

Evaluation of the Cold Chain Equipment Optimization Platform Endline Evaluation Report

January 7, 2022

Submitted by the CCEOP Evaluation Team to Gavi, the Vaccine Alliance







The CCEOP Evaluation Team is led by JSI Research & Training Institute, Inc. (JSI), and includes research partners from JaRco Consulting, Research and Development Solutions (RADS), and Stat View International.

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ACRONYMS

30DTR	30 DTR 30-day temperature recorder
BCG	bacille Calmette-Guérin vaccine
CCE	cold chain equipment
CCEOP	Cold Chain Equipment Optimization Platform
DPT3	diphtheria, pertussis, and tetanus
EPI	Expanded Program on Immunization
EVM	effective vaccine management
HFA	health facility assessment
HMIS	health management information system
HSS	health systems strengthening
ILR	ice-lined refrigerator
JSI	JSI Research & Training Institute, Inc.
KII	key informant interview
LMIS	logistics management information system
MCV	measles-containing vaccine
МОН	Ministry of Health
NLWG	national logistics working group
NVIP	National Vaccines and Immunization Program
ODP	operational deployment plan
PMT	project management team
PQS	performance, quality, and safety
RADS	Research and Development Solutions
RTMD	remote temperature monitoring device
SBP	service bundle provider
SD	Supply Division
SDD	solar direct drive
тсо	total cost of ownership
TPP	target product profile
UNICEF	United Nations Children's Emergency Fund
WAP	weighted adjusted price
WHO	World Health Organization

EXECUTIVE SUMMARY

BACKGROUND

The Gavi Cold Chain Equipment Optimization Platform (<u>CCEOP</u>) was established in 2015, recognizing that functional cold chain equipment (CCE) is a critical precondition to strengthening vaccine supply chains and ultimately achieving Gavi, the Vaccine Alliance's immunization equity and coverage goals. At the global level, CCEOP includes a specific market-shaping component to improve the availability and installation of high-performing CCE, underscoring the need to ensure the market for CCE is healthy and that countries are procuring optimal yet durable and high-performing products.

This prospective evaluation of CCEOP conducted between 2018 and 2021 in three countries — Guinea, Kenya, and Pakistan — aims to assess the progress of CCEOP against its original objectives and understand details of the processes followed in the deployment process. The country-level implementation focuses on achievements in upgrading and expanding CCE and creating a more efficient and effective supply chain. The market-shaping aspect considers progress in promoting healthy markets and improved optimal market conditions, while also considering any unintended consequences. Results of this evaluation will ultimately inform improvement in the platform's design, with both market-shaping and country-level implementation in mind.

This evaluation includes an assessment of CCEOP planning and implementation at four timepoints — baseline, midline, progress report, and endline — to gauge the relevance, effectiveness, efficiency, outcomes, and sustainability of the CCEOP investment in each country, as well as one additional timepoint to examine the effects of COVID-19 on immunization services and CCEOP implementation. This endline evaluation focuses more on objectives related to relevance and CCEOP outcomes, as well as the platform's sustainability. Specifically, it examines the differences, over time, in immunization frequency, vaccine stock, equipment availability, maintenance, and training between two types of health facilities, to the extent possible: those receiving CCEOP equipment in Year 1 (program facilities), and those not receiving CCEOP equipment in Year 1 (control facilities). It builds on findings from the previous evaluation reports and considers the impact of COVID-19 on the related deployment and management processes.

CCEOP IN GUINEA, KENYA, AND PAKISTAN

Activity	Guinea	Kenya	Pakistan
CCEOP approval ¹	\$10.9 million (Oct. 2017)	\$8.2 million (March 2017)	\$41.1 million (Nov. 2016)
Percent country financing	20 percent	50 percent	50 percent
Total number of CCE deployed to date ²	Deployment 1: 853 (848 SDD (and 5 PVSD) Deployment 2: 130 SDD and 2 PVSD. Operational deployment plan (ODP) not finalized at time of evaluation Total: 985 (978 SDD, 7 PVSD Planned Deployment 1: 848 Deployment 2: data not available	Deployment 1: 1,004 (500 ILR and 504 SDD) Deployment 2: 1,559 (1,264 ILR and 295 SDD) (proposed) Total: 2,563 (1764 ILR and 799 SDD) Planned Deployment 1: 1,004 Deployment 2+3: 1,559	Deployment 1: 6,705 (5,736 ILR and 969 SDD Deployment 2: 4,300 (2,965 AC-Powered ILRs and 1,335 SDD refrigerators) Total: 11,005 (8,701 ILR and 2,304 SDD) Planned Deployment 1: 6,828 Deployment 2: 4,476 Deployment 3: 3,350
Date and number of deployments ³	Deployment 1: Nov. 2018– July 2019 Deployment 2: Nov. 2021– May 2022 (proposed)	Deployment 1: July–Dec. 2018 Deployment 2: June–Dec. 2021 (proposed)	Deployment 1: May–Oct. 2018 Deployment 2: Nov. 2019– Oct. 2020 Deployment 3: June 2021– Dec. 2021 (proposed)

Sources:

¹ CCEOP final approved application, operational development plans (Government of Guinea 2017; Government of Kenya 2016; Government of Pakistan 2017).

² Database with cost information per CCE shared by Gavi (Gavi 2019)

³ CCEOP monitoring sheet shared by UNICEF Supply Division. In the case of Kenya, monitoring forms submitted by SBPs (Gavi, 2019).

⁴ De-linking removes the SBP requirement for installation, and the MOH will be responsible for installation instead.

METHODS

The evaluation sought to understand the differences between areas receiving and not receiving new equipment through CCEOP in the three countries. The endline assessment focused on understanding the CCE installation process under CCEOP. It also aimed to document any changes in CCE-related outputs and outcomes between the program facilities, which were scheduled to receive CCEOP equipment in Year 1, and the control facilities, which were not scheduled to receive equipment in Year 1, both before and after CCEOP deployment.

The evaluation used a mixed-methods case-control research design that was mainly prospective, involving key informant interviews (KIIs) at multiple levels of the health system, document reviews, direct observation (when possible), and a health facility assessment (HFA). Data from the health management information system (HMIS) or logistics management information system (LMIS) could not be used to the extent intended because of data quality issues.

Data from all sources were triangulated to draw the results and recommendations. The evaluation team worked with the Ministry of Health (MOH) and other stakeholders in each country to identify the sample. Final sampling areas at the district/sub-county and health facility levels were selected using the following criteria: vaccination coverage, remoteness, and priority status of CCE deployment.

The endline evaluation focused particularly on understanding the situation across the three countries soon after CCE was installed under CCEOP, and to document any pre-existing differences between program facilities and control facilities. Because some control facilities received CCE in the next round of deployment, the sample was aligned based on data on the deployment of CCE procured through other funding sources, depending on the data available during sample selection.

KEY FINDINGS

The key findings from the country-level evaluation are presented in the table below. While these findings are based on all data available, comparisons between program and control facilities were not always possible. Nevertheless, the HFA provides a snapshot of progress made in the two groups over time, highlighting comparative improvements between the groups, which in turn can provide insight into the effect of equipment acquired through CCEOP. Findings related to sustainability for the most part reflect the situation across the health system as a whole.

	Guinea	Kenya	Pakistan
CCEOP RELEVANCE			
Transparent Process and Stakeholder Engagement			
Finding 1: CCEOP planning was a transparent, inclusive, government- led process in general but with limited contribution from the sub- national level for planning and application processes.		O	O
Finding 2: Some gaps exist in the transparency of the decision-making process for equipment selection.		•	•
In Response to Country Needs			
Finding 3: Previous experience with the equipment and information from UNICEF, WHO, and Gavi influenced equipment selection.	0	0	
Finding 4: Country-level decision makers will consider the cost and implementation of the warranty and the effort to standardize CCE models for future equipment selection.	Đ	Đ	•
IMPLEMENTATION AND EFFECTIVE	ENESS		
CCE Availability			
Finding 5: CCEOP has successfully and substantially increased the availability and capacity of the cold chain system.	Ð	Ð	•
Finding 6: Some facility-level respondents felt the current capacity through new CCE procured was not appropriate to facility needs.		•	•

	Guinea	Kenya	Pakistan
Finding 7: The manufacturing issue with the equipment from one manufacturer cast doubts on the quality of equipment promoted by CCEOP and the necessity of the warranty.		•	
Maintenance			
Finding 8: While training improved technicians' capacity considerably, there still appears to be some gaps in expectations and quality of the training provided on CCE maintenance, including preventive maintenance with health workers. *Also relevant for sustainability	•	•	Ф
Finding 9: The maintenance system for CCE has yet to see improvements. New models of equipment installed in countries have exacerbated this divergence in maintenance systems, as SBPs are currently engaged. *Also relevant for sustainability	•	•	•
Finding 10: Having multiple brands of CCE has negatively affected knowledge of warranties and corrective and preventive maintenance practices. *Also relevant for sustainability	•	•	•
SBP Implementation			
Finding 11: There are inconsistencies in services provided by SBPs and warranty coverage across the three countries.	•	•	•
Coordination and Communication			
Finding 12: The CCEOP is coordinated with other donors and partners for overall system strengthening, although better documentation could improve the coordination and planning.	¢	•	¢
Finding 13: There was a lack of clarity in the requirements during the proposal stage, with long delays and continued back and forth between the PMT and UNICEF related to the de-linking approach.		•	
Finding 14: While communication between and within health system levels has improved since baseline, critical vertical communication gaps persist, such as between the facilities and higher levels around warranty issues. Horizontal communication gaps also continue between the SBPs and the MOHs.	•	•	•
Temperature Monitoring			
Finding 15: Largely, temperature monitoring at the facility level is implemented using 30-day temperature recorders (30DTRs), even if remote temperature monitoring devices (RTMDs) are available.	((
Finding 16: While national staff was very satisfied with the RTMDs, the RTMD dashboard is often unavailable for sub-national staff, especially at the facility level.	(Ð	
EFFICIENCY			
CCE Performance and Maintenance			
Finding 17: Most respondents are very satisfied with the CCEOP equipment, which brings cost savings, less maintenance required, and better performance.	¢	•	O

	Guinea	Kenya	Pakistan
Finding 18: The new CCE is functioning very well, with high levels of safe time within the expected temperature range.	Ð	¢	Ð
Finding 19: Decommissioning of old equipment is still not clearly implemented.		•	
OUTCOMES AND RESULTS			
Finding 20: There were fewer vaccine stockouts reported at the endline in Guinea and Kenya, although the reasons are unclear.	Ð	e	
Finding 21: New equipment has expanded the reach of immunization services and increased CCE capacity.	e	O	e
Finding 22: While there is evidence that the frequency of immunization sessions has increased, the impact of CCE on the immunization coverage rate is inconclusive.	Ð	Ð	Ð
SUSTAINABILITY			
Country Ownership			
Finding 23: CCEOP has contributed to the growth of some national- level planning and management structures and systems, such as the PMT and national logistics working group (NLWG), yet it is not clear that it has fostered ownership through all levels of the system.	•	•	•
Finding 24: There was little indication that the joint investment (Gavi and country government funds) contributed to financial sustainability or country ownership.	θ	⊜	θ
System Strengthening			
Finding 25: Warranties will soon expire, and weak maintenance systems will find it challenging to fill the gap.	•	•	•
Finding 26: The overall health system has not kept pace with the new CCE in terms of the need for more resources.	•	•	•
Positive finding Negative finding Neutral finding A r Note: Cells without a marking indicate no response or not applicable			indings

The market-shaping evaluation followed a different timeline due to annual procurement cycles and related performance indicators, as well as a strategy shift mid-CCEOP. A comprehensive <u>market-shaping evaluation report</u> detailing the approach, methodology, data collection process, and findings was finalized in late 2020. A summary of the findings from the market-shaping evaluation is outlined below.

Globally, CCEOP has successfully **stimulated a market for — and catalyzed awareness**, **availability, and use of — higher-performing CCE** in many countries. There is value in more organized and aggregated procurement and information sharing for CCE. The original CCEOP market-shaping strategy highlighted some of the potential challenges to achieving the market-shaping objectives that ultimately played out but was insufficiently robust to address them. The revised market-shaping strategy appears to address some of those limitations and has made progress in promoting a healthier market and shifting demand to some lesser-utilized CCE suppliers.

The endline evaluation in the three focus countries and updated review of procurement data and platform-eligible CCE yielded the following findings relevant to the CCEOP market-shaping objectives:

PRODUCT OPTIONS AND AVAILABILITY

- The number of platform-eligible ice-lined refrigerators (ILRs) and solar direct drive (SDD) models increased from 55 in 2016 to 78 by the end of 2020. Currently, there are more than two suppliers per CCE product type and segment.
- Demand from the three focus countries over the course of CCEOP implementation has been for CCE from four different manufacturers. Not all were the first preference.

PRODUCT SELECTION AND COUNTRY PREFERENCES

- Brand preferences influence product selection and country preference. Respondents indicated that CCE is often selected based on prior experience with a particular CCE brand and/or SBP. Cost analysis was a secondary consideration for CCE selection when offered CCE from a different supplier.
- The desire to standardize CCE models across the country is another factor in selection, to help rational management of resource needs for training maintenance technicians and more efficient management of spare parts.
- Many respondents expressed strong feelings that countries should be allowed to choose the CCE models they want and that choice should be respected, without outside influence or pressure to change.

EQUIPMENT PERFORMANCE MONITORING AND REPORTING

 Issue reporting is very ad hoc, with no reliable system to report malfunctioning equipment. Service and maintenance requests may reach technicians at the district level, but there is no system to compile/aggregate that data at the central level, which limits the ability to track and monitor trends in CCE issues

DE-LINKING THE SERVICE BUNDLE

- Some respondents expressed concern about unskilled government technicians and voiding the warranties if de-linking was allowed. Additional capacity needed for project management was another concern.
- Some respondents from countries that feel that they can manage installation on their own appreciate the opportunity to do so and to be able to compare to their experience with SBPs; there was a strong sense that this would increase the sense of ownership and responsibility and be suitable for overall capacity building.

LESSONS LEARNED AND CONCLUSIONS

COUNTRY EVALUATION

- **Maintenance systems**. To protect Gavi's investment in CCE, countries need to strengthen maintenance systems for longevity of the new equipment.
- Accurate CCE inventories. Having accurate information on CCE inventories is important for planning new equipment and planning immunization services. However, updating inventories is typically a high level of effort and can delay CCE deployment, as it did in Kenya.
- **Operational deployment plans (ODPs)**. The ODPs were largely accurate in each country. Last-minute changes inevitably occurred but caused minimal or no disruptions to the SBP activities; SBPs adjusted easily and with no additional costs.
- **Communication about warranty**. Stakeholders at each level of the system were not clear about the warranty or the SBP's role post-installation, despite the information being shared to national-level decision makers.
- Systems perspective. CCE is only one aspect of ensuring potent vaccines are available. All supply chain elements — data, CCE maintenance, trucks, staff, and such — as well as program elements, such as nurses and demand creation, are important for an immunization program to thrive.
- Adaptation of procedures. UNICEF has been quite responsive with adapting to needed changes to CCEOP processes for example, shortening the application time and adapting the service bundle provision.
- **COVID response.** To respond to the need for COVID vaccines, Gavi adapted the CCEOP methodology to expand CCE criteria to meet the urgent need for walk-in cold rooms and regional CCE for introduction of the COVID vaccine.

MARKET SHAPING

- **CCE innovation and pricing**. The CCEOP market-shaping strategy was highly effective at promoting innovation; suppliers reacted to early target product profiles (TPPs) and continued to actively innovate to differentiate their products in this market. CCE pricing overall has been less responsive, potentially due to the focus on innovation and/or lower volumes. Efforts to bolster the selection of lower-priced CCE have been implemented via the differentiated tender approach.
- Market shaping for CCE. Market shaping for CCE (expensive, durable goods) is more complex than for consumable products, like vaccines and medicines. While much of the original CCE market shaping was based on experience with vaccines, lessons quickly emerged that needed to be addressed with more nuanced market-shaping approaches, including brand familiarity, uneven annual demand, and limited price sensitivity.
- Market-shaping objectives vs country preferences. An ongoing challenge is the desire to shape the market while respecting country choice in terms of CCE brands and

models. The differentiated tender process seeks to address this, but this continued tension underscores the need to understand and affect the drivers of demand and not focus primarily on supply side efforts.

• **Performance monitoring**. Countries appreciate the data visibility provided via remote temperature monitoring. Field performance monitoring efforts need further attention to determine how to comprehensively collect, share, and use this data to improve product comparisons and selection across procurers.

RECOMMENDATIONS

Based on this endline evaluation, we propose the recommendations in the table below for countries; timing for their implementation (short-, medium-, and long-term) is highlighted. While this list is extensive, three broad themes address the priorities:

- Strengthen maintenance systems. To protect the Gavi's investment in CCE, countries need to strengthen maintenance systems at the national and sub-national level for longevity of the new equipment. The PMT and MOH should prioritize a strong and funded maintenance system that covers all equipment, including that acquired through CCEOP. UNICEF also has a role to play with updating maintenance guidance to be forward thinking and leveraging new technology. Gavi's role is to support and shape maintenance investments. It is refreshing to see the shift in the global conversation related to maintenance; now, more concrete action needs to be taken to implement these priorities.
- 2. Reinforce and adapt best practices and guidance, both those designed through CCEOP and general guidance. A specific example of this is adapting processes and standards developed for the SBPs for the MOH to use where de-linking is implemented to ensure proper tracking of installations and equipment location (specifically in Kenya). This is applicable to UNICEF, as many guidance documents already exist for some of these recommended areas (decommissioning guidance, CCE maintenance, temperature monitoring) yet may not be accessible to stakeholders when needed. Procedures to roll out and make available such guidance need to be revamped to ensure its use while leveraging new technology and methods available for this purpose.
- 3. **Improve lines of communication.** Many of the recommendations are linked to faulty communication lines between stakeholders. The PMT can be more proactive in engaging the sub-national level in planning for CCE needs and designing maintenance systems that are feasible and appropriate. It is recommended that UNICEF engage the MOH more closely when contracting with the SBPs for more oversight and ownership.

RELEVANCE OF CCEOP			
РМТ/МОН	Short	Medium	Long
Incorporate reporting processes established through CCEOP into regular management activities through the NLWG and other established systems.			
Continue to strengthen the NLWG to monitor and manage the supply chain regularly.			
More actively engage sub-national-level stakeholders in CCE planning.			
Closely monitor SBP and warranty utilization.	Ŏ		
UNICEF			
Develop a mechanism to receive country feedback on the SBP's implementation.			
Share documentation of CCE performance, SBP performance, de-linking experience, and warranty utilization.			
Gavi			
Assess the effectiveness of the warranty.			
IMPLEMENTATION AND EFFECTIVENE			
РМТ/МОН	Short	Medium	Long
Ensure access to RTMD dashboards and/or create a reporting system for data from 30DTRs.			
Continue to monitor CCEOP activities, including use of the temperature data in regular system monitoring.			
Continue monitoring SBPs for equipment under warranty.			
Provide clear documentation of planning and implementation decisions and coordination efforts.			
Include innovative on-the-job training or refresher training on CCE preventive maintenance.			
Reinforce the maintenance system with improved funding and resources.			
UNICEF			
Clarify training expectations and implementation with SBPs and the MOH.			
Develop guidance on different maintenance models.			
Clarify training details with manufacturers and SBPs.			
Develop standardized training CCE packages adapted to mobile platforms or distance learning.			
Identify SBP successes to refine roles and oversight of the SBPs.			
Continue efforts to clarify warranties with the MOH.			
Ensure manufacturers of RTMD provide access to the dashboard.			
Continue efforts to clarify proposal processes, especially as requirements are updated.		•	
For future deployments, ensure precise and direct communication with the MOH and inclusive decision making when changes are made.			
Gavi			
COVID-19 vaccine rollout gains traction and additional funding sources are			
COVID-19 vaccine rollout gains traction and additional funding sources are available.			
COVID-19 vaccine rollout gains traction and additional funding sources are available. Clarify the proposal process, including the joint investment aspect and equipment selection process, to streamline the proposal timeline.	•		
COVID-19 vaccine rollout gains traction and additional funding sources are available. Clarify the proposal process, including the joint investment aspect and equipment selection process, to streamline the proposal timeline. Strengthen and expand support for maintenance for the cold chain system beyond CCEOP-specific equipment.	•	•	
Continue coordinating across partners and donors, particularly as the COVID-19 vaccine rollout gains traction and additional funding sources are available. Clarify the proposal process, including the joint investment aspect and equipment selection process, to streamline the proposal timeline. Strengthen and expand support for maintenance for the cold chain system beyond CCEOP-specific equipment. Support systems and processes to collect and use temperature monitoring data, regardless of the technology.	•	•	
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Increase opportunities for more active vertical communication with all levels.			
Develop plans for decommissioning obsolete older equipment.			
Strengthen the overall maintenance system.			
Integrate a performance evaluation rating for the SBP.			
Ensure systematic data collection on CCE performance and needs.			
For future deployments, ensure optimal use and placement of CCE to guarantee sufficient capacity.			
UNICEF	Short	Medium	Long
Reiterate available guidance on decommissioning.			
Reinforce knowledge sharing of best practices for preventive and corrective maintenance.			
Gavi	Short	Medium	Long
Support a system for tracking CCE status and performance; include periodic reporting from the system on CCE status to feed into the grant performance framework.		•	
Require countries to develop and fund more robust maintenance plans and report on CCE performance.			
OUTCOMES AND RESULTS			
РМТ/МОН	Short	Medium	Long
Determine factors influencing routine immunization provision and tailor region-specific interventions.			
UNICEF	Short	Medium	Long
Provide technical support to the PMT/MOH to develop a comprehensive package of improvement for health facilities that includes all necessary materials to strengthen the overall supply chain and immunization program.		•	
Gavi	Short	Medium	Long
Consider commissioning a study to examine the impact of the supply chain on immunization coverage.			
SUSTAINABILITY			
РМТ/МОН	Short	Medium	Long
Leverage expertise and processes from the SBPs now to strengthen the overall maintenance system.			
Develop a systematic way to update the cold chain inventory within the			
regular monitoring system.			
regular monitoring system. Ensure close collaboration between the MOH's service delivery and supply		•	
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Recommendations from the market-shaping evaluation are outlined below. These recommendations include those from the final market-shaping report completed in 2020 plus additional recommendations relevant to market shaping based on findings from the three country endline assessments.

