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The Market Shaping Goal

Ensure healthy markets for vaccines and related products

Gavi Alliance Market Shaping Roadmap

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

Public Summary

May 2021 UPDATE

Public Summary

Roadmap scope

Market shaping roadmaps are foundational tools of the Gavi Alliance's market shaping strategies for vaccines and immunisation-related products and articulate the long-term view as to how the Alliance would like to see a market evolve. This Roadmap summarizes the Alliance's market shaping strategy for the Ice-lined Refrigerators/Freezers (ILR) and Solar Direct Drive (SDD) refrigerators/freezers market. It includes the market shaping objectives and target outcomes, the set of Alliance partner agreed upon interventions to reach these objectives and target outcomes, and will be used to inform procurement strategies and decisions. Given that Gavi's Cold Chain Equipment Optimization Platform (CCEOP) programme and market goals strongly influence the standards for all ILR/SDD procurements through UNICEF Supply Division (SD) and that Gavi has historically been the largest funder of this market, this Roadmap goes into particular detail about the CCEOP. However, the content and strategies defined in this Roadmap applies to all ILR/SDD procurements through UNICEF SD whether they are Gavi-funded (CCEOP and non-CCEOP) or non-Gavi funded procurements.

Background

Gavi established the CCEOP in June 2015 as a strategic and targeted approach to address the challenges of improving the vaccine cold chain with higher-performing CCE. Functional CCE is a critical component of improving countries' immunisation supply chain systems, strengthening immunisation programmes, and supporting the Alliance's coverage and equity goals. The initial CCEOP programme was a \$250 million co-investment funding scheme over the 2016-2020 Gavi strategic period ('Gavi 4.0') (with 2017-2021/22 as the procurement period) and has aimed at improving the availability and installation of CCE in Gavi-supported countries. The success of the CCEOP led to the continuation of the CCEOP platform into the 2021 – 2025 Gavi strategic period ('Gavi 5.0'). An additional \$150M will be invested in CCEOP during Gavi 5.0, bringing the total CCEOP investments from 2016-2025 (Gavi 4.0 and Gavi 5.0) to \$400M, with country joint investments adding to this funding.

The CCEOP continues to be a joint investment model: for countries to benefit from Gavi CCEOP funding support, they are required to jointly invest in equipment as well as make clear investment commitments to cold chain management and maintenance¹. UNICEF SD is the procurement agency for the CCEOP. Implementation of the CCEOP under Gavi 4.0 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-2020, through the CCEOP under Gavi 4.0 more than 65,000 units were approved in country applications, 54,000 units were placed on purchase orders (PO), 52,000 units shipped, and 40,000 units installed in countries. The project is on track to procure 80,000 - 85,000 units approved under the Gavi 4.0 CCEOP funding envelope by end of 2022².

In addition to CCE funding through the CCEOP, the COVID-19 pandemic led to the creation of the COVID-19 Vaccines Global Access (COVAX) Facility aimed at ensuring equitable access to COVID-19 vaccines, including ~\$53 million of Gavi support designated for CCE to 92 Advanced Market Commitment (AMC) countries. The funding focuses on the procurement of 2-8°C vaccine storage profiles at the national, regional and district levels, where impact on storage capacities for COVID-19 vaccines is most acute, bundled with the procurement of remote temperature monitoring devices (RTMDs) at the highest levels, as well as the procurement of passive devices. Following the COVID-19 pandemic, the intention is for this CCE to be redeployed to support the routine immunisation system.

¹ The joint investment model, and specifically sources of funding for it, may be revisited during Gavi 5.0.

² This represents a slight delay of the goal to complete all procurements funded by the Gavi 4.0 CCEOP funding envelope by the end of 2021 due to delays incurred because of the COVID-19 pandemic and other factors. An estimated 70,000-75,000 units are expected to be procured under the CCEOP by the end of 2021. New procurements under the Gavi 5.0 envelope are expected to begin in 2021-2022 despite these delays.

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 earlier WHO Target Product Profiles (TPPs). The CCEOP also requires product procurement to be accompanied by delivery, installation, training, and commissioning – a “service bundle”, which suppliers are responsible for implementing, helping ensure CCE is installed and maintained properly.³ At the start of Gavi 5.0, CCEOP platform eligible products⁴ and technical requirements⁵ will remain the same. Notably, country ownership of any data generated by CCE products procured with Gavi funding was added to the CCEOP platform eligibility requirements in September 2020.

