Oral Polio Vaccine Supply Outlook – May 2017

This note provides updated information on 2016 and 2017 oral polio vaccine supply and demand, including supply management and lessons learned related to the cessation of type 2 oral polio vaccine supply in April 2016. The note includes key oral polio vaccine supply considerations for the Endgame Strategic Plan through 2022.

1. Summary

- In April 2016, 155 countries and territories undertook a globally synchronized switch from trivalent oral polio vaccine (tOPV) to bivalent OPV (bOPV). UNICEF and partners ensured sufficient and timely bOPV supply availability for all 76 countries procuring through UNICEF, and sufficient tOPV to meet all pre-cessation supplementary immunization activities (SIA) and routine immunization (RI) requirements.
- Total tOPV residual stocks under UNICEF contracts remaining with suppliers at the time of cessation amounted to approximately 5% of total tOPV procurement over 2015-2016.
- In 2016, UNICEF finalized the contracting arrangements and operating procedures to establish a monovalent OPV type 2 (mOPV2) stockpile to respond to any type 2 poliovirus (wild or vaccine derived) outbreaks after the OPV type 2 market cessation. UNICEF has since delivered more than 25 million doses of mOPV2 to Nigeria, the Lake Chad basin, and Pakistan in response to outbreaks.
- The Global Polio Eradication Initiative’s (GPEI) partners including UNICEF, the World Health Organization (WHO), suppliers, and countries are now preparing for the final phase of bOPV cessation in line with the Polio Eradication Endgame and Strategic Plan (PEESP). UNICEF anticipates bOPV cessation will take place one year after the certification of wild poliovirus (WPV) interruption by the Global Certification Commission (GCC), which is at least three years of zero polio cases due to wild poliovirus in the presence of certification-standard surveillance in all six regions. UNICEF will aim to ensure adequate bOPV supply until cessation, as well as subsequent stockpile requirements beyond.
- For 2017, UNICEF anticipates bOPV supply will be sufficient to meet all SIA and RI requirements, including additional buffer capacity to meet unplanned demand. UNICEF’s current bOPV tender ends December 2017, and a new tender was issued end 4Q 2016 for supply to start in January 2018. UNICEF’s tender will seek to ensure sufficient OPV supply to meet the demand of polio eradication, as well as to guide the cessation of the bOPV market in a responsible manner while maintaining affordability.

2. Programme Update

The GPEI is entering into the final phase of polio eradication, and despite some delays, is close to achieving its objectives under the PEESP 2013-2018/2019. Last year, WHO recorded 37 WPV cases, which was the lowest number of cases recorded annually, continuing the downward trend from 74 cases in 2015.

The GPEI met a number of critical milestones in 2016 and made significant strides towards eradication, notably:

- Even though Afghanistan and Pakistan have not yet interrupted WPV1 transmission, they reported the lowest number of confirmed cases ever in 2016.
Leading up to the switch in 2016, the GPEI focused on targeting countries and regions where populations required an immunity boost against type 2 with tOPV. Concurrently, GPEI continued efforts to stop WPV1 transmission in Pakistan and Afghanistan.

In line with the PEESP’s second objective on immunization systems strengthening and OPV withdrawal, to eliminate the risk of vaccine-derived polio caused by the type 2-vaccine strain, 155 countries and territories implemented the globally synchronised switch from tOPV to bOPV. It required all countries to stop using tOPV by April 2016, to withdraw and destroy all residual stocks of tOPV, and begin using bOPV for all RI and SIAs.

In August 2016, Nigeria reported four WPV1 cases caused by orphan viruses in the Northern State of Borno, which was a considerable setback for the programme. Nigeria had not reported a case of WPV1 since July 2014, and had been removed from WHO’s list of polio-endemic countries in September 2015. Therefore, Africa will not achieve polio-free status by July 2017 as anticipated. The genetic sequencing of the viruses suggested links to a strain last detected in Borno in 2011, which implied the virus had circulated undetected for more than four years. GPEI undertook an aggressive response with multiple immunization campaigns in both the Northern region of Nigeria, as well as the Lake Chad basin (Cameroon, Central African Republic, Chad, and Niger).

In addition, as of February 2017 GPEI had registered 28 vaccine derived poliovirus type two (VDPV2) isolates globally since the switch, grouped in to 20 emergencies, three of which were classified as circulating VDPV (cVDPV) outbreaks. It required a response with mOPV2, for which WHO had a stockpile of finished product prior the switch.

