



JSI RESEARCH & TRAINING INSTITUTE, INC.

Evaluation of the Cold Chain Equipment Optimization Platform

Midline Cross-Country Report:
Intermediate Assessment (Market Shaping, Kenya, Pakistan, and Guinea)

October 2019

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.

JSI exists to improve the health and well-being of underserved and vulnerable people and communities throughout the world, and to provide an environment where people of passion and commitment can pursue this cause.

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ACRONYMS

CCE	cold chain equipment
CCEOP	Cold Chain Equipment Optimization Platform
CHAI	Clinton Health Access Initiative
DHS	Demographic and Health Survey
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
iSC	immunization supply chain
iSCM	immunization supply chain management
JSI	JSI Research & Training Institute, Inc.
KII	key informant interview
LMIS	logistics management information system
MCV	measles-containing vaccine
MOH	Ministry of Health
NVIP	National Vaccines and Immunization Program
ODP	operational deployment plan
PII	post-installation inspection
PMM	post-market monitoring
PMT	project management team
PO	purchase order
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
SOP	standard operating procedure
TCO	total cost of ownership
TPP	target product profile
UNICEF	United Nations Children’s Fund
WHO	World Health Organization

SUMMARY

BACKGROUND

The Gavi Cold Chain Equipment Optimization Platform (CCEOP) was established in 2015, recognizing that functional cold chain equipment (CCE) is a critical precondition to strengthening vaccine supply chains and, ultimately, to achieving the Alliance's immunization equity and coverage goals, yet remains a gap for many countries. 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 that the market for CCE is healthy, and that countries are procuring optimal, yet durable and high-performing products.

This prospective evaluation of CCEOP, being conducted by JSI Research & Training Institute, Inc. (JSI) between 2018 and 2020 in three countries, Kenya, Pakistan, and Guinea, aims to assess the progress of the CCEOP against its original objectives and understand details of the processes followed in the deployment process. The country-level implementation focuses on achievements made in upgrading and expanding CCE and creating a more efficient and effective supply chain. The market-shaping aspect considers progress made in promoting healthy markets and improved optimal market conditions, as well as any unintended consequences. Results of this evaluation will ultimately improve the design of the platform with both market shaping and country-level implementation in mind.

This cross-country report presents findings from the midline intermediate assessment from this evaluation. It includes (1) assessing the CCEOP planning and deployment process and understanding the situation post deployment in three countries, Kenya, Pakistan, and Guinea, and (2) evaluating the procurement landscape and market shaping progress as of December 2018. These findings will serve as a comparison point to assess progress between the baseline and endline stages of the CCEOP evaluation.

COUNTRY CONTEXT

Kenya, Pakistan, and Guinea all face situations of poor immunization coverage. Based on effective vaccine management (EVM) assessments in recent years, they also face shortages of CCE in health facilities. Even when available, the equipment often fails to meet established performance, quality, and safety (PQS) standards, and has not kept pace with the massive increase in the quantity of vaccines. At both the national and sub-national levels, common cold chain system gaps include maintenance, stock management, and effective distribution and information systems.

The table below summarizes CCEOP-related activities in the three countries.

Activity	Kenya	Pakistan	Guinea
Date of CCEOP approval	March 2017	Nov 2016	Oct 2017
Amount approved ¹	\$8.2 million	\$41.1 million	\$10.9 million
% financing by country	50%	50%	20%
Year 1 priority	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 higher demand for vaccinations, and to a lesser extent (deferred for later years) equipping new facilities	Equipping health posts for the first time to expand immunization services by increasing the number of fixed posts for vaccination
Year 1 # CCE deployed ²	1,004 (500 ILR and 504 SDD)	6,828 (5859 ILR and 969 SDD)	853 (210 HTCS-160, 638 TWC 2043 SDD, and 5 Arktek)
Date of deployment ³	July – Nov 2018	May – October 2018	Dec 2018 – June 2019
Manufacturers, service bundle providers, warranties	B-Medical, Sanica Limited, 3 years on AC powered, 10-year warranty on SDDs	Sure Chill, Technology Links, 2- year warranty	B-Medical, Soguimap, 10-year warranty on SDDs
	Vestrost, Total Hospital Solutions, 2-year warranty	Vestfrost, Capri Medicals, 2-year warranty	Haier Medical, Menerga, 3-year warranty

Source:¹ CCEOP final approved application

² Database with cost information per CCE shared by Gavi

³ CCEOP Monitoring sheet shared by United Nations Children’s Fund (UNICEF) SD. In the case of Kenya, monitoring forms submitted by service bundle providers.

DATA AND METHODS

The evaluation examines the differences between areas receiving and not receiving new equipment through CCEOP in the three countries. The midline assessment focuses on understanding the CCE installation process under CCEOP. It also aims to document any changes in CCE-related outputs and outcomes between facilities scheduled to receive CCEOP equipment in Year 1 (program facilities) and those not scheduled to receive equipment in Year 1 (comparison or control facilities) both before and after CCEOP deployment.

The evaluation used a mixed-methods case-control research design that is largely prospective involving key informant interviews (KIIs) at multiple levels of the health system, document reviews, direct observation (as and when possible), and a health facility assessment (HFA). Data from the health management information system/logistics information management system (HMIS/LMIS) could not be used to the extent intended because of issues with data quality. Data from all sources were triangulated to draw the results and recommendations. JSI 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.

RESULTS

Data on maintenance and breakdowns of CCE, temperature monitoring, stock management, and changes in immunization services are summarized below based on HFA findings after the CCEOP Year 1 deployment. Due to changes in deployment plans and other reasons, such as CCE availability from other sources, the comparisons between the program and control group of facilities are difficult to interpret at midline and need to be reviewed with caution, particularly in Pakistan. For this midline, quantitative information is available only for Kenya and Pakistan; the HFA was dropped from the midline assessment in Guinea due to a setback in CCE deployment as a result of delays in contracting and procurements as well as payments to service bundle providers (SBPs).

Maintenance and Breakdowns of CCE

During baseline, more than 80–90 percent of equipment was functional across Kenya and Pakistan. This percentage increased by a small amount as well between baseline and midline. A few small declines are evident, which may be attributed to equipment that was moved from another facility, or instances of CCE that remained unplugged, as was observed in Pakistan. CCE breakdowns ranged around 15–20 percent at baseline and consistently decreased at midline. Though facilities in Kenya showed a significant increase in maintenance manuals observed at midline, the opposite was true in Pakistan. On average, only 40–45 percent of health facilities had a repair and maintenance manual in Pakistan at baseline. Surprisingly, this decreased even further at midline, going down to less than 20 percent in Sindh. The reasons for this decline are unclear and will be investigated at the next data collection.

Temperature Monitoring

Significant increases in the use of Fridge-Tag was observed in both Kenya and Pakistan, and especially in the program group. In Kenya, all models of B-medical equipment included a remote temperature monitoring device (RTMD), which accounted for the increases seen between baseline and midline. In Pakistan, we saw greater increases in CCE monitored by a fridge tag and decreases in equipment monitored by stem/dial thermometer. There is a decrease in equipment not monitored in program facilities in Kenya as a result of these new monitoring devices, but an increase in Pakistan, which could be due to nonfunctional or unplugged equipment.

Stock Management

Stockouts of both DPT/pentavalent and measles vaccines were considerably higher in Kenya than Pakistan at both time points. Interestingly, declines between baseline and midline were observed for pentavalent vaccine in Kenya, but not for measles vaccine. Stockouts of measles vaccine also occurred in some facilities in the Kenya control group, possibly due to a national-level stockout of measles in 2018, reported in the June 2018 Kenya EPI program review report (NVIP 2018).

The percentage of health facilities with well-organized vaccines was consistently high across all groups in Kenya and Pakistan, over 80 percent and in some cases between 95–100 percent,

and no clear patterns were evident. It is important to note that these proportions are restricted to facilities with stock ledgers, and do not show data on facilities with missing or unavailable stock ledgers.

Changes in Immunization Services Offered

Though all facilities in the sample in Pakistan already provided immunization services at baseline, the CCEOP deployment resulted in a considerable increase in the percentage of facilities providing immunization among the program group in Kenya. In both Kenya and Pakistan, the majority of health facilities provided immunization services five or more days a week. This increased even further in the program arm in Kenya after CCEOP deployment. Some declines in Pakistan were observed, particularly in Sindh, the reasons for which are unclear and will be investigated at the next round of data collection.

HIGH-LEVEL INSIGHTS

Six high level insights from this midline evaluation in Kenya, Pakistan and Guinea are listed below. More specific findings are outlined in more detail in the following table.

High-Level Insights	
1.	CCEOP responds to country needs and priorities and is well coordinated by the PMT* in-country with other partners.
2.	Proper preparation for CCEOP deployment requires significant investment in time and budget, and needs to be taken into account during planning.
3.	Not all implementation guidance, policies, or plans are well communicated, understood, or implemented at the country level.
4.	Stakeholders were generally satisfied with SBP installation of equipment, although in Kenya stakeholders were concerned that the cost was too high for a service the MOH felt they could provide.
5.	The SBP monitoring system for deployment was effective and allowed for minor deviations.
6.	Training provided by SBPs was insufficient; training needs and topics need to be clarified.

*PMT: project management team

The table below summarizes findings from the midline evaluation in Kenya, Pakistan, and Guinea also highlighting areas where they apply to the market-shaping component of this evaluation.

	Market Shaping	Kenya	Pakistan	Guinea
RELEVANCE OF CCEOP				
IN RESPONSE TO COUNTRY NEEDS				
Finding 1: At the macro level, the CCEOP responds to country priorities and needs, although some manageable specifications still need to be addressed (details: trays for equipment, stabilizers, freezer capability).	X	X	X	X
TRANSPARENT PROCESS AND STAKEHOLDER ENGAGEMENT				
Finding 2[†]: Stakeholders do not fully understand all of the details of the warranty, type of corrective maintenance/repair that is covered, and how to access those services.	X	X	X	X

	Market Shaping	Kenya	Pakistan	Guinea
Finding 3: Many respondents were unclear on SBP terms of reference and what they were/were not contracted to do to set expectations for performance.	X	X	X	X
ALIGNMENT WITH GAVI GUIDELINES AND OTHER DONOR/PARTNER SUPPORT				
Finding 4: The CCEOP is coordinated with other donors and partners for overall system strengthening, although better documentation could improve coordination and planning (i.e., deployment of World Bank/other donor-funded refrigerators and cold rooms, and limited information on where old fridges were moved).		X	X	X
Finding 5: Respondents were satisfied that the CCEOP application and operational deployment plan (ODP) adhered to Gavi guidelines, used available systems and cold chain inventory data, and responded to country priorities.		X (information from baseline)	X	X
EFFECTIVENESS				
SBP IMPLEMENTATION				
Finding 6: Respondents at all levels were mostly satisfied with the installation and commissioning of the CCE by the SBPs with some areas for improvement, such as clarity on roles and responsibilities and warranty coverage.	X	X	X	X
MOH INVOLVEMENT IN IMPLEMENTATION				
Finding 7: The robust system of monitoring and documentation established for equipment deployment was effective at tracing equipment and ensuring accountability from the SBPs.		X	X	X
Finding 8: The few deviations were effectively handled locally, with no reported additional costs incurred. Accurate deployment plans must also include a level of flexibility, especially at lower levels, to respond efficiently and effectively to on-the-ground situations in a timely manner.	X	X	X	X
Finding 9: The PMT played an active and effective role in CCEOP deployment and coordination, demonstrating ownership and strategic thinking, although documentation could be improved (also relevant to sustainability).		X	X	X
COORDINATION AND COMMUNICATION				
Finding 10: Respondents were generally satisfied with the deployment and installation process, although relevant information on the deployment schedule did not always uniformly extend to all key stakeholders.	X	X	X	X
EFFICIENCY				
SBP IMPLEMENTATION				
Finding 11: Satisfaction with the efficiency and quality of work of SBPs is generally good, but varies by SBP and facility preference on equipment.	X	X	X	X

	Market Shaping	Kenya	Pakistan	Guinea
Finding 12: Although the MOH was capable of installing CCE and procuring additional CCE units, respondents at the national level recognized the trade-off between the speed and effectiveness of SBPs deploying CCE and value for money.	X	X	X	NR
SUSTAINABILITY				
COUNTRY OWNERSHIP				
Finding 2[†]: Stakeholders do not fully understand all of the details of the warranty, type of corrective maintenance/repair that is covered, and how to access those services.	X	X	X	X
Finding 9: The PMT played an active and effective role in CCEOP deployment and coordination, demonstrating ownership and strategic thinking, although documentation could be improved.		X	X	X
CAPACITY FOR CCE				
Finding 13: SBPs provided insufficient training to facility staff. Training needs are insufficiently defined or understood by facility staff to ensure long-term maintenance of CCE.	X	X	X	X
Finding 14: For longer-term sustainability, technicians currently have insufficient capacity for corrective maintenance. Countries are not implementing a maintenance plan at national and sub-national levels.		X	X	X
OVERALL				
SYSTEMS STRENGTHENING				
Finding 15: There is no reported plan for decommissioning equipment.		X	X	NR
Finding 16: There is a need for an updated inventory using existing information systems and automated processes.		X	NR	X
Finding 17: Some facility personnel in Kenya and Pakistan are not well oriented about the shift to using cool packs (instead of ice packs) for outreach activities. In Guinea, health post staff are 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, not only specific to CCEOP but also to the overall system.		X	X	X
Finding 18: Currently there is no clear mechanism for monitoring CCE performance over time (after installation check) and providing feedback to manufacturers. With warranty processes unclear in many places, it is uncertain if SBPs or the UNICEF Country Office would report breakdowns to UNICEF SD.	X	X	X	X

*NR - Not reported but still applicable

[†]Applicable across multiple evaluation objectives

MARKET SHAPING

Given the current stage of implementation and expected changes to the procurement approach and market-shaping strategy, early findings described the initial strategy's effectiveness (to

date) design, and the relevance of CCEOP based on the market-shaping strategy and objectives published in 2016. Many of the early trends were summarized in the July 2018 Market Shaping Summary report. A few additions are highlighted here based on more recent outcomes and additional KIIs with representatives from CCEOP eligible suppliers; and linked with relevant findings from Kenya and Pakistan data collection.