CCEOP programme goals in 5.0

The CCEOP programme is still expected to represent ~50% of the UNICEF SD ILR/SDD market in 2021-2025, and will focus on the following four goals:

- Fulfil unmet CCE needs in eligible countries: This includes a focus on addressing unmet needs in line with Gavi’s equity goals and reaching zero dose communities (both urban and rural), with supply chain strategies and selection of appropriate types of CCE (and level of the cold chain to place the CCE) prioritised by countries and tailored to their specific contexts.
- Improve systems strengthening: Ensure that CCE and other investments (e.g., HSS grants, Technical Assistance funding) lead to improvements in CCE maintenance, visibility of CCE uptime, increased collection and use of performance data and energy access, and improved use of CCE performance data for planning, maintenance and informing innovation priorities (e.g., TPPs) and future procurements, and also engaging the private sector where relevant and feasible.
- Improve sustainability: This includes a focus on ensuring resources are available to support immunisation supply chain systems that are financially, socially and environmentally sustainable, while promoting domestic investments in both CCE procurement and maintenance.
- Improve CCE market health: The Alliance currently focuses its CCE market shaping strategies on two products, ILRs and SDDs, and will focus these efforts across the nine attributes of the updated ILR/SDD Healthy Market Framework (see below), both sustaining and building on the market health gains from Gavi 4.0. It will also have an increased focus on the development and uptake of critical innovations and collection and use of field performance data to ensure CCE performance and inform future standards. In addition, during Gavi 5.0 the Alliance’s market shaping efforts will be expanded to include other CCE product categories.

Alliance Market Shaping Objectives for the UNICEF SD ILR/SDD Market

1. Improve and sustain ‘market sustainability and attractiveness’ and demand health including increasing ‘balanced demand of appropriate products & timely uptake of new innovative products’ and ‘predictability of demand’
2. Achieve competitive pricing for CCE while maintaining incentives for new innovations to improve ‘balanced demand of appropriate products & timely uptake of new innovative products’
3. ‘Incentivise & scale up innovations’ through systemising field performance data collection and country-supplier-Alliance feedback loops that drive product improvements, catalyse necessary innovations, and inform procurement decisions

³ In some cases, a country may select to ‘opt out’ of or need to forego the service bundle requirement and perform their own installations.

⁴ CCEOP platform-eligible product categories include ILRs / SDDs, freeze-preventive passives (long term storage, cold boxes, carriers), 30 DTRs (including bundled with ILR/SDDs), RTMDs for fridges/freezers including subscription and data costs, PQS voltage stabilisers (regular and extended) and spare parts.

⁵ The platform-eligibility technical requirements for ILR/SDDs include: 1) User independent (“Grade A”) freeze protection; 2) Extended ambient temperature operating range (+10C to + 43C); 3) ILR/SDDs bundled with 30 DTRs; 4) ILRs bundled with voltage stabilisers; and 5) country ownership of data (new as of Sept 2020)

4. When applicable, continue to have high quality service bundle delivery and, as appropriate / pending pilot evaluations, introduce options for CCEOP projects to ‘de-link’ the service bundle from equipment procurement

Market Health Assessment

The Alliance’s Healthy Market Framework (HMF) provides a common way of communicating and assessing market health and improves analysis of potential trade-offs between market attributes. The HMF was updated in 2021 to reflect evolving market considerations and Gavi 5.0 priorities (see Figure 2). The new HMF comprises nine attributes across three domains (supply dynamics, demand health, innovation) that are assessed as met, partially met and not met, and are listed by tiers, with the ‘high’ tiers representing the attributes most fundamental to the ILR/SDD market in its current state, followed by the ‘medium’ and ‘low’ tiers. The ILR/SDD HMF is primarily focused on the market for equipment more so than for the service bundle, and this assessment covers all procurement through UNICEF SD.

