The Market Shaping Goal

Shape markets for vaccines and other immunisation products to achieve moderate or high levels of healthy markets dynamics.

Supply and Procurement Roadmap

Ice-lined (ILR) and Solar Direct Drive (SDD) Refrigerators/ Freezers
Public Summary

Gavi established the Cold Chain Equipment Optimization Platform (CCEOP) in June 2015 as a strategic and targeted approach to address the challenges of improving the vaccine cold chain with higher-performing CCE. The CCEOP is a $250 million co-investment funding scheme over the 2016-2020 Gavi strategic period1 (with 2017-2021 as the procurement period) and aims to improve the availability and installation of CCE in Gavi-supported countries. Functional CCE is a critical component of the immunization supply chain system, and improved immunization supply chains strengthen immunization programmes and support the Alliance’s coverage and equity goals.

The CCEOP works as a joint investment model: for countries to benefit from Gavi CCEOP funding support, they must jointly invest in equipment as well as make clear investment commitments to cold chain management and maintenance. UNICEF Supply Division (SD) is the procurement agency for the CCEOP. Implementation of the CCEOP commenced in early 2016 with the first country applications recommended for approval in March and November 2016 and procurement began in September 2017. As of end 2018, through the CCEOP more than 20,000 units were placed on purchase orders (PO), 17,000 units shipped, and 11,000 units installed in countries. The project is on track to meet target procurement of 65,000 units by end of 2020, however, challenges exist with irregular spikes in demand materialising.

The CCEOP requires all CCE to meet World Health Organization (WHO) Performance, Quality and Safety (PQS) standards and also requires CCE to be “platform-eligible”, which entails a higher-level of technology and performance standards than current PQS standards. These additional attributes are derived from the WHO Target Product Profiles (TPP). The CCEOP also requires product procurement to be accompanied by delivery, installation, training, and commissioning – a “service bundle”, which suppliers are responsible to implement, helping ensure CCE is installed and maintained properly.2

Two CCE product categories, Ice-lined Refrigerators/Freezers (ILR) and Solar Direct Drive (SDD) refrigerators/freezers, represent critical nodes in the cold chain and accounted for between 80-90% of all annual CCE expenditures prior to the CCEOP (based on 2014 UNICEF SD procurement data). Given this, the Alliance currently focuses its CCE market shaping strategies on these two products.

Market overview

Eight ILR and SDD suppliers are active in the CCE market with PQS products that are platform eligible. The business size and focus of the eight suppliers vary significantly. There is currently a market concentration for both ILRs and SDDs, with two suppliers comprising 80% of the market in 2018. Suppliers also vary in their experience to date of implementing the service bundle for ILR and SDD products in CCEOP countries, and the cost of the service bundle often varies significantly between countries and between suppliers. While good progress has been made to increase understanding of CCE field performance through initiatives including post installation inspections and post market monitoring, there are still limited data on field performance of CCE.

Demand-side Analysis

The CCEOP aims to catalyse an increase in country demand up to the level of true country need. Before the CCEOP was launched, between 2010-2014 total procurement through UNICEF SD of vaccine refrigerators represented just 12% of potential CCE needs at the lowest level immunization system distribution points in Gavi-eligible countries. Under the CCEOP, however, materialized country demand

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1 Potential Gavi support beyond this timeframe will be evaluated prior to Gavi’s next strategic period (2021-2025).
2 In some cases, a country may select to ‘opt out’ of or need to forego the service bundle requirement and perform their own installations.
has increased significantly. In the region of 65,000 units are targeted for procurement by end of 2020, and between 80,000 - 90,000 units in total are estimated to be placed on POs by end 2021 through the CCEOP.

Preliminary estimates of the current CCEOP-eligible countries’ ILR and SDD needs during the next Gavi strategic period (2021-2025) are included below. This initial need-based estimate is not linked to any Gavi funding envelope for the next strategic period. The need-based estimate will be further validated and updated as required throughout 2019. The uncertainty within this future needs-based estimate is driven by unknowns in expected country prioritization of future cold chain needs, deviations compared to country funding applications in size segments procured and placement of equipment within health systems, variability in the final level of procurement for 2017-2021, and variation that is expected in the actual useful lifespan of ILRs/SDDs. A demand forecast for the 2021-2025 period is expected to be published in 2020.