FINDINGS

- The original market-shaping goal was to ensure two platform-eligible suppliers of ice lined refrigerators (ILRs) and solar direct drives (SDDs) per size segment. The supply of CCE continues to expand, with 9 of the 18 CCE segments tracked exceeding the original goal. As of September 2019, there are seven suppliers of platform-eligible ILRs producing 23 different platform-eligible models, up from 20 in July 2018 (15% increase). For SDDs, there are eight platform-eligible suppliers producing 36 different platform-eligible models, up from 33 models in July 2018 (9% increase). Procurement has not kept pace with the initial annual forecasts for CCE that were shared with suppliers at the outset of CCEOP, due to delays in implementation. As of December 2018, procurement orders had been placed for ~20k units of CCE, roughly 43% of the 46k units forecasted to be procured by end of 2018. Tenders for the first 25 countries (including Year 2 procurement) have skewed towards 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 to date have 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, feel that the tender award process is opaque and is not currently rewarding investments already made in product innovation and lower TCO (total cost of ownership) options; they would like 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 ability to compare across a wide set of features makes it difficult to accurately assess for various contexts and compare value for money or TCO in selecting equipment.
- Questions and concerns persist regarding the tendering and CCE selection processes and role of country preferences. For the suppliers who 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 is the greatest source of conflicted feedback. Global and national stakeholders feel that it has complicated price negotiations and efforts to ensure value for money. Countries, specifically national level stakeholders, value the service provided but are concerned that the added costs of SBPs on top of CCE limit their ability to obtain the number of CCE they need. Suppliers appreciate the opportunity to ensure that their CCE is properly installed, but feel that they are bearing all of the risk and uncertainty. Some suppliers feel that the service bundle mandate forces them into a service area outside of their core competency.
- Information flow and transparency among partners, countries and manufacturers have made progress under CCEOP. Gavi, UNICEF (Supply and Programme Division), and WHO have all been cited by stakeholders for their efforts to coordinate and improve information sharing among themselves, countries, suppliers, and service bundle providers.
- Progress has been made to improve price transparency through the UNICEF SD websites, but information is not updated regularly, and it is not clear how the UNICEF reference prices relate to CCE prices in the CCEOP budget template or actual prices paid via country specific tender awards. Therefore, it is unclear how this price transparency will affect competition and decision-making.

RECOMMENDATIONS

PMT/NVIP/FEDERAL EPI

Activity	Timing
Engage stakeholders at all levels of the system to review and update the ODP at the beginning of the deployment year to ensure that it is as accurate as possible, to minimize deviations.	Immediate
Develop a communications plan for the installation process; develop contingency plans and processes for deviations.	Immediate
Update the maintenance plan to incorporate details of the warranty and the services provided by the SBPs; and a transition plan for the best way to maintain CCE after the warranty ends. This could include developing an optimum staffing structure for long-term maintenance.	Immediate
Clarify deviation protocol with SBPs and sub-national stakeholders who are most directly involved during deployment and installation; ensure a level of flexibility of the deviation protocol to respond to changing needs.	Immediate
Develop a systematic way to update the cold chain inventory within the regular monitoring system of the immunization program. This is particularly timely after installation of CCEOP equipment, but should also be part of the regular system to reduce the burden typically required of data collection for updating inventory.	Immediate
Develop a training plan with the SBPs to ensure a high level of satisfaction of training for each cadre of health worker; clarify standard operating procedures (SOPs) of SBPs and the expectations on and communication and installation standards.	Immediate
Develop a decommissioning plan for old, unusable equipment, when such a plan is not available.	Immediate
Continue to meet regularly to monitor the progress of CCE installation, SBP performance, and CCE performance throughout the warranty period. Incorporate additional processes to ensure that data on deployment and installation are captured and incorporated into regular review processes.	Ongoing
Coordinate and align with all CCE stakeholders on the planning and deployment process for CCE from CCEOP and other donors.	Ongoing
Possibly through supportive supervision, clarify with all facility staff the policy to use cold packs (instead of ice packs) for outreach activities where it is a policy; this may help with better understanding as to the choice of equipment without freezers.	Ongoing
Consider incorporating feedback on CCE performance (from facilities and on the SBP) to UNICEF SD into a regular process.	Long term

GAVI

Activity	Timing
Ensure that countries applying for CCEOP understand the level of effort required to implement CCEOP and have in place a system of collecting regular information on their health facilities and equipment inventory.	Ongoing
As part of the CCEOP, consider including a requirement for an updated inventory after each year of equipment deployment, encouraging a system that builds on current resources (i.e., LMIS, regular reports and processes). This could also build on the strong documentation requirements put into place for the SBPs and possibly extending it beyond new CCE to capture where other equipment has been moved.	Long term

If reconsidering the structure of the SBPs, any revisions must take into account the effectiveness of the SBP approach, including the specific complaint that it is too expensive and has the effect of reducing the pieces of equipment that can be procured.	Long term
Consider financially supporting transition planning, updating maintenance plans, and longer-term HR capacity building for CCE technicians.	Long term
Use the Gavi guidelines for CCEOP to incorporate more system strengthening activities such as developing a systematic approach to updating inventory or updating the maintenance plan.	Long term

UNICEF SD

Activity	Timing
Following contracting with the SBP, the suppliers should ensure that SBP contractual agreements and terms of reference are shared with the MOH, including SOPs and warranty agreements. Involve the MOH from the outset in discussions of implementation with the SBPs, to better set expectations and as an opportunity to increase MOH ownership.	Immediate
Clarify training details with manufacturers and SBPs and Ministries of Health.	Immediate
Clarify deviation procedures and expectations to prevent surprises in the future. Ensure that quality checks of installation are included as part of post-installation inspection (PII) plans and feedback on quality flows back to UNICEF SD to inform future SBP awards.	Immediate
Clarify the details of the warranty with the manufacturers and SBPs; ensure that country-level stakeholders understand the warranty and requirements.	Immediate
Ensure that the “Decommissioning and Safe Disposal of Cold Chain Equipment” document is available and accessible to country-level stakeholders; provide guidance on applying.	Immediate
Clarify stabilizer expectations/local voltage levels with the MOH during the application and product selection process to ensure clear communication of requirements to manufacturers.	Immediate
Develop a mechanism to receive country feedback on the implementation of the SBP contract for installation, as well as on the warranty and process for repairs. Ensure that this feedback on SBP performance flows back to UNICEF SD to inform future awards.	Long term
Explore the possibility of including trays/baskets with the equipment. Continue to provide feedback to the manufacturers on the performance of the CCE.	Long term
Promote a community of practice for a vaccine cold chain maintenance and repair system to develop innovative approaches and solutions for countries to adopt.	Long term

SBP

Activity	Timing
Clarify training and installation expectations and SOPs with MOH. Ensure that training includes processes for reporting maintenance issues (agreed upon with MOH) and warranty issues. Training and supporting materials and equipment manuals should be in local languages when feasible.	Immediate
Ensure high levels of communication and transparency with sub-national level stakeholders and particularly facility level staff to coordinate installation and any necessary changes to the ODP. Maintain the high level of flexibility and adaptability for minor changes in the ODP.	Immediate/ Ongoing

MARKET SHAPING RECOMMENDATIONS

The table below summarizes global recommendations based on the market-shaping evaluation.

Gavi

Activity	Timing
Update longer-term CCE demand forecasts, reassess the optimal number of suppliers, and evaluate these against the supply capacity in the CCE market, with a more nuanced analysis by CCE type and size segment. These assessments should be used to refine the strategic objectives and stakeholder action plan for market shaping.	Long term
Consider different models for service bundle mandate depending on local capacity and needs – offer tiered levels of support (white glove, basic, etc.) or options to choose services from an a la carte menu (e.g. distribution, SDD-installation, etc.); also consider allowing third-party bidding (one SPB for all CCE suppliers in a given country, not supplier-relationship dependent). Ensure that past performance of suppliers and SBP management are included in future award criteria.	Long term

UNICEF SD

Activity	Timing
Consider implementing a mechanism for feedback from countries on supplier and SBP performance, including the number of times SBPs respond to warranty requests by CCE supplier and/or model, to understand prevalence of CCE issues within the warranty period.	Immediate
Update CCEOP platform eligible model list and prices more regularly, based on actual prices from country tender awards, to improve transparency and potential use of these data.	Immediate
Provide suppliers with increased feedback on tender awards, as possible within procurement policies.	Immediate/ Ongoing
Provide SBP benchmarks earlier in tender process; provide more guidance and information on benchmark data sources; provide country MOH partners with better estimates up front in application process. Consider opportunities to select tiered levels of SBP support (also see related country-level recommendation). Involve MOH earlier on in the SBP contract startup to build country ownership; increase transparency; and improve understanding of SBP activities and value added (compared to costs).	Immediate/ Ongoing

Gavi and UNICEF SD

Activity	Timing
Align on prices so that they are consistent across CCEOP-related information sources (e.g., UNICEF website and Gavi CCEOP budget template). Ensure that these reflect actual prices from recent contracts, and include updates for SBP cost estimates based on actual costs from existing contracts.	Immediate
Provide suppliers with clearer understanding of the product selection process. As the differentiated tender process is implemented, provide specifics on how countries indicate preference and for those for whom an allocation will be recommended, and clarify the criteria that will be used.	Immediate
Revisit role of biannual (every two years) updates to target product profiles (Update CCEOP platform eligible model list and prices more regularly, based on actual prices from country tender awards, to improve transparency and potential use of these data.s) in market-shaping strategy and overall objectives to determine if changes are warranted more frequently, and to ensure that platform eligibility also reflects potential for programmatic value. Update CCE equipment guides and other sources reflecting platform-eligible CCE and product selection tools more frequently to show where there have been advances in technology (and associated programmatic value of such advances); consider publishing a regular annual or twice-yearly addendum to the CCEOP Equipment guide to highlight innovations and new platform-eligible CCE, without requiring a full update to the document.	Medium term

Gavi, UNICEF, and WHO

Activity	Timing
Following pilots and implementation of post-market monitoring (PMM) and post-installation inspection, ensure that there is a clear feedback mechanism and data-sharing platform so that a variety of stakeholders can access and analyze this information to inform future decisionmaking.	Long term

BACKGROUND

The role of immunization is particularly important 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 (iSCM) systems are being stretched to accommodate ever-increasing volumes and varieties of vaccines and presentations. The Gavi Cold Chain Equipment Optimization Platform (CCEOP) was established in 2015 in recognition that functional cold chain equipment (CCE) is a critical precondition to strengthening vaccine supply chains, and ultimately to 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. At the country level, CCEOP provides phased support to selected countries 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 greatest bottlenecks to coverage and equity). The second scale-up support phase allows the country additional time to further elaborate and fine-tune 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 appropriate CCE, and stimulate the market to respond to that demand with affordable and accessible equipment.

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. This 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 project management teams (PMTs) to strengthen the leadership component; 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 Logistic 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 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, largely due to the scale of the CCEOP.

This prospective evaluation of CCEOP is being conducted over almost three years between 2018 and 2020 in three countries—Kenya, Pakistan, and Guinea—and is led by JSI Research & Training Institute, Inc. (JSI) with its research partners, JaRco Consulting in Kenya, Research and Development Solutions (RADS) in Pakistan, and Stat View International in Guinea. This cross-country report presents findings from the intermediate midline assessment analysis as part of this evaluation and includes (1) assessing the situation soon after CCEOP distribution of equipment in three countries (Kenya, Pakistan and Guinea¹), and (2) evaluating the market-shaping landscape and global procurement outcomes for CCE through December 2018. These midline findings will serve as a comparison point to assess progress at the post-midline and endline stages of CCEOP.