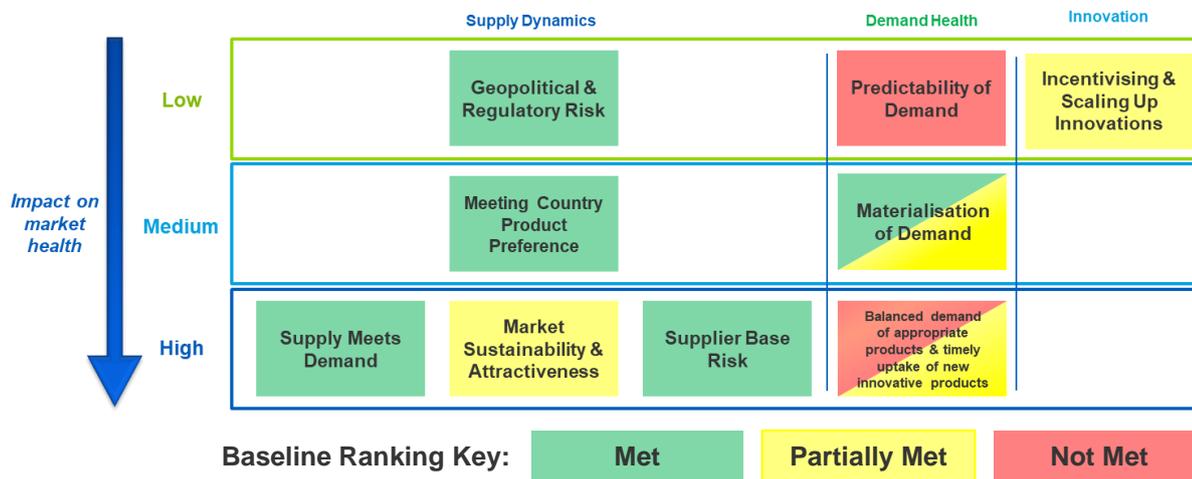
New Healthy Market Framework attributes & ratings for the year 2020:

- Demand Health
 - *Materialisation of Demand (medium tier; met/partially met)*: Overall procurements materialized in 2020 as forecasted at an aggregate level for the total UNICEF SD market; the CCEOP forecasted procurements experienced some delays in a few countries and did not reach the forecasted levels.
 - *Predictability of Demand (low tier; not met)*: On a quarterly basis, country procurements did not match the forecasted PO placement dates or aggregate quantities expected.
 - *Balanced demand of appropriate products & timely uptake of new innovative products (high tier; partially met/not met)*: Demand for products was not sufficiently balanced per Alliance targets nor was country decision making sufficiently informed by evidence, particularly given insufficient field performance data currently available.
- Supply Dynamics
 - *Supplier Base Risk (high tier; met)*: All suppliers were able to supply their ILR/SDD orders.
 - *Geopolitical & Regulatory Risk (low tier; met)*: There were no issues of countries being unable to access preferred CCE because of country of manufacturing /other geopolitical issues, and ILRs/SDDs did not experience significant global regulatory hurdles delaying market access.
 - *Market Sustainability & Attractiveness (high tier, partially met)*: The market remains attractive for incumbent suppliers with no market exits experienced; however, questions remain about market attractiveness to sustain the current number of suppliers.
 - *Supply Meets Demand (high tier; met)*: Supply volumes were sufficient to meet demand.
 - *Meeting Country Product Preference (medium tier; met)*: Available supply (product offerings) were sufficient to meet countries’ product choices. *Note: ‘Product preference’ refers to technical features of products.*
- Innovation
 - *Incentivising & Scaling Up Innovations (low tier; partially met)*: In 2020, priority innovations for Gavi 5.0 period were not yet finalized and hence not communicated to suppliers; however, the TPP process was well underway and represents innovations needed to address countries’ unmet needs.

The ILR/SDD market currently has moderate levels of healthy market dynamics (rated as ‘acceptable with risks’) but is at risk of dropping to lower levels of health without interventions by the Alliance. Nearly half of the healthy market attributes are met, most importantly ‘supply meets demand’ and ‘supplier base risk’. Three to four attributes are partially met and one to two are not met. In Gavi 5.0, interventions will focus on improving the partially met and not met attributes, while monitoring the met attributes to ensure these remain in a healthy state. In addition, trade-offs between improving the health of different attributes will be assessed. We will also assess any impacts from interventions for one attribute on other attributes,

particularly impacts on the attributes most fundamental to the market (e.g., the ‘high’ tier attributes will be prioritized if trade-offs are required).