Note: This needs estimate is in addition to the ILR/SDD procurement forecasted in 2019-2021 forecast at the top of this page.

<table>
<thead>
<tr>
<th>Preliminary estimate of ILR NEEDS (range), 2021-2025</th>
<th>Preliminary estimate of SDD NEEDS (range), 2021-2025</th>
<th>Preliminary estimate of total ILR/SDD NEEDS (range), 2021-2025</th>
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</thead>
<tbody>
<tr>
<td>30,000 - 47,000</td>
<td>35,000 - 48,000</td>
<td>65,000 - 95,000 units</td>
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Source: Based on preliminary need-based ILR/SDD forecast for CCEOP-eligible countries, developed by PATH for the Alliance, April 2019

Through the CCEOP, countries can request ILRs and SDDs based on five vaccine storage capacity size segments, thus demand can be segmented into the following size categories: <30 Litres (l), 30l-60l, 60l-90l, 90l-120l, and ≥120l. Nearly all ILR/SDD size segments with large demand have more than one manufacturer offering platform-eligible equipment. Forecasted need by size segment listed below for 2017-2025 includes demand that has already materialized to date. An update reflecting only future volume size segment estimated needs is being developed by the Alliance and is expected to be published in 2020. Of note, materialized demand since 2017 for size segments in some cases is larger than the forecasted size segment need, as countries may have selected CCE larger than their immediate need. According to stated preferences in CCEOP applications received through end 2018, smaller size volume segments, or <30l and 30l-60l, are forecasted to account for 47% of remaining CCE demand over the remainder of the current CCEOP period. Particularly for SDDs, this is consistent with expected expansion of the immunization cold chain to more remote, and likely smaller population clusters in target countries, increasing the reach of national immunization programmes.
Under the CCEOP, country demand has already shifted toward CCE that meets WHO PQS TPPs beyond the CCEOP platform-eligibility requirements. Since the first publication of the CCEOP platform-eligibility TPP requirements, several CCE product categories have seen unprecedented reductions in the lead times between definition of WHO TPPs and suppliers bringing products to market, with products arriving on the market well ahead of the stated timelines expected for these TPP requirements to be taken up as PQS specifications. The WHO PQS is currently revising the TPPs, with draft publication expected by end 2019 and finalization in 1H 2020. The Alliance will use the updated TPPs as the basis to review the current CCEOP optimal criteria to consider possible updates to CCE procurement eligibility (CCEOP) for the next Gavi strategic period.

**Supply-side Analysis**

The CCEOP also aims to catalyse an increase in CCE supply up to the level of true country needs. Supply capacity for all product categories is adequate to meet country demand. However, demand-side challenges, such as unpredictability and variability/spikes in demand across a given year, may present challenges to suppliers. Supply of service bundle activities also currently meets demand. However, given that deployment services are not a pre-existing core competency of many suppliers and all rely on contracting with local service providers, the service bundle requirement may represent a market entry barrier, and opportunities to explore separating the purchase of equipment and services from a supplier (referred to as ‘de-linking’) in line with country preferences could reduce market entry barriers for new manufacturers.

**Pricing Analysis**

CCE pricing varies significantly between suppliers. While equipment prices have decreased on average across manufacturers versus pre-CCEOP prices, prices for some CCE selected by countries have increased. Given country preferences for CCE that have not experienced price decreases, the Alliance has not fully benefited from this downward pricing trend with regards to equipment procured to date. Service bundle prices are also highly variable between countries and suppliers. However, as suppliers gain experience implementing the service bundle, and with greater use of benchmarks in the tendering process, lower, more standardized costs are expected to materialize. Exploring options to ‘de-link’ equipment and services – when requested by countries – could also lead to reduced service bundle prices. Ensuring high quality delivery, installation, training, and commissioning of CCE nevertheless remains the primary objective of the service bundle component.
Healthy Market Analysis
The Alliance’s Healthy Markets Framework (HMF) was developed in 2016 and originally designed for vaccine markets to provide a common way of communicating and assessing market health and improve analysis of potential trade-offs between market attributes. In 2018, an HMF customised for the ILR/SDD market was developed comprising of six attributes that address the unique dimensions of the marketplace for CCE, as a market that includes global supply of equipment and local supply of service bundles.