COUNTRY CONTEXT

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 Survey² (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 therefore 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 (which do not store vaccines) are tasked with transporting vaccines from regional depots to sub-county stores on a quarterly basis, and from the stores to the service delivery point.

In Kenya, major 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 1 in 5 health facilities in Kenya do not have any CCE, and 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 (NVIP 2016a). Furthermore, the results of the 2013 effective vaccine management (EVM) assessment demonstrated major 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. 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 for supporting the immunization supply chain. Counties' varying degrees of commitment to immunization has, in turn, affected coverage rates and interrupted

¹ Deployment of equipment was delayed in Guinea. As a result, midline data collection in Guinea took place almost 5 months after Kenya and Pakistan.

² Fully vaccinated refers to BCG, measles, three doses each of pentavalent (DPT-HepB-Hib), polio (excluding polio vaccine given at birth), and pneumococcal vaccine.

implementation of planned activities (Gavi 2017).

CCEOP IN KENYA

In March 2017, Kenya received approval for CCEOP in the amount of \$8,231,741 to provide CCE to health facilities and sub-county depots with the country responsible for financing 50 percent of the support. This is 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 focuses on replacing equipment in all facilities with 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 service bundle providers (SBPs), Sanica Limited and Total Hospital Solutions, completed delivery and installation of on-grid equipment and solar direct drive (SDD) equipment manufactured by B-Medical Systems and Vestfrost, respectively. Their warranties cover repairs for up to two years on Vestfrost AC-powered equipment, three years on B-medical AC-powered equipment and up to ten years for B-Medical 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.

PAKISTAN

Pakistan has a history of sub-optimal levels of immunization coverage, with 51.3 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 the quantity of vaccines. Common challenges include old equipment, weak distribution systems, 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). At both the national and sub-national levels, common areas of cold chain system gaps 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 in the amount of \$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, the 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 the course of three years. Of these, approximately 25 percent will receive additional fridges to expand their existing storage capacity. Over the course of the grant, the ODP states that 11,686 of the existing 15,418 refrigerators in 8,710 facilities will be replaced or allocated new equipment. The priority is to replace malfunctioning equipment, furnish existing facilities that have higher demand for vaccinations and, to a lesser extent, equip new facilities later in the process. Deployment for Year 1 was carried out between May and October 2018 and included the distribution and installation of 6,828 refrigerators (5859 ILR and 969 SDD). One SBP, Vestfrost, which is represented by Capri Medicals in Pakistan, provides delivery, installation, and post-installation repairs for two years. Sure Chill represented by Technology Links is responsible for 123 pieces of an SDD model. The Sure Chill warranty period is also two years.

GUINEA

Guinea with one of the world's lowest health and human development indicators, is also considered a low-income country, with a high under-five mortality rate of 101 deaths per 100,000 live births. Results from the 2012 Demographic and Health Survey, the WHO and UNICEF revision, and the 2016 Multiple Indicator Cluster Survey confirmed consistently low rates of DTP3 and measles immunization, with only 37 percent of children fully immunized (INS, PNLP and ICF 2017, INS and ICF 2012, WHO 2016). The supply chain for vaccines in Guinea is organized into four levels: national, regional, district, and health center. The national Expanded Program on Immunization (EPI) vaccine store receives vaccines every six months and distributes to district stores quarterly. In turn, health centers pick up from the district stores every month, with the exception of a number of urban district stores and health centers that are supplied directly from the central store. Health posts are not equipped with CCE, and thus do not offer regular immunization services, even though they are the most numerous and most accessible facilities to communities throughout the country.

A 2016 EVM assessment and cold chain inventory found that 21 percent of the 619 pieces of equipment in Guinea do not function, and 14 percent needed repair. Findings also illustrated the country's shortcomings in meeting set standards in the nine areas of effective vaccine management. Additional inadequacies in the cold chain storage system include electricity-powered central stores that, in the case of power outages, individually depend on a single backup generator. Other gaps concern the regional stores' lack of involvement in vaccine distribution, partly due to the lack of cold storage capacity.

CCEOP IN GUINEA

In March 2017, Guinea’s application for CCEOP support, which includes the procurement of 1,361 CCE, was approved in the amount of \$15.39 million. The country’s plan prioritizes CCE installation in health posts with no CCE, followed by health centers with non-functioning equipment, those with CCE more than 10 years old, and those with non-PQS and less than 10-year-old refrigerators. The ODP for Year 1 was carried out between mid-December 2018 and June 2019, and included the distribution and installation of 848 refrigerators (210 HTCD-160 and 638 TCW 2043 SDD) in health facilities across all eight regions and 38 districts of the country, covering all health posts in Guinea. In addition, five Aucma ARKTEK-YBC-5 were included—three were installed in the regions of Boké, Mamou and Labe, while the remaining two were installed at the central level. Two SBPs, Haier and SOGUIMAP, provided delivery, installation, maintenance, and repairs, and are contracted to provide warranty support for three years and ten years, respectively. This equipment completes the initial 235 solar fridges procured in 2017 within the post-Ebola recovery plan; and most recently the 240 fridges procured with UNICEF funding.

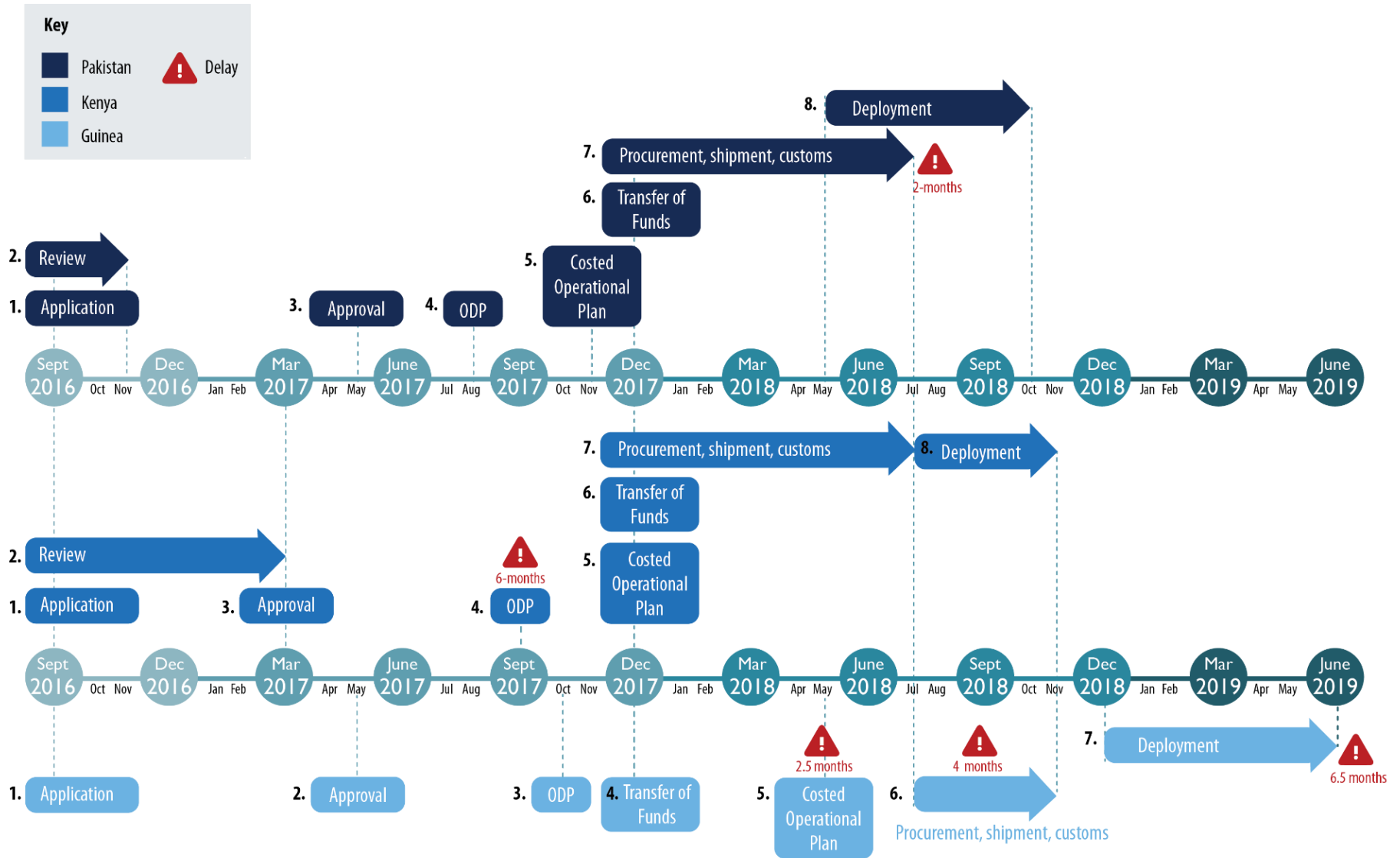
Table 1 shows the duration of CCEOP activities in the three countries; Figure 1 shows a timeline of these activities.

Table 1: Overall Timing of CCEOP-Related Activities in Kenya, Pakistan, and Guinea

Activity	Kenya	Pakistan	Guinea
Total time from application to deployment completion	27 months	25 months	36 months

Note: Data sources are CCEOP grant application materials from each country and the CCEOP milestones sheet dated Feb 18 2019 shared weekly by UNICEF SD.

Figure 1: Timeline and Mapping of CCEOP-Related Processes in Kenya, Guinea, and Pakistan.



GLOBAL CONTEXT

CCEOP includes a specific market-shaping component to improve the availability and installation of high-performing CCE. This reflects the need to ensure that the market for CCE is healthy and that optimal, yet durable and high-performing products are being procured with Gavi funding. In establishing the market-shaping approach, Gavi conducted market analyses in 2015-2016 around CCE to identify market failures on both the supply and demand side that would need to be addressed by CCEOP to enable widespread adoption of higher-performing CCE. On the supply side, the major challenges identified were limited understanding by manufacturers of desired product characteristics, lack of visibility of potential demand/procurement volumes (and therefore limited incentives to develop new or improved technologies or expand production capacity), and general lack of information to generate interest in Gavi-supported markets. On the demand side, procurement and funding were generally ad hoc and fragmented, leading to weak forecasting, limited information on new technology options and their potential benefits, and sporadic country-level planning that affected maintenance and installation capacity. The market-shaping strategy was developed to address these limitations. The market shaping objectives and target outcomes developed at the outset of CCEOP are outlined in Annex 1.

The market shaping evaluation timeline has shifted, in consultation with Gavi, to reflect a number of developments since the original proposal timeline. Table 2 outlines activities and milestones for global-level CCEOP market shaping.

Table 2: Activities and Milestones Related to CCEOP Market Shaping at the Global Level

Activity/Milestone	Date
Ice-lined refrigerator (ILR) and SDD Supply and Procurement and Roadmap published	August 2016
First CCEOP PO placed (Haiti)	September 2017
UNICEF Industry Consultation held	March 2018
Market Shaping “Light Touch” Summary Report submitted	July 2018
First new CCEOP tender for 2018 awarded	September 2018
Differentiated tender approach implemented	January 2019
Revised CCE Supply and Procurement Roadmap	June 2019

SCOPE AND OBJECTIVES

Gavi seeks to assess the relevance, effectiveness, efficiency, outcomes, and sustainability of the CCEOP investment in three countries—Kenya, Pakistan, and Guinea—which were selected by Gavi for this evaluation given their stage of CCEOP deployment. As a whole, the evaluation aims to assess the progress of the CCEOP against its original objectives, while keeping in mind

the other channels through which countries are obtaining CCE and taking such channels into account, when possible, as part of the evaluation. The country-level component focuses on achievements made in upgrading and expanding CCE and creating a more efficient, effective supply chain. The market-shaping component includes achievements made in promoting healthy markets and improving optimal market conditions while also considering any unintended consequences. The specific objectives of both components of the evaluation are listed in Table 3. Results of this evaluation will ultimately improve the design of the platform with both market shaping and country-level implementation in mind.

Table 3: CCEOP Evaluation Objectives

Country Level	Market Shaping
<ul style="list-style-type: none"> • Determine the relevance of the 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 the CCEOP has improved cold chain management and processes and immunization outcomes and results. • Determine the nature and extent to which the 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. 	<ul style="list-style-type: none"> • 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.

More specific details of the research questions to be asked at each stage of the country evaluation are outlined in Annex 2. The country-level evaluation findings provide important inputs and insights to the market-shaping evaluation, and will also be addressed in this report.