Figure 2: Updated CCE Healthy Market Framework: Assessment of the entire UNICEF SD ILR/SDD Market as of end-2020



Alliance Market Shaping Roadmap Objectives and Target Outcomes

The Alliance market shaping objectives for the overall UNICEF SD ILR/SDD market (including CCEOP) were analysed resulting in the following target outcomes and interventions. The desired goal is to incentivise a market where available ILRs/SDDs are balanced based on selection of more cost-effective / higher value-for-money (VfM) products that meet country needs and results in healthy market competition. The long-term goal is to create a healthy ILR/SDD market where high performing equipment and services are widely available at sustainable prices and lowest total cost of ownership (TCO) / highest VfM for countries from a supplier base large enough for meaningful competition but small enough to uphold individual manufacturer sustainability.

Objective 1: Improve and sustain ‘market sustainability and attractiveness’ and demand health including increasing ‘balanced demand of appropriate products & timely uptake of new innovative products’ and ‘predictability of demand’

Sub-objectives:

- a) Reform application, procurement, and decision-making processes for increased demand health (i.e., predictability transparency and efficiency)
- b) Overcome unbalanced demand due to strong preference for installed base brands and facilitate selection of more cost-effective / higher VfM products that meet country needs, resulting in healthy market competition
- c) Increase evidence-based decision-making

Target Outcomes for Objective 1:

- Minimum of 3 suppliers with at least [Confidential target] market share in each product segment (ILR /SDD) by volume
- No one supplier with more than [Confidential target] market share in each product segment (ILR/SDD) by volume
- Minimum of 5 suppliers offering products to the CCEOP

- Minimum of 3 manufacturers in high demand size segments⁶
- Suppliers have regular updates on procurement progress and other market updates and regular exchange of information between Alliance and suppliers is ongoing
- Application and procurement reforms implemented and demand health activities launched by 2022, resulting in healthier demand-side dynamics

Eight ILR and SDD suppliers are active in the market with PQS products that are CCEOP platform eligible. Supplier's business size and focus varies significantly. Despite the many new product offerings in the CCEOP in Gavi 4.0, not all products or brands were equally in demand, and the market was characterised by a duopoly situation with a dominant supplier in each product segment (ILRs and SDDs). As a result, market shaping interventions were implemented in 2019 to address this challenge⁷. As of end-2020, there is a healthier market concentration for ILRs, with three suppliers holding significant market shares by volume. The SDD segment is also moving towards a healthier market composition, with all eight suppliers obtaining volumes in Gavi 4.0. Improving and sustaining the market balance is an important goal of CCEOP in 5.0, both in improving sustainable competition and in improving demand health around uptake of appropriate products. CCEOP process optimisations are being identified and implemented to increase efficiency and add transparency to the market, as well as help countries consider the full range of products that provide good VfM and meet their programmatic requirements.

Demand Forecast

The CCEOP also aims to meet as much of countries' unmet needs as possible. After Gavi 4.0, there remains significant unmet CCE needs in the 52 CCEOP-eligible countries⁸, with ~65,000-95,000 ILR/SDD units estimated to be needed across all cold chain levels (e.g., regional, district, health facility levels) from 2022-2025.⁹ CCEOP funding in Gavi 5.0 is estimated to cover ~30-40% of these remaining needs. Of the total UNICEF SD ILR/SDD market forecast, Gavi-funded demand (CCEOP and other Gavi funds) is estimated to comprise 40-60% of the total market, with additional demand expected to materialise from other funding sources (e.g., domestic resources or other donors), and from non-CCEOP countries.