Address the tension between country preference and mark	et-shaping	obiectives	
Gavi and UNICEF	Short	Medium	Long
Consult with countries on brand preferences/perceptions.			
Assess the allocation approach for high-volume countries (whereby countries are requested to allocate 25 percent of procured CCE to a second supplier) to determine if/how this could be increased (to 30 percent to 40 percent) to advance market-shaping objectives further.	•		
Look at models used for procurement of other durable equipment (procured by UNICEF and others).			
Pilot a specifications-based procurement model and create funding			
incentives for countries that agree to use this model. Improve demand visibility to achieve efficie	ancies		
UNICEF and alliance partners	Short	Medium	Long
Ensure forecasts are realistic and updated, and shared routinely.		mourum	Long
Review demand fluctuations and set out a deliberate schedule and timeline for annual processes (across applications, approval, ODPs, and purchase orders) to better smooth demand,	•		
Work with manufacturers to understand their production planning schedules and when more concrete inputs would be needed to help planning; work to align forecasts with these schedules.		•	
Establish minimum annual order quantities with suppliers to improve production planning, efficiencies, and ultimately prices; pass savings onto countries in terms of incentives for procurement.		•	
Foster greater price sensitivity and compe			
Gavi and Alliance partners	Short	Medium	Long
Explore ways for countries to "test" or try different models of CCE to build familiarity with new/different brands.			
Alliance partners needs to clarify role/goals with market-shaping with Gavi to determine the "ideal" number of suppliers in the market to meet healthy market goals and establish a clearer strategy to do so.			
Explore pricing, allocation, and financing levers to achieve the set goal, even if at odds with country choices,			
Promote product innovation and total cost of ownershi			
Gavi and UNICEF	Short	Medium	Long
Clarify how country input is feeding into future innovation requirements. Systematize reporting of maintenance issues for CCE to improve broader			
performance monitoring. Agree on the next set of TPPs (or set new platform-eligibility criteria) and communicate clearly to manufacturers.			
Clarify and stick to timing for any new feature requirements.			
Establish comparison tool based on required product features; determine if/how to include field performance data.			
Better inform the evaluation of CCE options and value asses	ssment of n	ew features	
Gavi, UNICEF, and Alliance partners	Short	Medium	Long
Define set of essential characteristics; help set value/notional use case for additional features and warranties.			
Develop clear communication around warranties, coverage, and responsibilities, especially for countries with multiple manufacturers and different SBPs and policies.			
Ensure decision-support tools are user friendly (less text, easier to access and use outcomes for both decision making and advocacy).			
Promote informed decision making around SBP and d			
Gavi and UNICEF	Short	Medium	Long
The Alliance should support better costing tools to assess the true cost of deployment and maintenance.			

Benchmark timelines and costs for comparison with countries that choose to de-link.		
Ensure criteria for de-linking the service bundle (some or all components) are transparent and well understood in advance of application process.		

RATIONALE AND BACKGROUND INFORMATION

The role of immunization is significant in the context of the Sustainable Development Goals, especially Goal 3 on improving health and well-being. With one in five children still not immunized and therefore at risk of preventable life-threatening diseases in low- and middle-income countries, immunization programs are under pressure to improve performance and efficiency, increase coverage, and reach the fifth child. At the same time, new vaccines are being introduced and immunization supply chain management systems are being stretched to accommodate ever-increasing volumes and varieties of vaccines and presentations.

The Gavi Cold Chain Equipment Optimization Platform (<u>CCEOP</u>) was established in 2015, recognizing that functional cold chain equipment (CCE) is a critical precondition for strengthening vaccine supply chains and ultimately achieving the Alliance's immunization equity and coverage goals.

CCEOP was created to expand the reach of enhanced cold chain technology and thus increase the effectiveness and efficiency of immunization supply chains and the sustainability of coverage and equity in immunization programs. CCEOP provides phased support to selected countries at the country level for up to a maximum of five years. The initial support phase addresses the most urgent CCE needs for the first one to two years (e.g., where there are the highest risks to vaccine stocks or the most significant bottlenecks to coverage and equity). The second scale-up support phase allows the country additional time to elaborate further and finetune its long-term CCE needs over the next three to five years.

CCEOP seeks to address both the supply and demand side for optimal CCE, generate demand for technologically innovative and appropriate CCE, and stimulate the market to respond to that demand with affordable and accessible equipment. It is important to note that deployment of equipment through CCEOP works alongside efforts to improve the supply chain by other donors, such as the World Bank and partners. An overview of the CCEOP results framework, including the theory of change and logic model outlined by Gavi, is presented in Appendix A.

Through CCEOP, the Alliance pledged US\$250 million over five years to support 55 countries to upgrade and expand their CCE footprint while simultaneously stimulating the market to provide affordable, technologically advanced, and accessible equipment. In 2019, two additional countries, Syria and Congo, became eligible for support through CCEOP. Deployment for Syria and Congo is expected to complete in January and February 2022, respectively.

The CCEOP approach is guided by Gavi's immunization supply chain strategy, which provides an end-to-end perspective of the supply chain and emphasizes the five supply chain fundamentals: supply chain leadership, continuous improvement and planning, supply chain data for management, CCE, and supply chain system design. CCEOP is expected to contribute to the five fundamentals in different ways, such as creating PMTs to strengthen the leadership component and creating a coordinating mechanism across all donors and partners; requiring updated inventory and CCE maintenance plans as part of continuous improvement; and tracking CCE performance linked to overall supply chain performance through improved data use. The PMT overlaps with the national logistics working group (NLWG) in several countries, including Kenya. CCE placement is often done within the context of system design to optimally place equipment to respond to low coverage, low access, or poorly performing equipment. According to the Immunization Supply Chain Steering Committee (iSC2) Mid-Term Strategy Review, countries have moved the other fundamentals forward with varying degrees of success (Gavi 2017). Gavi has noted that the CCE fundamental is more advanced than the other fundamentals, mainly due to the scale of the CCEOP.

This prospective evaluation of CCEOP was conducted between 2018 and 2021, in three countries — Guinea, Kenya, and Pakistan — and was led by JSI Research & Training Institute, Inc. (JSI), with its research partners Stat View International in Guinea, JaRco Consulting in Kenya, and Research and Development Solutions (RADS) in Pakistan. This cross-country report presents findings from the endline assessment analysis as part of this evaluation. It includes:

- 1. Assessing the effect of CCEOP implementation in the three countries
- 2. Evaluating the market-shaping landscape and global procurement outcomes for CCE through December 2020

These endline findings will serve as a comprehensive analysis of CCEOP implementation, with recommendations for program improvement in the countries assessed as well as for rollout in other countries.

COUNTRY CONTEXT

GUINEA

Guinea's immunization coverage has remained low in the last 20 years. According to four demographic health surveys (DHSs), the percentage of children ages 12–23 months who received all basic vaccines was 24 percent in 2018 (INS and ICF, 2018). Across regions, this number varies from 8 percent in Labé to 36 percent in Kankan. Guinea has strived to improve vaccine service delivery through improving program coordination and increasing investment in the vaccine supply chain management system. Despite these efforts, challenges remain, such as low human resource capacity in rural health centers, minimal cold storage capacity at the district and health center level, poor accessibility of rural health centers, and poor data quality.

Findings from the 2016 EVM assessment illustrated the country's shortcomings in meeting the set standards in the nine areas of effective vaccine management. The score for each criterion of effective vaccine management was well below the WHO-recommended minimum standard of 80 percent. In the program review in 2017, during the joint appraisal, several objectives were outlined in the action plan (Gavi, 2017a). Prior to CCEOP, Guinea procured a number of pieces of CCE using funds from the HSS grant. With CCEOP support, the MOH planned to extend the

cold chain coverage, equipping all health posts in the country that previously did not stock vaccines. Guinea has also taken steps to strengthen its end-to-end vaccine supply chain to improve vaccine availability and increase efficiency at all levels of the health system through an ongoing supply chain redesign exercise.

CCEOP in Guinea

In October 2017, Guinea received approval for CCEOP for \$10.9 million to provide CCE to health posts and health centers, with the country responsible for financing 20 percent of the support. The application included the procurement of 1,361 pieces of CCE based on the 2016 cold chain rehabilitation plan for the country. For the first deployment, a total of 848 solar direct drive (SDD) combined refrigerators and freezers were installed in health posts. These facilities were a priority for the Expanded Program on Immunization (EPI) as the entry point for the health system and were storing vaccines for the first time. The EPI also received five passive vaccine storage devices (PVSD) that require no power source. The procurement of these CCE did not include after-sale service, hence there was no SBP. An additional 42 pieces of SDD equipment included in the first deployment plan were not procured.

KENYA

On average, approximately 75 percent of children ages 12–23 months in Kenya are fully vaccinated, according to the 2014 Kenya Demographic and Health Survey¹ (National Bureau of Statistics-Kenya and ICF International 2015). However, in remote and hard-to-reach areas, such as the Rift Valley and northeastern regions, as many as two-thirds of children are not fully vaccinated and are at risk of preventable life-threatening diseases (National Bureau of Statistics-Kenya and ICF International 2015).

The immunization supply chain in Kenya is organized into four levels: central/national depots, regional depots, sub-county stores, and health facilities. The national government is responsible for operating the central and regional depots. Counties do not store vaccines and are tasked with transporting vaccines from regional depots to sub-county stores quarterly and from the stores to the service delivery point.

Significant gaps in the cold chain, particularly at the sub-county and facility levels, likely contribute to low vaccination coverage across the country. According to a 2016 national cold chain inventory, approximately one in five health facilities do not have any CCE. A majority (81.1 percent) of the CCE in the remaining facilities does not meet performance, quality, and safety (PQS) standards set for the immunization supply chain in Kenya (National Vaccines and Immunization Program (NVIP) 2016).

Furthermore, the results of the 2013 effective vaccine management (EVM) assessment demonstrated significant limitations in almost all nine key cold chain capacity domains of vaccine management and scores short of the minimally acceptable 80 percent on many of the domains (Kenya EVM Assessment 2014). The results of the EVM provided a benchmark for the

¹ Fully vaccinated refers to BCG, measles, three doses each of pentavalent (DPT-HepB-Hib), polio (excluding polio vaccine given at birth), and pneumococcal vaccine.

supply chain's performance, highlighting areas that need strengthening, including cold chain capacity.

Since 2013, decentralization in Kenya has added another layer of complexity to health programs and administration, with counties becoming responsible for procuring injection supplies for traditional vaccines and supporting the immunization supply chain. Counties' varying degrees of commitment to immunization have, in turn, affected coverage rates and interrupted implementation of planned activities (Gavi 2017).

CCEOP in Kenya

In March 2017, Kenya received approval for CCEOP for \$8,231,741 to provide CCE to health facilities and sub-county depots, with the country responsible for financing 50 percent of the support. These funds are in addition to the \$20,339,960 grant to provide health systems strengthening (HSS) activities in 17 priority counties in Kenya between 2017 and 2020. CCEOP Year 1 deployment focused on replacing equipment in all facilities that had equipment gaps throughout the country and then extending immunization services to new sites in the 17 HSS grant priority counties.

In Year 1, 1,004 pieces of equipment were deployed between July and November 2018. Two SBPs completed the delivery and installation of on-grid equipment and SDD equipment. Their warranties cover repairs for up to two years on [Manufacturer 1] AC-powered equipment, three years on [Manufacturer 2] AC-powered equipment, and up to 10 years for [Manufacturer 2] SDD models from commissioning date. The warranty covers failures due to manufacturer-related issues, production errors, defective design, materials, or workmanship. However, warranties do not cover failures due to misuse of equipment, wrongful installation, lack of preventive maintenance, expected wear and tear, or any failure not caused by a production or hardware error.

The PMT decided to move forward with the next application/equipment procurement and developed a Year 2/Year 3 application based on a rapid inventory conducted in July and August 2019. The proposal requested to proceed with the next equipment deployment without the use of SDPs. At the time of this report, comments have been submitted and the country is waiting to hear back about the proposal to de-link. The next deployment is tentatively scheduled to take place between June and December 2021.

PAKISTAN

Pakistan has a history of sub-optimal levels of immunization coverage, with only 65.6 percent of children ages 12–23 months and 39.5 percent of children ages 24–35 months receiving all age-appropriate vaccinations (National Institute of Population Studies and ICF International 2017– 18). Pakistan's cold chain suffers from poorly optimized equipment and infrastructure, as equipment-related improvements have not kept pace with the massive increase in quantity of vaccines. Common challenges include old equipment, weak distribution systems, a shortage of trained staff, and a lack of reliable data and comprehensive evaluations to facilitate concrete improvement plans. Yet, improvements are more urgent than ever because vaccine volumes are expected to increase exponentially in the coming years due to the anticipated high population growth rate.

A 2014 EVM assessment conducted at the national, provincial, and district levels demonstrated major limitations, with all but one of the nine key cold chain capacity domains falling below the minimum required acceptable score of 80 percent (WHO 2015). Common cold chain system gaps identified by the EVM at both the national and sub-national levels included maintenance, stock management, and distribution and information systems. The central-level store has an 800,000-liter capacity to store vaccines, of which only 22 percent (175,000 liters) met international quality standards. Though the capacity of some provincial stores met requirements for existing vaccines, it will likely be insufficient as newer vaccines, such as those for rotavirus, are introduced.

CCEOP in Pakistan

Pakistan received approval for CCEOP for \$41.1 million in November 2016, with the cost split equally between Gavi and the Government of Pakistan. Based on data from a 2016 inventory of cold chain and related infrastructure, an operational deployment plan (ODP) was developed to upgrade CCE in facilities to ensure compliance with international standards by 2020. Seventy-five percent of all facilities in Pakistan were selected to receive replacement refrigerators over three years. Of these, approximately 25 percent will receive additional fridges to expand their existing storage capacity.

The distribution plan was designed for breadth, meaning it sought to place a lot of equipment in a lot of facilities across a lot of places. The grant sought to procure 15,418 pieces of CCE to be distributed across Pakistan over four years in three stages of deployment, based on results from a complete inventory of health facilities and their CCE and infrastructure in 2016.² To date, 11,005 pieces of CCE (8,701 AC-powered ILRs and 2,304 SDD refrigerators) have been installed in two phases of deployment. Two SBPs were selected to deliver and install the new CCE for Deployment 1, covering most of the country, and another SBP covered Balochistan. A change was made for Deployment 2, with the involvement of two additional SBPs. One SBP provides delivery, installation, and post-installation repairs for two years. The other SBP is responsible for 123 pieces of an SDD model and also has a warranty period of two years.

Specific details of CCEOP-related activities in the three countries are listed in Table 1 and Figure 1 below.

² Pakistan Operational Deployment Plan, 2017.

Table 1. CCEOP Related Activities in Guinea, Kenya, and Pakistan

Activity	Guinea	Kenya	Pakistan
Date of CCEOP approval	Oct 2017	March 2017	Nov 2016
Amount approved ¹	\$10.9 million	\$8.2 million	\$41.1 million
Percent financing by country	20 percent	50 percent	50 percent
Deployment 1 priority	Equipping health posts for the first time to expand immunization services by increasing the number of fixed posts for vaccination	Replacing equipment in facilities with storage gaps in all counties and equipping new facilities in 17 HSS priority counties	Replacing malfunctioning equipment, furnishing existing facilities that have a higher demand for vaccinations, and to a lesser extent (deferred for later years) equipping new facilities
Deployment 2 priority	Equipping health centers with non-functioning CCE (PQS and non-PQS)	Capacity gaps and replacement in Mombasa and Nairobi (counties with large populations in informal settlements), remaining public service facilities with capacity gaps and replacement requirements, and equipping private service- delivery facilities that lack the resources to upgrade their CCE located where coverage and equity are problematic	Increasing coverage and access; new facilities were opened in several districts equipped with CCE to provide coverage to previously unserved/underserved communities
Total number of CCE deployed to date ²	Deployment 1: 853 (848 SDD (and 5 PVSD) Deployment 2: 130 SDD and 2 PVSD. Operational deployment plan (ODP) not finalized at time of evaluation Total: 985 (978 SDD, 7 PVSD) Planned Deployment 1: 848 Deployment 2: data not available	Deployment 1: 1,004 (500 ILR and 504 SDD) Deployment 2: 1,559 (1,264 ILR and 295 SDD) (proposed) Total: 2,563 (1764 ILR and 799 SDD) Planned Deployment 1: 1,004 Deployment 2+3: 1,559	Deployment 1: 6,705 (5,736 ILR and 969 SDD Deployment 2: 4,300 (2,965 AC Powered ILRs and 1,335 SDD refrigerators) Total: 11,005 (8,701 ILR and 2,304 SDD)) Planned Deployment 1: 6,828 Deployment 2: 4,476 Deployment 3: 3,350
Date and number of deployments ³	Deployment 1: Nov. 2018– July 2019 Deployment 2: Nov. 2021– May 2022 (proposed)	Deployment 1: July – Dec. 2018 Deployment 2: June – Dec. 2021 (proposed)	Deployment 1: May–Oct. 2018 Deployment 2: Nov. 2019 – Oct. 2020 Deployment 3: June 2021– Dec. 2021 (proposed)

Source:

¹ CCEOP final approved application, operational development plans (Government of Guinea 2017; Government of Kenya 2016; Government of Pakistan 2017).

² Database with cost information per CCE shared by Gavi (Gavi 2019)

³ CCEOP monitoring sheet shared by UNICEF Supply Division. In the case of Kenya, monitoring forms submitted by SBPs (Gavi, 2019).

⁴ De-linking removes the SBP requirement for installation, and the MOH will be responsible for installation instead.

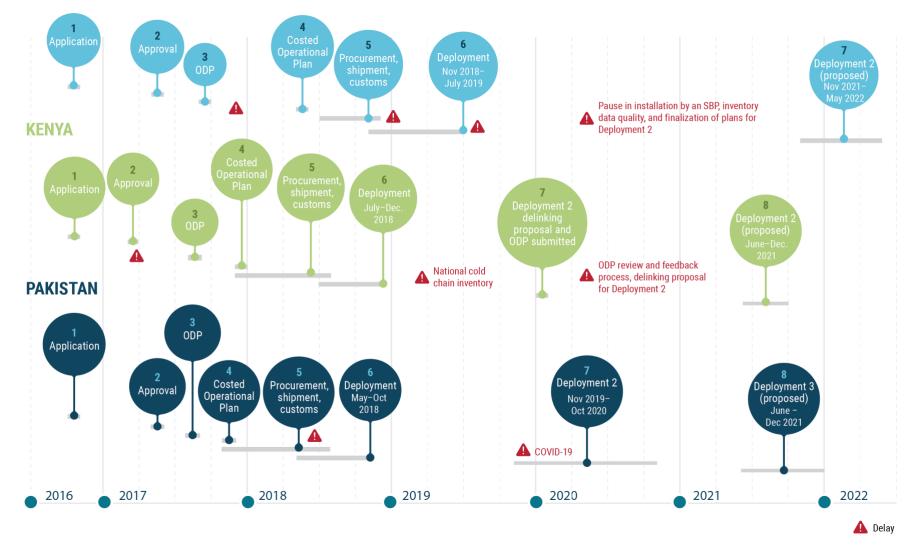
COVID-19 CONTEXT

At the global level, CCE suppliers cited minimal impact of COVID-19 on manufacturing and supply availability but did encounter delays in shipping. All three countries in this evaluation experienced lockdowns at one or more points throughout the pandemic. Lockdowns and stayat-home directives also delayed some in-country activities, most notably the SBPs' ability to move around the country to install CCE. In most cases, following initial delays, the SBP teams received special permission for installation because it was seen as a priority for the countries. The teams only experienced slight delays. Overall, there were minimal disruptions to CCEOP implementation.

Immunization services experienced disruptions early in the pandemic, as there was a decrease in care seeking and outreach services were suspended for several weeks. Since the initial surge, however, services have mainly returned to normal with minimal shifts in service delivery due to some facilities being used as isolation centers (Kenya specific). In terms of the health system, there were some reports of funding initially allocated for vaccine distribution or maintenance being shifted toward activities to address the pandemic.







Note: According to CCEOP Milestones sheet (July 14, 2021)

PURPOSE, SCOPE, AND OBJECTIVES

Gavi sought to assess the relevance, effectiveness, efficiency, outcomes, and sustainability of the CCEOP investment in three countries — Guinea, Kenya, and Pakistan — that Gavi selected for this evaluation given their stage of CCEOP deployment. As a whole, the evaluation aimed to assess CCEOP progress against its original objectives while keeping in mind the other channels through which countries were obtaining CCE and taking such channels into account, when possible, as part of the evaluation.

The country-level component focused on achievements made in upgrading and expanding CCE and creating a more efficient, effective supply chain while also focusing on the effect on immunization outcomes and results. The market-shaping component included achievements made in promoting healthy markets and improving optimal market conditions while also considering any unintended consequences. (More specific information on the scope of the evaluation is available in the Request for Proposal for the Evaluation of the Cold Chain Equipment Optimization Platform (CCEOP) in the Annex to this endline report.)

The country-level evaluation findings provide important inputs and insights to the marketshaping evaluation addressed in this report. The results and recommendations also inform CCEOP planning, scale-up, rollout, and implementation in other countries as Gavi expands this approach to new geographic areas.

EVALUATION OBJECTIVES

The specific objectives of both components of the evaluation are listed below in Table 2. The findings from this evaluation will ultimately improve the platform's design, with both country-level implementation and market-shaping in mind.

Table 2. CCEOP Evaluation Objectives

COUNTRY LEVEL	MARKET SHAPING
 Determine the relevance of CCEOP support with respect to alignment with existing government processes and the identified needs and priorities. Assess the effectiveness of the platform in achieving the objectives of the CCEOP investment. Identify the comparative efficiency of the CCE over time, from pre-CCEOP through Phase 1 implementation (initial phase), as well as the efficiency in management of the CCEOP investment. Determine to what extent CCEOP has improved cold chain management and processes and immunization outcomes and results. Determine the nature and extent to which CCEOP has contributed to the sustainability of the cold chain and immunization program. Identify the lessons learned from the rollout of CCEOP, including the challenges and how they were overcome. 	 Determine the relevance of the CCE market-shaping strategy and the market-shaping monitoring and evaluation. Determine the extent to which market-shaping activities are implemented as planned. Assess the effectiveness of the market-shaping strategy and activities in achieving the objectives and targets of the CCEOP investment. Examine continuous innovation of high-performing and optimal total cost of ownership (TCO) products. Determine the extent to which CCE market-shaping results are sustainable and the extent to which they result in unintended positive/negative consequences.

Note: Where applicable, the findings on CCEOP's effectiveness, efficiency, and outcomes/results will compare program facilities and control facilities in each country to the extent possible.

Appendix B outlines the country-level evaluation questions asked at each stage of the evaluation. Although the evaluation examined the effect of CCE improvements through CCEOP, it also examined the entire immunization supply chain system as a whole.

CHANGES TO EVALUATION QUESTIONS

Based on feedback from the midline evaluation as well as global context shifts over the course of this evaluation, such as the COVID-19 pandemic, we have adjusted some aspects of the overall evaluation questions to better understand a few key issues and drivers of relevance, effectiveness, efficiency, outcomes/results, and sustainability. These topics were discussed with Gavi before the endline assessment. Specifically, the endline assessment further probed on the following topics:

- Joint investment and how/if that contributes to sustainability and ownership. As Gavi was considering revisions to CCEOP, the joint investment of Gavi and country government funding was one element under consideration for change, to identify if it actually contributes to sustainability or if a different approach would do more for sustainability and to build country ownership.
- SBPs and de-linking. De-linking removes the SBP requirement for installation and enables the MOH to be responsible. This became a priority of the evaluation, as some CCEOP countries did not have an SBP option (e.g., Afghanistan), and in the case of

Kenya, the MOH felt it had the capacity to install and maintain CCE and preferred that the money that would have been spent on SBPs be invested instead in additional equipment.