FRAMEWORK AND EVALUATION APPROACH

In order to assess the effectiveness of the CCEOP mechanism at the global and country levels, the team developed two different evaluation frameworks, one each for the country level and the 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 that align with the Gavi CCEOP theory of change and results framework and country reporting requirements.

The success of the CCEOP 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. The 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 focus of CCEOP is primarily on replacing underperforming equipment in existing sites and increasing equipment availability in the early years, the framework also takes into account provision of CCE to new sites, which will take place later. Furthermore, to the extent possible, the availability of CCE through other channels and partners will also be taken into account. Overall, the success of the CCEOP is measured not necessarily based on its effect on a more efficient immunization supply chain (and in the longer term, vaccination coverage), but on 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 will examine the linkages in the proposed pathways to understand where blockages may be impeding achievement of expected outputs and outcomes, or reasons why the process may have been successful in selected areas. Undertaking data collection at multiple time points, before CCEOP installation in countries and two years after, enables observation of changes over time. This evaluation takes into account 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 will be made to examine the linkages from inputs to outcomes, the effect on all outcomes may not be observed in Phase 1 of the evaluation.

MARKET SHAPING

Gavi's market-shaping evaluation framework (Figure 3) looks at the market characteristics before and after the introduction of the CCEOP to see how the platform addressed the identified root causes of the unhealthy market conditions that catalyzed creation of the CCEOP; and how the platform achieved the desired outcomes. Specific details of the market-shaping outcomes and objectives as outlined in the original Gavi Supply and Procurement Roadmap for ILR & SDD CCE (2016) are presented in Annex 1. The evaluation increase understanding of the

overall market health, market changes, and unintended consequences, both positive and negative, over time. The market-shaping component will use both quantitative and qualitative metrics to provide insight into the overall health outputs and impact. With each data collection time point, this component will examine how well the CCEOP has achieved its goals to date, and how well it is set up to continue to achieve its goals.

Figure 2: CCEOP Country Evaluation Framework, Based on the Gavi CCEOP Theory of Change

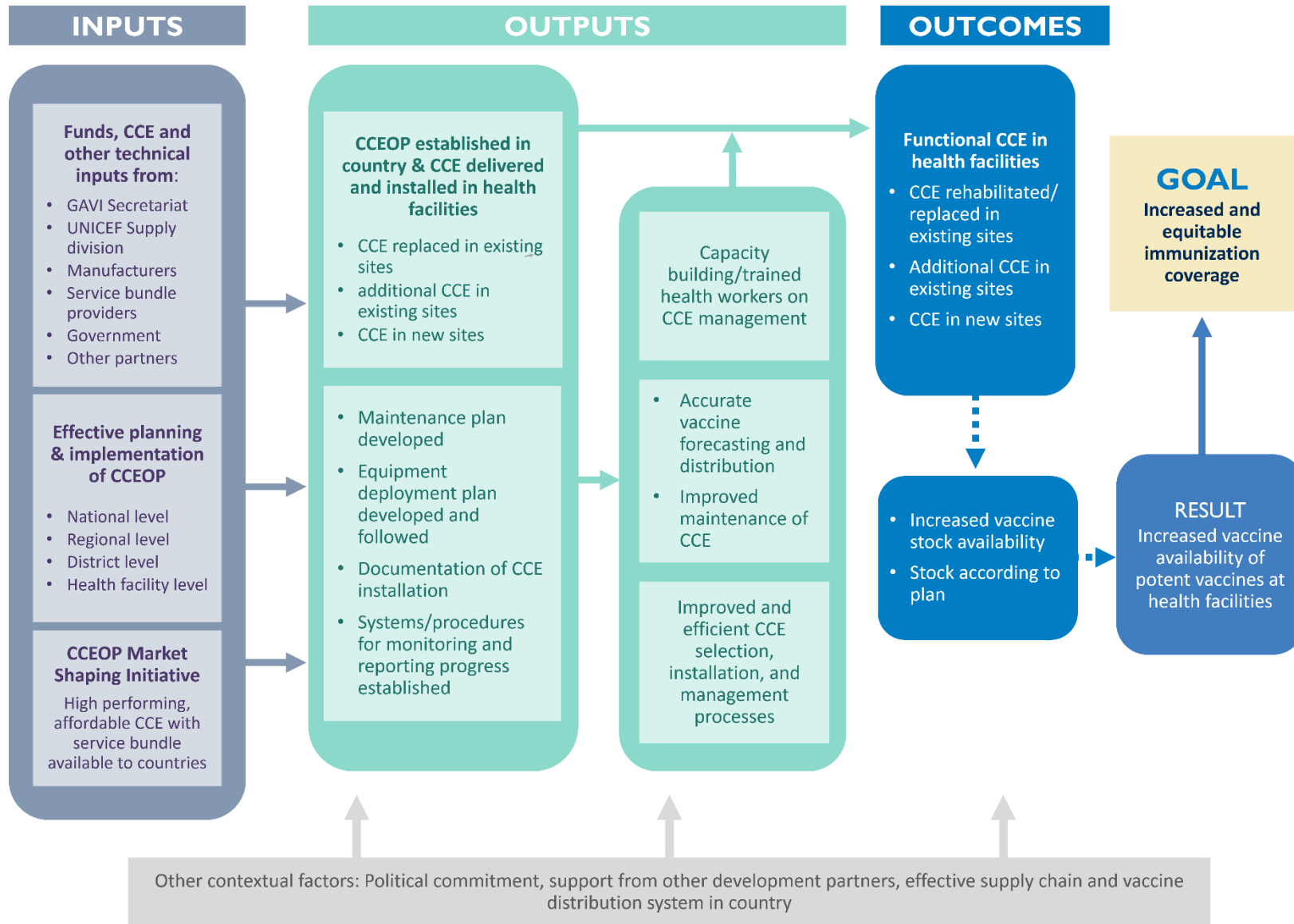
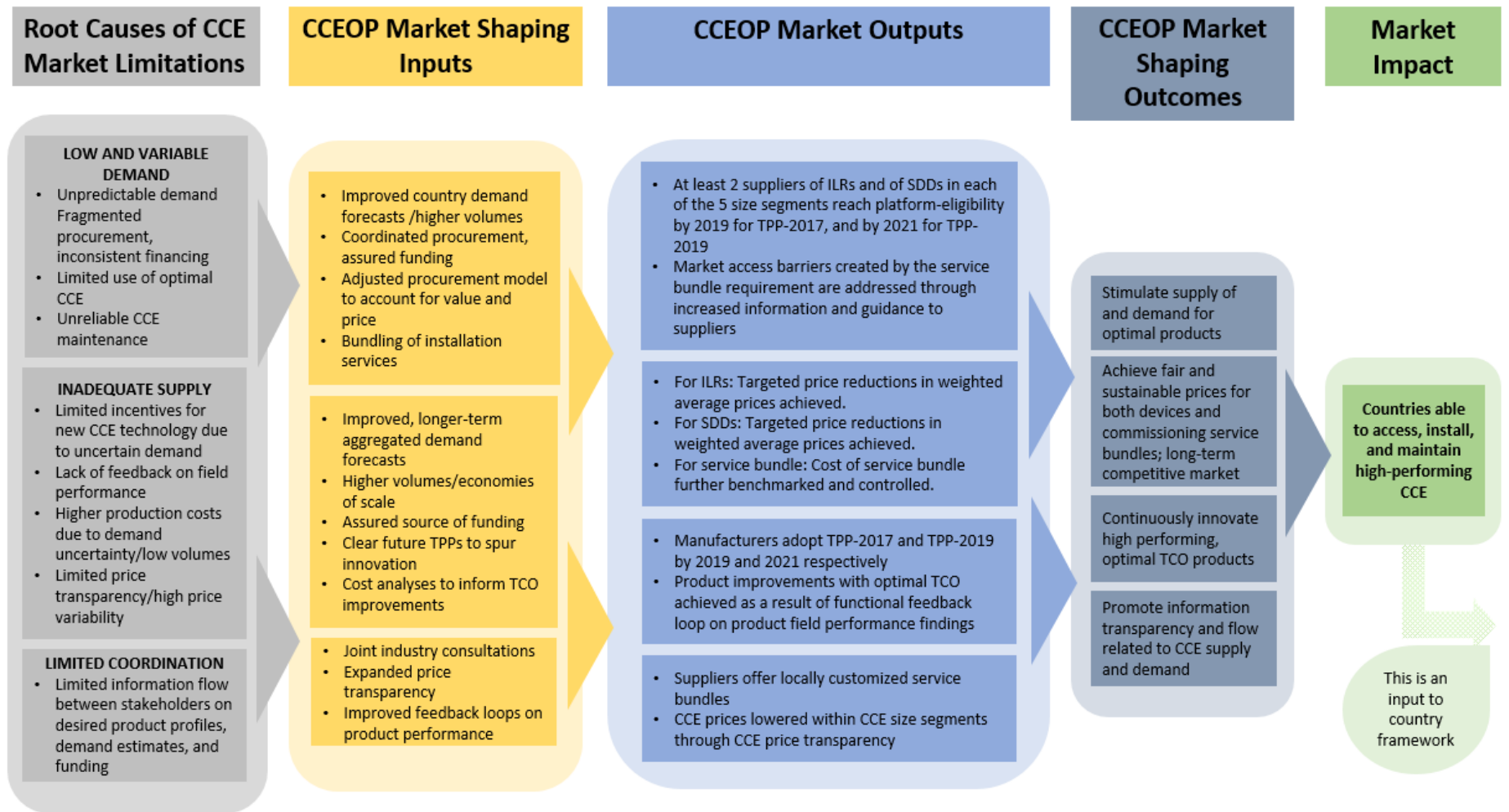


Figure 3: Gavi’s Market Shaping Evaluation Framework, Based on the Gavi CCEOP Theory of Change



DESIGN AND METHODS

COUNTRY EVALUATION

DATA SOURCES AND METHODOLOGY

As described in the country evaluation protocols, the country level midline assessments followed a mixed-methods approach including data collection from a variety of sources—document review, direct observation of the CCEOP planning and implementation process (when possible), key informant interviews (KIIs), and a health facility assessment (HFA). Data from the health management information system/logistics information management system (HMIS/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 including all stakeholders and the SBPs in each country. The KIIs were conducted using semi-structured interview guides, customized for respondents at the various levels of the health system that were used for this midline assessment. National-level respondents were asked about the procurement, choice of CCE and cold chain gaps, ODP and its implementation, the role of SBPs, maintenance and repair and warranty for CCE, and overall satisfaction and possible effect on outputs and outcomes. Interviews with SBPs focused on market shaping and the 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 purpose of the HFA was to establish a follow up measure of indicators at health facilities and sub-county/district stores/depots, including frequency of immunization services provided, CCE inventory and functional status, maintenance history and procedures, stock history and stock-on-hand of two tracer vaccines, pentavalent/DPT and measles, and staff training on stock management and CCE maintenance.

SAMPLING

The sampling approach is somewhat consistent across the three countries, to facilitate cross-country 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. JSI worked with the Ministry of Health (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 include 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 of the selected provinces/regions/counties across the three countries. More

specific details on sample selection at each level of the health system in each country are outlined in each midline country report and the associated research protocols.

In all three countries, the majority of facilities in both 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; health posts were predominantly rural. In all countries, an overwhelming majority of facilities is publicly owned. In Guinea and Pakistan, 100 percent of the facilities are publicly owned. Kenya had a small percentage of privately owned facilities: 6 percent among program facilities and 14 percent in control facilities.

The midline assessment in each country used the same sample of facilities selected for the baseline. In Kenya, a few adjustments were made to the midline sample because it was found that some program facilities did not receive equipment, while some control facilities did, because of deviations during deployment. Although the situation was similar in Pakistan, sample adjustments could not be made because of lack of information at the time of midline data collection. More specific details on the data, sample, and methodology are available in the country evaluation protocols and in the country midline assessment reports.

DATA ANALYSIS PLAN

The evaluation uses 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 are addressed. The midline assessment focuses on understanding the situation across the three countries right after CCE was installed under the CCEOP; and to document any pre-existing differences between the two types of health facilities: those scheduled to receive CCEOP equipment in Year 1 (program facilities) and those not scheduled to receive equipment in Year 1 (comparison or control facilities). It is possible that some of the facilities in the second group will also receive CCE at the next round of deployment. We made efforts to align the sample based on data on deployment of CCE procured through other funding sources, depending on the data available during sample selection.

Data from the HFA are analyzed throughout the evaluation to demonstrate these changes and how they relate to CCEOP implementation in the country. The analysis also documents 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 effect on selected outputs, the endline will focus more on the effects and expected outcomes of CCEOP, along with overall systems strengthening.

For the midline 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 the selection of sites for CCE, the overall

implementation process, and knowledge of procedures for repair and maintenance. Examples of themes developed at the national level relate to 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.

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 falling 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 midline 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 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 as needed.