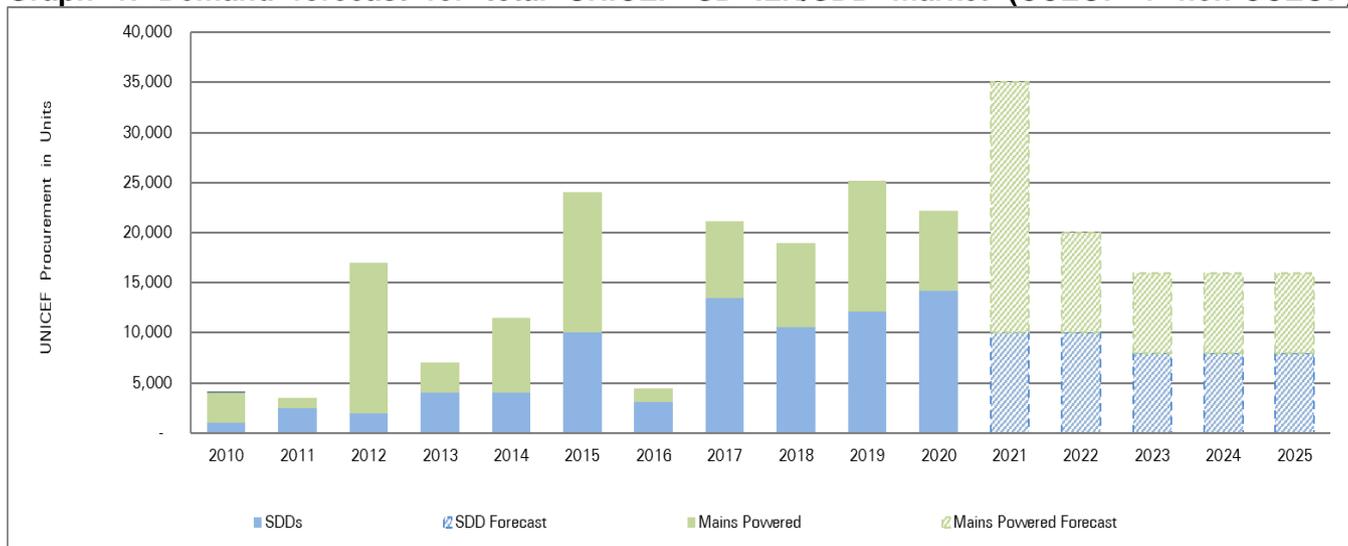
⁶ High demand volume segments as of 2021 include SDD Combined refrigerator/freezer <60L, SDD Refrigerator <60L, ILR Refrigerator ≥60 - <120L, ILR Refrigerator >120L

⁷ Market shaping interventions included the 25% allocation mechanism, whereby countries procuring large volumes were required to procure from at least 2 suppliers, with both suppliers receiving at least 25% of volumes. Additional market shaping interventions included the differentiated tender strategy.

⁸ 52 countries are estimated to be CCEOP-eligible as of the start of 2021.

⁹ These unmet needs refer to remaining needs not met during the Gavi 4.0 period and additional needs that are estimated to arise in Gavi 5.0, primarily from the need for CCE expansion, extension and rehabilitation. It does not take into account that countries may eventually repurpose CCE procured for COVID-19 vaccines for RI programmes, of which the majority of CCE is expected to be used at higher levels of the cold chain.

Graph 1: Demand forecast for total UNICEF SD ILR/SDD market (CCEOP + non-CCEOP)



Variability in the above demand forecast is driven by uncertainty around the total number of units that will be procured through the initial Gavi 4.0 CCEOP funds (estimated at 85,000 units cumulatively), demand from the pandemic for CCE to store COVID-19 vaccines (with a spike in demand estimated for 2021 outside of the CCEOP), uncertainty in ILR/SDD units procured by countries outside of UNICEF SD, and uncertainty in countries' plans to equip new health facilities / service delivery points or the private sector as well as variations between countries' cold chain strategies (e.g. which levels of the cold chain they prioritize) as they aim to prioritise zero-dose populations and achieve immunisation equity goals. Further variation may arise from differences in the actual useful lifespan of ILRs/SDDs versus the projected 10 years.

Updated CCE Volume Band Categories and Forecast

The volume bands used to segment ILR and SDD storage sizes have been consolidated for Gavi 5.0 to: 1) help concentrate demand across high demand product categories; 2) reduce the number of equipment models countries must select between; and 3) reduce the number of products suppliers must be prepared to manufacture. However, countries may continue to have limited demand for equipment that is different than the means listed below, including for small volume CCE at the health facility level, and will be able to procure these in selected cases with CCEOP funding (as well as with non-CCEOP funding).

During the CCEOP initial years, country demand materialised for equipment with larger vaccine storage volumes than what was projected based upon country needs. As such, in addition to the three new consolidated volume bands, UNICEF SD will aim to include products that are closest to the average vaccine storage capacities (litres) matching highest country demand (to be noted in UNICEF equipment tenders). However, countries may have needs that fall outside of these means (outliers), and the target average capacities may change during the course of 5.0. An estimated demand forecast by volume band is included below. Forecasts will be updated regularly during Gavi 5.0.

