounts of OPV stocks taking up their cold chain storage capacity, tying up capital, and risking a halt to production as freezers fill up and storage space runs out. UNICEF is coordinating closely with all manufacturers to address this issue, recurrent from 2014, to build confidence and demonstrate that all supply is required.

• Despite the current healthy supply situation noted above, tOPV supply availability is expected to be constrained during 1Q 2016. At this time, the remaining required tOPV doses are in the final stages of production. There will be short-term increased requirements to meet the needs of SIAs to boost immunity and avoid further outbreaks prior to the withdrawal of tOPV from programmes. To mitigate global supply shortage risks, bOPV and tOPV requirements will need continuous monitoring and management leading to the switch. If required, GPEI will establish a transparent system for
prioritisation of limited supply to guide tOPV allocations. UNICEF will try to balance countervailing pressures to avoid stock-outs of tOPV at country-level prior to the switch, while minimizing tOPV oversupply during the switch.

- OPV licensing requirements in certain endemic and high-risk countries remains a challenge (Table 1). With only a subset of prequalified products licensed for use in some countries, UNICEF’s flexibility in making the most efficient allocation of supply is reduced.

- bOPV supply from certain licensed suppliers will be prioritised in 1Q 2016 for Pakistan and other countries with stringent registration requirements. All other countries will receive bOPV from primarily Indian suppliers. Due to the short timeline, it is likely that countries will need to issue import waivers, as manufacturers may not have completed full licensure processes in time, as there are a high number of countries requiring bOPV licensure for use of the vaccines in their RI programmes.

- As part of the post-switch response capacity to any OPV2 outbreak, a licensed manufacturer is producing 50 million mOPV2 doses for the mOPV2 stockpile to be available by March 2016. The supply requirement, combined with the supplier’s earlier loss of 140 million doses of OPV has reduced its overall capacity for 1Q 2016.

- While the additional awarded supply to a supplier with a newly WHO prequalified vaccine increases the overall vaccine supply available through UNICEF, it will not offset any increased requirements to meet the expected needs of Pakistan due to their registration requirements currently imposed by the government. In-country OPV vaccine stock management and monitoring requires tighter inventory control (Table 1). When requesting additional supply for SIAs, countries need to adjust requirements to account for all leftover vaccine from previous SIAs, and include updated wastage rates. For RI programme requests submitted to UNICEF, a review and dose requirement adjustment will be required, based on the projected stock level and factoring in April 2016 switch timelines.

Table 1 OPV Availability Risk Factors to Supply

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<th>Issues</th>
<th>Considerations</th>
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| Licensing Requirements | - Only two suppliers have bOPV and tOPV vaccines licensed in Pakistan and Middle Eastern countries, and three suppliers have products licensed in Nigeria. As Pakistan and Nigeria together take deliveries of approximately 60% of total annual supply, a limited licensed supplier base can present challenges to ensure supply allocations in a timely manner.  
- Possible unforeseen OPV demand by other countries from the same supplier base could add further pressure on supply allocations.  
- Nigeria has granted several ad-hoc waivers to suppliers that do not have vaccines licensed in the country. Similarly, UNICEF recommends that Pakistan accept licensure applications from additional OPV suppliers. Pakistan could consider a blanket waiver or an expedited review process to ensure supply availability and allocation flexibility to these countries. |
| Risks to Supply | - Countries should avoid requesting more vaccines than needed for SIAs and RI, considering the switch. Countries should take in-country stock and leftover quantities from SIAs into account upon each request. It will secure maximum availability to meet requests, and not reduce the availability for other countries.  
- Delays in the release of OPV orders for the switch are a critical risk factor. If UNICEF cannot release tOPV orders on time, supply may not meet timely delivery to ensure planned campaign activity, which could risk campaign cancellation. GPEI prioritisation will be required to ensure the programme achievement of objectives. It is a requirement that all countries have access to bOPV for RI in order to proceed with the switch. UNICEF can undertake part shipments to split bOPV available supply to ensure doses for all countries procuring through UNICEF. |

Source: UNICEF Supply Division.