- The impact of "dual brands" in a system that already has multiple brands. "Dual brands" refers to the two (or sometimes three) brands/models of CCE that are procured for each country. This topic is included to understand how the two brands procured by CCEOP are incorporated into the cold chain system that already has multiple brands, in terms of management and maintenance complexity.
- The effectiveness of training done by the SBPs. Baseline results indicate that stakeholders were not completely satisfied with the training provided by SBPs. This topic was further explored to gain more insight into this aspect of the SBPs.
- The impact of COVID-19 on the CCEOP process. The COVID-19 pandemic disrupted the entire world, and as such, it was included in the evaluation to understand the context of and impact on CCEOP activities.

Gavi's request for proposal (RFP) for the CCEOP evaluation identified key questions regarding the relevance, implementation, effectiveness, and sustainability of the market-shaping component of CCEOP. These questions guided the evaluation team's earlier evaluation efforts and deliverables related to CCEOP market-shaping activities and outcomes. With the release of Gavi's updated CCE market-shaping strategy (Gavi 2019) and changes from the previous strategy, the evaluation approach adapted in response to these changes and shifts in objectives and targets, while not losing sight of what was achieved and learned in Phase 1. We therefore updated the approach to the evaluation's market-shaping component to recognize the progress to date, the changes implemented in response to early learning, and progress toward achieving the updated market-shaping objectives. The original and updated market-shaping evaluation questions are presented in Appendix C.

FRAMEWORK AND EVALUATION APPROACH

To assess the effectiveness of the CCEOP mechanism at the global and country levels, the evaluation team developed two different evaluation frameworks, one each for the country-level and market-shaping components.

COUNTRY LEVEL

Drawing on the expected processes in CCEOP design, planning, installation, and maintenance; the CCEOP results framework; and the performance framework, we developed an evaluation framework to guide the country-level evaluations (see Figure 2). This framework examines the pathway toward achieving the expected objective of immunization coverage as a result of establishing the CCEOP in selected countries. It uses indicators and demonstrates pathways aligned with the Gavi CCEOP theory of change, results framework, and country reporting requirements.

CCEOP success relies on the inputs of and coordination among all partners — Gavi, procurement organizations, manufacturers, SBPs, and technical assistance providers — who

will work closely with country governments. CCEOP also depends on an effective, participatory, coordinated, and planned effort by different levels of the health system, both in putting the CCEOP application together and in ensuring that it is implemented as per plan. Although the CCEOP focus is primarily on replacing underperforming equipment in existing sites and increasing equipment availability in the early years, the framework also takes into account CCE provision to new sites, which will take place later. Furthermore, to the extent possible, CCE availability through other channels and partners is also taken into account.

Overall, CCEOP success is measured not necessarily based on its effect on a more efficient immunization supply chain (and, in the longer term, vaccination coverage) but on the development of a long-term sustainable system that countries are interested in sustaining over time.

This framework guides the evaluation process and has been fine-tuned and finalized in consultation with Gavi to ensure that it is appropriate and feasible for the proposed evaluations. The evaluation examined the linkages in the proposed pathways to understand where blockages may impede the achievement of expected outputs and outcomes or why the process may have been successful in selected areas. Undertaking data collection at multiple timepoints — before CCEOP installation in countries and two years after — enabled observation of changes over time. The evaluation considered the country context, the supply chain distribution system in the country, and coordination with other development partners, all of which may have played an influential role.

Although all efforts were made to examine the linkages from inputs to outcomes, it is essential to note that the effect on all outcomes was not observed in this current evaluation. For example, the effect on long-term outcomes, such as increases in immunization services, will likely be observed over a longer timeframe.

MARKET SHAPING

Gavi's market-shaping evaluation framework (see Figure 3) looks at the market characteristics before and after introducing CCEOP to see how the platform addressed the identified root causes of the unhealthy market conditions that catalyzed CCEOP's creation, and how the platform achieved the desired outcomes. The evaluation increases understanding of overall market health, market changes, and unintended consequences, both positive and negative, over time.

The market-shaping component used both quantitative and qualitative metrics to provide insight into the overall health outputs and impact. With each data collection timepoint, this component examined how well CCEOP achieved its goals to date and how well it is set up to continue to achieve its goals.

Figure 2: CCEOP Evaluation Framework

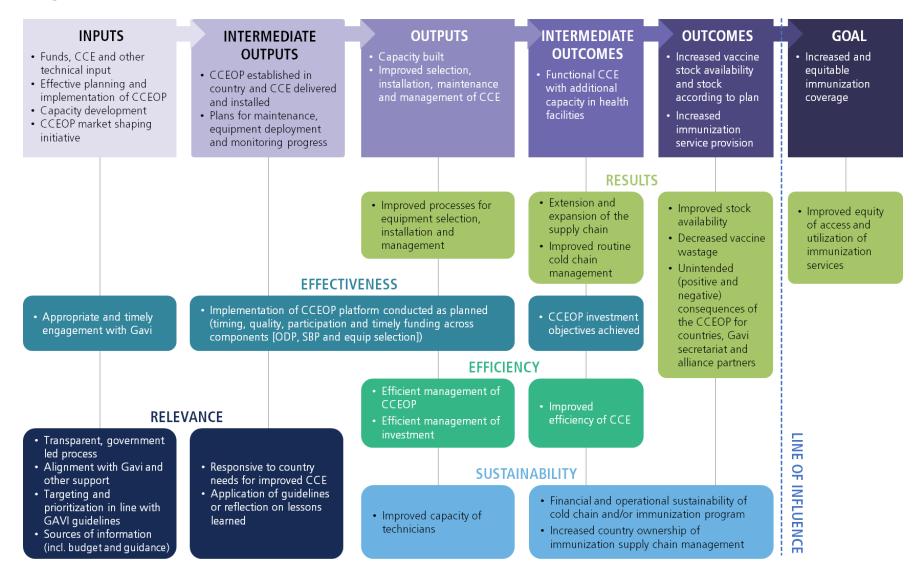
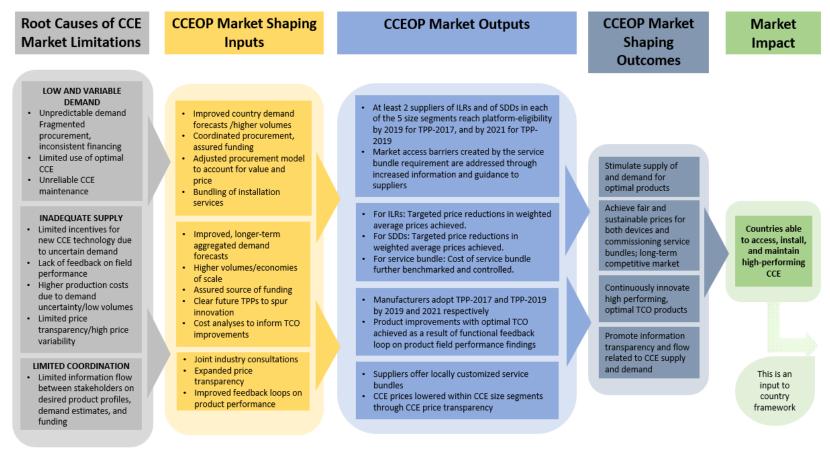


Figure 3: Gavi's Market-Shaping Evaluation Framework, Based on the Gavi CCEOP Theory of Change (Gavi, n.d.)



DESIGN AND METHODS

COUNTRY EVALUATION

DATA SOURCES AND METHODOLOGY

As described in the country evaluation protocols, the country-level endline assessments followed a mixed-methods concurrent design approach, including data collection from a variety of sources — document review, direct observation of the CCEOP planning and implementation process (when possible), KIIs, and an HFA. Data from the health management information system (HMIS) or logistics information management system (LMIS) could not be used to the extent intended because of problems with data quality.

The qualitative component included KIIs at different levels of the health system, from the national level to the health facility level, and included all stakeholders and SBPs in each country. The KIIs were conducted using semi-structured interview guides customized for respondents at various levels of the health system. National-level respondents were asked about procurement, choice of CCE, and cold chain gaps; ODP and its implementation; the role of SBPs; CCE maintenance, repair, and warranty; and overall satisfaction and the possible effect on outputs and outcomes. Interviews with SBPs focused on market shaping and SBPs' role in ODP implementation. Interviews at the county/province levels and below asked respondents about their role in CCEOP, the choice of CCE, how the first year of CCEOP deployment was managed on the ground, their overall satisfaction, and their views on expected outputs, outcomes, and sustainability.

The quantitative component was an HFA in selected facilities in the sampled districts. The HFA's purpose was to establish a follow-up measure of indicators at health facilities and subcounty/district stores/depots, including frequency of immunization services provided; CCE inventory and functional status; maintenance history and procedures; stock history and stockon-hand of two tracer vaccines, Pentavalent/DPT (diphtheria, pertussis, and tetanus) and measles-containing vaccine (MCV); and staff training on stock management and CCE maintenance. Both qualitative and quantitative data were collected simultaneously at each data collection timepoint.

SAMPLING

The sampling approach is somewhat consistent across the three countries to facilitate crosscountry comparison. Because it is not feasible to conduct the evaluation in all areas receiving CCEOP support, the approach focuses on targeting selected regions and obtaining in-depth information.

The evaluation team worked with the MOH and other stakeholders in each country to identify the provinces/regions/counties to be sampled. The final sampling areas at the district/sub-county and health facility levels for baseline and future assessments were selected using a list of criteria that included low vaccination coverage, remoteness, and priority status for CCE

deployment. In general, a mix of high- and low-CCEOP-coverage districts/sub-counties was selected in each selected province/region/county across the three countries. Each endline country report and the associated research protocols provide more specific details on sample selection at each level of the health system in each country.

In all three countries, most facilities in both the program and control arms (more than 80 percent) were located in rural areas, in alignment with CCEOP deployment patterns in countries to ensure equity in immunization coverage. In Guinea, with the further disaggregation of health facilities into health centers and health posts, slightly more than 60 percent of health centers in both arms were in urban areas, while health posts were predominantly rural.

In all countries, a significant majority of facilities are publicly owned. In Guinea and Pakistan, 100 percent of facilities are publicly owned. Kenya had a small percentage of privately owned facilities included in the sample: 6 percent among program facilities and 14 percent in control facilities due to the CCEOP Year 1 deployment priorities, which focused on public facilities.

The endline assessment in each country used the same sample of facilities selected for the baseline and midline but made small adjustments. In Kenya, the endline sample was adjusted because it was found that deviations during deployment resulted in some program facilities not receiving equipment, while some control facilities did. Similarly, there were slight adjustments in Pakistan as well; baseline and endline data collection covered the same facilities. More specific details on the data, sample, and methodology are available in the country evaluation protocols and endline country assessment reports.

The annex to this report includes a summary of the country evaluation methodology, including details of the sampling for each country, as well the KII guides and HFA tool used in the endline assessment. Figure 4 presents the timeline of different evaluation-related activities at the country level.

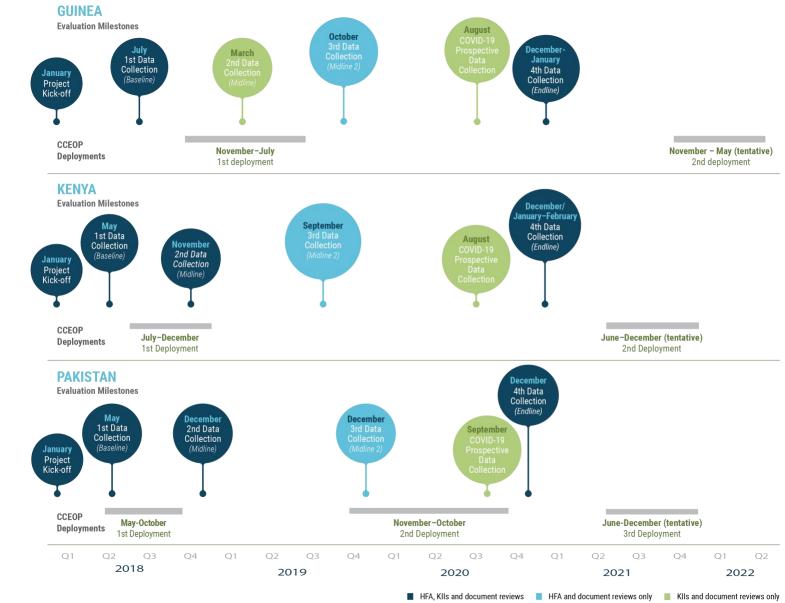


Figure 4: Timeline of Country Evaluation Activities in the Three Focus Countries

DATA MANAGEMENT AND ANALYSIS

The evaluation used a case-control research design to understand the differences between areas receiving and not receiving new equipment through CCEOP over the entire evaluation period. At each data point of this prospective evaluation, different questions were addressed. The endline evaluation focused more on understanding the situation across the three countries soon after CCE was installed under the CCEOP, and to document any pre-existing differences between the two types of health facilities: program facilities (scheduled to receive CCEOP equipment in Year 1) and control facilities (not scheduled to receive CCEOP equipment in Year 1). Because some control facilities also received CCE in the next round of deployment, we made efforts to align the sample based on data on the deployment of CCE procured through other funding sources, depending on the data available during sample selection.

The HFAs were analyzed throughout the evaluation to demonstrate these changes and how they relate to CCEOP implementation in the country. The analysis also documented aspects of the CCEOP planning and implementation process, including deployment and details about maintenance, repairs, and warranty. Whereas the midline captured changes through the post-deployment period, including the effect on selected outputs, the endline focused more on the effects and expected outcomes of CCEOP, along with a focus on overall systems strengthening.

The evaluation obtained approval under the non-research category from the JSI Institutional Review Board (IRB), followed by MOH/EPI approval in each country at each data collection timepoint. All data were collected after sufficient training of data collectors and receiving informed consent from all respondents. All data were anonymized so that identification of respondents was not possible, and all data were stored securely. More detail on ethics and other data management procedures are available in the section on the evaluation methodology for each country in the annex to this report.

For the endline assessment, the KIIs were transcribed, coded according to thematic areas based on the evaluation questions, and then analyzed using NVivo 12 software. Themes at the county/province level and below focused on site selection for CCE, the overall implementation process, and knowledge of procedures for repair and maintenance. Examples of themes developed at the national level were the CCEOP planning process, oversight of implementation, interaction with SBPs and plans for maintenance and repair, the warranty, expected outputs and outcomes, and long-term sustainability. While all effort was made to ensure availability of quality data also through comparison of findings obtained from difference stakeholder groups, the possibility of information bias as a result of social desirability exists.

Data from the HFA were analyzed using Stata 14, and frequency tables were generated. Analysis at the sub-regional level comparing high- and low-intervention areas was not feasible given the small number of facilities in each category by district. Thus, data were disaggregated by county/province to make regional comparisons between all program facilities and control facilities. Data analysis at endline examined changes over time and noted any trend differences between the two groups. Because the actual deployment, especially in Pakistan, did not follow the grouping of program and control facilities, findings from the quantitative analysis (in Pakistan, in particular) need to be interpreted with caution. Results from the HFA were triangulated with responses from the KIIs to ensure consistency and accuracy and to provide further explanation.

VALIDATION OF FINDINGS

The country-level evaluation findings and recommendations were shared with key stakeholders in each focus country at each stage of this prospective evaluation. To the extent feasible, subnational-level stakeholders also participated in these discussions. Validation and dissemination meetings conducted in each country informed key stakeholders, and the final recommendations were refined based on their input.

Issues of concern in each country also contributed to the data collection instruments in that country at the next stage of the evaluation. For example, issues related to SBP de-linking were especially relevant in Kenya, and discussions of equipment from one manufacturer played a prominent role in Kenya.

On the endline assessment's completion, validation meetings were held in Kenya and Pakistan to review the findings and recommendations, and preliminary findings were shared in Kenya. A meeting with all key stakeholders was held in June 2021, and all findings and proposed recommendations were reviewed and revised with country input. A discussion was possible in Pakistan also at the province level, and the meeting in Guinea is scheduled for the near future.

MARKET-SHAPING EVALUATION

The market-shaping component of the evaluation focuses on the global-level CCE marketshaping activities and results. It complements the deep dive, three-country evaluation in Guinea, Kenya, and Pakistan, which covers the results framework from inputs to outcomes, looking at achievements over three years from 2017 through the end of 2020.

The CCEOP market-shaping evaluation followed a different timeline due to annual procurement cycles and related performance indicators and a strategy shift mid-CCEOP. The first report was completed in 2018 and then updated with new findings in the midline cross-country report. In mid-2020, the evaluation team completed the final, comprehensive market-shaping evaluation report detailing the approach, methodology, data collection process, and findings. The market-shaping evaluation provides a better understanding of the overall market health for CCE, market changes, and unintended consequences, both positive and negative.

Over the three-year period, the evaluation team has assessed how well the CCEOP marketshaping strategy has achieved its goals to date, assessed how well it is set up to continue to achieve its goals, and provided recommendations for fine-tuning the approach as appropriate. Throughout the evaluation period, the market-shaping reports were shared with Gavi and UNICEF for review and input before being finalized. Early findings were reviewed by relevant CCEOP working groups and informed updates to the market-shaping strategy. The <u>final report</u> has helped support adjustments to the longer-term market-shaping plans for CCE. To complement that report, this report captures findings from global-level KIIs conducted from March 5th–April 15th, 2020, with stakeholders who were either implementing or affected by the market-shaping strategy, and links to market shaping-related findings from the endline in the three focus countries to round out the understanding of relationships between the country experiences and global-level market-shaping efforts.

In addition to KIIs, this evaluation relies on secondary data related to initial procurement experience and results and CCE pricing, provided by Gavi and the UNICEF Supply Division (SD), and findings from the endline evaluations conducted in Guinea, Kenya, and Pakistan. Details of the methodology for the market-shaping evaluation, including KII respondents and secondary data sources, are available in the 2020 market-shaping report.

STRENGTHS AND LIMITATIONS

This evaluation has several strengths and limitations, outlined below:

STRENGTHS

- This evaluation follows a prospective design that enables an understanding of the entire process of CCEOP planning and implementation and its effect on relevant outcomes at different stages. It allows us to follow the same group of health facilities over time to examine changes taking place in real time over almost four years, with a three-year period between the baseline and endline assessments.
- The mixed-methods approach uses data from all relevant sources at each timepoint of the evaluation. While the quantitative data show trends and changes in indicators over time, the qualitative data help demonstrate the reasons for these changes and provides information on planning and implementation processes related to the CCEOP in each country. These data are triangulated with data compiled through document review and routine data sources as appropriate.
- The study's case-control design enables a comparison of these changes over time in facilities with greater exposure to CCEOP versus those with less or delayed exposure.

LIMITATIONS

- The three-year timeframe of the evaluation (focusing on the initial support phase of CCEOP) may limit the evaluation to examining changes in outputs related to CCEOP installation and deployment. It may not provide sufficient information on changes in key immunization outcomes within this timeframe.
- This mixed-methods evaluation relies on the triangulation of data from multiple data sources. However, without primary data collection on immunization outcomes, it may be hard to establish causality and attribution to demonstrate the effect and impact of CCEOP best. Furthermore, the ability to make district-level comparisons attributing expected changes to CCEOP may be limited even when using district-level HMIS/LMIS data for which quality is not guaranteed.

- Overall, aspects of the evaluation design and real-world complexity affected implementation and interpretation of findings from this evaluation:
 - Given the small sample size of health facilities in the HFA, the analysis and comparisons (broken down by region in each country) are purely descriptive. In the HFA, we cannot compile data and control for characteristics such as funding, supervision, and community engagement at the facility level. At a broader level, following the mixed-methods approach, we try to take into account these influences as we analyze these data alongside the qualitative data.
 - Although a case-control design is followed in conducting the HFA, the number of facilities in the HFA sample is insufficient to conduct statistically meaningful comparative analyses between intervention areas and low- or late-intervention areas. Nevertheless, the HFA does provide a snapshot of the progress in intervention facilities and low- or late-intervention facilities over time and comparative improvements between the two groups, which in turn can provide insight into the effect of equipment acquired through CCEOP.
 - In some countries, such as Kenya, other donors, such as the World Bank, also provide CCE. After CCEOP deployment, the country has also seen the movement of older equipment among facilities. Though this evaluation attempts to take these into account and separate out the specific effect of CCEOP, it is limited by the information available. It, therefore, relies to a great extent on the country's CCEOP deployment strategy. The evaluation also tries to compare districts with high and no/low CCE installation through CCEOP.
 - The evaluation design is based on available information at baseline deployment of CCE in Year 1. We are aware that facilities in the no/low CCE comparison group may have had CCE installed in Year 2. Adjustments in the design and interpretation were needed in that case. Deviations in the deployment of CCE from the ODP, as well as other movements of older equipment by the MOH among facilities, also affected the study design and resulted in changes in facilities sampled later.
 - Sampling for the endline was based on the ODP; sometimes changes were made to deployment, but this information was not always available prior to data collection. As a result, some control facilities received CCE in Year 1 and some program facilities did not. In addition, in Pakistan, most facilities were scheduled to receive CCE by midline and/or endline (late intervention). In Kenya, adjustments to the sample based on this information were made before data collection, but this was not possible in Pakistan. Therefore, there is not a true control group in Pakistan, and any difference in findings between the program and control groups from the HFA are not as meaningful.
- The expansion of the analysis to cover RTMDs is restricted based on the availability of current data and how assessing RTMDs fits with the evaluation design.

- Although some information on costs is provided based on available data, the evaluation did not include an in-depth cost-effectiveness analysis examining expenditures on CCE.
- There were challenges in accessing relevant HMIS and LMIS data in all three countries. Data accessed could not be triangulated with HFA data at the endline as planned because the data were of poor quality. When drafting this report, data on relevant CCEOP-related indicators were also not available from the country Grant Performance Frameworks.
- Although the broader context is taken into account, the focus of this analysis is restricted to CCEOP and does not cover overall supply chain performance. As a result, examining the effect of CCE on, for example, transport frequency or missed opportunities was beyond the evaluation scope. However, some of this information was captured in the data on stocks compiled. The analysis also excludes other program-specific detailed implications and cannot measure changes in demand size as a result of CCE.
- The COVID-19 pandemic caused disruptions in routine immunization and supply chain in each country. The pandemic also delayed endline data collection, moving it from March 2020 to December 2020. While the evaluation conducted a prospective monitoring activity during the pandemic, the findings of which are mentioned in this report, it is hard to assess the residual effects of the pandemic on the evaluation outcomes.

Overall, this evaluation relies most on the qualitative data collected and analyzed. While program/control group differences in the quantitative data are presented, the findings are most useful to represent a snapshot of the situation in health facilities in general and how they have changed from baseline. The quantitative data are better suited to capture outputs and intermediary outcomes of CCEOP implementation, such as breakdowns, stockouts, and temperature monitoring, and are able to capture immunization outcomes and results to a limited extent. This could be attributed to both the timing of the evaluation in the early stages of post-CCEOP implementation and the fact that there are other confounding factors that influence the relationship between CCEOP implementation and these outcomes.

SUMMARY OF PRIOR FINDINGS

This section summarizes findings from the baseline and midline assessments conducted as part of the country and market-shaping evaluations. These findings were documented in the baseline and midline evaluation reports, results of which were shared in the three countries, and action steps were taken, which are also documented below.