The ILR/SDD market currently has moderate levels of healthy market dynamics but is at risk of dropping to lower levels of health in the short- to mid-term. Two of the six healthy market attributes are met, most importantly supply meets demand, and innovation. Three attributes are partially met: meet country preferences, maximum value for countries, and country ownership and capacity. However, long-term competition is not met and is a key issue that may impact other attributes over time.

Supply Meets Demand: Met. Supply meets demand for equipment in all relevant ILR/SDD size segments and manufacturers have demonstrated capacity to meet service bundle needs.

Meet Country Preferences: Partially met. Country preferences for equipment have largely been met, but there have been some limitations resulting from service bundle implementation considerations. There is still limited knowledge and experience of field performance across all brands and CCEs, and as this grows country preferences may further evolve. While for choice of equipment, as with other Gavi programmes, country sovereignty is prioritised, there may be significant trade-offs with other HMF attributions including maximum value for countries, long-term competition and potentially in longer-term innovation, and the risk of these trade-offs requires further consideration. The extent to which country preferences for services is being met will be further explored and monitored over the remaining CCEOP period.

Maximum Value to Countries: Partially met. At current CCE and service bundle prices, this is partially met. In addition, more data on field performance is needed to understand true total cost of ownership (TCO) of products to countries and to understand the longer-term impact of new innovations, such as extended supplier warranties, on TCO.

Long-Term Competition: Unmet. The market is characterized by a market concentration in both product categories, with two suppliers comprising 80% of the ILR/SDD market in 2018. The risk of market exits by some suppliers if this trend continues, and the potential impact on supply security and meeting country preferences that could follow, must be monitored.
Innovation: Met. Manufacturers have innovated to make available high-performance products that meet the CCEOP platform eligibility criteria, several products already meet future TPP criteria and several promising innovations are on the horizon. However, the impact of other HMF attributes on long-term innovation, such as ‘long-term competition’ must be carefully monitored.

Country Ownership and Capacity: Partially met. Suppliers currently have ownership of service bundle execution, however in-country capacity to implement these services beyond the current CCEOP period may be reduced, as well as capacity to deliver maintenance services. Operational modalities for ‘de-linking’ and country capacity for self-procurement or self-implementation merits further consideration.

Supply and Procurement Objectives and Target Outcomes

The supply and procurement objectives were analysed resulting in the following target outcomes. The desired goal is to incentivize a market where CCE is made available at an optimal TCO. The long-term goal is to create a healthy CCE market where high performing equipment and services are widely available from a solid supplier base at sustainable prices

1st Strategic Objective: Improve ‘long-term competition’ and increase evidence base to inform ‘country preferences’
In the short term it is critical to address the issue of fostering a genuinely competitive market. Increasing the evidence base of field performance of equipment will help inform country preferences, increase understanding of TCO, and can feed into WHO PQS standards for CCE in the longer term, and should also help increase the overall competitiveness of the market.

- By 2021, at least four viable manufacturers offer ILR/SDD equipment, with [confidential] market share targets by ILR and SDD segments.
- By 2021, a minimum of two manufacturers offer products in each of the high demand ILR and SDD size segments.
- By 2021, field performance data on multiple brands is available, informs understanding of TCO, and can be used by countries to inform their investment decisions.
- By end 2019, increase visibility of demand through publishing updated long-term demand forecasts of ILRs and SDDs and sharing with suppliers.

2nd Strategic Objective: Achieve reductions in WAP to ‘maximise value to countries’
While equipment prices have decreased on average across manufacturers versus pre-CCEOP prices, the equipment prices from some suppliers have increased in certain cases. Short-term ‘deployed WAP’ targets are set below but should not be prioritized at the expense of achieving ‘long-term competition’.

- UNICEF-SD ‘CCE WAP’ for each of the four highest volume product segments achieve target reductions (confidential) in 2019 and 2020 versus 2018 CCE WAP baselines. No annual increase in ‘CCE WAP’ for each product segment in 2019 and 2020 versus combined 2017-2018 WAP baselines.
- UNICEF-SD ‘Service bundle WAP’ for each of the highest volume product segments achieve target reductions (confidential). No annual increase in ‘Service bundle WAP’ for any product segment in 2019 and 2020.