Table 1: Updated CCEOP ILR and SDD volume bands and forecast by volume band for Gavi 5.0

Type	Volume (liters)	Mains-powered estimated # of units	SDD estimated # of units
Freezer	<60	1,500	500
	≥60 <120		
	>120	2,500	-

Refrigerator	<60	1,200	9,000
	≥60 <120	11,000	3,000
	>120	11,000	1,000
Combo	<60	3,000	13,500
	≥60 <120	1,800	5,000
	>120	-	-

Interventions for Objective 1:

- Raise awareness with countries of product offerings (pre-application) and on what CCE features are needed to meet programmatic needs
- Implement a new application & procurement approach for CCEOP in Gavi 5.0 (i.e., the ‘3-perferences’ approach)¹⁰ with countries and share relevant information about the new approach with all stakeholders
- Explore innovative contracting arrangements (i.e., firm order contracts) to secure competitive (lower) pricing (see obj. 2) and improve supplier predictability of demand; implement if feasible and the benefits of such arrangements are expected to be greater than the associated risks
- Standardise contracting / cost components of specific features of product offerings
- Implement consolidation approach to volume bands and listed products
- Share annual forecast (procured + estimated) updates with suppliers
- Regularly update relevant information (e.g., approved applications) on Gavi and SD websites
- Annual industry consultations and supplier meetings; quarterly outreach to share updates

Objective 2: Achieve competitive pricing for CCE while maintaining incentives for new innovations to improve ‘balanced demand of appropriate products & timely uptake of new innovative products’¹¹

Sub-objective: Address demand volatility root causes

Target Outcomes for Objective 2: `

- No price increase on any existing (non-upgraded) products
- New innovation CCE pricing is aligned to the value-add of the new innovation and within [confidential] targets
- No increase to WAP for 4 highest volume ILR/SDD volume bands
- Market shaping is driven by TCO by the end of Gavi 5.0, provided that TCO is sufficiently informed by field performance data; *note: until TCO is informed by sufficient field performance data the price of equipment will still be used as a proxy for TCO*
- Main (influenceable) drivers of volatility of demand identified and addressed by Q2 2022, allowing for improved production planning

Pricing Trends

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. Across the four largest CCE categories by procurement volumes in Gavi 4.0¹², two categories

¹⁰ The 25% allocation mechanism will remain in place until any new approach is implemented

¹¹ This may need revisiting as the critical next generation innovations are identified over the short to medium-term

¹² These 4 categories include SDD combo ≥30 – <60L; SDD Refrigerator ≥30 – <60L; Mains Refrigerator ≥60 – <90L; and, Mains Refrigerator >120L

have experienced a downward trend due to the diversification of the supplier mix, resulting in reduced weighted average price (WAP). The remaining two categories experienced an upward trend in WAP primarily due to lower demand leading to diminished access to volume-based discounts, along with an increased demand for higher priced models. Additionally, the CCE market under Gavi 4.0 has had tensions between incentivising further innovation and achieving price reduction goals, and this tension and balancing these goals is anticipated to remain in Gavi 5.0.

Given country preferences for equipment that have not experienced price decreases, the Alliance has not fully benefited from reduced listed prices with regards to equipment procured to date. Service bundle prices are also highly variable between countries and suppliers. However, with greater use of benchmarks in the tendering process, lower, more standardised costs are expected to materialise. Exploring options to 'de-link' equipment and services – when requested by countries – could also lead to reduced service bundle prices.

Under the CCEOP the goal has been to focus on countries procuring equipment with the lowest TCO over the lifespan of equipment. TCO estimates to date, however, are based on modelled assumptions and not currently informed by field performance data. In the short term, in the absence of such field performance data the Alliance will focus on highest VfM / most cost-effective CCE with an emphasis on purchase price and understanding the value (premium) of innovative features and services. Once TCO estimates across a wide range of CCE brand and models are sufficiently informed by field performance data (*see interventions under objective 3*), a greater emphasis will again be placed on TCO.

Volatility of Demand

The CCEOP also experienced challenges around the volatility and visibility of demand during Gavi 4.0 across both ILR and SDD segments. Demand-side challenges, such as unpredictability and variability/spikes in demand across a given year, present challenges to suppliers, including planning production and optimising prices. Demand volatility includes variations in both timing and quantity of demand. During the CCEOP (2017-2020), the overall demand materialising from countries was characterised primarily as erratic (large variation in quantities of demand that materialised) or intermittent (large variations in timing of when demand materialised). Different suppliers experienced varying degrees of demand volatility (including year to year differences), with varying strategies employed by each supplier to manage the demand volatility. While some demand volatility is inherent to the market given the nature of durable goods, other sources of volatility arise from the processes and actors present in the market and are potentially manageable.