BASELINE AND MIDLINE ASSESSMENT FINDINGS

CCEOP RELEVANCE

- CCEOP responds to country needs and priorities and is well coordinated by the PMT in country with other partners for overall systems strengthening. However, better documentation could improve coordination and planning.
- At baseline, stakeholder engagement was high but limited beyond the national level. In Kenya and Pakistan specifically, the PMT played an active role in CCEOP deployment and coordination; by midline, this was the case in all three countries.
- Respondents were satisfied that the CCEOP application and ODP adhered to Gavi guidelines and used available systems and cold chain inventory data.

IMPLEMENTATION AND EFFECTIVENESS

- Respondents at all levels were mostly satisfied with the installation and commissioning of CCE by the SBPs. However, stakeholders in Kenya were concerned that the cost was too high for a service they felt the MOH could provide.
- The robust system of monitoring and documentation established for equipment deployment was effective at tracing equipment and ensuring accountability from the SBPs.
- The few deviations in deployment were effectively handled locally, with no reported additional costs incurred. Accurate deployment plans must include a level of flexibility, especially at lower levels, to respond efficiently and effectively to on-the-ground situations in a timely manner.
- The PMT played an active role in CCEOP deployment and coordination, demonstrating ownership and strategic thinking, although documentation could be improved.

EFFICIENCY

 Satisfaction with the SBPs' efficiency and quality of work was generally good, but concerns remain about the cost and their response to warranty issues, particularly in Kenya.

OUTCOMES AND RESULTS

• **Stockout data is inconsistent**, with fewer stockouts of Pentavalent at midline yet more stockouts of measles vaccine, with variations among the countries. This implies that

there are many influencers, including national-level stockouts in the case of the measles vaccine in Kenya.

SUSTAINABILITY

- Stakeholders did not fully understand all the details of the warranty. Many were unclear on SBP terms of reference and what they were/were not contracted to do to set expectations for performance.
- SBPs provided insufficient training to facility staff. With regard to long-term sustainability, technicians in Guinea and Pakistan at midline had inadequate capacity for corrective maintenance, unlike in Kenya. However, even in Kenya, technicians at the sub-county level expressed interest in more training. Countries were not implementing a maintenance plan at the national and sub-national levels.

OVERALL

- In Kenya and Pakistan at midline, there was no reported plan for decommissioning equipment. This was not applicable in Guinea since facilities selected to receive CCE did not have other cold chain equipment.
- At midline, some facility personnel in Kenya and Pakistan were not well oriented on the shift to using cool packs (instead of ice packs) for outreach activities. In Guinea, health post staff were unclear on whether/when to start using the installed CCE for stocking vaccines. This indicates the challenge of ensuring that policy changes are fully communicated and implemented specific to CCEOP as well as the overall system.
- Despite global guidance, there was no clear mechanism in country to monitor CCE performance over time (after the installation check) and provide feedback to manufacturers at the time of the midline assessment. With warranty processes unclear in many places, it was uncertain whether SBPs or the UNICEF Country Office would report breakdowns to the UNICEF SD.

MIDLINE MARKET-SHAPING ASSESSMENT FINDINGS

Findings from the market-shaping evaluation conducted in 2019 are outlined below. These findings were communicated and considered part of the updated market-shaping strategy finalized in mid-2019.

- The original market-shaping goal was to ensure two platform-eligible suppliers of ILRs and SDDs per size segment. The supply of CCE continued to expand, with 9 of the 18 CCE segments tracked exceeding the original goal. As of February 2019, there were 6 suppliers of platform-eligible ILRs producing 23 different platform-eligible models, up from 20 in July 2018 (15 percent increase). For SDDs, 7 platform-eligible suppliers produced 36 different platform-eligible models, up from 33 models in July 2018 (9 percent increase).
- Procurement did not keep pace with initial annual forecasts for CCE shared with suppliers at the outset of CCEOP due to delays in implementation. As of December

2018, procurement orders had been placed for approximately 20,000 units of CCE, roughly 43 percent of the 46,000 units forecast to be procured by the end of 2018. Tenders for the first 25 countries (including Year 2 procurement) were skewed toward two suppliers based on country preferences, undermining the CCEOP market-shaping objectives to create a healthy market.

- Delays in applications, decision letters, implementation, and procurement trends raised questions about the credibility of CCEOP demand forecasts, which may undermine ongoing decisions by suppliers to produce or innovate for this market.
- Suppliers, particularly those not seeing significant procurement volumes, felt that the tender award process was opaque and did not reward investments already made in product innovation and lower-TCO options. They wanted UNICEF SD to provide more timely feedback on expected award dates and feedback on tender outcomes.
- Limited data on longer-term CCE field performance and the ability to compare across a wide set of features made it difficult to accurately assess various contexts and compare value for money or TCO in selecting equipment.
- Questions and concerns persisted around the tendering and CCE selection processes and the role of country preferences. For the suppliers that had not seen significant volumes of POs as of Q3 2018, there was a particular sense that the practices and outcomes to date were at odds with the CCEOP goal of promoting innovation, competition, and value for money.
- The service bundle mandate was the most significant source of conflicting feedback. Global and national stakeholders felt that it had complicated price negotiations and efforts to ensure value for money. Countries, specifically national-level stakeholders, valued the service provided but were concerned that the added costs of SBPs on top of CCE costs limited their ability to obtain the number of CCE needed. Suppliers appreciated the opportunity to ensure that their CCE was installed correctly but felt they were bearing all the risk and uncertainty. Some suppliers felt the service bundle mandate forced them into a service area outside of their core competency.
- Information flow and transparency among partners, countries, and manufacturers made progress under CCEOP. Gavi, UNICEF (the Supply and Programme Divisions), and WHO were all cited by stakeholders for their efforts to coordinate and improve information sharing among themselves, countries, suppliers, and SBPs.

ACTIONS TAKEN AND GLOBAL LANDSCAPE SHIFTS

In the course of the evaluation and in response to the evaluation's findings, feedback from countries and partners, and a global pandemic, Gavi and UNICEF have implemented some changes to CCEOP processes and priorities that are worth noting here.

COVID-19 PANDEMIC

Immunization services experienced disruptions early in the pandemic, as there was a decrease in care seeking and outreach services were suspended for several weeks. Since the initial

surge, however, services have mainly returned to normal, with minimal shifts in service delivery due to some facilities being used as isolation centers (Kenya specific). In terms of the health system, there were some reports of funding allocated initially for vaccine distribution or maintenance being shifted toward activities to address the pandemic. There were minimal disruptions to CCEOP implementation.

Additionally, Gavi quickly adapted the CCEOP mechanism to support the COVID-19 response and cold chain procurement for the new vaccine.

MAINTENANCE

Recognizing that CCE maintenance is still a gap in ensuring that the investment in new CCE is kept safe, the global conversation has shifted to highlight the importance of maintenance. Gavi recognizes that using SBPs is not a long-term solution and does not encompass non-CCEOP equipment. Through this global shift in conversation, Gavi and partners are exploring different modalities of CCE maintenance systems, a much-needed focus on this system gap.

SERVICE BUNDLE DE-LINKING

While the SBP approach has shown to be effective in certain situations, it is recognized that using SBPs is not feasible in some countries and is not preferred by others. In response, UNICEF has redesigned the service bundle options to be tailored to the country's expertise, preference, and feasibility, and approval is based on a clear set of criteria and is determined on a case-by-case basis.

CCEOP PROCESSES

Initial findings from the baseline indicated a somewhat slow CCEOP process from application until CCE installation. In response, UNICEF revised the proposal process to shorten the timeline from proposal submission to approval and ultimately to CCE installation. Additionally, to provide more options for country preference, the proposal process now requests countries to identify three top choices of CCE to facilitate the approval process; this also allows for more contribution to the market-shaping efforts.

MARKET SHAPING

The Alliance and partners recognized early on that the original market-shaping strategy for CCE needed to be revised to address some of the initial results and unique challenges posed by CCE. In response to this, in 2019, Gavi and partners released the revised Supply and Procurement Roadmap for ILRs and SDDs. Four strategic objectives support the market-shaping strategy:

- Improve long term competition and increase the evidence base to inform country preferences
- Achieve reductions in weighted adjusted price (WAP) to maximize value to countries
- Reform procurement processes for greater efficiencies

• Ensure innovation is driven by country preferences and future target product profiles

The revised market-shaping strategy allowed more active management of procurement. It provided a limited opportunity to inject competition into the market, while simultaneous efforts were underway to continue improving the information available to countries to inform product selection.

The revised strategy introduced the differentiated tender approach to better allocate demand across multiple suppliers to:

- Create opportunities for less established suppliers
- Create both familiarity and an evidence base on new CCE
- Ultimately try to prevent suppliers from prematurely leaving the market

The differentiated approach segments countries by volume to optimize efficiency and market outcomes. For lower-volume countries, the tender process is limited to one to three suppliers invited to bid. In high-volume countries, countries are requested to allocate 25 percent of procured CCE to a second supplier.

CCEOP PLATFORM ELIGIBILITY CHANGES

Information received after the pre-midline assessments shows that WHO PQS received complaints from UNICEF that specific models of [Manufacturer 1] equipment, including those recently deployed in Kenya and Pakistan, had an abnormally high rate of freeze alarms as a result of repeatedly recording temperatures below -0.5 °C for more than one hour.

'This resulted in eight CCE models being temporarily suspended, and a corrective action plan was drafted to address the issue in places where these models were already installed. The corrective action plan also ensured that newly produced models met PQS standards. During the temporary suspension period, some countries chose to wait for these models to be reinstated, whereas others shifted procurement plans to other CCE. The endline evaluation took this into account in the analysis conducted.

ENDLINE EVALUATION FINDINGS

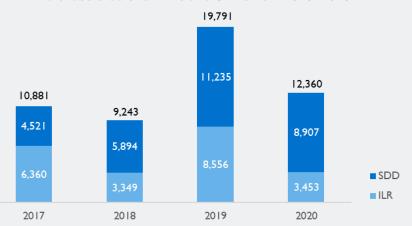
SUMMARY FINDINGS

GLOBAL MARKET

CCEOP achieved the overall goal of getting large quantities of optimal products procured, distributed, and deployed in a short amount of time. New and functional CCE is installed and helping to protect the more than \$1 billion of vaccines that Gavi and governments procure. Overall, CCEOP is considered a success in rapidly expanding the use of longer-lasting CCE with lower TCO, replacing broken and obsolete equipment, and increasing use of SDDs that require minimal maintenance.

Over the course of the first five years of CCEOP (2016 to 2020, though the first procurement did not occur until 2017), purchase orders were placed for 52,275 units of ILRs and SDDs (21,718 ILRs and 30,557 SDDs) for 45 countries* with CCEOP funding.

Procurement volumes were on track to meet the revised forecast of 65,000 units of ILRs and SDDs to be procured by the end of 2020 with CCEOP funds. Delays in processes due to COVID-19 meant this target was not met, yet overall procurement of CCE via UNICEF (CCEOP and non-CCEOP) exceeded this target.



Purchase orders for ILRs and SDDs from 2016–2020

Source: Gavi 2021. Gavi CCEOP Database — CCEOP procurement database_January 2021.xls (confidential) Gavi CCE Procurement database

*NOTE: CCEOP-funded procurement only. All procurement data was provided by Gavi. In some cases, discrepancies were noted with annual figures reported by UNICEF SD, but Gavi and the evaluation team agreed to use these figures.

COUNTRY ACHIEVEMENTS AND CHANGES FROM BASELINE/MIDLINE

- CCEOP successfully improved the availability of optimal CCE. The availability of highperforming and reliable equipment at endline significantly improved over baseline, as to be expected. CCE is largely performing well across the countries.
- CCE maintenance needs to be prioritized. Even though the new CCE introduced improved efficiency of the system through less immediate need for maintenance, endline uncovered concern for the ongoing maintenance required of all CCE (not just that procured through CCEOP). Globally, key stakeholders have begun prioritizing maintenance by developing innovative approaches and exploring funding mechanisms.
- CCEOP strengthened country-level management systems through the PMT. This was evident at all data collection points. Endline findings reinforced the PMT's capacity for strategic thinking and applying lessons learned from CCEOP implementation for planning cold chain needs and model preferences.
- Innovation offered through the SBPs. At midline, respondents were mostly satisfied with the quality of services provided by SBPs for installation (with notable concern in Kenya over the additional cost and MOH capacity to do the same work). At endline in Kenya and Pakistan, there was less satisfaction with the quality of services provided by SBPs for ongoing maintenance and support. By contrast, one SBP in Guinea demonstrated exceptional services, providing routine preventive maintenance to the facility level. An additional finding from midline was the robust system of monitoring and documentation for the SBPs; this process should be applied to countries moving forward with de-linking the SBPs.
- Immunization services are now offered more days per week. This became apparent at endline through the HFA. However, results showed inconclusive influence on improvement in immunization coverage rate.
- Vaccine stockouts continued to be as inconsistent at endline as they were at midline, albeit slightly improved in Guinea and Kenya without any documented reason. This reinforces the finding that many influencers beyond CCE can impact the availability of vaccine stock.
- **Training performed by the SBPs was considered insufficient**. This finding did not change at endline. However, training requirements and expectations should be refined to the specific audience. Cold chain technicians need a more detailed technical training, while health workers at facilities need a training focused on basic preventive maintenance.
- Communication can improve across all lines and stakeholders. Endline findings did not change from midline in terms of the need for improved communication and information sharing between national- and sub-national-level stakeholders. Additionally, there are opportunities for UNICEF to more actively engage with the PMT and MOH — for example, during the SBP contracting process. The need to understand the warranty and the role of the SBP continued to be prevalent at endline.

COUNTRY-LEVEL FINDINGS

A summary of country-level findings for Guinea, Kenya, and Pakistan from the endline evaluation is presented below. While these findings are based on all data available, comparisons between program and control facilities were not always possible. Nevertheless, the HFA does provide a snapshot of the progress in the two groups over time, highlighting comparative improvements between the groups, which in turn can provide insight into the effect of equipment acquired through CCEOP. Findings related to sustainability for the most part reflect the situation across the health system as a whole.

	Guinea	Kenya	Pakistan
CCEOP RELEVANCE			
Transparent Process and Stakeholder Engagement			
Finding 1: CCEOP planning was a transparent, inclusive, government- led process in general but with limited contribution from the sub- national level for planning and application processes.		•	O
Finding 2: Some gaps exist in the transparency of the decision-making process for equipment selection.		•	•
In Response to Country Needs			
Finding 3: Previous experience with the equipment and information from UNICEF, WHO, and Gavi influenced equipment selection.	Ð	0	
Finding 4: Country-level decision makers will consider the cost and implementation of the warranty and the effort to standardize CCE models for future equipment selection.	O	Ð	Ð
IMPLEMENTATION AND EFFECTIVE	ENESS		
CCE Availability			
Finding 5: CCEOP has successfully and substantially increased the availability and capacity of the cold chain system.	O	•	¢
Finding 6: Some facility-level respondents felt the current capacity through new CCE procured was not appropriate to facility needs.		•	•
Finding 7: The manufacturing issue with equipment from one manufacturer cast doubts on the quality of equipment promoted by CCEOP and the necessity of the warranty.		•	
Maintenance			
Finding 8: While training improved technicians' capacity considerably, there still appear to be some gaps in expectations and quality of the training provided on CCE maintenance, including preventive maintenance with health workers. *Also relevant for sustainability	¢	¢	¢
Finding 9: The CCE maintenance system has yet to see improvements. New models of equipment installed in countries have exacerbated this divergence in maintenance systems, as SBPs are currently engaged. *Also relevant for sustainability	•	•	•
Finding 10: Having multiple CCE brands has negatively affected knowledge of warranty and corrective and preventive maintenance practices. *Also relevant for sustainability	•	•	•
SBP Implementation			
Finding 11: There are inconsistencies in services provided by SBPs and warranty coverage across the three countries.	•	•	•

	Guinea	Kenya	Pakistan
Coordination and Communication			
Finding 12: The CCEOP is coordinated with other donors and partners for overall system strengthening, although better documentation could improve the coordination and planning.	•	•	•
Finding 13: There was a lack of clarity in the requirements during the proposal stage, with long delays and continued back and forth between the PMT and UNICEF related to the de-linking approach.		•	
Finding 14: While communication between and within health system levels has improved since baseline, critical vertical communication gaps persist, such as between the facilities and higher levels around warranty issues. Horizontal communication gaps also continue between the SBPs and the MOHs.	•	•	•
Temperature Monitoring			
Finding 15: Largely, temperature monitoring at the facility level is implemented using 30DTR, even if RTMDs are available.	•	•	•
Finding 16: While national staff was very satisfied with the RTMDs, the RTMD dashboard is often unavailable for sub-national staff, especially at the facility level.		•	
EFFICIENCY			
CCE Performance and Maintenance			
Finding 17: Most respondents are very satisfied with the CCEOP equipment, which brings cost savings, less maintenance required, and better performance.	Ð	Ð	Ð
Finding 18: The new CCE is functioning very well, with high levels of safe time within the expected temperature range.	0	•	¢
Finding 19: Decommissioning of old equipment is still not clearly implemented.		•	
OUTCOMES AND RESULTS			
Finding 20: There were fewer vaccine stockouts reported at endline in Guinea and Kenya, although the reasons are unclear.	0	Ð	
Finding 21: New equipment has expanded the reach of immunization services and increased CCE capacity.	0	•	¢
Finding 22: While there is evidence that the frequency of immunization sessions has increased, the impact of CCE on the immunization coverage rate is inconclusive.	•	•	¢
SUSTAINABILITY			
Country Ownership			
Finding 23: CCEOP has contributed to the growth of some national- level planning and management structures and systems, such as the PMT and NLWG, yet it is not clear that it has fostered ownership through all levels of the system.	€	¢	•
Finding 24: There was little indication that the joint investment (Gavi and country government funds) contributed to financial sustainability or country ownership.	⊜	⊖	⊖
System Strengthening			

	Guinea	Kenya	Pakistan	
Finding 25: Warranties will soon expire, and weak maintenance systems will find it challenging to fill the gap.	•	•	•	
Finding 26: The overall health system has not kept pace with the new CCE in terms of the need for more resources.	•	•	•	
Positive finding Negative finding Neutral finding Mix of positive and negative findings Note: Cells without a marking indicate no response or not applicable for that country				

More details on the country-level findings based on the evaluation themes are presented below. A summary of the findings from the HFA in each country is available in the annex to this evaluation report.

Transparent Process and Stakeholder Engagement

Finding 1: CCEOP planning was a transparent, inclusive, government-led process in general but with limited contribution from the sub-national level for planning and application processes.

Finding 2: Some gaps exist in the transparency of the decision-making process for equipment selection.

CCEOP RELEVANCE

Aggregated Findings

Results of the evaluation show that planning, preparing, and monitoring CCEOP activities was a government-led process across all three countries. The planning was a data-driven approach, using the cold chain inventory, cold chain expansion, and replacement strategy; budget ceilings; and priority strategies to improve coverage and equity. Baseline and midline results show that the availability of warranties was attractive in equipment selection; results of endline, however, cast doubts as to the full utility of the warranties. The PMT was a strong coordinating and planning mechanism and closely engaged with UNICEF and the SBPs for ongoing monitoring of implementation. A factor that persisted across all three countries throughout the evaluation is limited involvement at the sub-national level in planning and communication sharing. Not all relevant teams at the sub-national level were aware of the timelines and logistics of equipment delivery and installation, for example.

Guinea

Initial CCEOP planning was country led, by PMT members and key stakeholders. The continuous exchange of ideas and problem solving, backed by Gavi and UNICEF's technical expertise, reinforced PMT coordination for equipment selection, installation, and management of the cold chain system.

Kenya

Respondents indicated transparency and close engagement, particularly across stakeholders at the national level and with UNICEF and Gavi. Precise sub-national level engagement and information sharing was still lacking, as demonstrated by some inaccuracies in the ODP, which

required county officials to reallocate equipment to facilities where the equipment could be used more effectively.

Also related to transparency, Kenya requested to de-link the SBP, which added to delays in the approval process for the proposal and led to the "back and forth" before the de-linking was approved. Other national stakeholders noted frustration with requests for feedback or revisions, which were felt to give insufficient time for the country to prepare.

Pakistan

Respondents consistently indicated that CCEOP built upon country needs and was inclusive and transparent. Initial planning was a collaborative process between the federal EPI, WHO, UNICEF, and Gavi, in consultation with the PMT, NLWG, district officials, and facility staff.

One gap in transparency identified during endline was the lack of information available on the decision to not procure one manufacturer's equipment. Procurement of this equipment was temporarily suspended based on a WHO directive, despite its satisfactory receipt and use in country through the CCEOP mechanism. However, within the country system, the reasons for the decision were not clearly articulated at all levels of the system, nor was there clear communication to facilities on the extent of the problem.

Since the first deployment, the PMT has not been as active. Respondents also pointed out gaps in active engagement of the different levels of the health system, which could provide greater insight into cold chain-related issues for PMT decisions.

Response to Country Needs

Finding 3: Previous experience with the equipment and information from UNICEF, WHO, and Gavi influenced equipment selection.

Finding 4: Country-level decision makers will consider the cost and implementation of the warranty and the effort to standardize CCE models for future equipment selection.

Aggregated Findings

As the midline evaluation showed, stakeholders in all three countries reported that CCEOP and the equipment received to date through the procurement process met their needs. Equipment was selected based on a country-led process and determination of needs at the sub-national level through a cold chain inventory. Previous experience with the equipment, especially a negative experience, influenced future selection, particularly in Guinea and Kenya. The equipment cost and the terms of the procurement and warranty also played a role in the selection process.

Guinea

The main strategy employed in Guinea for prioritization of location and type of CCE to improve coverage and equity was to increase the number of service provision points (results of baseline and midline). Facilities with no equipment were equipped with CCE as a priority.

For the first deployment, the PMT played a significant role in selecting CCE, including visiting to examine the CCE and select the most suitable models. Initial CCE selection was based on prior experience with equipment and the intent to harmonize CCE in the country. The PMT selected CCE for the first deployment based on their experience first with the battery-powered solar refrigerator, followed by the solar-powered models. Other information for selection was existing information from UNICEF, WHO, and Gavi on CCE performance.

Other criteria for CCE selection were remote temperature monitoring and the CCE's ability to accommodate the anticipated volume of vaccines during its 10-year life. The PMT also expressed some concern about the non-availability of manuals in French for one of the CCE models and the implications of that for end users in facilities.

Although the COVID-19 pandemic affected the PMT's role in planning for the second deployment, some considerations in the choice of equipment included the performance of the installed CCE, ease of handling the CCE, cost of the warranty, efforts to standardize CCE models across the country and reduce the number of models being used, and plans for vaccine introduction over the next 10 years. Standardizing CCE models across the country was an important consideration because having fewer models installed would help improve management of installation, maintenance, and repairs over the long term.

Kenya

Baseline and endline results showed that the targeting and prioritization of location and type of CCE was informed by the cold chain inventory and the country's cold chain equipment expansion and replacement plan. Most respondents were very satisfied with the CCEOP equipment received. They noted that experience with certain pieces of equipment (positive and negative) was the main driver behind selection for the second deployment. In some instances, equipment from the first deployment did not always align well with the electricity available in a facility, resulting in different choices in the future. Specifically, dissatisfaction with the one manufacturer's equipment's performance affected CCE choice for the second deployment.