3rd Strategic Objective: Reform procurement processes for greater efficiencies
a) Continued improvements to procurement processes and ongoing communications with suppliers to increase visibility and predictability of demand will contribute to improving overall market health.
- Optimised procurement processes in place by 2020 to improve timelines and predictability of demand.
- By 2020, systematic engagement is in place to share ongoing demand updates and other market information with suppliers.
b) Continued improvements to the service bundle implementation to ensure quality deployments and installation. When countries express interest, opportunities to “de-link” the service bundle from purchase of equipment should be explored and implemented if feasible. Risks of ‘de-linking’ will need to be carefully evaluated and managed, including through piloting alternative approaches in some countries.

- By 2021, at least three-quarter of installations are assessed as ‘acceptable’ and all installations are at a minimum ‘adequate’.
- By 2021, when requested, countries have alternative options for procurement and implementation of the service bundle for ILRs/SDDs, provided that countries meet evidence-based requirements.

4th Strategic Objective: Innovation driven by country preferences and future TPPs

WHO TPPs have channelled to market innovative product features despite many not currently being a requirement for PQS and CCEOP-eligibility. Alliance efforts to better understand country needs and field performance of CCE should also feedback information to manufacturers to support product development. In addition, Alliance efforts to assess the quality of CCE installations should link back to manufactures to help inform service bundle improvements.

- By 2021, at least two manufacturers offer latest future TPP product features.

Supporting Stakeholder Action Plan

A concerted action plan ensures the coordination between Gavi Alliance stakeholders and is designed to facilitate the achievement of the above supply and procurement target objectives. The action plan includes the following items:

1st Strategic Objective: Improve long-term competition

- In high-volume countries, procure from at least two suppliers in line with country preferences.
- Ongoing communication with suppliers to increase visibility of CCE demand and for the Alliance to better understand business models, production capacity, production economies of scale, and help inform sustainable market health.
- Publish updated short and long-term demand forecasts across ‘important’ size segments. Ongoing engagement with industry to communicate where additional CCE is needed.
- Update the CCEOP Technology Guide annually, with publication mid-year.
- Implement selected post-market inspections and post-market monitoring of CCE.
- Ensure field performance data on multiple brands is available to countries to help inform investment decisions, and that data is available to WHO to help inform PQS standards and follow up as relevant with manufacturers.

2nd Strategic Objective: Achieve reductions in WAP

- Monitor and evaluate countries’ CCE selection under procurement mechanism whereby high-volume orders will be allocated to two or more suppliers (see strategic objective 1).
- Explore opportunities to achieve volume-based discounts.
- Revise and publish updated TCO tool that incorporates revised service bundle cost benchmarks and reflects greater nuances in added value of innovations.
- Refine service bundle cost benchmarking in 2020.

3rd Strategic Objective: Reform procurement processes for greater efficiencies

a) CCE procurement reforms

- Develop and implement interventions to continue optimising procurement processes to improve the timelines and predictability of demand.
- Systematize regular sharing of market information with suppliers, in line with SO1 above.
b) **Service Bundle procurement reforms**

- In selected countries (based upon country interest, and readiness and capacity criteria), initiate pilots of country-led deployment of ILRs in 2019, and report on findings.
- Pending success of country-led deployments of ILRs, explore possible pilots of country-led deployment of SDDs in 2020, and report on findings.
- Based upon experiences with alternate deployment options, establish full “menu” of options for deployment in countries, dependent upon country interest, readiness and capacity to implement ‘de-linking’ options.

4th Strategic Objective: Innovation driven by country preferences and future TPPs

- WHO PQS to finalize next generation TPP features by early-2020.
- Alliance to decide on optimal features to include in updated CCEOP optimal criteria by early 2020.
- Alliance to establish quality benchmarks for service bundles and other service options.
- Conduct a study across several CCEOP countries to better understand the drivers of country innovation needs.
- Engage with manufacturers to facilitate adoption of prioritized innovations based on identified country needs.