6. **Ensuring a Smooth Transition for the Switch**

- A key objective for the switch has been to ensure the sustainable uninterrupted supply of appropriate OPVs for SIAs and RI prior to, and after the switch, and to simultaneously avoid in-country stock-outs while minimizing risks of suppliers’ and in-country excess stocks.
Since June 2014, UNICEF, along with GPEI partners, have engaged suppliers to coordinate and plan effectively for the switch, including to ensure sufficient availability of tOPV and bOPV supply through April 2016 (Table 2). It continues to require close monitoring and demand forecast coordination with suppliers, as well as regular OPV forecast updates and reviews with the Vaccine Supply Task Team (VSST) under the EOMG. At this late stage, supply through to the switch is fixed.

In addition, to ensure a smooth operational implementation of the switch for countries procuring OPV through UNICEF, UNICEF has established mechanisms for enhanced monitoring of country stock levels in line with tOPV orders, proactively reaching out to countries to minimize risk of excess stocks by April 2016, and to track more closely country bOPV orders (Table 2).

For self-procuring countries, the GPEI’s Immunization Systems Management Group (IMG) provides focused support to secure access to bOPV supply and ultimately manage the aforementioned risks associated with the switch (Table 2).

Table 2 Endgame Strategic Planning and Coordination

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<th>Aspects</th>
<th>Planning steps for the Switch</th>
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| Coordination with industry       | - During 2014 and 2015, UNICEF and WHO consulted bulk suppliers on multiple occasions. Discussions included mitigating the risks to the programme and suppliers associated with a global cessation of OPV2, the switch, and to ensure transparency and alignment of switch timelines, production requirements, as well as to ensure common understanding of regulatory issues.  
  - Consultations with Indian fillers regarding switch timelines and their production plans seek to ensure sufficient access to type 2 bulk and finished tOPV product.  
  - A WHO/UNICEF industry consultation with all OPV suppliers took place early May-2015 to further align production requirements, timelines and switch planning.                                                                                                                                                        |
| Implementation                   | - UNICEF completed a supply strategy to implement and operationalize the type 2 cessation and switch to bOPV in 2014, to ensure a smooth procurement transition and delivery between products.  
  - In line with the global guidance from WHO and the IMG, all countries should have conducted at least one full national inventory of tOPV stocks one year prior to the switch in April 2016 to minimize the risk of tOPV overstocking or stock-outs. UNICEF recommended a second inventory between October and November 2015, to allow countries to redistribute in-country supply.  
  - Since early 2015, UNICEF has monitored country tOPV orders, projected stock levels, and planned deliveries, coordinating tOPV requirements closely with all countries procuring OPV through UNICEF, to minimize the risk of any excess stocks remaining by April 2016.  
  - UNICEF issued guidance through workshops and regional conference calls to all countries for procurement planning in the context of the switch, including timelines for ordering bOPV and managing tOPV orders pending with UNICEF, and fund transfers to ensure timely procurement.  
  - To map bOPV needs by 3Q 2015, a questionnaire on estimated bOPV requirements was completed by all countries procuring through UNICEF, to better understand initial delivery, registration requirements, and potential funding challenges. Eighty-five percent of the countries responded to the survey, which facilitated planning for initial bOPV estimated requirements for supply planning. WHO, with technical support from UNICEF, organized a separate survey for self-procuring countries related to the status of tOPV and bOPV procurement, risks, and expected challenges with accessing bOPV supply. UNICEF continues to be available to facilitate access to bOPV to self-procuring countries, should they have challenges to do so in the market. |
| OPV bulk stockpile planning      | - A key requirement for type 2 cessation is the availability of a global mOPV2 stockpile and inactivated polio vaccine (IPV) for rapid response in case of OPV2 outbreaks after the switch. UNICEF has contracts with two bulk suppliers to ensure access to all three OPV strains in bulk presentation through 2018. Manufacturers will have completed production of bulk stocks by end-2015.  
  - UNICEF has issued a tender to ensure the availability of 100 million doses of mOPV2 in finished product in line with the Endgame strategic objectives. UNICEF awarded one supplier 50 million doses to be available by March 2016 as finished product, with the remaining 50 million doses made available by July 2016 in semi-finished product form.                                                                 |