Interventions for Objective 2:

- Explore special contracting opportunities on high volume categories and other opportunities to achieve price reductions (*see obj. 1*)
- Develop a VfM-based pricing model to compare products / features, including to better understand the value of new innovations
- Identify and implement application and procurement process reforms to address the main drivers of volatility of demand for which the Alliance can influence; work with suppliers to manage demand volatility inherent to the market
- Update TCO models with field performance data and implement the systematic collection of field performance data (*see objective 3 TOs and interventions*)

Objective 3: 'Incentivise & scale up innovations' through systemising field performance data collection and country-supplier-Alliance feedback loops that drive product improvements, catalyse necessary innovations, and inform procurement decisions

Sub-Objective: Clarify priority innovations / TPPs

Target Outcomes for Objective 3:

- By Q1 2023 (or earlier), at least 3 manufacturers offering next generation TPP product features (as prioritised by the Alliance)
- By Q4 2024 (*date to be reconfirmed*), all suppliers offering EMS in all ILR/SDD products (*note: this TO will be further defined*)
- Functional feedback loop between Alliance partners, countries and suppliers in place with field performance data systematically being collected / reported and informing new innovations and product improvements performance findings by 2023
- Greater standardisation among product offerings and innovative features aligned to priority TPPs & new innovations

WHO PQS TPPs

During the Gavi 4.0 period, the CCEOP successfully incentivised new ILR/SDD product offerings and led to the early and widespread uptake of the 2015-2019 WHO PQS' TPPs¹³, with over 100 products prequalified by the end of 2020 (more than 75 of which were CCEOP platform eligible). Under the CCEOP, country demand has shifted toward CCE that meets WHO PQS TPPs beyond the CCEOP platform-eligibility requirements. Since the first publication of the CCEOP platform-eligibility 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.

In Gavi 5.0, updates to CCEOP platform eligibility requirements will be aligned to the critical TPPs, which will be communicated to suppliers well in advance. The WHO PQS is currently finalising the TPPs (with supplier feedback as part of the process) and expects to complete this in 2H 2021. No updates to CCEOP platform-eligibility based on these TPPs are expected in 2021; timelines for any other updates will be communicated at the earliest to countries and suppliers. Additionally, the Alliance plans to systemise field performance data collection and country-supplier-Alliance feedback loops to drive product improvements, catalyse necessary innovations, and inform procurement decisions. The Alliance will use the updated TPPs as the basis to review the current CCEOP optimal criteria to consider possible updates to CCEOP platform eligibility during Gavi 5.0. Any updates to CCEOP platform eligibility will be focused on TPPs/innovations that most further the Gavi 5.0 goals and learning agenda (e.g., fridges and freezers optimised for a solarised health facility, or fridges that are optimised for joint storage of vaccines and other health commodities).

Data and performance monitoring

WHO PQS is updating their RTMD specification to expand to the broader category of 'equipment monitoring systems' (EMS), focusing more broadly on the 'connected cold chain'. These updates include new specifications for EMS (including RTMD), Machine-to-Machine (M2M) interface connection, and data standards.¹⁴ Procurement of integrated or standalone RTMD / EMS through CCEOP support will align to these new standards. In the longer term, Gavi expects to move toward EMS systems as the standard performance monitoring modality for CCE procured with Gavi funding support.

¹³ In addition to some of the CCEOP platform eligibility requirements, this included extended autonomy or holdover time, integrated energy harvesting control, and integrated or standalone RTMDs, among other TPPs.

¹⁴ Equipment Monitoring Systems (EMS) refers to either a standalone or integrated system that provides advanced monitoring of CCE performance, events and alarms across administrative levels of the cold chain; Machine-to-Machine (M2M) interface connection refers to a standardized hardware interface on a monitored appliance and the interface outputs real-time data and can provide limited power to standalone EMS; and, data standards refers to the PQS requirements around the format(s) in which monitored data must be provided to any external software or application with a key aspect of the update focusing on interoperability of data

All data generated by CCE procured with Gavi support is deemed under the ownership of the country. Country ownership of data includes data (raw and processed) originating from CCE products or accessories procured for a CCE. Under this, governments should have full control of data, including definition of terms of access and use of data by third parties, storage, data protection requirements, transmission and internal processing throughout the full lifespan of data. There is no intent to prevent supplier access to the data, but ownership must lie with the country, including how it is used.