Preliminary findings from this intermediate midline assessment were shared in all three countries. In Kenya, a meeting with all key stakeholders including the SBPs was held on February 5, 2019 and all findings and proposed recommendations were reviewed and revised with country input. A similar validation meeting was held in Pakistan on February 20, 2019 with the Federal EPI where recommendations from the assessment were shared. The RADS team made a second presentation of the findings and recommendations at the PMT meeting on March 19, 2019. In Guinea, the validation meeting took place on June 20, 2019, providing an opportunity for PMT members to review the preliminary findings and recommendations before contributing their input and suggestions.

MARKET-SHAPING EVALUATION

The market-shaping component of the evaluation is both retrospective and prospective to capture the market's trends for optimal CCE over time; and to assess the overall health of the market, the outlook for the future, and the role of the CCEOP in ensuring availability of affordable, high-performance CCE. This report presents the procurement situation as of December 2018, looking at changes observable from the data collected and the perspectives shared by key informants. Our approach considers the results of the market shaping for CCE to date as well as the trajectory of the CCEOP to continue to affect the market. To do this, we employed a mixed-methods approach, combining our experience using both qualitative and quantitative methods, a successful evaluation approach which informs lessons learned as well as recommendations for programmatic changes.

Built on the foundation of the Healthy Market Framework (developed by Gavi, UNICEF, and the Bill & Melinda Gates Foundation 2016), the market-shaping evaluation activities are organized around three main strategies: **document review**, including relevant CCEOP and market shaping resources, target product profiles, road maps, and strategies; **data review**, focusing on procurement and other monitoring data such as the number of CCE manufacturers, prices,

forecasts, procurement volumes; and **semi-structured KIIs** with representatives from multiple institutions, CCEOP-approved suppliers, countries, and SBPs. Each country adapted these data sources and data collection tools according to their country context.

MARKET SHAPING DATA SOURCES, METHODOLOGY AND SCOPE

This cross-country report summarizes high-level findings on the CCEOP market outcomes as of December 31, 2018, including the links of market-shaping work with the findings from the midline data collection in Kenya and Pakistan. This report summarizes market shaping findings from all work conducted in 2018, including 24 global-level KIIs conducted from May 15th – October 3rd, 2018 with stakeholders who were part of the design or early implementation of the market-shaping strategy and representatives from the seven suppliers of platform-eligible CCE. Annex 3 provides a full list of organizations engaged in KIIs. In addition to KIIs and data collection from Kenya, Pakistan, and Guinea, including interviews with SBPs contracted in each country, the summary relies on secondary data related to initial procurement experience and results and CCE pricing provided by Gavi and UNICEF SD through December 2018.

The findings discussed here reflect a point-in-time analysis of market shaping outcomes. The evaluation is meant to be updated at regular intervals as agreed to with Gavi, recognizing that the market will continue to evolve over the life of CCEOP both as a result and consequence of the market shaping strategy. Given that an updated market shaping strategy via the Gavi Supply and Procurement Roadmap for SDDs and ILRs was released in late June 2019, the evaluation team is planning a more comprehensive market-shaping update and report in Q3/Q4 2019 to reflect how changes to the strategy are affecting global market shaping outcomes. The update to the cross-country report upon the completion of the midline in Guinea reflects new findings relevant to market shaping from that context. This report is the first time the outputs from the supplier interviews have been summarized, so these feature prominently, so that these perspectives are captured and can be contrasted to any changes in the more comprehensive report expected in later 2019.

STRENGTHS AND LIMITATIONS

This evaluation has several strengths and limitations that are outlined below.

STRENGTHS

- This evaluation follows a prospective design that enables understanding of the entire process of CCEOP planning and implementation and its effect on relevant outcomes at different stages. It also enables us to follow the same health facilities over time to examine changes taking place in real time over almost three years, with a two-year period between the baseline and endline assessments.
- The mixed-methods approach uses of all relevant data sources at each time point 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. Information from these data sources are triangulated with data compiled through document review and routine data sources as appropriate.

- The study's case-control design enables comparison of these changes over time in facilities with greater exposure to CCEOP versus those with less, or delayed, exposure.

LIMITATIONS

- The two-year time frame 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, and may not provide sufficient information on changes in key immunization outcomes within this timeframe. The timing between baseline and this midline assessment is also quite short to capture all elements covered in the evaluation questions, especially those pertaining to effects on the supply chain and immunization outputs and outcomes.
- This mixed-methods evaluation relies on 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 best demonstrate the effect and impact of CCEOP. Furthermore, the ability to do district-level comparisons attributing expected changes to CCEOP may be limited even when using district-level HMIS/LMIS data, whose quality are not guaranteed.
- Given the small sample size of health facilities, the analysis and comparisons (broken down by region in each country), are purely descriptive. In the HFA, we are unable to 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 and low- or late-intervention facilities over time, as well as comparative improvements between the two groups, which in turn can provide insight on the effect of equipment acquired through CCEOP.
- Given significant delays in deployment in Guinea, the HFA was dropped from the midline assessment because little difference was expected from the situation at baseline. Therefore, the Guinea assessment primarily relies on findings from qualitative data collection without quantifiable findings on the situation in health facilities. Furthermore, many of the sites that had received equipment at midline had not actually started using them to store vaccinations, and thus could not fully answer questions about their experience using the CCE and providing routine vaccination services to the community.

Sites that were using the new CCE to stock vaccines had only been doing so for a short time.

- In some countries, such as Kenya, other donors, such as the World Bank, are also providing CCE. After CCEOP deployment, the country has also seen the movement of older equipment between 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 and so relies to a great extent on the country's CCEOP deployment strategy. The evaluation also tries to make comparisons between districts that have high and no/low CCE installation through CCEOP.
- The evaluation design is based on available information at baseline deployment of CCE in Year 1. It is possible that districts in the no/low CCE comparison group may have CCE installed in Year 2. Adjustments in the design and interpretation are needed in that case. Deviations in deployment of CCE from the ODP, and other movements of older equipment by MOH between facilities, also affect the design of the study and result in changes in facilities sampled at later times.
- Although the sampling for the midline was based on the ODP, 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. Adjustments to the sample based on this information were made in Kenya prior to data collection, while this was not possible in Pakistan. Therefore, the difference in findings between the program and control groups from the HFA in Pakistan may be underestimated.
- The expansion of the analysis to cover remote temperature monitoring device (RTMDs) is restricted based on availability of current data and how assessing RTMDs fits with the evaluation design.
- At this point of the evaluation timeline, no cost-effectiveness analysis examining expenditures on CCE has been conducted in Kenya. This will be reviewed after the midline evaluation and sharing of results. The cost of SBPs compared to MOH installation of CCE themselves will be explored in Kenya as part of this evaluation (based on data availability). However, such an analysis will not be possible in the other countries.
- There were challenges in accessing relevant HMIS and LMIS data in all three countries. Data accessed could not be triangulated with HFA data at midline as planned because they were of poor quality. At the time of the drafting of this report, data on relevant CCEOP-related indicators were also not available from the country Grant Performance Frameworks.
- The qualitative approach reflects respondents' individual interpretations and perceptions, and carries potential for respondent and recall bias if analyzed in isolation and not in conjunction with data from other sources.

- 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 transport frequency, missed opportunities, and so on is beyond the scope of this evaluation. However, some of this information will be captured when data on stocks are compiled. The analysis also excludes other program-specific detailed implications, and cannot measure changes in demand size as a result of CCE.

OTHER ASPECTS

Kenya has a similar evaluation activity currently ongoing and being implemented by the Clinton Health Access Initiative (CHAI) in consultation with the MOH. It compares CCEOP deployment through SBPs and MOH deployment of World Bank-funded CCE. Though there are many areas of overlap, their approach, based on the information received, appears to be a little different from this CCEOP evaluation. Findings from this Kenya evaluation, which also covers a cost-effectiveness component, have been shared. Any differences found between the two evaluations will need to be discussed and the reasons for the differences understood.

Various delays have affected evaluation activities. There has been a considerable delay in the deployment process in Guinea. As a result, the midline assessment in Guinea was moved to March 2019, delaying the completion of the cross-country analysis covering all three countries. Furthermore, the need to share results from the midline assessment with Gavi in February/March necessitated advancing data collection for the midline in the other two countries, Kenya and Pakistan, to November 2018. Although the midline in these two countries will still continue to capture some of the effects of CCEOP deployment, we expect it to be far less than if the midline assessment were scheduled in February 2019, as originally scheduled. The main reason for this is the continued movement of older CCE between facilities post CCEOP deployment. As a result, the data from the HFA, especially in Kenya, show a snapshot of the current situation with regard to CCE at the time of data collection, which may change over time. Another HFA data collection is proposed in October 2019, which will present a better picture of the changes post CCEOP deployment since it will be conducted 9-12 months after Year 1 deployment was completed. Findings from this assessment will be shared in a progress report.

Information received after the pre-midline assessments show that WHO PQS has received complaints from UNICEF that specific models of Vestfrost equipment, including those recently deployed in Pakistan and Kenya, had an abnormally high rate of freeze alarms as a result of repeatedly recording temperatures below -0.5°C for more than one hour. The evaluation will take this into account and investigate further in subsequent analysis as part of this evaluation.

Both Guinea and Pakistan are undergoing processes to redesign the supply chain. The process has been completed in Pakistan with analysis of the supply chain in progress. Guinea is just starting the redesign process, which will be followed by analysis. These developments will be taken into account in greater detail at the endline.

Market Shaping

With regard to market shaping, delays in the release of the updated Supply & Procurement Roadmap and revised market-shaping strategy and stakeholder action plan have affected the completion of evaluation activities as originally planned. The original market-shaping evaluation design, and specific questions about relevance, implementation, effectiveness, and sustainability are still valid and relevant; but it will be important to align with Gavi once the revised Procurement and Supply Roadmap is released. This will ensure that the evaluation can capture any changes to the market-shaping strategic objectives and specific outcomes at both the global and country levels. In particular, it will be important to confirm that the data collection and analysis are aligned with these changes, and that there is agreement on how to assess progress towards both the original and revised objectives.

KEY FINDINGS AND LESSONS LEARNED

This report describes findings from the midline evaluation for both the market-shaping and cross-country evaluations. The focus at the midline covers the evaluation questions that were outlined earlier in this report. The country evaluation covers two main topics:

- 1) Descriptive information on the changes in status of immunization and CCE in the sampled areas pre- and post-deployment in each country. These data provide context for the qualitative findings from the midline assessment in each country. These indicators are also monitored over time through the endline assessment to better understand changes over time. A dashboard also presenting these data for each country is available.
- 2) Process indicators that include stakeholder observations and experiences with the CCEOP planning and implementation process, aligned with the evaluation questions that were addressed in the midline. Stakeholders' perceptions on anticipated improvements to efficiency and outcomes, and long-term sustainability as a result of CCEOP, are also captured in this section. Any effect of the country-level findings on the market-shaping evaluation findings are also included here.

The global-level findings on market shaping aligned with the framework presented earlier appear in the last section.

CHANGES IN HEALTH FACILITIES POST YEAR 1 CCEOP DEPLOYMENT

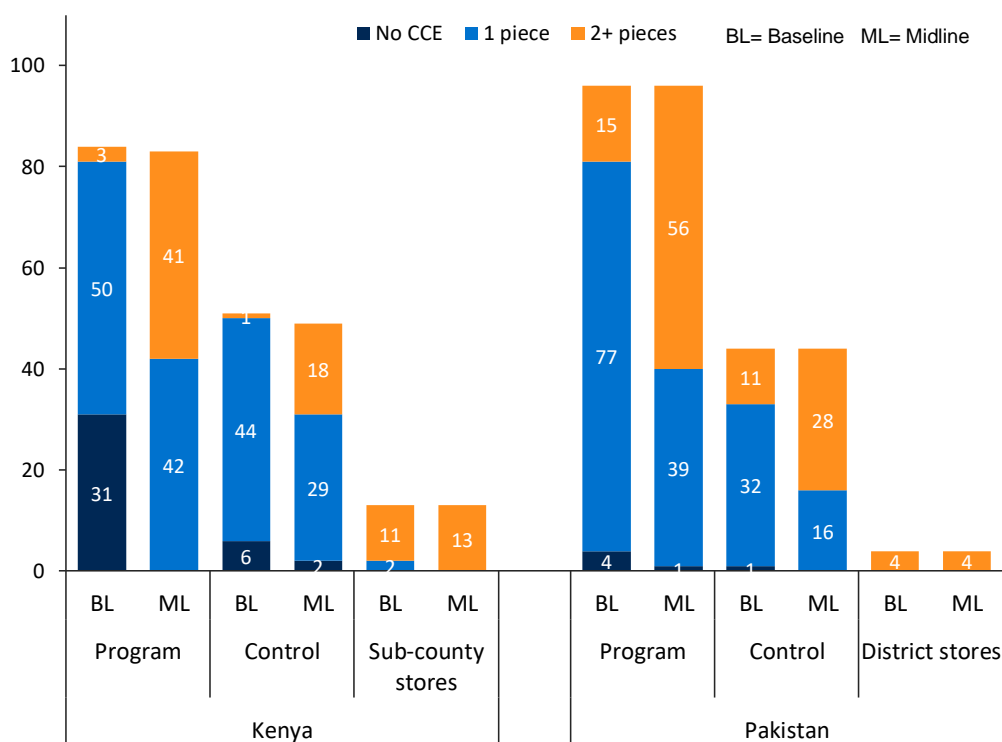
Using data from the HFA, this section outlines the current status of health facilities after the CCEOP Year 1 deployment in Kenya and Pakistan, also outlining changes from the baseline assessment conducted pre-deployment. This includes the availability of functional CCE;

information on their temperature monitoring, maintenance, and repair; and changes in immunization services offered and immunization coverage levels. As mentioned earlier, because of changes in deployment plans, and other reasons, such as CCE availability from other sources, the comparisons between the program and control group of facilities are more difficult to interpret in the midline. Therefore, these findings need to be reviewed with caution, particularly in Pakistan. Quantitative findings are not available for Guinea, given that the HFA was dropped due to delays in contracting and procurement of SBPs' payments, and in CCE deployment.