For example, a company like [Manufacturer 3] that was not part of CCEOP, but [the counties] are indicating that they are performing well, so they procured [for the next round of CCEOP]. That's how the selection of the equipment for the latter application came in. It was guided by the ministry and also the field experiences." RTMD capabilities were also found to be important when selecting equipment. Despite this, there is limited information on whether the remote monitoring and SMS-alert functionality are accessible by sub-county and facility staff.

The planning process for the first CCEOP equipment deployment was extended. Stakeholders reported confusion about equipment selection; duration of warranties; type of corrective maintenance/repair covered; the process for communicating equipment issues back to the SBPs and how the process would be monitored; and the total cost of equipment, including the SBP cost. These were areas of consideration for future CCE receipt and particularly the request to de-link the SBP.

Pakistan

The initial selection and placement of CCE was a data-driven approach, as shown by the baseline and midline results. The list of facilities that would receive new CCE was generated by the federal EPI and shared with the districts through the provincial EPI. The initial lists were developed using data and recommendations from the 2014 EVM assessment and the 2016 cold chain inventory.

There was general satisfaction with the CCE models selected for deployment. Equipment requirements considered the locality's population, hard-to-reach areas, and coverage plans to ensure the country's CCE needs were represented. Key criteria for selection were also the ability to provide increased storage capacity and to maintain temperature. In the second deployment, a decision was made to switch from one manufacturer because of an issue with the stabilizers.

While the models selected were found to be favorable, facility staff still had some confusion about the different warranty details and repair procedures, due to CCE having been procured from two different manufacturers with different warranty conditions and a lack of clear communication around those details. This lack of clarity, largely driven by lack of clarity at the national level, may, over time, affect the preventive maintenance on CCE and thereby affect the continuity of services due to repair delays.

IMPLEMENTATION AND EFFECTIVENESS

CCE Availability

Finding 5: CCEOP has successfully and substantially increased the availability and capacity of the cold chain system.

Finding 6: Some facility-level respondents felt the current capacity through new CCE procured was not appropriate to facility needs.

Finding 7: The manufacturing issue with equipment from one manufacturer cast doubts on the quality of equipment promoted by CCEOP and the necessity of the warranty.

Aggregated Findings

CCEOP has deployed and installed more than 13,156 ILR and SDD CCE in the three countries, with proposed deployment of 1,689 CCE later in 2021 (see Figure 5). As mentioned earlier, over the course of CCEOP's first five years (2016 to 2020, though the first procurement did not occur until 2017), purchase orders were placed for 52,275 units of ILRs and SDDs (21,718 ILRs and 30,557 SDDs) for 45 countries* with CCEOP funding.

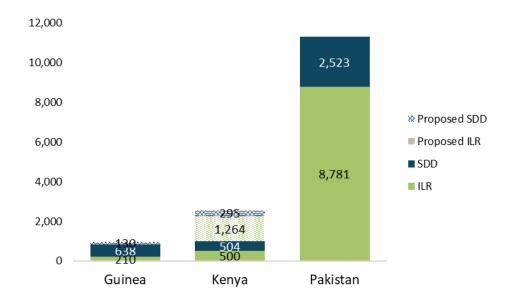


Figure 5: Number of Pieces of Cold Chain Equipment Deployed in the Three Focus Countries

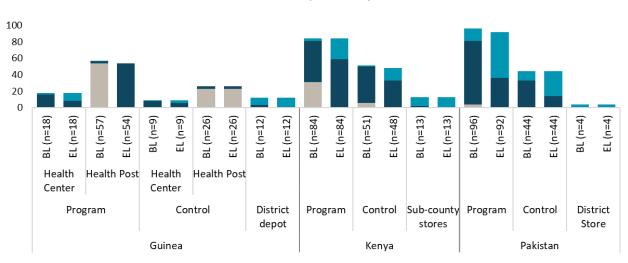
Note: The first deployment in Guinea included five PVSD models that require no power source.

Data from the HFAs in the three focus countries demonstrate an increase CCE availability, especially in the program areas (see Figure 6). This effort has increased the availability of PQS-approved equipment and has removed domestic equipment from the supply chain, which is a notable success in ensuring equipment functionality and contributing to vaccine quality. This new equipment extended the reach of immunization services, particularly in Guinea, and has provided more reliable equipment, thus making a more efficient system.

In addition, this has resulted in all three countries better utilizing their CCE capacity between baseline and endline, At endline, a greater number of facilities were categorized as underutilization or appropriate utilization of the CCE as compared to baseline (see Figure 7). This indicates room for disruptions in the supply chain and greater flexibility.

The "under-utilization" category implies that the current EPI schedule uses less than 10 percent of the CCE space; however, this allows for growth in the population and number of vaccines (and potentially other cold chain products) provided through the health system.

While the manufacturing issue with equipment from one manufacturer was resolved, the initial equipment failure negatively affected country preferences for that manufacturer.

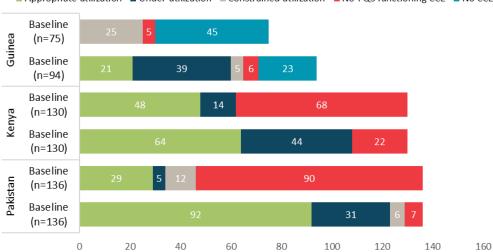




■ No CCE ■ 1 piece ■ 2+ pieces

Source: Health facility assessments, baseline (BL) and endline (EL).

Figure 7. Number of Facilities by Capacity Utilization in the Focus Countries, by Timepoint



Appropriate utilization Under-utilization Constrained utilization No-PQS functioning CCE No CCE

Source: Health facility assessments, baseline and endline

Utilization category definitions: under-utilization (<10 percent of capacity); appropriate utilization (10 percent–80 percent of capacity); constrained utilization (>80 percent of capacity). Appropriate utilization is the most desirable category.

Analysis of capacity required was based on the current EPI schedule, stated distribution schedule (i.e., monthly distribution to facility level), ideal buffer stock (25 percent), and target population of that facility. This was assessed against the net cubic liters of the PQS-approved CCE used for vaccines (Gavi 2018). CCE inventory was collected during the HFAs at baseline and endline. Freezers and freezer space was not included in this assessment. Non-PQS approved is displayed as a category of equipment and does not reflect utilization. Facilities not vaccinating were excluded from the analysis. In Kenya and Pakistan, facilities without CCE and facilities not visited at both baseline and endline were excluded.

Guinea

Notably, equipment was deployed largely to health posts that did not have CCE previously. This greatly extended the reach of the immunization program and introduced efficiencies into the system, reducing the need for health workers to collect vaccines on a daily or weekly basis for immunization sessions and reducing the time that vaccines spend in transport during distribution. Presumably, it has reduced the distance caregivers need to travel to access services in some areas.

There has been a significant improvement in the cold chain storage capacity, with more than sufficient space in 40 percent of the sampled facilities using less than 10 percent of their capacity. This allows for growth in the program or potentially supply chain design changes to better utilize CCE. The number of sampled facilities with constrained space also greatly reduced, allowing for more flexibility and disruptions in the supply chain.

Kenya

In facilities included in the analysis, the use of non-PQS equipment declined considerably with the new CCEOP equipment, and fewer CCE are constrained based on the regular vaccine distribution schedule. While 34 percent of the new CCE sampled for the HFA is under-utilized — implying the equipment is using less than 10 percent of its capacity based on the current EPI schedule and standard delivery frequency — this does allow for growth in the population, new vaccine introduction, and even adjusting supply chain design to optimally use the equipment.

However, there were complaints in one county that the new SDD equipment did not have the same capacity as prior gas-powered models, requiring more frequent trips to pick up vaccines from a long distance. Conversely, respondents from another county noted that the additional capacity had allowed them to streamline vaccine collection for the entire county.

Notably, one of the manufacturer's equipment malfunctioning negatively affected the supply chain due to the large quantity of that equipment received during the first deployment. More importantly, the SBPs procured the spare parts required to fix the manufacturing issue, but NVIP was responsible for performing and paying for the corrective maintenance on this equipment. As this was understood to be part of the warranty, it has cast doubt on both the quality of the equipment and the warranty. This experience also influenced NVIP to not select that manufacturer's equipment for future procurement.

Pakistan

CCEOP has achieved its goal of ensuring that a large quantity of CCE is distributed, installed, and functioning in a relatively short time period. By endline, the proportion of facilities with two or more pieces of CCE has at least doubled, in some cases almost quadrupling.

Adding new CCE or replacing broken or obsolete CCE has increased storage capacity to absorb new vaccines, improved facilities' ability to replace stock and maintain minimum/maximum stock levels to reduce stockouts, reduced the need for more frequent restocking of vaccines, and provided uninterrupted vaccination services. The increases in

storage capacity has also saved on the time and cost for facility personnel to retrieve stock from the district level.

Appropriate CCE utilization more than tripled between baseline and endline. At endline, almost one-third of CCE were under-utilized, providing an opportunity for growth in the population or immunization program. Notably, the number of non-recommended domestic refrigerators was significantly reduced, with these unreliable pieces of equipment removed from the supply chain.

Pakistan did not select [Manufacturer 1] equipment for subsequent deployment rounds, but the lack of clear communication about this decision led to some misperceptions by sub-national-level stakeholders about the transparency and inclusivity of the process. The reasons for the decision to discontinue [Manufacturer 1] procurement were not clearly articulated at all levels of the system, particularly the facility level, where the extent of the malfunctions was not perceived to be extensive. This communications gap still need to be addressed.

Maintenance

Finding 8: While training improved technicians' capacity considerably, there still appear to be some gaps in expectations and quality of the training provided on CCE maintenance, including preventive maintenance with health workers.

*Also relevant for sustainability

Aggregated Findings

Similar to previous data collection points, respondents were dissatisfied with the quality and depth of training provided by SBPs. The need for additional training, including on-the-job training, was felt to be a recurring need across the three countries and at each level of the health system. It should be noted that the request for training largely came from facility-based health workers who need a different training focus than cold chain technicians. This finding is also relevant for sustainability and the ongoing requirement for maintenance.

Guinea

All regional technicians were trained by the SBPs, with additional training provided by the EPI. However, the technicians' differing educational background and skills limited the training's impact. Health workers were also trained on preventive maintenance yet pointed out that it lacked in depth.

Kenya

Results from the endline reinforce the findings from previous data collection points that respondents considered the training insufficient. The training was limited to two technicians per county, with the expectation that the remaining technicians in a county would receive cascade training. In most counties, there was not a concerted, formal effort to conduct this training of additional engineers and technicians, with lack of funding being the most common challenge. This lack of training due to lack of resources was compounded by turnover among technicians and engineers, leaving the counties with very few trained technicians.

Respondents at the facility level also noted that more training on cleaning and preventive maintenance of equipment would be useful. Facility staff received a basic orientation on equipment from the SBPs and MOH staff when the equipment was installed in 2018 but had not received any training on the equipment since.

Pakistan

Despite the initial training provided by the SBPs and installation team, it was often felt that the information provided was insufficient, necessitating re-training in many cases. UNICEF and other partners arranged for follow-up training, yet there was a lack of clear delineation of training topics by the different groups. This led to some ambiguity about which type of training each group would conduct and their overall responsibility within the facility. SBP respondents thought training should be MOH entities' responsibility given the need to ensure systematic monitoring and reinforcement of the training, whereas MOH respondents indicated that preventive maintenance should be included as part of orientation on new CCE.

Facility-level respondents expressed a need for local trained technicians to be available at the district level to reduce downtime, due to technician travel, for equipment repairs. Evidence from the current and previous assessments indicate that appropriate orientation on new CCE and on proper maintenance remains inconsistent.

Finding 9: The CCE maintenance system has yet to see improvements. New models of equipment installed in countries have exacerbated this divergence in maintenance systems, as SBPs are currently engaged.

*Also relevant for sustainability

Finding 10: Having multiple CCE brands has negatively affected knowledge of warranty and corrective and preventive maintenance practices.

*Also relevant for sustainability

Aggregated Findings

The CCEOP equipment has generally performed very well, with little need for corrective maintenance (see Figure 8). The percentage of facilities reporting a breakdown of the CCEOP-procured equipment has decreased in all countries.

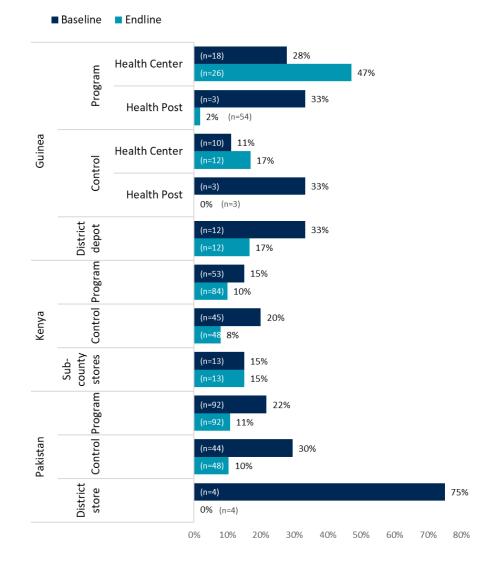
One oddity is among health facilities in Guinea because deployment through CCEOP was primarily focused on health posts, especially those that did not have CCE. Health centers did not receive any new equipment and were therefore more susceptible to older equipment breaking down. This can partially explain the higher percentage of health centers experiencing a breakdown at endline compared to baseline. Another exception is the manufacturing issue in Kenya, which is addressed elsewhere in this report.

The gap in maintenance remains for non-CCEOP equipment, and there is growing concern for the CCEOP-procured equipment when the warranties expire and SBPs are no longer providing maintenance. Having a parallel maintenance system for CCEOP-procured equipment has complicated an already weak and under-funded system with unclear processes and multiple

CCE models. In each country, the processes for reporting maintenance issues and complaints are not clear and may differ for CCEOP and non-CCEOP equipment, meaning that it is likely that there is no systematized national-level tracking of performance issues to provide feedback to UNICEF SD to potentially identify broader CCE performance trends.

Another challenge is that sub-national staff do not have clear details on the warranty and associated duration for CCEOP-procured equipment. Moreover, with multiple models, there are additional considerations for training and procuring spare parts to ensure long-term functioning. The two or three new models procured through CCEOP are part of the larger CCE system with multiple brands and models, thus complicating corrective and preventive maintenance. This finding is also relevant for sustainability and the ongoing maintenance requirements.

Figure 8: Percent of Facilities Reporting a Breakdown in the Last Six Months, by Study Arm and Timepoint



Source: Health Facility Assessment, Baseline and Endline

Guinea

Each region where the study was conducted has a slightly different approach to CCE maintenance (of non-CCEOP equipment). One region uses technicians from the MOH's national equipment service division; another region uses an independent contractor for medical equipment; a third region has a technician attached to the district hospital.

The maintenance technicians noted the that they received technical support virtually from the EPI's Cold Chain Unit, which offered step-by-step instructions on video calls to diagnose and repair. This approach appears to be quite successful despite occasionally being hindered by the need for spare parts. All regional maintenance technicians pointed out the lack of financial resources as the main challenge.

Kenya

Despite fewer breakdowns since the CCEOP installation, all three Kenyan counties in the evaluation reported challenges repairing and maintaining equipment due to lack of a system to support maintenance, including funding availability. As an example related to inadequate training, a technician from one sub-county traveled to another sub-county to address CCEOP equipment issues, as the sub-county's cold chain technician had not been trained on that model. This maintenance request was delayed due to a lack of funding for travel.

Sub-county-level respondents felt they lacked the resources and the authority to repair equipment without involvement from the county.

Pakistan

CCE breakdowns in the previous six months have substantially decreased, presumably due to the availability of new CCE. However, there is still a lack of clarity, especially among facility-level staff, around warranties and maintenance, in some cases necessitating use of the parallel maintenance system for non-CCEOP equipment to address CCEOP maintenance issues. Facility personnel were unaware of warranty details and used their own local technicians for repairs.

SBP Implementation

Finding 11: There are inconsistencies in services provided by SBPs and warranty coverage across the three countries.

Aggregated Findings

While there is interest in exploring de-linking opportunities, respondents also expressed appreciation for most SBPs' work, both in executing the project and installing equipment within the expected timeframe, and in their assistance training government technicians and ensuring that, in many cases, they were included in facility visits for maintenance requests to reinforce training and skills. This reinforces findings from the midline that show timely deployment, flexibility with ODP changes, and largely prompt responses to immediate adjustments post-installation.

Despite the successful installation approach, it had inconsistencies for providing ongoing maintenance after installation. In all three countries, questions and confusion remained over who was responsible for what, and there were different views on the value of warranties and the SBP function. These questions and uncertainties spanned the MOH, EPI, UNICEF, SBP representatives, and others interviewed at each health system level.

Respondents understood that the warranty does not cover anything caused by an operator's negligence or altered by another (unauthorized) mechanic/technician. But beyond that, there was widespread uncertainty on what would be covered by a warranty. There was also ambiguity around the responsibility for third-party fridge tags (an issue was raised with fridge tag batteries); SBPs were called to address the issue, but because there was no maintenance agreement between the SBP and third-party supplier, SBPs could not assist.

Guinea

For the first deployment, the ODP and other resources required for installation, which the PMT shared, facilitated SBPs' work. In turn, the PMT's monitoring and supervision of SBPs ensured that CCE were installed and trainings were conducted according to the contract agreement. For planning and implementation of the proposed second deployment, the PMT was not as active, partly due to the COVID-19 pandemic.

Guinea makes an interesting case study, as one of the SBPs provided regular, scheduled preventive maintenance visits to the health facility. This is definitely a best practice but was not mentioned in the other countries. The SBP for [Manufacturer 1] equipment (with built-in RTMD) mentioned monitoring the remote temperate data for better targeted maintenance to equipment with the most immediate need. The SBPs resolved issues not typically covered by warranty and had a very timely response.

Even though the need for corrective maintenance for the new CCE was minimal, there was evidence of coordination between the SBPs and regional technicians to diagnose problems and ensure SBP technicians had the necessary tools or parts for repair prior to traveling to the site.

Kenya

A significant gap in SBP performance was replacing the equipment part that was identified as a manufacturing error that caused a freezing risk. While the manufacturer agreed to a corrective action plan and supplied the necessary components to countries, the SBP delegated the responsibility to MOH technicians for distribution, deployment, and replacement of the accessory (for both CCEOP-procured and World Bank-procured equipment). This had not been planned or budgeted for, which limited the ability to track what had been distributed/corrected or not.

Additionally, different understandings of the repair and reporting processes between facilities and SBPs may be contributing to some less-than-optimal SBP performance. Facilities perceived a slow response time by SBPs, while SBPs felt that established notification procedures were not followed.

The Kenya MOH has successfully made the case for de-linking the SBP to leverage its own technicians and expertise for future deployments.

Pakistan

Findings suggest there were different understandings of the repair and reporting processes between facilities and SBPs, which may have influenced the time to repair for some equipment. Facilities perceived a slow response time by SBPs, while SBPs felt that established notification procedures were not followed.

The SBP extended the warranty and their maintenance services without the involvement of the manufacturer to resolve maintenance issues. The warranty was extended for an additional three months, from end of December 2020 to end of March 2021.

"They [the SBP] gave us phone numbers after they installed at our facilities and email as well. We contacted them later, send them ILR's picture as they had told us the protocol. But they didn't give any response. Consequently, we have to get it repaired from local technician."

-District Official

Coordination and Communication

Finding 12: The CCEOP is coordinated with other donors and partners for overall system strengthening, although better documentation could improve the coordination and planning. **Finding 13:** There was a lack of clarity in the requirements during the proposal stage, with long delays and continued back and forth between the PMT and UNICEF related to the delinking approach.

Finding 14: While communication between and within health system levels has improved since baseline, critical vertical communication gaps persist, such as between the facilities and higher levels around warranty issues. Horizontal communication gaps also continue between the SBPs and MOHs.

Aggregated Findings

The baseline showed that the application process was supported by Alliance partners through a dedicated consultant in each country who ensured clarity on guidance and the application process. The CCEOP is a coordinated effort, with maximum success stemming from effective communication among the PMT, MOH, SBPs, and partners at the national level, along with clear lines of communication and sharing of information among health system levels. While this is essential in the early planning and implementation stages to ensure successful deployment, long-term communication across levels is also critical to ensure the system works efficiently, there is a shared understanding of warranties, and maintenance and repair are timely.

Guinea

The CCEOP process involved effective coordination among a multi-disciplinary group of stakeholders, engaging them through each step of the process and achieving a successful public–private partnership for the rapid distribution and installation of CCE across the country for the first deployment.

Even at the time of the midline, respondents recognized the strong coordination that the EPI provided by clearly communicating what was required during planning at all levels of the health system. At the national level, the MOH also continuously engaged and coordinated all national-level stakeholders.

"When the equipment arrived, at the level of transit and customs clearance, there was a good coordination that was put in place with the PMT to know exactly when the equipment arrived and how to facilitate our task to bring them out. Also, when we got into distribution and installation, we sometimes had difficulties with customs or the police at various checkpoints, the PMT got involved to help us resolve these situations through the communications we had"

-SBP, Guinea

More recently, the PMT was inactive and not meeting regularly. Partly due to the COVID-19 pandemic, meetings were not conducted and PMT members did not have detailed information on the deployment plan's status. The PMT and NLWG were not actively coordinating to address immunization supply chain, maintenance, and program performance issues.

Kenya

Coordination among national groups, donors, and partners was especially evident in Kenya. The PMT coordinated efforts with donors, particularly Gavi and the World Bank, to make sure supply chain needs were optimally and efficiently met, promoting financial sustainability. The logistics working group also worked actively in this process, resulting in concurrent procurements of more than 3,000 pieces of CCE equipment from Gavi and the World Bank over a short period. They also liaised well with SBPs.

However, the application process was protracted and very delayed. In the first deployment, stakeholders reported confusion about equipment selection, warranties, and the equipment's total cost. National-level stakeholders remarked on the delays and lack of clarity around the proposal's current status, as well as the "back and forth" that had taken place around the proposal to de-link. Other national stakeholders noted frustration with requests for feedback or revisions, which were felt to give insufficient time for the country to prepare.

At the time of data collection for this evaluation, few national-level respondents knew where things stood in terms of UNICEF approval for next rounds or whether de-linking had been finalized. The de-linking proposal was submitted to UNICEF-SD in January 2020 just before COVID-19 restrictions were implemented in March 2020, including national lockdowns and

curfews. The proposal was to begin the next round of deployment in June 2021 but it has been delayed.

A lack of common understanding about warranties was evident. Most respondents at the subnational level, including some county-level EPI logisticians, did not know that the equipment was under warranty or that service bundles were in place. At the national level, respondents were aware of the warranties and their duration but were unclear about what they covered.

Pakistan

Coordination among the Gavi Secretariat, WHO, and Government of Pakistan took place primarily at the federal level. Before the endline evaluation was conducted, coordination of efforts for the planning and deployment process started to improve. The Ministry of National Health Services, Regulation and Coordination (MoNHSRC) encouraged provinces to involve and solicit input from district-level stakeholders. Respondents, especially from facility and district levels, indicated they felt they were consulted to a greater extent in subsequent ODP planning processes and that provincial and federal planners were more proactive in soliciting that input.

The MOH-led PMT took an active role in resolving issues related to deployment and other concerns. The PMTs were also a forum for the provincial level to voice concerns and requirements.