3. The Switch

The globally synchronized switch from tOPV to bOPV took place in April 2016 and required the coordinated deliveries of tOPV for SIAs and RI leading up to the switch, as well as the supply of bOPV to replace tOPV. Sufficient bOPV supply was available for all 76 countries procuring through UNICEF for delivery with no interruption to RIIs. Two countries did not receive vaccines in time for in-country distribution: one due to late requirement confirmation, while the other could not take delivery due to in-country issues. However, tOPV supply through UNICEF was sufficient to meet all pre-switch SIAs and RI requirements. More than 150 million doses of tOPV remained available at the global level at the time of the switch, therefore, also self-procuring countries were fully able to meet their requirements from the market.

Below is an outcome summary of various aspects and key lessons to apply to a future OPV cessation (Table 1).

Table 1 UNICEF’s OPV Switch Supply Planning, Implementation, Outcome, and Lessons Learned – Continued overleaf.

<table>
<thead>
<tr>
<th>Aspects</th>
<th>Comments</th>
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<tbody>
<tr>
<td>Planning and Implementation</td>
<td>- UNICEF and WHO initiated discussions with suppliers two years in advance of the switch. They included close consultations with suppliers and coordination that led to plans adaptable to change as the situation evolved.</td>
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<td>- Suppliers that started planning years in advance of the switch, and that were involved multiple functions in organizational planning, considered the switch a success from a business perspective, whereas other suppliers with shorter planning and less cross-functional involvement considered the switch only somewhat successful.</td>
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### Aspects

| UNICEF had completed its supply strategy for the switch three years ahead of implementation, and had provided a roadmap of required activities related to supply. |  |
| UNICEF had temporarily adjusted its internal processes to meet the context of the switch, allocated resources across functions including allocation of additional dedicated resources, and established a special project structure to immediately address switch related issues. |  |
| Global collaboration and coordination with partners, countries, and all stakeholders prevented the duplication of any efforts, and ensured transparent accountabilities. |  |
| A resolution by the World Health Assembly (WHA) encouraging countries to accept WHO prequalified vaccines without additional licensure requirements had a positive impact on the response from countries, and enabled UNICEF greater supply allocation flexibility. |  |
| GPEI finally reconfirmed the switch in October 2015, six months ahead of planned activities; UNICEF established a pre-financing mechanism for countries that had not budgeted for bOPV introduction due to late confirmation to provide bridge funding. The mechanism ensured that temporary funding constraints would not prevent countries timely access to bOPV supplies, and benefitted seven countries. |  |

### Outcomes

- Sufficient bOPV vaccine was available for all 76 UNICEF procuring countries in time for the switch.
- Five out of six suppliers to UNICEF noted they considered the outcomes of the switch somewhat successful or successful from a business perspective.
- UNICEF’s monitoring and advice to countries prevented the delivery of more than 18 million doses of tOPV to countries. It prevented higher residual stocks remaining in countries, as well as the need for their withdrawal and local destruction, post switch, at additional cost.
- Suppliers ended up with 63 million doses of residual tOPV stocks under contract with UNICEF post switch, the equivalent of 5% of UNICEF’s supply availability in 2015 and 2016 across five suppliers. As the GPEI had agreed to co-share the financial risks of tOPV, UNICEF negotiated partial cost compensation to affected suppliers.

### Challenges

- Not all countries undertook national tOPV stock inventories by mid- and end-2015 as recommended, to adjust requirements towards the switch. UNICEF was therefore not able to provide guidance and advice on projected tOPV stock levels as a basis for procurement decisions.
- Late orders from countries, including self-procuring countries, hindered them from securing sufficient supply towards the switch.
- Some countries faced funding challenges to secure sufficient bOPV for timely delivery.
- Lack of clarity and last minute changes in regulatory requirements led to delays in bOPV delivery to some countries.
- The WHO Strategic Advisory Group of Experts’ (SAGE) late timing confirmation for the switch left only six months for UNICEF, countries and partners to plan OPV supply, whereas the production lead-time for OPV is 18-24 months.
- Last minute changes in a large country’s SIA calendar accounted for 40 million doses of residual tOPV stocks under contracts with suppliers at the time of the switch.