CHANGES IN CCE IN HEALTH FACILITIES

Overall, there was an increase in the number of CCE in health facilities in Kenya and Pakistan (Figure 4). The increase in the number of facilities with 2 or more pieces of CCE consistently increased at midline, while those with 0 or 1 piece of CCE decreased. This was particularly evident in the program arms. Sub-county stores in Kenya and district stores in Pakistan all received CCE and show increases as well.

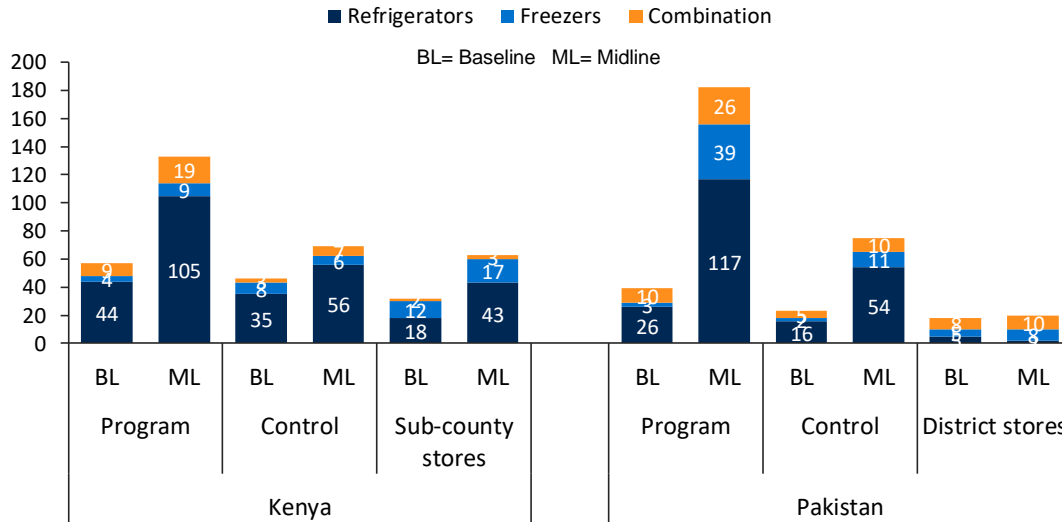
Figure 4: Number of Pieces of Equipment by Evaluation Arm and Country



These increases were consistently reflected in increases in the number of refrigerators that fit with country policies of the need to use cool water packs rather than freeze vaccines for vaccine carriers used during outreach (Figure 5). There were some increases in the number of freezers

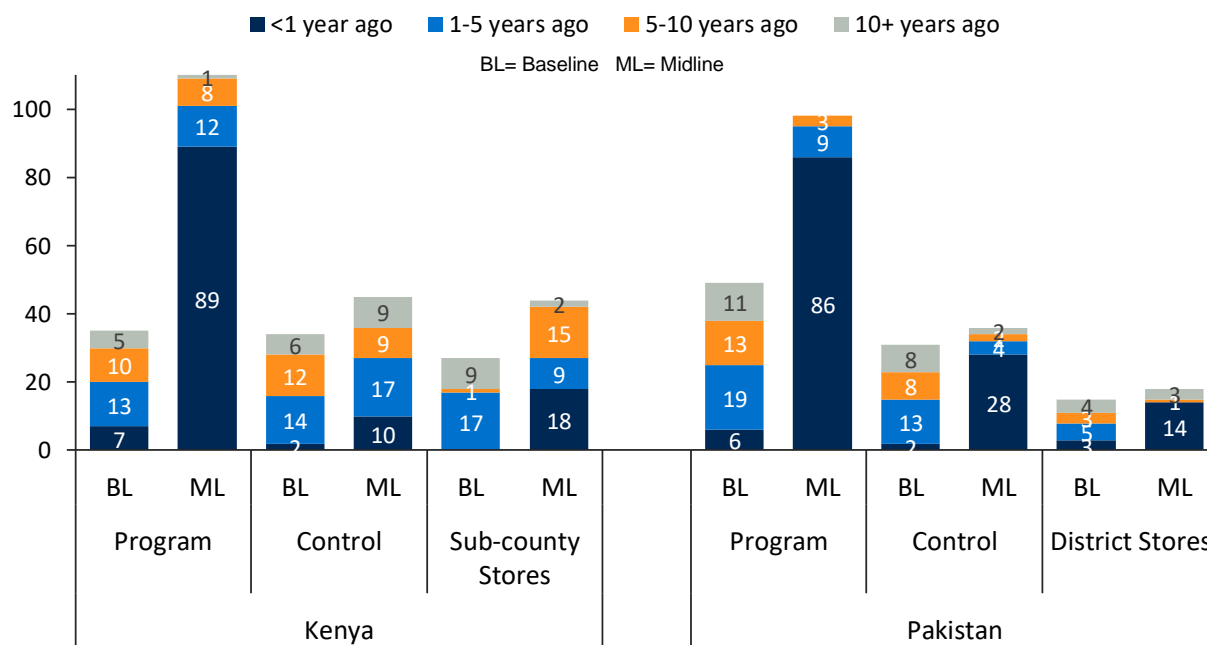
and refrigerator/freezer combinations as well. It is possible that these may have been obtained from other sources, including movement of older equipment between facilities.

Figure 5: Type of CCE in Health Facilities by Evaluation Arm and Country



The large increase in the number of new CCE (less than 1 year since installation) between baseline and midline is clearly evident in Kenya and Pakistan (Figure 6). These increases are particularly noticeable in the program group and in the sub-county/district store, which were the ones scheduled to receive equipment during this first phase of CCE deployments. There was an increase in the control group in Pakistan as well, likely because some of them received equipment through CCE or from other sources. The data collected through the HFA refers to the time since installation. However, because the age of the CCE is not always known, some of the increase could also be attributed to general movement of equipment between facilities.

Figure 6: Years since Installation of CCE in Health Facilities by Evaluation Arm and Country



MAINTENANCE AND BREAKDOWNS OF CCE

During baseline, more than 80–90 percent of equipment was functional across Kenya and Pakistan (Figure 7). This percentage increased by a small amount as well between baseline and midline. A few small declines are evident which may be attributed to equipment that was moved from another facility or instances of CCE that remained unplugged, as was observed in Pakistan. The HFA also recorded information on equipment breakdowns in the last 6 months. CCE breakdowns ranged around 15–20 percent at baseline (Figure 8). This percentage consistently decreased at midline.

Figure 7: Percent CCE Currently Functional by Evaluation Arm and Country

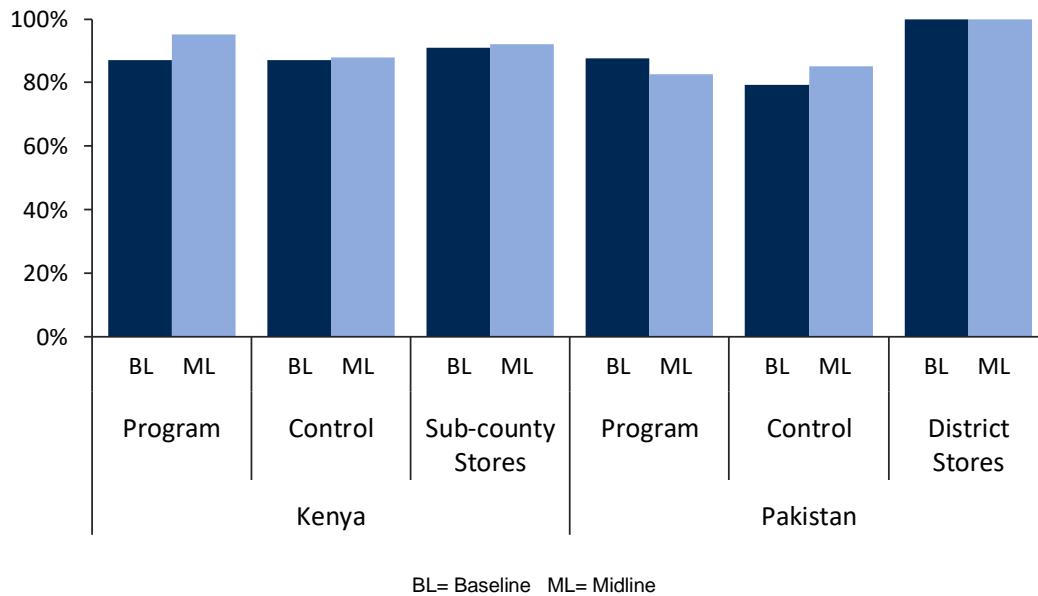
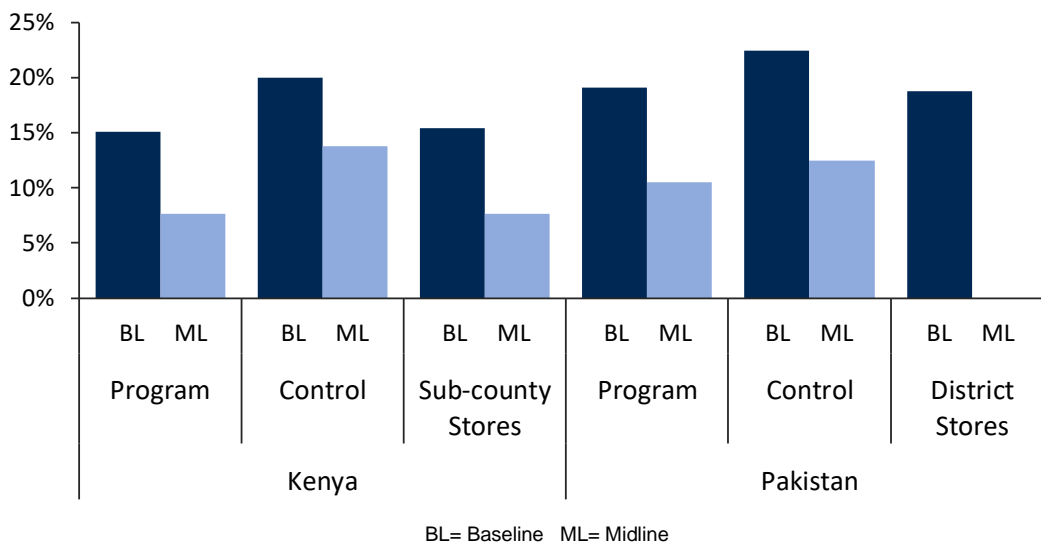


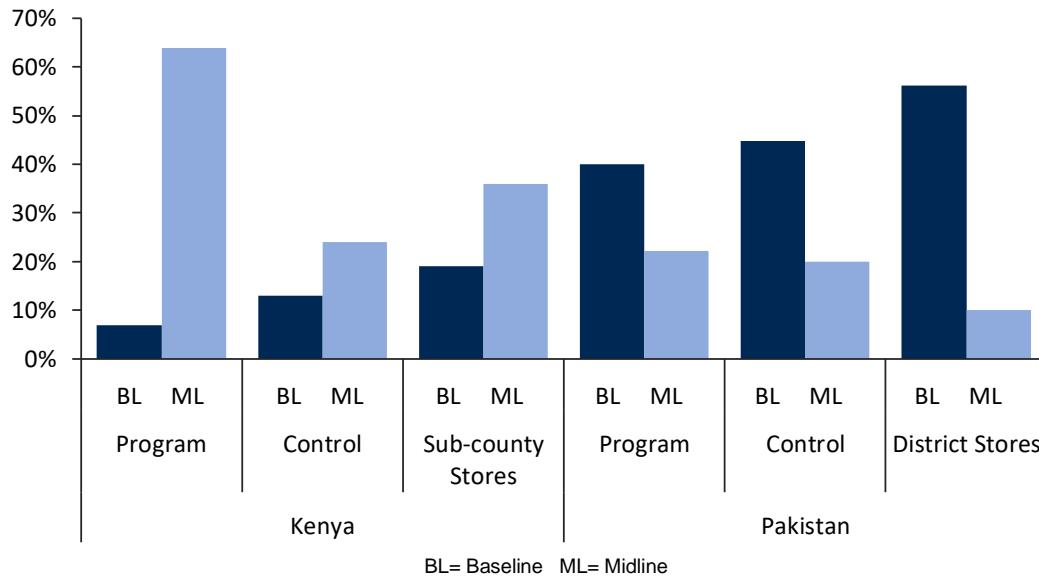
Figure 8: Percent CCE that had a Breakdown in the Last 6 Months, by Evaluation Arm and Country



Significant differences were observed between Kenya and Pakistan in the availability of a repair and maintenance manual at the health facility (Figure 9). Facilities in Kenya showed a significant increase in the manuals observed, but the opposite was true in Pakistan. On average, only 40–45 percent of health facilities had a repair and maintenance manual in Pakistan at baseline. Surprisingly, this decreased even further by midline, going down to less

than 20 percent in Sindh. The reasons for this decline are unclear and will be investigated at the next data collection.