However, there was still some concern that information did not always regularly flow among health system levels. For example, some respondents noted that there was a lack of clear communication from the federal level to the facility level about the decision to suspend [Manufacturer 1] procurement after the first deployment in 2018.

Temperature Monitoring

Finding 15: Largely, temperature monitoring at the facility level is implemented using 30DTR, even if RTMDs are available.

Finding 16: While national staff was very satisfied with the RTMD, the RTMD dashboard is often unavailable for sub-national staff, especially at the facility level.

Aggregated Findings

Temperature monitoring is largely being conducted now using 30DTR or RTMD, both more reliable than the stem thermometers that were still being used in some cases at baseline but have mostly disappeared at endline. However, a gap still exists in access to temperature data — particularly data generated by RTMD and at lower levels of the health system — and use of that data to drive decisions.

There is also indication of duplication of effort, with health workers reporting using 30DTR for twice daily temperature recording even if an RTMD is available. It is unclear if the reason for not using the RTMD data is because of lack of access to the dashboard or a function of change management and introduction of a new technology.

Guinea

The SBP for equipment from one manufacturer with built-in RTMD reported using the RTMD data for daily monitoring of CCE performance and identification of issues. This level of data access, however, did not extend to the rest of the health system. Of the 12 districts in the sample, only one reported having access to the RTMD data and was actively using the data; others either did not have access or were unaware if there were individuals in the district administration who had access to the data.

Most health post heads received SMS alerts from the RTMD but relied on the 30DTR to monitor daily temperature and update the chart. Similarly, districts used data from temperature monitoring charts and 30DTRs during supervision to assess proper temperature logging and CCE performance.

Kenya

National-level respondents noted strengthened monitoring of equipment via RTMD, indicating that some counties have developed maintenance/tracking systems (although not in counties that were part of this evaluation). However, facility-, sub-county-, and even county-level staff do not have access to the data generated by the equipment and continue to rely heavily on 30DTR for temperature monitoring, requiring them to be physically present in the facilities to know that a deviation has occurred.

Pakistan

30DTR is in wide use and the reports are regularly submitted. However, 30DTR data are collected and compiled at the district health office level and sent to the provincial level, but an analysis of these data are not universally provided to the facility level.

EFFICIENCY

CCE Performance and Maintenance

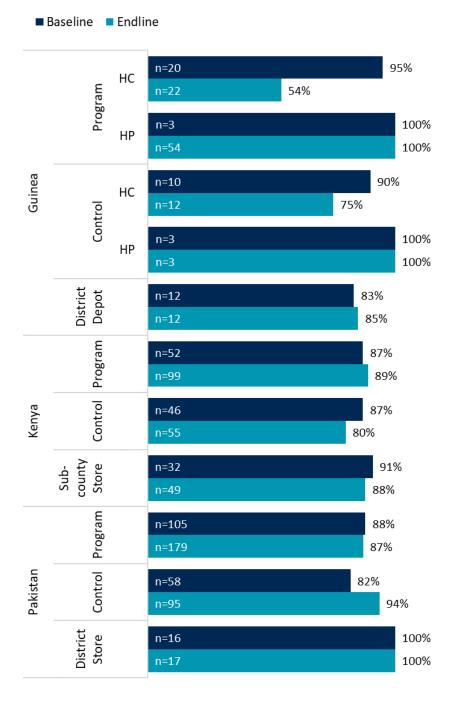
Finding 17: Most respondents are very satisfied with the CCEOP equipment, which brings cost savings, less maintenance required, and better performance.

Finding 18: The new CCE is functioning very well, with high levels of safe time within the expected temperature range.

Finding 19: Decommissioning of old equipment is still not clearly implemented.

Aggregated Findings

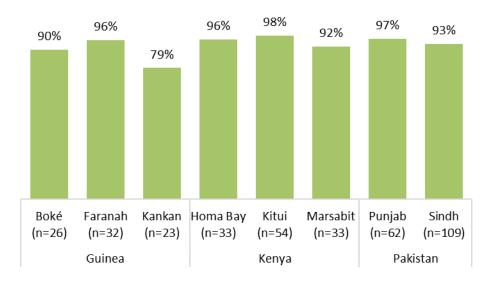
Facility-level data from the HFA in the sampled areas in the three countries showed high levels of CCE functionality for the most part. This was evident in terms of both CCE not under repair and the ability to maintain a safe temperature for vaccines (see Figures 9 and 10). While the increases over time were not large, they were found to be consistent. The ability to monitor temperature was also found to be valuable; however, access to the RTMD data at the facility level was a challenge.





Source: Health facility assessment, baseline and endline

The one challenge faced was in decommissioning old equipment when the new equipment was installed. Countries did not have a clear plan, and often older equipment was moved to smaller, more rural facilities. Moreover, there was also no clear record of which equipment was placed in which facility. Particularly in Kenya, this movement of CCE was responsible for the PMT's interest in conducting a CCE inventory to plan for the second deployment.





Source: Temperature data was based on data from 30DTRs in the sampled facilities during the health facility assessment for the previous 60 days at endline data collection. Safe time is defined as the 2-8 C temperature range.

Guinea

CCE installation was predominantly in health posts in Guinea. As a result, the endline evaluation showed a high number of functional CCE at endline after installation through CCEOP. In Boké, for example, there were only 2 health posts with functional CCE at baseline, which increased to 27 by endline.

Temperature monitoring of the CCE was done twice a day in most facilities, as prescribed in the preventive maintenance training. In Boké and Faranah, the percent of CCE in health facilities with updated monitoring charts at endline reached nearly 50 percent and 75 percent, respectively, following CCEOP deployment.

The new equipment also was largely performing well at endline (see Figure 10). The lower safe time in Kankan (79 percent) is a result of fewer CCEOP-procured equipment in this district so is reflecting older equipment. Of the CCE out of the safe range, 4 of the 92 CCE with temperature data were not working at all and were not being used for vaccines. Other pieces of equipment that had alarms were variable in performance — one ran slightly hot, maintaining at 10° C; another ran hot for the first part of the data-reporting period but had stabilized in the ideal temperature range by the end of the period; another maintained around 9° C or 10° C for the majority of time, with a spike toward the end of the reporting period, suggesting a breakdown.

Kenya

Most respondents were very satisfied with the performance of the new equipment installed, specifically emphasizing the equipment's reliability as compared to gas equipment. Multiple facility and sub-county depot staff respondents remarked that they did not fear leaving

equipment over the weekend because the new equipment remains at the necessary 2–8°C for longer periods.

Data from the temperature analysis (conducted as part of the HFA) showed the equipment in the three sampled counties remained in the 2–8° C range ("safe time") more than 95 percent of the time in the 60 days preceding the survey. Only seven of the 134 CCE with temperature data were not functioning at all and were not currently in use for vaccines. Of the other CCE reporting some alarms, one CCE had 46 percent of time with hot alarms more than 12° C, presumably due to power outages; one ran only

"These fridges are friendlier, efficient and effective. They do not need maintenance all the time as compared with the old ones that used gas. These ones use solar which is plenty here." –Kenya Sub-County Respondent

slightly hot, maintaining around 10° C; and one was consistently maintaining below freezing temperatures.

The [Manufacturer 2] equipment procured through CCEOP has RTMD capabilities, but access to data is extremely limited (mostly to national level staff), and functionality, like SMS-alerts, were not being used to their fullest potential to ensure vaccine quality.

Respondents noted that decommissioning of old equipment, regardless if in CCEOP or non-CCEOP supported sites, has not been fully implemented.

Pakistan

The addition of high-functioning, more efficient equipment through CCEOP strengthened cold chain performance in the country. All facilities in the sample were provided with 30DTRs as part of CCEOP. 30DTR data showed that there were fewer breakdowns and fewer temperature excursions.

In Punjab and Sindh provinces, HFA data showed that equipment in the sampled health facilities was in an ideal temperature range for, on average, 98 percent and 97 percent of the time, respectively, in the 60 days prior to endline. Only five of the 177 CCE with temperature data were not working at all and not being used for storing vaccines. One CCE that spent 22 percent of time in the hot range greater than 12° C most likely experienced electricity outages; two CCE had fluctuating hot alarms but had stabilized by the end of the reporting period; one CCE had a breakdown during the reporting period and spent 20 percent of the time in the hot zone (above 15° C); and one CCE consistently was fluctuating too cold, down to -10° C.

While interview respondents noted significant improvements in the ability to monitor and respond to temperature issues to protect vaccines, under-utilization of temperature alarm data was still anecdotally reported. The monitoring capabilities provided by the 30DTRs (through monthly or bimonthly temperature histories) were not used at the facility level. District health officers collected the data and sent it to provincial focal persons, but the facility and district levels had no system to utilize the temperature data for more effective vaccine cold chain.

"Now, new CCE has freezing as well as heating alarms so appropriate actions could be taken. It has caused a drastic change.

–Pakistan Provincial Official

OUTCOMES AND RESULTS

Finding 20: There were fewer vaccine stockouts reported at endline in Guinea and Kenya, although the reasons are unclear.

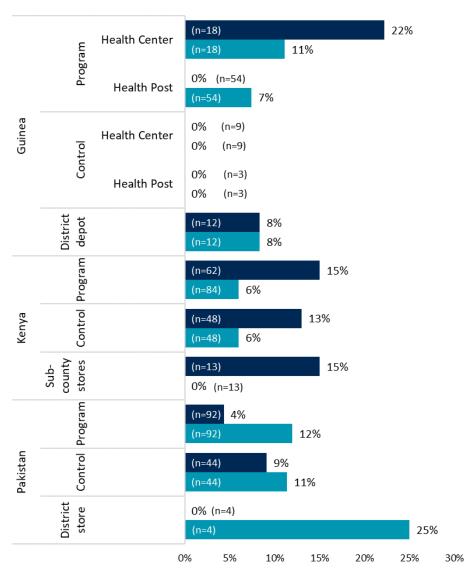
Aggregated Findings

The HFA provided information on stock availability and changes in vaccine management processes, including updating of stock ledgers, organization of vaccines, and vaccine stockouts (see Figures 11 and 12). The assumption is that with new equipment, facilities will also make changes to these processes. Overall, the COVID-19 pandemic and associated national-level stockouts affected procedures in the facilities; however, stockouts decreased in general in facilities in Guinea and Kenya over the course of the evaluation, although a few exceptions were noted. A similar decline was not evident in Pakistan.

Regarding vaccine wastage, the data are inconclusive and do not indicate any trends for improvement. Stakeholders indicated that with better-performing and more reliable equipment, the rate of closed vial wastage would decline, yet the data do not support this assumption.

Figure 11. Percent of Facilities Reporting Stockout of Pentavalent/DPT, by Study Arm and Timepoint

Baseline Endline



Source: Health facility assessment, baseline and endline

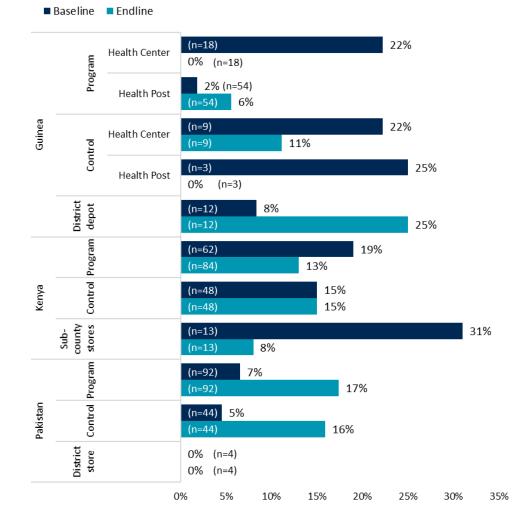


Figure 12. Percent of Facilities Reporting Stockout of MCV, by Study Arm and Timepoint

Source: Health facility assessment, baseline and endline

Guinea

Stockouts decreased in Guinea. Health centers in the HFA sample showed a decrease in stockouts in the previous six months. At endline, they were increasing or sustaining stock of both DTP and MCV vaccines. While few sampled health posts managed vaccines at baseline due to lack of CCE, at endline, less than 20 percent of health posts were stocked out of DTP and MCV, with availability ranging from 89 percent to 100 percent.

With the installation of new CCE, the health posts were now integrated into the supply chain system. As a result, they now placed monthly or bimonthly orders and collected vaccines from the health center. Despite the irregular vaccine distribution from the central to district level due to financial constraints, all districts used their own means to collect vaccines to preempt stockouts when distribution was delayed.

Data collected during the HFA indicated poor vaccine stock recordkeeping across health posts in general. The qualitative data support this finding. Respondents indicated that training on vaccine management across the sampled health posts varied; while some staff had received formal training, others relied on their health centers' support to get information on proper vaccine management.

Kenya

Between baseline and endline, program and control facilities had similar increases in the proportion of updated Pentavalent and MCV stock ledgers. Sub-county stores had a more significant increase in the proportion of updated Pentavalent ledgers, from 77 percent to 100 percent between baseline and endline. Staff in all three counties noted that they had received support or training from CHAI and UNICEF in stock management practices, which may have contributed to the improved documentation.

Between baseline and endline, there was an overall increase in the proportion of facilities with well-organized vaccines in both the program and control arms. The increase may have coincided with some facilities receiving trays to organize vaccines, which they did not have when the equipment was delivered.

The number of immunizing facilities reporting a Pentavalent stockout in the previous six months declined in all three counties between baseline and endline for program facilities. MCV stockouts decreased in program facilities in Kitui and Marsabit counties but increased in Homa Bay for both program and control arms, showing no overall decline. Some respondents suggested that most stockouts in the past were at the national level, which CCEOP would not have prevented.

Pakistan

While the CCEOP platform increased stock-holding capacity, it did not necessarily result in a corresponding decrease in stockouts. In both the sampled provinces, stockouts increased for both DPT and MCV vaccines. However, it is difficult to fully tease out the effect of COVID-19 disruptions to procurement and distribution on stockouts.

These findings reflect nationwide shortages of Pentavalent, as the vaccine could not be imported and distributed due to COVID-19 disruptions in transportation.

The percentage of facilities with well-organized vaccines did not increase considerably from baseline and remained a concern. In addition, stock ledger improvements were also uneven for both DPT and MCV stock ledgers.

"[Over the past two years], there have been cases of stock outs of BCG which has been on and off. This has been nationwide stock out. We have never stock outs specific to this region. Sometimes we have also had OPV and Td stock outs, these have also been nationwide stock outs."

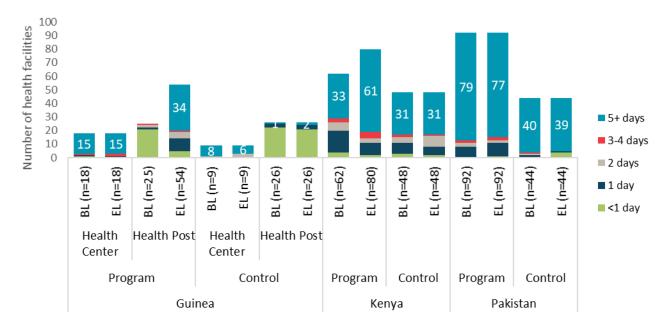
-Regional Depot Manager, Pakistan

Finding 21: New equipment has expanded the reach of immunization services and increased CCE capacity.

Finding 22: While there is evidence that the frequency of immunization sessions has increased, the impact of CCE on immunization coverage rate is inconclusive.

Aggregated Findings

HFA data at baseline and endline showed that the frequency of immunization services offered in health facilities remained consistently high or increased over time in sampled program facilities that received CCE in all three countries (see Figure 13). At endline, 61 percent of facilities in this group offered immunization services five or more days per week in Kenya, and more than 75 percent did so in Pakistan. Improvements in Guinea, though lower, were evident, especially in health posts that were the focus of CCEOP Phase 1.





Source: Health facility assessment, baseline (BL) and endline (EL)

Note: Facilities not vaccinating were not including in the graph. Less than one day represents facilities providing vaccination services less frequently than 1 day per week such as through outreach.

Guinea

At baseline, less than 50 percent of health posts provided any immunization services in the two program regions, Boké and Faranah. The majority of these health posts offered immunization services through outreach. At endline, following CCEOP deployment, immunization service provision at these health posts more than doubled, while the proportion of services provided through outreach declined. This shift can be attributed to the new CCE installations, which supported increased capacity to provide routine immunization services while decreasing need for outreach service provision.

After CCEOP deployment, the frequency of service provision increased in the program regions; 74 percent of sampled health posts in Boké and 52 percent of sampled health posts in Faranah offered immunization services five or more days per week.

"The most important change is getting children immunized on time. Children get the vaccines when they need them on schedule, it is extremely important. When a child is born, the child can go three months without having BCG, it is difficult. But with the fridge on site as soon as the child is born he is not even a month, he has his BCG. This is the best change because children get their immunizations on time and when it is needed. The presence of the fridge is very important."

-Health Post Service Provider, Guinea

KII respondents at the health posts also pointed out how vaccine availability at the health posts had contributed to timely vaccination and catch-up vaccination of infants and increases in antenatal care attendance.

CCE availability has also contributed to the quality and accessibility of immunization services, reducing the distance mothers needed to travel to access services (50 km–75 km) and ensuring vaccine quality and effectiveness by improving storage and

handling. In the past, transporting vaccines to distant locations during outreach vaccination, after picking them up from the health center, impacted vaccine quality. Today, vaccines are kept in CCE at health posts, and health workers can travel to villages and return in time to put vaccines back in the refrigerator, reducing the potential of vaccine exposure to temperatures outside recommended ranges.

Previously, when unvaccinated children came to the health post, health workers had to refer them to the health center, which meant additional travel for the mother and child and had been a contributing factor to missed immunization. After CCE installation, the health post now addresses the urgent need to immunize zero-dose children.

Despite an increase in immunization service availability due to the new CCE, the number of immunizations in the previous six months in health posts in Boké and Faranah was still not very high.

With CCE now installed, health posts provide routine immunization services for the first time, and data on the number of children immunized at health posts are found in vaccine registers. However, there are no previous numbers to compare to the endline monthly averages to show change over time.

Kenya

Considerable increases in immunization service provision were evident. The number of facilities offering immunization services at least five days per week increased in program facilities between baseline and endline. Control facilities had minimal change. Additionally, the number of program facilities not offering immunization services decreased from 22 facilities at baseline to just one facility at endline.

"As part of CCEOP, we [.... county officials] worked closely with the national immunization program. [...] We benefited as a county with 95 fridges. [...] Before we benefited from this program, we had 214 immunizing facilities, and now we can say we have 279 immunizing facilities. So we were able to increase by over 65 facilities, and also the other bit we were able to replace CCE, which was experiencing frequent breakdowns."

-County representative, Kenya

There were, however, declines in the average number of immunizations per month, likely due to a number of factors, including decreases in service provision during COVID-19 and a nurses' strike in December 2020 and January 2021. Additionally, decreases in average number of children vaccinated per facility were noted at previous timepoints, which may be due to the extension of immunization services to additional facilities, which may increase accessibility to services but would not necessarily increase the average number of children vaccinated per facility.

Pakistan

HFA data show that the number of immunizations administered in Sindh increased between baseline and endline, largely in program areas. Greater storage capacity through the new CCE may have contributed to facilities' ability to increase vaccinations despite the stockouts due to COVID-19 logistical disruptions. Vaccinations also stopped for a period during COVID-19, but existing stock levels may have been

"Coverage has become better over time. We had 76.5 percent immunization coverage before, now it has gone to 80 percent according to a survey conducted last year. Since phase 3 is in process, it will add to the coverage further. Coverage has been sustained and it not only depends on CCE but on supply chain, doctors, and supervision."

-Pakistan Provincial Official

sufficient to meet demand once vaccinations re-started. The same pattern, however, was not seen in Punjab, although the reason(s) for the discrepancy is unclear.

SUSTAINABILITY

Country Ownership

Finding 23: CCEOP has contributed to the growth of some national-level planning and management structures and systems, such as PMT and NLWG, yet it is not clear that it has fostered ownership through all levels of the system.

Finding 24: There was little indication that the joint investment (Gavi and country government funds) contributed to financial sustainability or country ownership.

Aggregated Findings

The establishment of the PMT was successful in creating a system for planning and monitoring CCEOP implementation. Closely aligned with the NLWG, the PMT in each country was able to prepare the application, develop and revise the ODP, and work closely with SBPs for equipment installation and monitoring. This decision-making structure, however, did not cascade to the sub-national levels in Guinea and Kenya, leaving gaps in ownership, involvement, and coordination at the lower levels. While the PMT established successful coordinating mechanisms, there are indications that the responsibilities may be folded into the NLWG for longer-term structures.

The joint investment (co-financing was 20 percent in Guinea, 50 percent in Kenya and Pakistan) was designed to promote a sustainable approach, with governments also investing in CCE, yet this did not bear out. For the most part, countries found other donor streams, including Gavi HSS funds, instead of government resources to meet the joint investment requirement. This does not imply any lack of commitment to immunization and CCE on the government's part; it does imply that donors are willing to support joint investments when it is prioritized and strategically planned by governments.

Guinea

Although the PMT was instrumental during the first deployment, it was found to be stagnant at the endline evaluation. Similarly, partners reported little engagement from the NLWG.

Although the joint investment required for CCEOP procurement was taken from the HSS grant, respondents saw the government's contribution toward the clearing and transportation of CCE as an investment. However, the lack of resources for transportation and for maintaining the cold chain system indicate the heavy reliance on donor funding, detracting from a sustainable solution. One positive result of the emphasis on CCE and maintenance is that the government has included a line item for fuel for maintenance in the coming fiscal year's budget, an important step in operationalizing a stronger maintenance system.

Kenya

The establishment of the PMT, with representatives from partner organizations and national cold chain technicians, helped strengthen systems for planning and monitoring implementation of national-level investments in health. The PMT, in coordination with the NLWG, effectively coordinated concurrent equipment deployments to avoid duplication of efforts. At each data

collection point, counties consistently remarked that they had a very limited role in planning and coordination through CCEOP, with their main contribution being updating the CCE inventory.

The PMT is responsible for monitoring equipment and liaising with SBPs, but without support, it is likely that this group will be absorbed back into the logistics working group, which has a greater focus than CCE alone.

The Kenyan government, through HSS funds, contributed 50 percent of the overall CCE investment as its joint investment. However, the evaluation showed no indication that this joint investment contributed to a more sustainable approach, which could be demonstrated by government funds being invested in CCE. Additionally, when asked about the joint investment, respondents did not mention whether it contributed to sustainability or not.

Pakistan

The PMT was active and effective in facilitating the overall CCEOP process through planning and deployment, in part due to clear expectations for the PMT's roles and responsibilities provided in the CCEOP guidance. The PMT was also a forum for the provincial level to voice concerns and requirements, ensuring multiple levels were able to share information. However, there was no evidence to support the PMT playing a discernable monitoring role or that it directed a change in the course of action.

The joint investment was partly supported by the Multi-Donor Trust Fund (MDTF, administered by the World Bank on behalf of donor partners as a financing platform) and partly supported by the National Immunization Support Project (NISP). This joint investment seemed to be readily available through strong partnerships that already existed during preparation of the CCEOP application. While this joint investment does not necessarily imply ownership, it does demonstrate strong advocacy skills and the ability to align all partners around a focus on improving immunization services.

System Strengthening

Finding 25: Warranties will soon expire, and weak maintenance systems will find it challenging to fill in the gap.