Source: UNICEF Supply Division.
Table 3 Actions and Follow-Up to Facilitate the Switch

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<tr>
<th>Aspects</th>
<th>Actions required from countries and planned support by UNICEF</th>
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<tr>
<td>Minimizing tOPV excess</td>
<td>- UNICEF urges countries to conduct a final inventory of their tOPV stocks to at least district level, and to ensure rigorous tOPV stock consumption and distribution monitoring.</td>
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<td>- Countries should confirm remaining tOPV needs and communicate to UNICEF as soon as possible any further tOPV requirements for UNICEF to coordinate with suppliers.</td>
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<td>- Any remaining tOPV supply requests should take into consideration supply received for SIAs planned for 1Q 2016. The requirements should be based on consumption data, instead of population data, to minimize risk of overstocking.</td>
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<td>Timely bOPV orders</td>
<td>- Initial bOPV supply requirements for delivery should be sufficient to fill country supply chains for at least 4-6 months.</td>
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<td>- Given the April 2016 switch deadline and the timelines for in-country distribution, countries that have not yet submitted bOPV orders should do so immediately. They must ensure funds are available at UNICEF by latest 11th January 2016, to ensure the timely procurement and delivery for in-country distribution.</td>
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<td>- UNICEF advises countries facing funding challenges to identify any existing funding balances remaining on UNICEF cost estimates or sales orders for reprogramming to bOPV, and to urgently communicate with UNICEF country offices and UNICEF any risks to delayed funds transfer.</td>
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<td>Self-procuring countries</td>
<td>- Self-procuring countries that are not able to access bOPV supply on the global market should urgently advise the WHO and UNICEF Country Office.</td>
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<td>- UNICEF will work with self-procuring countries to ensure access to a minimum supply of bOPV for initial switch implementation until countries are able to access on the global market.</td>
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<td>Regulatory</td>
<td>- In line with the World Health Assembly resolution 68.3, UNICEF urges governments to minimize the risk of delays in bOPV procurement and delivery associated with licensing processes, through expediting the registration of bOPV for use in routine immunization programmes or authorizing its use, on an interim basis, based on WHO prequalification.</td>
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<td>- UNICEF will not deliver vaccine without confirmation of licensure or authorisation for importation.</td>
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<td>- UNICEF advises countries to inform the relevant authorities under the Ministry of Health and the national regulatory authority of the WHA resolution and timelines for delivery.</td>
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Source: UNICEF Supply Division.

7. Steps Forward

- UNICEF and GPEI partners will continue to review and map vaccine requirements for 1Q 2016 to avoid tOPV shortages towards the switch.
- UNICEF and partners require countries to improve in-country stock management, consider existing stocks, and calculate orders based on consumption data, instead of population data, in new vaccine requests. Countries must submit improved stock balance reports with requests.
- UNICEF continues to work with partners to plan supply for the switch. RI requirements remain a priority. However, countries should monitor tOPV stocks to minimize the risk of excess tOPV remaining at country level after the switch in April 2016.
- UNICEF anticipates the actions taken to date will ensure sufficient tOPV and bOPV supply during the rest of 2015 and 1Q 2016 as well as secure emergency response capacity to polio outbreaks, based on currently projected demand.
- Countries should ensure that the required funds are available by latest 11th January 2016, so UNICEF can place bOPV orders with suppliers no later than early January. Countries must urgently notify UNICEF and WHO of any financing risks.
- Self-procuring countries that require a one-time supply support through UNICEF should urgently contact their WHO and UNICEF Country Office.
- UNICEF will continue to support WHO’s efforts to encourage countries to license or grant temporary import waivers for WHO prequalified OPV vaccines to increase flexibility during the switch.
- Please see the link to a detailed breakdown of the procurement timeline process for procuring through UNICEF and the Guidance for Supply and Procurement Planning through UNICEF for the Switch.
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Other UNICEF information notes can be found at: http://www.unicef.org/supply/index_54214.html.