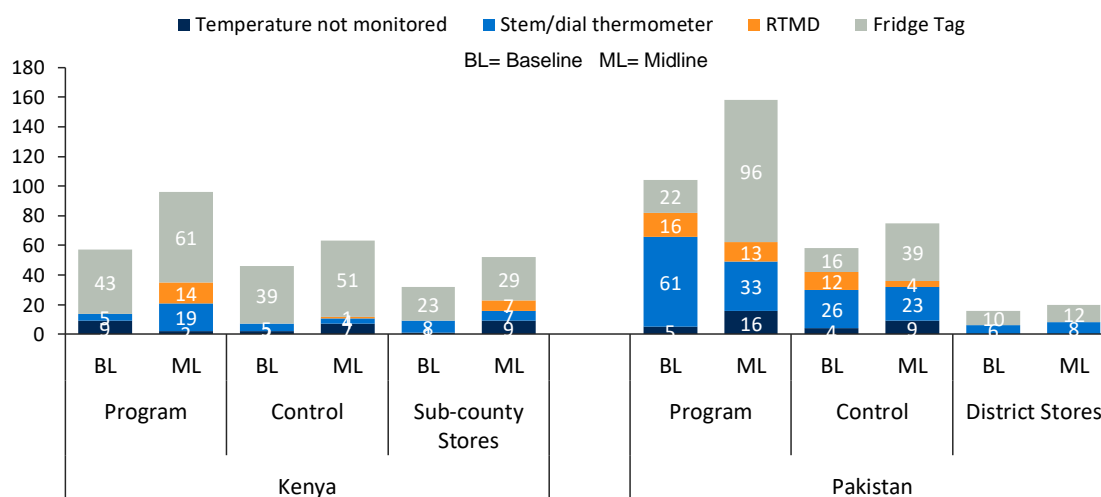
Figure 9: Percent CCE with a Repair and Maintenance Manual, by Evaluation Arm and Country



TEMPERATURE MONITORING

Significant increases in the use of Fridge-Tag is observed in both Kenya and Pakistan, and especially in the program group (Figure 10). There is a steady decline in the use of stem/dial thermometers. In Kenya, all models of B-medical equipment included an RTMD, which accounts for the increases seen between baseline and midline. In Pakistan, we see greater increases in CCE monitored by a fridge tag, and decreases in equipment monitored by stem/dial thermometer. There is a decrease in equipment not monitored in program facilities in Kenya as a result of these new monitoring devices, but an increase in Pakistan. The reason for this could be the non-functionality of equipment or instances where the equipment was unplugged.

Figure 10: Number of CCE by Type of Temperature Monitoring, by Evaluation Arm and Country



STOCK MANAGEMENT

Figures 11 and 12 show the extent of stockouts of DPT/pentavalent and measles vaccines in Kenya and Pakistan. Stockouts of both vaccines were considerably higher in Kenya than Pakistan at both timepoints. Interestingly, declines between baseline and midline were observed for pentavalent vaccine in Kenya, but not for measles vaccine. And in some facilities in the control group, there was an increase in stockout of measles vaccine as well in Kenya. These stockouts are possibly due to a national-level stockout of measles in 2018, reported in the June 2018 Kenya EPI program review report (NVIP 2018).

Figure 11: Stockout of DPT/Pentavalent in Health Facilities in the Last 6 Months by Evaluation Arm and Country

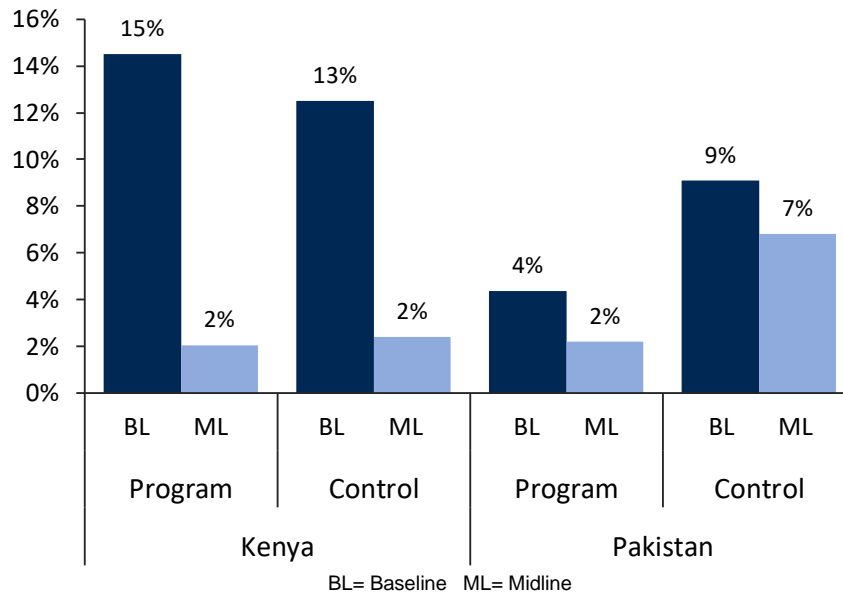
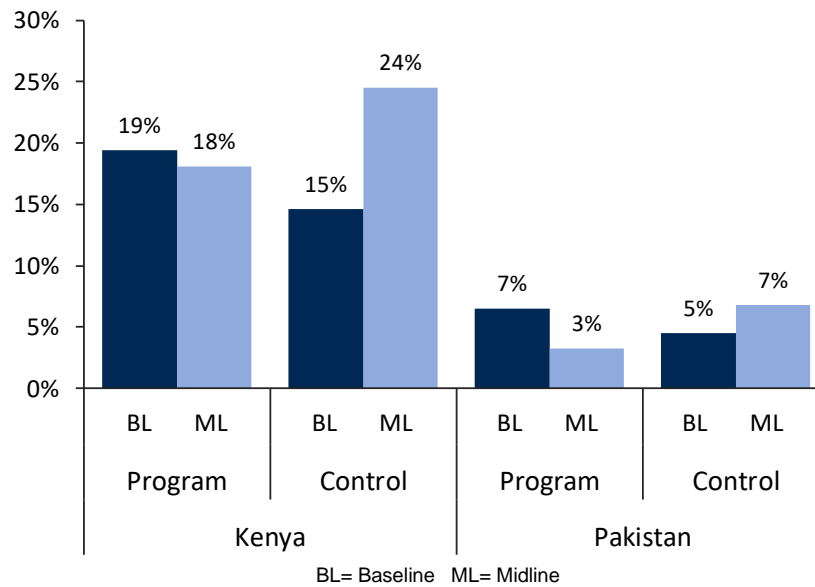


Figure 12: Stockout of MCV in Health Facilities in the Last 6 Months by Evaluation Arm and Country



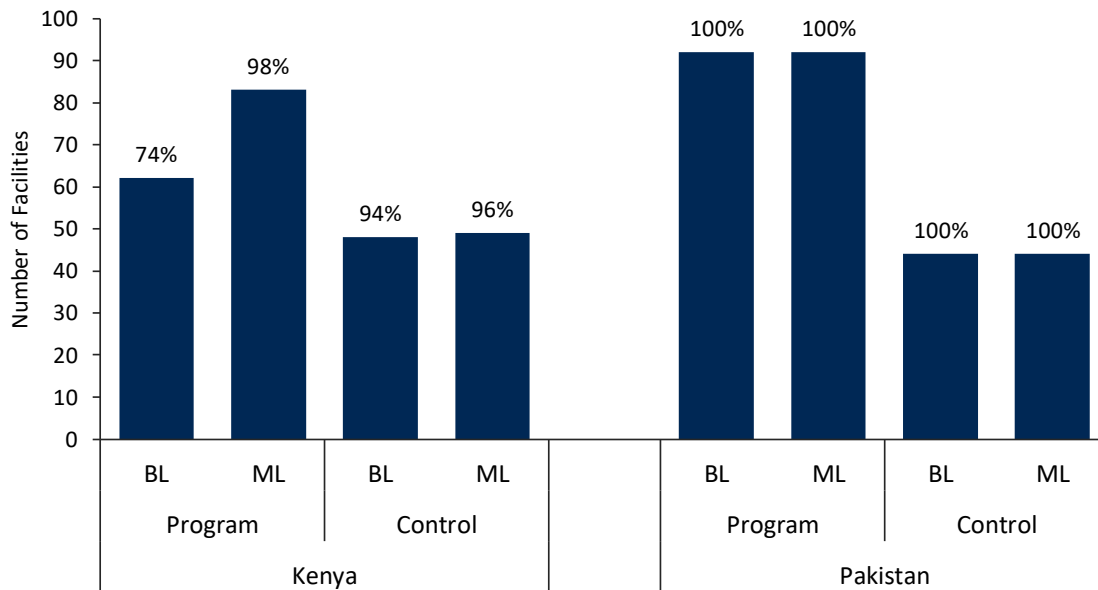
Data were also available on well-organized vaccines and updated vaccine ledgers. The percentage of health facilities with well-organized vaccines was consistently high across all groups in Kenya and Pakistan, over 80 percent and in some cases between 95–100 percent, and no clear patterns were evident. This was true for data on updated pentavalent/DPT and measles vaccine ledgers, where some changes were observed; but they were relatively small. It

is important to note that these findings are restricted to facilities with stock ledgers, and do not show data on facilities with missing or unavailable stock ledgers.

CHANGES IN IMMUNIZATION SERVICES OFFERED

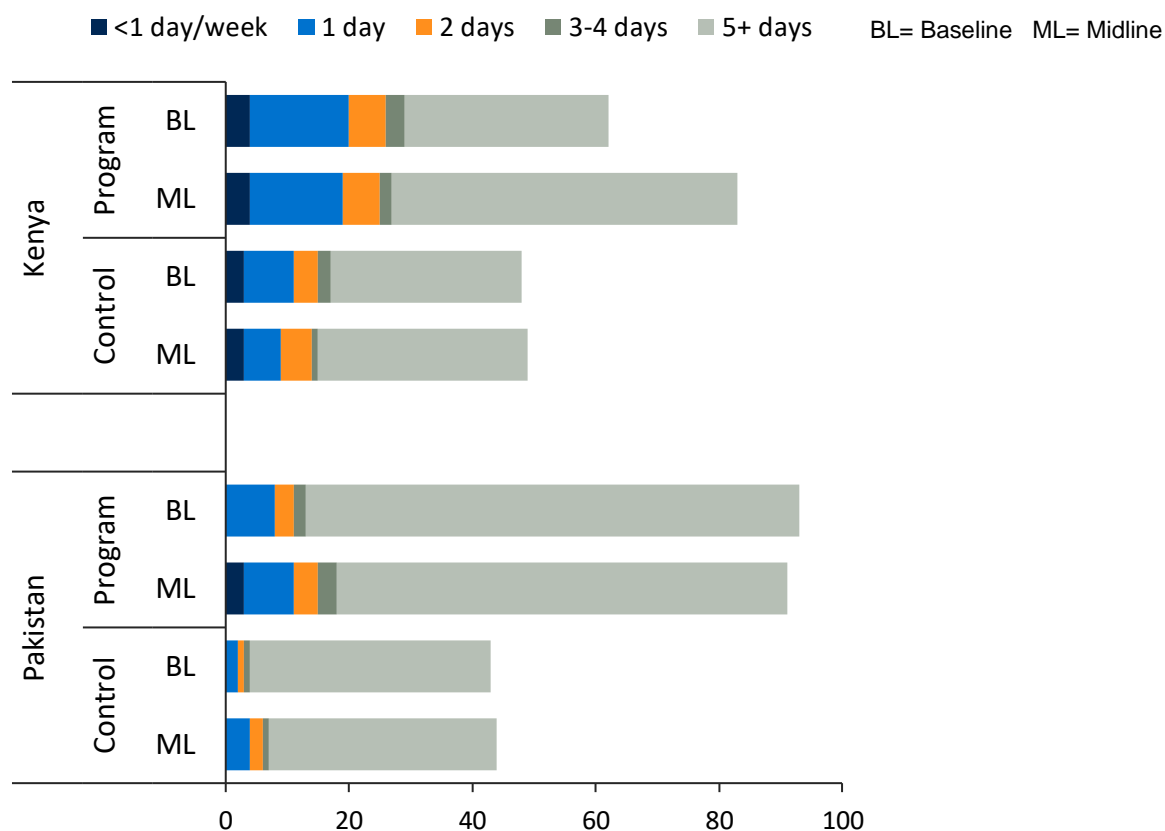
All facilities in the sample in Pakistan already provided immunization services (Figure 13). The recent deployment of CCE through CCEOP resulted in a considerable increase in the percentage of facilities providing immunization among the program group in Kenya.