Finding 26: The overall health system has not kept pace with the new CCE in terms of the need for more resources.

Aggregated Findings

The challenges with warranties and the SBPs addressing warranty issues had varying degrees of success. Guinea demonstrating a successful approach to the SBPs responding to maintenance issues, while Kenya had the opposite experience, with the SBPs not fixing a manufacturing issue, something that was clearly covered under warranty.

Regardless of the warranty, CCEOP deployment has shed light on the multiple aspects of the overall health system that have not kept pace with the new CCE procured by CCEOP. While this finding validates what is widely known is needed, in terms of a system approach to

improving immunization activities, it is a somewhat unexpected finding in this study. Respondents expressed concern over warranties that are close to expiring and how maintenance will continue.

Additionally, as immunization services have expanded due to the new CCE, this requires more vaccinators for service delivery, as well as updating forecasting estimates and revising distribution schedules.

Regarding the other supply chain fundamentals and specifically system design, the evaluation results show that selection and location of CCE was based on evidence of need and prioritization to improve coverage and equity. This decision-making criteria is one part of a system design approach.

Results also show that the other fundamentals need a higher prioritization to improve performance, such as data for management and supply chain leadership, which would include human resource capacity building.

Guinea

Interestingly, the significant investment in the cold chain has, in turn, expanded the supply chain and brought additional focus on logistics, communication, coordination, and other aspects of the immunization program. To build on HSS gains and respond to the program's growing needs, further HSS support is being provided to strengthen the national program's performance by restructuring EPI, including recruiting additional staff. The increase in CCE availability has highlighted the need for a dedicated trained staff with competencies to handle vaccines and CCE, as well as provide immunization services.

One recommendation specific to Guinea is to design a regional tailored comprehensive package of improvement for health posts that includes all necessary materials to strengthen the overall supply chain and immunization program: CCE; vaccines; means of transport; staff availability and capacity to immunize and manage vaccines and data (recording, analyzing, and reporting); correct stock management practices; CCE maintenance (regular preventive and prompt corrective when necessary); supportive supervision; and collaborative continuous improvement with health centers and districts using local data for course correction.

Kenya

One system aspect that came to light in Kenya is that old and obsolete equipment has not been disposed of or even removed from the immunization supply chain but has been reallocated to other facilities. As a result, the additional costs of running and maintaining this equipment have not been removed from the system. While beneficial to expanding immunization services, the human resources and financial resources needed to effectively manage this investment are lacking at the county, sub-county, and facility levels.

Pakistan

Respondents raised concern about the need for trained technicians for CCE maintenance for long-term planning and management after the warranties end. They also noted the need for

trained vaccinators to support expanding immunization services. The lack of improvement on stock available also highlights the importance of strengthening the overall supply chain system to ensure quality vaccines are available when and where needed.

MARKET-SHAPING FINDINGS

The objective of the CCEOP is to stimulate the market for optimal CCE while generating the demand in Gavi-supported countries to rapidly replace obsolete cold chain equipment and expand immunization services. CCEOP has been effective at promoting the supply and availability of optimal CCE.

The market-shaping goal of having two suppliers of ILRs and SDDs in each product size segment that are platform eligible has been achieved for all segments. The increase in number of suppliers and platform-eligible equipment has achieved the original target of ensuring that there were at least two suppliers per product size segment. Prior to CCEOP approval in 2015, there were six manufacturers of ILRs; now there are seven with platform-eligible CCE. For SDDs, there were four suppliers; now there are eight manufacturing platform-eligible equipment.

Findings from earlier rounds of KIIs and data analysis were covered in detail in the August 2020 <u>CCEOP market-shaping evaluation final report</u> submitted to Gavi and are summarized below:

- CCEOP has been successful in stimulating a market for and catalyzing awareness, availability, and use of higher-performing CCE in many countries. There is value in more organized and aggregated procurement and information sharing for CCE.
- The original CCEOP market-shaping strategy highlighted some of the potential challenges to achieving the market-shaping objectives that ultimately played out but was insufficiently robust to address them. The revised market-shaping strategy appears to address some of those limitations, and progress has been made in promoting a healthier market and shifting demand to some of the lesser-utilized CCE suppliers.
- The revised market-shaping objectives were appropriate to address some of the challenges observed with the original objectives, which at times were at odds or mutually inconsistent. However, the revised objectives have not fully reconciled the tensions among observing country preferences, achieving continuous product innovation, recognizing cost savings, and maintaining a relatively large number of interested suppliers, alongside a relatively static demand outlook.
- CCEOP's supply-side objectives have been met, supported by a strong base of platform-eligible suppliers and a range of options across ILRs and SDDs and size segments. It is unclear what the optimal number of suppliers is to maintain a healthy CCE market.
- Deliberate market-shaping efforts have resulted in a third supplier accumulating greater market share in 2019–2020 and alleviating concerns around the duopoly observed in the early years of CCEOP. However, procurement volumes will need to remain on track and maintain or expand market split to continue meeting market-shaping goals.

 The mandated service bundle component created initial complexity for CCEOP, and market-shaping efforts in particular, but as all parties involved became more familiar with implementation, valuable lessons have been learned about the benefits as well as opportunities to be more flexible with service bundle options in different types of country contexts.

Based on findings from the endline evaluation in the three focus countries and updated review of platform-eligible CCE, **additional findings relevant to market shaping** are highlighted below, linked to the four market-shaping strategy objectives. As indicated, these focus more on evaluation findings related to the specific connections between the experiences in the three focus countries and global level market-shaping efforts; broader market-shaping related findings are covered in detail in the 2020 report. The findings are structured around the market-shaping objectives included in the Gavi CCE market-shaping strategy (Gavi n.d.), while addressing the evaluation questions around relevance, implementation, effectiveness, and sustainability of the strategy to achieve the desired outcomes.

Objective	Relevant Findings from Focus Countries
1. Ensure 'long-term	Product Options and Availability
competition' and influence 'country preferences'	 The number of platform eligible models of ILRs and SDDs increased from 55 in 2016 to 78 by the end of 2020. Currently there are more than two suppliers per CCE product type and segment.
	 Demand from the three focus countries over the course of CCEOP implementation has been for CCE from four different manufacturers. Not all were a first preference.
	Product Selection and Country Preferences
	 Product selection and country preference are influenced by brand preferences; few respondents spoke of specifications or characteristics, indicating that typically they were requesting brands based on experience with a particular CCE and/or SBP.
	 Cost analysis was a second consideration for CCE selection when offered CCE from a different supplier.
	• A country's effort to standardize the CCE models across the country is also another factor in selection, since standardization can help in rational management of resource needs for training maintenance technicians and a more efficient management of spare parts. Representatives in Guinea referenced a deliberate strategy to limit the number of CCE suppliers to streamline management of spare parts, technicians, and maintenance knowledge; they preferred a narrowed supply base.
	 Many respondents expressed strong feelings that countries should be allowed to choose the CCE models they want and that choice should be respected, without outside influence or pressure to change.
	Equipment Performance Monitoring and Reporting
	 Issue reporting is very ad hoc, with no reliable system to report malfunctioning equipment. Service and maintenance requests may reach technicians at the district level but there is no system to compile/aggregate that data at the central level; this limits the ability to track and monitor trends in CCE issues to ultimately inform global performance monitoring.
2. Achieve reductions in WAP to 'max value to countries'	 Limited insights related to this objective were available from national-level data collection; however, respondents in all three countries said that the selection process was mostly based on brand and expected functionality, and less so on costs.

	 CCE procurements accompanied by spare parts has been very helpful. SBPs discussed incurring additional costs due to installations (e.g., blasting rocky)
	areas), deviations, and delays in installation requiring warehousing and insurance (due to COVID-19).
3. Reform procurement	Proposal and Procurement Process
processes to increase 'country ownership and capacity,' 'max value to countries,' increase 'long-term	• Feedback from one country was that the back and forth of the proposal process was inefficient and dragged on; the feedback implied that these delays were due to negotiations to have the country accept a second supplier (not originally selected).
competition,' and	De-linking the Service Bundle
meet 'country preferences'	Conflicting feedback on the opportunity to de-link the service bundle:
preferences	 On one side, respondents expressed concern about unskilled government technicians and voiding the warranties; concerns were also raised about the additional capacity needed for project management.
	 On the other side, respondents from countries that feel that they are able to manage installation on their own appreciate the opportunity to do so to be able to compare to experience with SBPs; there was a strong sense that this would increase the sense of ownership and responsibility and be good for overall capacity building.
	 UNICEF has established clear criteria for a country to be approved for de-linking, including internal technical capacity and SBP availability.
	 In Kenya, where de-linking is moving forward, the UNICEF country officewill manage clearing and distribution; government-employed biomedical engineering technicians are then responsible for installation, training, and, follow-up of the maintenance; the PMT will enhance monitoring. Based on their experience with World Bank procurement in Kenya, respondents felt positive about the de-linking opportunity; that experience took longer than the SBP, but the quality was comparable.
	• In Guinea, national-level respondents indicated they would need a much stronger group of trained technicians if Guinea were to choose to de-link (EPI only has three technicians who work at the national level); they anticipated there would be challenges coordinating with MOH technicians at regional and district levels.
 Innovation driven by 'country preferences' and aligned with 'max value to countries' 	 Remote temperature monitoring built national confidence in CCE performance. General concern that country preferences were at odds with some of the pressures to select CCE from new/different manufacturers than initially selected.

Words that were used consistently about CCEOP at all points of the market-shaping evaluation were "game changing" and "transformational." However, as with any undertaking of CCEOP's size and scope, there are always learnings and opportunities to improve. With the newly launched market-shaping strategy and planning for the next phase of CCEOP underway, there is still a lot to learn about what will ultimately be effective and what will not. Through conversations with stakeholders across all organizations and functions, the following key questions came up consistently about how to address recurring challenges with market-shaping and CCEOP objectives:

- Is it possible to reconcile the commitment to country preferences and market-shaping objectives?
- Can country preference be more generic (specifications based) rather than brand/model specific? What would this do to country ownership?

- If the goal is to reduce TCO, can we reward manufacturers to do that? How does CCEOP continue to promote innovation at the same time?
- How do countries assess the real value add of features versus those that may be "marketing"? Is TCO the right tool for this?
- How can CCEOP provide better visibility into demand to achieve production efficiencies and lower prices?
- What is Gavi's role to help foster greater price sensitivity and real competition?
- Will different co-financing models inject more price sensitivity into decision making?
- SBP is semi-institutionalized now and the quality of the bids have improved; how can countries better assess the value of this service?

LESSONS LEARNED

The successes in CCEOP implementation and challenges faced informed the lessons learned from this evaluation, both at the country and global market-shaping levels, and are presented below.

COUNTRY EVALUATION

- **Maintenance systems**. To protect the investment that Gavi has made into CCE, countries need to strengthen maintenance systems for longevity of the new equipment. The PMT and MOH have a role to play to prioritize a strong and funded maintenance system; UNICEF has a role to play with updating maintenance guidance to be forward thinking and leveraging new technology; and Gavi's role is to support and shape maintenance investments.
- Accurate CCE inventories. Having accurate information on CCE inventories is important for planning new equipment, as well as planning immunization services. However, updating inventories is typically a high level of effort and, as in the case of Kenya, delayed CCE deployment.
- **Operational deployment plans**. The ODPs were largely accurate in each country, yet last-minute changes inevitably occurred with minimal or no disruptions to the SBP activities; the SBPs adjusted easily and with no additional costs.
- **Communication about warranty**. Stakeholders at each level of the system were not clear about the warranty or the SBP's role post-installation, despite the information being shared to national-level decision makers. Additionally, communication lines across the stakeholders were often faulty.
- Systems perspective. CCE is only one aspect of ensuring potent vaccines are available. All supply chain elements data, CCE maintenance, trucks, staff, and such as well as program elements, such as nurses and demand creation, are important for an immunization program to thrive.
- Adaptation of procedures. UNICEF has been quite responsive with adapting to needed changes to the CCEOP processes — for example, with shortening the application time and adapting the service bundle provision. Many of the established processes (e.g., the PMT) and reporting requirements (e.g., for the SBPs and tracking installations) are best practices that could continue to be used.
- **COVID response.** To respond to the need for COVID vaccines, Gavi adapted the CCEOP methodology to expand the CCE criteria to meet the recent urgent need for walk-in cold rooms and regional CCE for introduction of the COVID vaccine.

MARKET SHAPING

- **CCE innovation and pricing**. The CCEOP market-shaping strategy was highly effective at promoting CCE innovation; suppliers reacted quickly to early target product profiles (TPP) and continued to actively innovate to differentiate their products in this market. CCE pricing overall has been less responsive, potentially due to the focus on innovation and/or lower volumes. Efforts to bolster the selection of lower-priced CCE have been implemented via the differentiated tender approach.
- Market shaping for CCE. Market shaping for CCE (expensive, durable goods) is more complex than for consumable products, like vaccines and medicines. While much of the original CCE market shaping was based on experience with vaccines, lessons quickly emerged that needed to be addressed with more nuanced market-shaping approaches, including brand familiarity, uneven annual demand, and limited price sensitivity.
- Market-shaping objectives vs country preferences. An ongoing challenge is the desire to shape the market, supporting the entry of new suppliers while respecting country choice in terms of CCE brands and models, which may favor known brands. The differentiated tender process seeks to address this, but this continued tension underscores the need to understand and effect the drivers of demand and not focus primarily on supply side efforts.
- **Performance monitoring.** Countries appreciate the information visibility provided via remote temperature monitoring. Field performance monitoring efforts need further attention to determine how to comprehensively collect, share, and use this data to improve product comparisons and selection across procurers.

CONCLUSIONS

CCEOP has achieved its goal in increasing the number of optimal CCE across Gavi countries, contributing to increased immunization services, a more reliable supply chain, and improved vaccine potency. Processes established, such as the PMT and SBP reporting requirements, have been effective at strengthening management capacity and country ownership. PMTs have demonstrated leadership in coordinating across donors and partners for supply chain strengthening and CCE procurement.

While CCEOP has improved the CCE availability, this evaluation has identified other areas of the immunization supply chain that need to be strengthened to ensure this new equipment continues functioning and that the ultimate goal of improving vaccine coverage and equity is reached. It is evident that CCE maintenance systems need investment and re-visioning to be more effective.

Additionally, many of the processes and reporting requirements established for CCEOP can be adapted and continued for ongoing monitoring of the CCE and the immunization supply chain in general to reiterate best practices and guidance.

Finally, it is clear that lines of communication between all stakeholders — between health system levels and between country-level and global-level decision makers — can be improved. While a complete institutional analysis was out of scope for this evaluation, the results do imply that many gaps in implementation, such as the lines of communication, reflect the system reality rather than the CCEOP structure.

Recommendations presented below include key stakeholders involved in CCE procurement and immunization supply chain management — the MOH and the PMTs and EPI stakeholders, UNICEF, and Gavi. While these recommendations are based on the experience in the three focus countries and the market-shaping aspect, the lessons learned are applicable to processes and procedures followed by any country using the CCEOP mechanism and can serve to reinforce guidance provided by Gavi and UNICEF.

RECOMMENDATIONS

The recommendations identified at midline still hold true, and many have been addressed or are being considered by the different decision makers. The recommendations listed here are based on insights from the endline findings. While this list is extensive, three broad themes address the priorities:

- 1. **Strengthen maintenance systems**. Investments need to be focused on supporting and strengthening CCE maintenance systems to ensure the functionality of CCEOP-procured equipment, as well as other CCE in use. It is refreshing to see the shift in the global conversation related to maintenance; now more concrete action needs to be taken to implement.
- 2. Reinforce and adapt best practices and guidance, both designed through CCEOP as well as general guidance. A specific example of this is adapting processes and standards developed for the SBPs for the MOH to use where de-linking is implemented to ensure proper tracking of installations and equipment location. This is applicable to UNICEF, as many guidance documents already exist for some of these recommended areas (decommissioning guidance, CCE maintenance, temperature monitoring) yet may not be accessible to stakeholders when needed.
- 3. Improve lines of communication. The PMT can be more proactive engaging subnational level in planning for CCE needs and designing maintenance systems that are feasible and appropriate. It is recommended that UNICEF engage the MOH more closely when contracting with the SBPs for more oversight and ownership and clarification of roles and responsibilities. There is also a need to improve information shared about the application process.

COUNTRY AND GLOBAL RECOMMENDATIONS

RELEVANCE OF CCEOP
Transparent Process and Stakeholder Engagement
Finding 1: CCEOP planning was a transparent, inclusive, government-led process in general but with limited
contribution from the sub-national level for planning and application processes.
Finding 2: Some gaps exist in the transparency of the decision-making process for equipment selection.
In Response to Country Needs
Finding 3: Previous experience with the equipment and information from UNICEF, WHO, and Gavi influenced
equipment selection.
Finding 4: Country-level decision makers will consider the cost and implementation of the warranty and the effort
to standardize CCE models for future equipment selection.
Recommendation:
Processes established for the PMT for CCE monitoring and planning, as well as SBP coordination, should
continue either through the PMT or the NLWG, as there is overlap in group members and responsibilities.
Countries should establish stronger coordination and communication loops with the sub-national level. Global
performance of CCE, SBPs, and warranty utilization should be well documented to assist in future equipment
selection.
PMT/MOH Pocommondation:

PMT/MOH Recommendation:

- Continue using monitoring and reporting processes established through CCEOP, incorporating them into regular management activities through NLWG and other established systems.
- Continue to strengthen the NLWG to regularly monitor and manage the supply chain, to support long-term sustainability.
- More actively engage sub-national-level stakeholders in management decisions and strategic planning for CCE, including updating inventory.
- Closely monitor SBP and warranty utilization to plan future procurements.
- If de-linked approach is used, continue to use processes established for SBPs (ODP, documentation of installation at which health facilities, establishment of proactive preventive maintenance processes).

UNICEF Recommendation:

- Develop a mechanism to receive country feedback on implementation of the SBP contract for installation and on the warranty and process for repairs.
- Share documentation of CCE performance, SBP performance, de-linking experience, and warranty utilization.
- Track performance of de-linked countries using standards established for SBPs (i.e., length of deployment time, documentation of installation, timely resolution of post-installation issues, preventive maintenance practices).

Gavi Recommendation:

Assess the effectiveness of the warranty and how best to ensure it is optimally utilized by countries.

IMPLEMENTATION and EFFECTIVENESS

CCE Availability

Finding 5: CCEOP has successfully and substantially increased the availability and capacity of the cold chain system.

Finding 6: Some facility-level respondents felt the current capacity through new CCE procured was not appropriate to facility needs.

Finding 7: The manufacturing issue with equipment from one manufacturer cast doubts on the quality of equipment promoted by CCEOP and the necessity of the warranty.

Maintenance

Finding 8: While training improved the capacity of the technicians considerably, there still appear to be some gaps in expectations and quality of the training provided on CCE maintenance, including preventive maintenance with health workers.

*Also relevant for sustainability

Finding 9: The CCE maintenance system has yet to see improvements. New models of equipment installed in countries have exacerbated this divergence in maintenance systems, as SBPs are currently engaged.

*Also relevant for sustainability

Finding 10: Having multiple CCE brands has negatively affected knowledge of warranty and corrective and preventive maintenance practices.

*Also relevant for sustainability

SBP Implementation

Finding 11: There are inconsistencies in services provided by SBPs and warranty coverage across the three countries.

Coordination and Communication

Finding 12: The CCEOP is coordinated with other donors and partners for overall system strengthening, although better documentation could improve the coordination and planning.

Finding 13: There was a lack of clarity in the requirements during the proposal stage, with long delays and continued back and forth between the PMT and UNICEF related to the de-linking approach.

Finding 14: While communication between and within levels has improved since baseline, critical vertical communication gaps persist, such as between the facilities and higher levels around warranty issues. Horizontal communication gaps also continue between the SBPs and MOH.

Temperature Monitoring

Finding 15: Largely, temperature monitoring at the facility level is implemented using 30DTR, even if RTMDs are available.

Finding 16: While national staff was very satisfied with the RTMDs, the RTMD dashboard is often unavailable for sub-national staff, especially at the facility level.

Recommendation:

Establish monitoring systems for SBP performance after installation to ensure warranties are being upheld; notably, draw from the successful implementation of the SBP in Guinea on preventive maintenance. Temperature data use should be reinforced. Training requirements need to be defined for the different target audiences. Integrate reinforcement of CCE preventive maintenance practices for health care workers at every opportunity. Develop long-term strategies for improving the maintenance system for all CCE, including capacity building of technicians.

PMT/MOH Recommendation:

- Ensure access to RTMD dashboards and/or create reporting system for data from 30DTRs.
- Continue to use the PMT, NLWG, and sub-national working groups to monitor CCEOP activities, as well as to make use of the temperature data and CCE function in regular system monitoring.
- Continue monitoring SBPs for equipment under warranty, leveraging their skills to build up the maintenance system through improved processes and capacity.
- With each level of the system, clarify warranty and procedures to access SBP services post-installation.
- Continue to work closely with SBPs to ensure close collaboration and a smooth transition to post-warranty responsibilities.
- Increase opportunities for more active vertical communication with all levels. This may help address some of the communication gaps and ensure decisions are appropriately contextualized to the on-the-ground situation.
- Include innovative, on-the-job training or refresher training on CCE preventive maintenance during supervision visits or novel methods of peer-to-peer support groups.
- Ensure systematic data collection on CCE performance with a database to capture CCE performance, facility needs, and additional information required to inform CCE selection and plans for future deployment.
- Provide clear documentation of planning and implementation decisions and coordination efforts across all partners for system strengthening.
- Reinforce the maintenance system with improved funding and resources (human, tools, transportation, spare parts).

UNICEF Recommendation:

- Clarify training expectations and implementation with SBPs and MOH.
- Develop guidance on different maintenance models.
- Clarify training details with manufactures and SBPs.
- Develop standardized training CCE packages adapted to mobile platforms or distance learning.
- Identify SBP successes to refine roles and oversight of the SBPs.
- Continue efforts to clarify warranties with the MOH.
- Ensure manufacturers of RTMDs provide access to the dashboard.
- Continue efforts to clarify proposal processes, especially as requirements are updated.
- For future deployments, ensure precise and direct communication with the MOH and inclusive decisionmaking when changes are made.

Gavi Recommendation:

- Continue coordinating across partners and donors, particularly as the COVID-19 vaccine rollout is gaining traction and additional funding sources.
- Clarify proposal process, including the joint investment aspect, and equipment selection process to streamline the proposal timeline.
- Strengthen and expand support for maintenance for the cold chain system, beyond CCEOP-specific equipment.
- Through landscape shaping, emphasize the need for systems and processes to collect and use temperature monitoring data, regardless of the technology.

EFFICIENCY

CCE Performance and Maintenance

Finding 17: Most respondents are very satisfied with the CCEOP equipment, which brings cost savings, less maintenance required, and better performance.

Finding 18: The new CCE is functioning very well, with high levels of safe time within the expected temperature range.

Finding 19: Decommissioning of old equipment is still not clearly implemented.

Recommendation:

CCEOP has offered countries the opportunity to build up their immunization capacity with more efficient equipment. This is now an opportunity to work with countries to build their maintenance system, not just focusing on the new equipment but taking into account older pieces as well to ensure continued breakdown-free functionality.