### Lessons Learned

- Early planning of operational aspects and securing the necessary human resources was a key determinant to ensure the success of the switch, and should apply to future OPV cessation activities.
- Efficient vaccine management, inventory, annual forecast review, and adjustments in cessation preparations were key determinants of the positive outcome. Countries should apply global and UNICEF supply and procurement planning guidelines to minimise costs and risks of oversupply.
- The time between the switch’s final timing confirmation and actual date was six months, which was not enough for optimal supply planning with suppliers, given they need up to 24 months of production lead-time. UNICEF requests SAGE to consider earlier cessation timing confirmation (preferably 18-24 months) for any future OPV withdrawal to reduce risks to suppliers and GPEI.
- UNICEF encouraged programme decision makers to factor in production and industrial investment timelines at the earliest opportunity to reduce the risks of residual stocks.
- The switch requires continuous close collaboration with industry, as well as requirements and timelines transparency and risk sharing.

Source: Supply Division

### 4. Supply and Demand 2016

Overall, OPV supply was relatively stable in 2016 and was sufficient to meet all planned activities for both SIAs and RI, including a buffer of around 100 million doses. In 2016, UNICEF supplied 1.4 billion...
doses of OPV for SIAs and RI, comprised of 500 million doses of tOPV, 900 million doses of bOPV, and 25.3 million doses of mOPV2.

During 1Q 2016, country demand from planned pre-switch tOPV SIAs to boost population immunity increased, as well as planned SIAs in response to outbreaks of cVDPV in DR Congo, Guinea, Lao PDR, Madagascar, South Sudan, and Ukraine. In addition, 76 countries required bOPV through UNICEF before the switch to ensure the uninterrupted supply for the switch in related RI from tOPV to bOPV, requiring additional buffer stocks, similar to the buffer stock requirements planned for in the introduction of new vaccines.

As aforementioned, in August 2016, Nigeria reported WP1 cases and required a response of more than 200 million bOPV doses to conduct five rounds of outbreak response targeting over 40 million children in several countries. UNICEF and partners managed to secure sufficient supply, through a mix of different interventions. Consequent to GPEI’s intervention, the government of India delayed a planned national campaign by two months, allowing UNICEF to divert 80 million bOPV doses to Nigeria. GPEI secured the remaining 21 million doses by cancelling a number of planned activities in lower-risk countries and by advancing the contracted supply with one supplier from 2017 to 2016, totalling 90 million doses.

Outbreak response supply preparations post tOPV cessation started in 2004-2006, and led UNICEF to tender for monovalent bulk vaccines types 1, 2, and 3 in 2009. UNICEF and WHO established a stockpile of mOPV2-finished product prior the switch considering the need for a phased withdrawal leading to type 2-containing OPV cessation. In 2016, UNICEF finalised and established a mOPV2 stockpile contract and its operationalisation with suppliers and partners. Suppliers filled and finished 100 million doses of mOPV2, of which UNICEF has since delivered 25.3 million doses in response to outbreaks in the Lake Chad basin, Nigeria, and Pakistan.

5. Supply and Demand 2017

Figure 1 bOPV Projected Supply and Demand and Cumulative Buffer 2017

Source: UNICEF Supply Division
As of March 2017, UNICEF anticipates projected bOPV demand for 2017 to reach 1.2 billion doses. UNICEF awarded bulk vaccine suppliers their maximum offered supply capacity and ensured fillers continued ongoing production through 2017. Figure 1 describes UNICEF’s projected bOPV supply and availability during 2017.

The GPEI’s Emergency and Outbreak Management Group (EOMG) requested UNICEF to ensure 265 million bOPV doses over five months to meet any unplanned outbreak following the WPV1 cases in Nigeria. For 2017, UNICEF seeks to ensure a rolling buffer stock of 150 million doses bOPV supply across suppliers to be immediately available, as well as 115 million doses of bulk for conversion to finished product within three months of a large outbreak.

Following the number of isolates of VDPV2 and the programmatic response required in 2016 after the switch, the EOMG requested UNICEF to maximise the mOPV2 stockpile. UNICEF will make an additional award of 119 million doses pending funding availability, adding to the 75 million doses anticipated in stock by April. The supplier’s production of mOPV2 will not affect their anticipated bOPV production capacity or supply in 2017.

OPV licensing requirements in certain endemic and high-risk countries remains a challenge. With only a subset of prequalified products licensed for use in some countries, it reduces UNICEF’s flexibility in making the most efficient allocation of supply. Fifty-four percent of the 76 countries supplied by UNICEF accept WHO prequalified vaccines without additional licensure requirements. However, UNICEF registers a growing number of countries requiring full licensure, and less than 20% accept WHO’s collaborative procedure for vaccines.