While progress has been made to increase understanding of ILR/SDD field performance through initiatives including post installation inspections and pilot projects on post market monitoring, there is still limited data on CCE field performance. Increasing collection and use of field performance data by countries and Alliance partners is a key goal for the Gavi 5.0 period.

Interventions for Objective 3:

- Work with PQS, Alliance partners, suppliers and countries to align on the highest impact TPPs, including timelines for inclusion into PQS specifications and/or CCEOP platform eligibility requirements; Update CCEOP platform eligibility as needed based on TPPs and any other priority innovations that further the Gavi 5.0 mission and learning agenda
- Align on approach to RTMD/EMS in 2021; update platform eligibility requirements as needed based on the forthcoming PQS EMS specification for new and existing equipment (standalone or integrated RTMD or EMS)
- Explore opportunities to facilitate technical assistance to suppliers on compliance with the new WHO PQS TPPs and other new specifications (e.g., for EMS)
- Continue to implement and scale up IMPT, PII and PMM including evaluations and expansion as required. Establish a system of coordination between these various platforms and ensure data flows between them
- Support establishment of feedback loops for field performance data and between Alliance partners, countries and suppliers; ensure this data is used by the relevant stakeholders to inform product improvements, specifications, maintenance, and procurement decisions and that the approach is aligned to and supports Gavi's 5.0 immunisation supply chain strategy.

Objective 4: Continue to have high quality service bundle delivery and, as appropriate / pending pilot evaluations, introduce options for countries to 'de-link' the service bundle from equipment procurement

Target Outcomes for Objective 4:

- Standardisation and improvement of quality achieved across the service bundle element, with emphasis on training, post-installation services and warranty clarification and fulfilment
- Pending positive evaluation of outcomes from de-linking pilots, countries have alternative options for procurement and implementation of the service bundle
- At least 95% installations are assessed through PII as 'acceptable'; 5% as 'adequate'; 0% as 'unacceptable'

All suppliers have gained experience implementing (or finding a solution to provide) the service bundle for ILR/SDD products in the CCEOP countries to date, and the cost of the service bundle, which often varied significantly between countries and between suppliers, has also decreased as suppliers gained additional experience. Uptake of the service bundle concept was also seen outside of the CCEOP (e.g., for procurements with Gavi HSS grants), showing growing traction for this option. Ensuring high quality delivery, installation, training, and commissioning of CCE remains the primary objective of the service bundle component.

In tandem, however, opportunities to explore separating the purchase of equipment and services from a supplier (referred to as 'de-linking') in line with country preferences was piloted during CCEOP in Gavi

4.0 and through the COVAX CCE procurements. Pending the outcomes of evaluations of these pilots and lessons learned through the COVAX CCE deployments, this option may continue to be explored in Gavi 5.0. It is also important to note that as the UNICEF SD total ILR/SDD market in Gavi 5.0 is anticipated to have additional countries and donors participating outside of the CCEOP, not all of these procurements are expected to come with service bundle requirements. In addition, the Alliance may also explore via a learning agenda other types of models for ancillary services, such as solarisation (including full health facility solarisation), leasing, pay-for-performance, or outsourced maintenance.

Interventions for Objective 4:

- Systematise data collection on warranty utilisation and standardise warranty offerings
- Informed by 'de-linking' pilots and COVAX CCE deployments, if evaluation results support new options, establish "menu" of options for countries to de-link, including 3PL, ILR de-linking, SDD de-linking, and/or full de-linking, when requested by countries and approved through a technical review process, approved by the Gavi Boarded if required
- Develop quality benchmarks for the service bundle to help improve all aspects of it (deployment, installation, training, commissioning); Assess service bundle proposals against these quality benchmark and incorporate into PII assessments if feasible
- Develop SOPs / guidelines for training elements as part of service bundle requirements
- Set a timing goal for the PII, including if the PII is performed by countries (*linked to interventions for objective 3*)
- Update service bundle archetypes / pricing benchmarks in 1H 2021. New global tender (LTAs) for ILR/SDD supplier service bundle issued by end of 2021
- Explore a learning agenda for ancillary service models, including models such as solarisation, leasing, pay-for performance and outsourced maintenance; implement via pilot projects if deemed feasible.