PMT/MOH Recommendation:

- Develop plans for decommissioning of obsolete equipment.
- Strengthen the overall maintenance system through regular and systematic CCE and spare parts inventories, appropriately trained technicians or outsourced maintenance, maintenance budget line, funding availability, adherence to preventive maintenance practices, etc. Create a maintenance plan that can be adapted by subnational levels.
- Integrate a performance evaluation rating for the SBP in the cold chain maintenance system to be established.

PMT/MOH Recommendation:

- Develop plans for decommissioning of obsolete equipment.
- Strengthen the overall maintenance system through regular and systematic CCE and spare parts inventories, appropriately trained technicians or outsourced maintenance, maintenance budget line, funding availability, adherence to preventive maintenance practices, etc. Create a maintenance plan that can be adapted by subnational levels.
- Integrate a performance evaluation rating for the SBP in the cold chain maintenance system to be established.

UNICEF Recommendation:

• Reiterate available guidance on decommissioning obsolete equipment.

Gavi Recommendation:

- Support developing a system for tracking CCE status and performance and include periodic reporting from the system on CCE status to feed into the grant performance framework.
- As part of future funding opportunities, require countries to develop and fund more robust maintenance plans and report on CCE performance as part of reporting requirements, with special attention on sub-national levels.

OUTCOMES AND RESULTS

Finding 20: There were fewer stockouts reported at the endline in Guinea and Kenya, although the reasons are unclear.

Finding 21: New equipment has expanded the reach of immunization services and increased CCE capacity. **Finding 22:** While there is evidence that the frequency of immunization sessions has increased, the impact of CCE on immunization coverage rate is inconclusive.

Recommendation:

CCEOP has successfully provided equipment meeting PQS standards to countries. There is a need to look at the immunization supply chain system as a whole to determine other blockages that limit immunization service provision, including vaccine management systems, transport, forecasting, etc.

PMT/MOH Recommendation:

Determine factors influencing routine immunization provision and tailor region specific interventions.

UNICEF Recommendation:

 Provide technical support to the PMT/MOH to study the constraints in the immunization supply chain and immunization program to develop a comprehensive package for its improvement.

Gavi Recommendation:

Consider commissioning a study to examine the impact of the supply chain as a whole (stockouts, CCE reliability, distribution standards, etc.) on immunization coverage.

SUSTAINABILITY

Country Ownership

Finding 23: CCEOP has contributed to the growth of some national-level planning and management structures and systems, such as PMT and NLWG, yet it is not clear that it has fostered ownership through all levels of the system.

Finding 24: There was little indication that the joint investment contributed to financial sustainability or country ownership.

System Strengthening

Finding 25: Warranties will soon expire, and weak maintenance systems will find it challenging to fill in the gap.

Finding 26: The overall health system has not kept pace with the new CCE in terms of the need for more resources.

Recommendation:

CCEOP has successfully increased availability and performance of optimal CCE; the focus should now shift to strengthening the overall system to ensure the CCE continue to perform well and the overall supply chain ensures vaccine availability. Maintenance systems need investment and reshaping to be more effective. Program planning should consider the impact of new CCE on expansion of new immunization services.

PMT/MOH Recommendation:

- Leverage expertise and processes from the SBPs now to strengthen the overall maintenance system.
- Still relevant from midline, develop a systematic way to update the cold chain inventory within the regular monitoring system of the immunization program.
- Ensure close collaboration between service delivery and supply chain planners and managers to optimize CCE and reaching all populations with immunization services.
- Continue to use successful processes established by the PMT to strengthen management structures; consider adapting key processes at lower levels of the system.

UNICEF Recommendation:

- Engage PMT/MOH more closely with SBP contracting to develop more ownership in the process
- Consider updating guidance on stock management and distribution frequency with better-performing and more reliable CCE, potentially holding stock for more than a month in facilities if cost efficiencies can be found (also relevant for the MOH).
- Continue to iterate on maintenance models to strengthen these systems.

Gavi Recommendation:

- Consider innovative approaches to the co-financing requirement, such as regarding government contribution to the maintenance system or dedicated time to manage the CCE as part of this requirement.
- Continue to shape maintenance models to fit country contexts.

MARKET-SHAPING RECOMMENDATIONS

These recommendations include those from the final market-shaping report completed in 2020, plus additional recommendations relevant to market shaping based upon findings from the three country endline assessments.

Address the tension between country preference and mark	et-shaping	objectives	
Gavi and UNICEF	Short	Medium	Long
Consult with countries on brand preferences/perceptions.			
Assess the allocation approach for high-volume countries (whereby countries are requested to allocate 25 percent of procured CCE to a second supplier) to determine if/how this could be increased (to 30 percent to 40 percent) to advance market-shaping objectives further.	•		
Look at models used for procurement of other durable equipment (procured by UNICEF and others).			
Pilot a specifications-based procurement model and create funding incentives for countries that agree to use this model.			
Improve demand visibility to achieve efficie	encies		
UNICEF and alliance partners	Short	Medium	Long
Ensure forecasts are realistic and updated, and shared routinely.			
Review demand fluctuations and set out a deliberate schedule and timeline for annual processes (across applications, approval, ODPs, to POs) to better smooth demand.	•		
Work with manufacturers to understand their production planning schedules and when more concrete inputs would be needed to help planning; work to align forecasts with these schedules.		•	
Establish minimum annual order quantities with suppliers to improve production planning, efficiencies, and ultimately prices; pass savings onto countries in terms of incentives for procurement.		•	
Foster greater price sensitivity and compe	tition		
Gavi and Alliance partners	Short	Medium	Long
Explore ways for countries to "test" or try different models of CCE to build familiarity with new/different brands.			
Alliance needs to clarify role/goals with MS; Gavi needs to determine the "ideal" number of suppliers in the market to meet healthy market goals and establish a clearer strategy to do so.		•	
Explore pricing, allocation, and financing levers to achieve the set goal, even if at odds with country choices.			
Promote product innovation and TCO redu	ctions		
Gavi and UNICEF	Short	Medium	Long
Clarify how country input is feeding into future innovation requirements.			
Systematize reporting of maintenance issues for CCE to improve broader performance monitoring.			
Agree on the next set of TPPs (or set new platform-eligibility criteria) and communicate clearly to manufacturers.			
Clarify and stick to timing for any new feature requirements.			
Establish comparison tool based on required product features; determine if/how to include field performance data.			
Better inform the evaluation of CCE options and value asses	ssment of n	ew features	
Gavi, UNICEF, and Alliance partners	Short	Medium	Long
Define set of essential characteristics; help set value/notional use case for additional features and warranties.			
Develop clear communication around warranties, coverage, and responsibilities, especially for countries with multiple manufacturers and different SBPs and policies.	•		

Ensure decision-support tools are user-friendly (less text, easier to access and use outcomes for both decision making and advocacy).			
Promote informed decision making around SBP and d	le-linking op	tions	
Gavi and UNICEF	Short	Medium	Long
The Alliance should support better costing tools to assess the true cost of deployment and maintenance.			
Benchmark timelines and costs for comparison with countries that choose to de-link.			
Ensure criteria for de-linking the service bundle (some or all components) are transparent and well understood in advance of application process.			

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APPENDIX A: CCEOP RESULTS FRAMEWORK

Note: The CCEOP Theory of Change and Logic Model were shared by Gavi in the Request for Proposal.

Cold Chain Equipment Optimisation Platform (CCEOP) Theory of Change

CCEOP Goal: Improve the effectiveness, efficiency, and sustainability of a country's vaccine supply chain by strengthening its cold chain system; and advance Gavi's vaccine coverage and equity goals as reflected in the Immunisation Supply Chain Strategy.

Problem/Issue	Assumptions	Strategies	Desired results
 The large majority of health facilities are poorly, under-, or not equipped with CCE, which severely impacts vaccine quality and coverage of immunisation programs.³ Old, inadequate equipment and technologies Broken, unreliable, poorly performing equipment Improper equipment in health facilities Additionally, the relatively high 	 Countries perceive a need to rehabilitate old⁴, non-functional, and non-PQS equipment in their supply chains Countries perceive a need to expand CCE to unequipped facilities Subsidy investment is a necessary intervention to achieving vaccine safety, improving and expanding services, growing coverage, and promoting equity Joint investment increases country ownership (stake in the ground) 	 Gavi and Countries will joint invest in high-end equipment and deploy them to the right places: Replacement of old and/or poorly functional equipment with high end, low maintenance ones Expansion of CCE to unequipped facilities to achieve equitable coverage 	 Up to 90,000 facilities upgraded with new CCE; 45,000 facilities newly equipped in 5-7 years Increased cold chain capacity Improvements in coverage and equity of immunisation services
purchasing costs of CCE provides reduced incentives for countries to invest in high-end , low maintenance equipment.	 Countries are able to source for their joint investment share Countries appropriately select and deploy equipment to meet their cold chain needs 		
These unmet needs are a major barrier to equity and sustainability of immunisation programs, particularly	 Poor installation is one of the main causes of non-functional equipment The service bundle will be implemented efficiently and health workers and technicians 	 Countries will plan for and execute regular preventive and corrective maintenance activities: Develop and implement a (preventive and corrective) maintenance plan 	Low equipment downtime and appropriately maintained CCE

³ In 2014, 20% of health facilities in low- and lower middle-income countries were unequipped with CCE to store vaccines and protect them against heat damage while 78% of facilities were equipped with non-functional or obsolete technology. WHO/UNICEF Joint Statement, 2016

⁴ According to guidelines, the lifecycle is approximately 10 years

in ability to cover hard-to-reach populations.	 will be trained in preventive and corrective maintenance, respectively Health workers and technicians will carry out regular preventive and corrective maintenance 	 Demonstrate financing for maintenance plan Have appropriate indicators for monitoring implementation of plans linked to their Performance Framework 	
	Gavi market-shaping strategies will lead to increased development of more efficient equipment, drive their uptake by countries and potentially (through economies of scale etc.) can lead to drive down device prices, making it more affordable to countries	through mechanisms such as demand forecasting, pooled procurement (via UNICEF), economies of scale and TPPs/PQS.	 Contribute to supply of higher-performing CCE products in appropriate size segments, at optimal TCO
	 Increased availability of highend CCE will improve availability and access to potent vaccines Platform investment is contributory to HSS supply chain and other Gavi supports Demand for vaccines will be sustained through complementary investments in advocacy strategies 	Platform investments and complementary supply chain investments will contribute to more potent vaccines being available for immunisation sessions.	 Increased access to potent vaccines Reduced vaccine wastages Catalysed contributions in the four other supply chain fundamentals

Logic Model

Activity	Inputs	Outputs	Outcomes/Results	Overall Goal(s)/Impact
 Planning, selection, installation and management of cold chain equipment 	 Provision of appropriate guidance and quality technical assistance from Gavi and partners on CCEOP Conduct collaborative, systematic and evidence based equipment selection processes Country and Gavi jointly invest in, and procure, high performing and low maintenance equipment 	 Appropriate guidance and quality technical assistance provided by Gavi and partners on CCEOP Collaborative, systematic evidence-based equipment selection processes conducted High performing and low maintenance equipment procured through joint investment by Country and Gavi 	 Potent vaccines available for immunisation services Reduced stockouts Reduced vaccine wastage Demand for Platform eligible cold chain equipment sustained Platform investments are aligned with, and complementary to, other support (from Gavi, other partners, government) e.g. supply chain leadership, data for management, system 	 Improved effectiveness, efficiency, and sustainability of vaccine supply chain through strengthened cold chain systems Increased coverage and equitable immunization

	Equitable deployment of equipment to targeted and prioritised sites	 Countries finalised readiness report and operational deployment plan Equipment equitably deployed to targeted and prioritised sites Obsolete equipment replaced with appropriately selected Platform eligible equipment Unequipped facilities equipped with Platform eligible equipment 	design and continuous improvement plans	
Management of service bundle	 Conduct efficient implementation of service bundle (distribution, installation, training of technicians and end users and commissioning) Develop regular preventive and corrective maintenance plans Conduct training of health workers and technicians to carry out preventive and corrective maintenance of CCE Advocate for adequate budget line allocation for CCE operation and maintenance 	 Service bundle implemented efficiently Preventive and corrective maintenance plans developed Health workers and technicians trained to carry out preventive and corrective maintenance of CCE Adequate financing provided to support operation and maintenance of CCE 	 Necessary preventive and corrective maintenance of installed CCE conducted on a regular basis, as per service bundle contract Reduced equipment downtime Lifespan of equipment maximized 	
Market Shaping	 Appropriate engagement with the CCE market through demand forecasts, pooled procurement, advocacy etc. Development and implementation of stakeholder Action Plan for ILR & SDD refrigerators/freezers Roadmap 	 Objective 1: At least 2 suppliers of ILRs and of SDDs in each of the 5 size segments reach platform-eligibility by 2019 for TPP-2017, and by 2021 for TTP-2019. Market access barriers created by the service bundle requirement are addressed in the short term through increased information and guidance to suppliers on in- 	 Supply meets demand Fair and sustainable prices for both devices and commissioning service bundles for ILRs/SDDs achieved Continuous innovation of high performing, optimal TCO products Improved information sharing, including increased price transparency 	

 country logistics and service landscape. Objective 2: For ILRs: Targeted price reductions in weighted average prices achieved. For SDDs: Targeted price reductions in weighted average prices achieved. For service bundle: Cost of service bundle further benchmarked and controlled. Objective 3: Manufacturers adopt TPP- 2017 and TPP-2019 by 2019 and 2021 respectively.
 Product improvements with optimal TCO achieved as a result of functional feedback loop on product field performance findings. Objective 4: Suppliers offer locally customized service bundles in response to information on product and service market demand. CCE prices lowered within CCE size segments through CCE price transparency.

APPENDIX B: COUNTRY-LEVEL EVALUATION QUESTIONS

EVALUATION QUESTION	BL	ML	EL	DATA SOURCES AND METHODOLOGY	FINDINGS	
RELEVANCE						
 To what extent was there a transparent, government- led process to apply for and implement the CCEOP support? 	•	•	•	KIIs at the national level, subnational level, and with immunization partners	Endline findings #1, 2	
 To what extent did the process ensure the CCEOP was aligned with and complementary to other support from Gavi (health system strengthening, vaccines, technical assistance, etc.), other partners, or the government? 	•	•	•	KIIs at the national level and with donors and immunization partners	Endline findings #9, 12	
 To what extent did the CCEOP respond to country needs for improved CCE as part of improved immunization supply chains? 	•	•	•	KIIs at the national and subnational levels; Document review of CCE reports and assessments	Endline findings #3, 4, 5, 6, 17, 21	
 To what extent was the targeting and prioritizing of location and type of equipment in line with Gavi CCEOP application guidelines? (Pay specific attention to coverage and equity components.) What are the main reasons for these results? 	•	•	•	KIIs at the national and subnational level; Document review of Gavi guidelines, facility selection methods, CCE inventory, and CMYP and HSS plans	Baseline finding #1 Midline findings #1, 5 Additional language has been added (p 33) to the endline report under discussion of Findings 3 & 4 to note these earlier findings	
 To what extent did the revised CCEOP application guidelines (if any during the evaluation period) reflect lessons over time? 	•	•	•	KIIs at the national level; Document review of previous CCEOP application versions	Noted on page 26 under "Global Landscape Shifts". Because of the timing of the application and changes to processes, these improvements were not noted in the evaluation countries as they had already gone through the full application process	

EVALUATION QUESTION	BL	ML	EL	DATA SOURCES AND METHODOLOGY	FINDINGS
 What were the main sources of information, including any budget ceilings and guiding country CCE choices in the application process? To what extent did these differ from pre-CCEOP? What were the incentives/criteria for equipment selection? 	•	•	•	KIIs at the national level; Document review of CCEOP applications	Baseline finding #1 Midline finding #1, 5 Additional language has been added (p 32)
 Does CCEOP replace other funding sources or fill a gap? 				KIIs at the national and subnational levels	Endline finding #24
EFFECTIVENESS					
 To what extent was the implementation of the platform support in each country conducted as planned⁵ (consider timing, quality of implementation, participatory approach, and timely flow of funds) across each component of the CCEOP such as the application, operational deployment plan (ODP), service bundle provider (SBP), and equipment selection, etc.? What are the main reasons for these results? 		•	•	KIIs at the national and subnational level, with a Gavi program officer, and with CC suppliers; Document review of the CCEOP application	Midline findings #2, 3, 5-13 Endline findings #3, 4, 8, 11, 13, 14 Additional language has been added (p 42) to highlight midline findings
 To what extent was engagement with the Gavi secretariat (including the independent review committee) and quality technical assistance from alliance partners (including WHO and UNICEF) provided in an appropriate, timely fashion in developing the application and implementation? 	•	•	•	KIIs at the national level and with country focal points from partner organizations	Baseline finding #5 Endline finding #13 Additional language has been added (p 44) to highlight baseline results
 To what extent has the CCEOP investment achieved (or is on track to achieve) its objectives as planned? What are the main reasons for these results (considering contextual factors including environmental, policy, political, financial, information and monitoring, human resources, macroeconomic)? 		•	•	KIIs at the national and subnational province levels; Reviews of HMIS and LMIS data	Endline finding #1, 5, 12, 23, 26

⁵ As per the country application, operational deployment plan, strategic operational plan, procurement plan, etc.

EVALUATION QUESTION	BL	ML	EL	DATA SOURCES AND METHODOLOGY	FINDINGS		
EFFICIENCY							
 To what extent has the alliance, country (Ministry of Health), procurement agent (headquarters, provincial offices), and SBP managed the investment efficiently (defined in terms of cost and time) across each component of the CCEOP and time? 		•	•	KIIs at the national and subnational levels and with SBPs; Document review of SBP and installation reports	Endline finding #8, 11, 19		
 To what extent have CCE efficiencies (as measured by operational costs—utilities, maintenance, replacement, CCE performance, etc.) improved compared to pre-CCEOP and across time? 		•	•	KIIs at the national and subnational, including facility level; HFA	Endline finding #18, 19, 20, 21, 22		
OUTCOMES/RESULTS ⁶							
 To what extent has the CCEOP contributed to the extension of the supply chain, replacement (i.e., rehabilitation), and expansion of CCE at national, provincial, district and health facility levels? 			•	KIIs at the national and subnational level including facility level; HFA	Endline finding #21, 22		
 To what extent has the CCEOP improved the processes for equipment selection, installation, and the national management of the cold chain by all key stakeholders (government, procurement agency, SBP)? 			•	KIIs at the national and subnational level, and with SBPs	Endline finding #3, 4, 9, 10, 23, 24, 25, 26		
 To what extent has the CCEOP contributed to appropriate stock availability of potent vaccines (measured by full stock availability, stocked according to plan)? 			•	KIIs at the national and subnational level including facility level; HFA; Review of HMIS/LMIS data;	Finding #20		
 To what extent has the CCEOP contributed to decreased vaccine wastage? 			•	KIIs at the national and subnational level including facility level; HFA; HMIS/LMIS data	Additional language from country findings has been added in Finding #20 (p 51), however the data are inconclusive and should be interpreted with caution		
 To what extent has the CCEOP contributed to improvements in access and utilization of immunization services in an equitable way? 			•	KIIs at the national and subnational level including facility level; Document review of session and micro plans; HMIS/LMIS data; HFA	Endline finding #21, 22		

⁶ CCEOP contribution to outcomes/results should not be assessed in isolation; other factors, including government, external, and Gavi support should also be considered.

EVALUATION QUESTION	BL	ML	EL	DATA SOURCES AND METHODOLOGY	FINDINGS	
 To what extent has the CCEOP improved routine cold chain management (corrective and preventative maintenance, temperature control, functionality) at the national, provincial, district, and health facility levels? 			•	KIIs at the national and subnational level including facility level; Document review of maintenance plans and requests; HFA	Endline findings #8, 9, 10, 15, 16, 17, 18, 19	
 To what extent did the design and implementation of the CCEOP support complement or advance progress on other supply chain fundamentals, particularly supply chain system design? 			•	KIIs at the national level	Baseline finding #1 Additional language has been added to endline under Finding #26 (p 59) to link to other supply chain fundamentals.	
 What have been unintended (positive and negative) consequences of the CCEOP for countries, the Gavi secretariat, and alliance partners? 		•	•	KIIs at the national and subnational level, KIIs with country focal points from partner organizations, and with a Gavi program officer	Endline findings #25, 26	
SUSTAINABILITY						
 To what extent has the CCEOP contributed to the financial and operational sustainability of the cold chain and/or wider immunization program (considering other investments and support)? 			•	KIIs at the national level	Endline finding #12, 24, 26	
 To what extent has managing the CCEOP strengthened the Project Management Team (PMT)/National Logistics Working Group (NLWG) and contributed to country ownership? 		•	•	KIIs at the national level; Document review	Endline finding #23	
 To what extent have the SBPs built the capacity of technicians for maintaining CCE? 				KIIs at the national and subnational levels; Document review	Endline finding #8, 9, 10	
 To what extent are the outcomes/results achieved through the CCEOP financially and operationally sustainable? What main factors contributed to these results? 			•	KIIs at the national level	Endline finding #23, 24	

APPENDIX C: MARKET-SHAPING EVALUATION QUESTIONS

Text in italics indicates a revision or addition to the original market-shaping questions to reflect the changing environment over the course of the 4 years of the evaluation.

RELEVANCE

- To what extent was the original CCE market-shaping strategy relevant and fit for purpose?
 - Did the CCE market-shaping strategy take into account other market-shaping strategies/approaches used by Gavi Secretariat (vaccines) and/or at other organizations?
- To what extent was the market-shaping monitoring and evaluation system relevant and practical?
- What were some of the ideas or assumptions in the original strategy that were addressed in the revised strategy? To what extent have these addressed limitations observed in early implementation?

IMPLEMENTATION

- To what extent were market-shaping activities (including stakeholder action plan) conducted as planned? [this will acknowledge original action plan, but focus on stakeholder action plan from revised strategy]
 - o What are the main factors explaining these results?

EFFECTIVENESS

- To what extent has the *original* CCE market-shaping strategy and activities achieved (or are on track to) their objectives and targets, specifically:
 - Stimulate supply to meet demand
 - Achieve fair and sustainable prices for ice-lined refrigerators (ILR)/solar direct devices (SDD) devices and commissioning of service bundles by type and volume categories
 - Continuous innovation of high performing and optimal total cost of ownership (TCO) products
 - Increased, equitable and transparent communication and flow of information with suppliers, service bundle providers etc.

- To what extent has the REVISED CCE market-shaping strategy and activities achieved (or are on track to) their objectives and targets, specifically:
 - Improve long term competition and increase evidence base to inform country preferences
 - Achieve reductions in WAP to maximize value to countries
 - Reform procurement processes for greater efficiencies
 - o Innovation driven by country preferences and future TPPs
- What are the main factors explaining these results?
- What has been the role of the demand forecast in achieving market-shaping goals? How has it evolved, what has been the accuracy, and what factors have affected its purpose and utility?

SUSTAINABILITY/RESULTS

- To what extent are the CCE market-shaping results sustainable?
- To what extent did the market-shaping strategy/activities result in any unintended positive/negative consequences?
- How has the revised market-shaping strategy addressed early signs of unintended consequences and/or altered the sustainability outlook for CCE?