6. Supply and Demand 2018 and Beyond

Following tOPV cessation and withdrawal in 2016, the GPEI is focusing on stopping poliovirus transmission in Afghanistan, Nigeria, and Pakistan, as well as plans to scale down SIAs in Africa in the near future, with further emphasis on outbreak response and RI strengthening.

The timing of WPV transmission interruption is uncertain and a challenge for suppliers and partners preparing for post OPV cessation. The challenge for the GPEI and suppliers over the coming years is to balance an anticipated decline in demand, notably over 2020-2022, while ensuring sufficient supply and production capacity to meet the demands that will be subject to change due to the possible delay in transmission interruption.

Table 2 describes a breakdown of a base and high scenario and associated milestones to reach bOPV cessation. Whereas GPEI will be planning towards the base scenario, UNICEF will be looking to secure supply against the high scenario, hedging possible anticipated delays in interrupting WPV transmission.

Table 2 GPEI Programme and UNICEF SIA Demand Projection Assumptions

<table>
<thead>
<tr>
<th>Considerations</th>
<th>Base Scenario</th>
<th>High Scenario</th>
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<tbody>
<tr>
<td>WPV interruption</td>
<td>2017</td>
<td>2018</td>
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<tr>
<td>Scaling down SIAs in African countries</td>
<td>2019</td>
<td>2020</td>
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<tr>
<td>Scaling down SIAs in endemic countries</td>
<td>2020</td>
<td>2021</td>
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<tr>
<td>Global eradication certification</td>
<td>4Q 2020</td>
<td>4Q 2021</td>
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<tr>
<td>Pre-cessation campaigns</td>
<td>4Q 2021</td>
<td>4Q 2022</td>
</tr>
<tr>
<td>Final cessation</td>
<td>End 2021</td>
<td>End 2022</td>
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</table>

Source: UNICEF Supply Division

UNICEF is currently reviewing the buffer stock requirements needed for OPV cessation with technical experts while ensuring sufficient supply to respond to unplanned activities. UNICEF has requested a rolling buffer of up to 200 million doses to meet unplanned demand in its next tender, as well as a request
to suppliers to maintain a minimum quantity of stock at all times. UNICEF will share any changes in demand projections with suppliers in a timely and transparent manner.

Similar to the activities that occurred prior to tOPV withdrawal, the GPEI is planning to conduct immunity-boosting activities that will lead to a peak in demand during one or two quarters prior to OPV cessation and final withdrawal.

UNICEF anticipates RI demand through UNICEF to reach an annual requirement of 260 million doses, based on the forecasts submitted by the 75 countries it received during the annual forecasting exercise in 2017.

UNICEF’s tender will cover the period from January 2018 to OPV cessation, with demand projected through to 2022. Figure 2 describes the annual projected bOPV requirements under two scenarios as per the Table 2.

UNICEF has based its annual projected demand on three scenarios: achieving polio-free certification by end-2020; by 2021, which would require pre-cessation campaigns during 4Q 2021; or by 2022. UNICEF also based the different demand scenarios on the projections provided by GPEI, taking into consideration the feedback from consultations with suppliers. UNICEF anticipates total demand for the period, excluding buffer requirements, to reach 4.2 billion doses. Should interventions not interrupt WPV1 transmission in 2018, or if the timeline between WPV1 transmission interruption and OPV cessation change, UNICEF will adjust the forecasts accordingly.

Figure 2: Total Annual Projected bOPV Demand under Two Scenarios Over 2018-2022

7. Steps Forward

- UNICEF and partners require countries to improve in-country vaccine management. They must report on all available polio SIA vaccine stock balances in their central and sub-national level stores when
requesting polio SIA vaccine supplies from UNICEF. Countries are required to use the Vaccine Balance Stock Information (VBSI) form accessible here \(^2\) (ref. page 45).

- UNICEF will continue to support WHO to encourage countries to license WHO prequalified OPV to increase vaccine security and supply allocation flexibility.
- UNICEF and the partners aim to secure bOPV supply through to cessation at affordable prices in the next tender. To achieve this, UNICEF requires the flexibility and commitment of suppliers to continue to supply OPV through to cessation.
- UNICEF will continue seeking to secure stockpiles for the post cessation period, including the future needs of mOPV1 and mOPV3, in addition to current needs for mOPV2.

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Other UNICEF information notes can be found at: http://www.unicef.org/supply/index_54214.html.

\(^2\) Global Polio Eradication Initiative, Guidance Note On Cold Chain Logistics and Vaccine Management During Polio Supplementary Immunization Activities, GPEI, Geneva, November 2015, p. 45.