Figure 13: Percent Facilities Offering Immunization Services by Evaluation Arm and Country



In both Kenya and Pakistan, the majority of health facilities provided immunization services five or more days a week (Figure 14). This increased even further in the program arm in Kenya after CCEOP deployment. Some declines in Pakistan were observed, particularly in Sindh, the reasons for which are unclear and will be investigated at the next round of data collection.

Figure 14: Frequency of Immunization Services Offered by Evaluation Arm and Country



THE CCEOP PROCESS

This section presents findings primarily from the qualitative interviews at midline in the three countries. It covers stakeholders’ observations and experiences with the CCEOP planning and implementation process, aligned with the evaluation questions that were addressed in the midline. Stakeholders’ perceptions on anticipated improvements to efficiency and outcomes, and long-term sustainability as a result of CCEOP are also captured in this section. Any effect of the country level findings on the market shaping evaluation findings are also included here.

Five high-level insights from this midline evaluation in Kenya and Pakistan are listed below in Table 4. These high level insights are drawn from specific findings that are outlined in more detail in the following table.

Table 4: High-level Insights from Midline Country Evaluation

High-level insights	
1.	CCEOP responds to country needs and priorities and is well coordinated by the PMT in-country with other partners.
2.	Proper preparation for CCEOP deployment requires significant investment in time and budget, and needs to be taken into account during planning.

3.	Not all implementation guidance, policies, or plans are well communicated, understood, or implemented at the country level.
4.	Stakeholders were generally satisfied with SBP installation of equipment, although in Kenya stakeholders were concerned that the cost was too high for a service the MOH felt they could provide.
5.	The SBP monitoring system for deployment was effective and allowed for minor deviations.
6.	Training provided by SBPs was insufficient; training needs and topics need to be clarified.

Table 5 presents summary findings from the midline assessment in the three countries, followed by a more detailed analysis of the themes of the evaluation. Findings from the country evaluation that are relevant to the market shaping component are also included here.

Table 5: Country Evaluation Findings

	Market Shaping	Kenya	Pakistan	Guinea
RELEVANCE OF CCEOP				
IN RESPONSE TO COUNTRY NEEDS				
Finding 1: At the macro level, the CCEOP responds to country priorities and needs, although some manageable specifications still need to be addressed (details: trays for equipment, stabilizers, freezer capability).	X	X	X	X
TRANSPARENT PROCESS AND STAKEHOLDER ENGAGEMENT				
Finding 2[†]: Stakeholders do not fully understand all of the details of the warranty, type of corrective maintenance/repair that is covered, and how to access those services.	X	X	X	X
Finding 3: Many respondents were unclear on SBP terms of reference and what they were/were not contracted to do to set expectations for performance.	X	X	X	X
ALIGNMENT WITH GAVI GUIDELINES AND OTHER DONOR/PARTNER SUPPORT				
Finding 4: The CCEOP is coordinated with other donors and partners for overall system strengthening, although better documentation could improve coordination and planning (i.e., deployment of World Bank/other donor-funded refrigerators and cold rooms, and limited information on where old fridges were moved).		X	X	X
Finding 5: Respondents were satisfied that the CCEOP application and operational deployment plan (ODP) adhered to Gavi guidelines, used available systems and cold chain inventory data, and responded to country priorities.		X (information from baseline)	X	X
EFFECTIVENESS				
SBP IMPLEMENTATION				
Finding 6: Respondents at all levels were mostly satisfied with the installation and commissioning of the CCE by the SBPs, with some areas for improvement, such as clarity on roles and responsibilities and warranty coverage.	X	X	X	X
MOH INVOLVEMENT IN IMPLEMENTATION				

	Market Shaping	Kenya	Pakistan	Guinea
Finding 7: The robust system of monitoring and documentation established for equipment deployment was effective at tracing equipment and ensuring accountability from the SBPs.		X	X	X
Finding 8: The few deviations were effectively handled locally, with no reported additional costs incurred. Accurate deployment plans must also include a level of flexibility, especially at lower levels, to respond efficiently and effectively to on-the-ground situations in a timely manner.	X	X	X	X
Finding 9: The project management team (PMT) played an active and effective role in CCEOP deployment and coordination, demonstrating ownership and strategic thinking, although documentation could be improved (also linked to sustainability).		X	X	X
COORDINATION AND COMMUNICATION				
Finding 10: Respondents were generally satisfied with the deployment and installation process, although relevant information on the deployment schedule did not always uniformly extend to all key stakeholders.	X	X	X	X
EFFICIENCY				
SBP IMPLEMENTATION				
Finding 11: Satisfaction with the efficiency and quality of work of SBPs is generally good, but varies by SBP and facility preference on equipment.	X	X	X	X
Finding 12: Although the MOH was capable of installing CCE and procuring additional CCE units, respondents at the national level recognized the trade-off between the speed and effectiveness of SBPs deploying CCE and value for money.	X	X	X	NR
SUSTAINABILITY				
COUNTRY OWNERSHIP				
Finding 2[†]: Stakeholders do not fully understand all of the details of the warranty, type of corrective maintenance/repair that is covered, and how to access those services.	X	X	X	X
Finding 9: The PMT played an active and effective role in CCEOP deployment and coordination, demonstrating ownership and strategic thinking, although documentation could be improved.		X	X	X
CAPACITY FOR CCE				
Finding 13: SBPs provided insufficient training to facility staff. Training needs are insufficiently defined or understood by facility staff to ensure long-term maintenance of CCE.	X	X	X	X
Finding 14: For longer-term sustainability, technicians currently have insufficient capacity for corrective maintenance. Countries are not implementing a maintenance plan at national and sub-national levels.		X	X	X
OVERALL				
SYSTEMS STRENGTHENING				

	Market Shaping	Kenya	Pakistan	Guinea
Finding 15: There is no reported plan for decommissioning equipment.		X	X	NR
Finding 16: There is a need for an updated inventory using existing information systems and automated processes.		X	NR	X
Finding 17: Some facility personnel in Kenya and Pakistan are not well oriented about the shift to using cool packs (instead of ice packs) for outreach activities. In Guinea, health post staff are 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, not only specific to CCEOP but also to the overall system.		X	X	X
Finding 18: Currently there is no clear mechanism for monitoring CCE performance over time (after installation check) and providing feedback to manufacturers. With warranty processes unclear in many places, it is uncertain if SBPs or the UNICEF Country Office would report breakdowns to UNICEF SD.	X	X	X	X

*NR - Not reported but still applicable

†Applicable across multiple evaluation objectives

RELEVANCE OF CCEOP

IN RESPONSE TO COUNTRY NEEDS

Finding 1: At the macro level, the CCEOP responds to country priorities and needs, although some manageable specifications still need to be addressed.

Overall, in all three countries, the general feeling among stakeholders was that CCEOP and the equipment received through the process met their needs. All planning kept the countries' priorities in mind using data compiled through a cold chain inventory. Allocation of equipment was made as per the need at the sub-national level. There were, however, some issues—with trays for equipment, stabilizers, and freezer capability, for example—that needed to be resolved.

Kenya

The process for selection of cold chain equipment in Kenya was data-driven, using the national cold chain inventory as well as PATH's Total Cost of Ownership Tool for Cold Chain Equipment. A number of factors were considered when selecting CCE, including the available energy source, temperature zones, facility type and capacity requirement, CCE hold over time, equipment performance, and purchasing and operating costs. Counties and facilities were selected based on pre-determined criteria. Sub-national respondents, however, regretted not having a larger role in the equipment selection and allocation processes. There were some areas of confusion with regard to the lack of trays with the equipment allocated to facilities, and the lack of freezing capability of the equipment.

Pakistan

The initial planning for demand generation, acquisition, and deployment of CCE for all the phases of the CCEOP grant in Pakistan was completed in 2016 and 2017. It was a data-driven process. 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. These lists were developed by the federal EPI in coordination with provincial EPI, and were supposed to be further refined with input from districts based on the on-the-ground situation. In reality, the consultative process appears to have been mixed. Many district personnel felt left out of the consultations.

Overall, there was satisfaction with the equipment received, but there was concern that the choice of equipment and stabilizers did not match the location, e.g., they were deployed in areas with lower voltage than what the stabilizers could handle. There were also instances of equipment being assigned to facilities and stores with space limitations.

Guinea

The main strategy for improving coverage and equity in Guinea was to increase the number of service provision points. Facilities with no equipment were equipped with a CCE as a priority. Health Center Heads, District Health Directors, and Regional Health Directors played a role in the selection and preparation of sites. After discussions with country partners, EPI decided to include the original equipment selection that had been used in the country previously (TCW-2043 SDD model) for the majority of sites (75 percent), with a 25 percent mix of the new CCE which was less expensive, the Haier SDD HTCD-160 model. For the selection of sites, per Gavi's guidance, data needed to complete the operational deployment plan were collected by Health Center Heads and transmitted to the national level via the District and the Regional Health Directors. EPI's coordination was found to be effective; information on CCEOP, requirements for the ODP and on receipt of CCE were clearly communicated down to the lowest level of the health system.

The PMT that was inaugurated in October 2018 played a major role in coordinating the preparation and implementation of the CCEOP, with significant support from its partners, UNICEF and WHO. The PMT played the role of monitoring the SBPs according to an initial agreed schedule, based on submission of documents such as the Installation checklist, facility verification checklist, and a checklist for documenting the installation.

TRANSPARENT PROCESS AND STAKEHOLDER ENGAGEMENT

Finding 2: Stakeholders do not fully understand all of the details of the warranty, type of corrective maintenance/repair that is covered, and how to access those services.

Finding 3: Many respondents were not clear on SBP terms of reference and what they were/were not contracted to do to set expectations for performance.

The equipment typically came with a two-year warranty. In some cases, such as the SDD models deployed by B-Medical Systems, the warranty covered a 10-year period. However, there was confusion at all levels on what the warranty entailed, what it covered, and what repair services could be accessed by health facility staff. Countries were not always provided the details of the terms of the warranty during the procurement process; and even if they had this information they did not pay enough attention to it. For the most part, the SBP followed guidelines as per the procurement order from UNICEF SD, without much country engagement on this count. When installing the equipment, the SBP provided information at the health facility level on contact procedures, but these were not always followed.

Kenya

In Kenya, the training of MOH technicians covered warranty and claims procedure. As many as two engineers from each county attended the training, and were expected to return to their counties and mentor or provide informal training to other engineers and technicians in the county. Sub-national-level staff, however, were largely unaware of many details of the warranty, including what it covers, for what time period, and the process for submitting requests or claims for repairs.

The SBP reported that they conducted on-the-job training when they installed the equipment to train users at the facility level. Sanica noted that facility staff were trained on how to operate the equipment, how to read and monitor the temperature, and when and how to conduct routine preventive maintenance. However, there was still confusion on the part of health facility staff on procedures to be followed. At the national level as well, not much effort was given to communicate the terms of warranty details to the sub-national level.

“We are still in the dark on how we work with the agents. We are not been able to have spare parts for solar fridges. They need to make clear the plan for maintenance of the agents.” –Homa Bay County Official

The expectation is that the SBPs would go and do any repairs if they receive calls from health facilities during the warranty period for issues that cannot be fixed over the phone. However, in one instance of interviewing in Kenya, the new equipment remained unrepaired because the SBP had not been contacted for a couple of months due to lack of clarity on the part of the health facility staff.

Pakistan

When the equipment was installed, the SBPs provided an orientation on operations to all health facility staff, covering topics such as how to place the equipment, plug it in and maintain its temperature, preventive maintenance procedures, and procedures to contact the SBP in case of problems. However, they did not necessarily discuss details about the warranty. In at least some cases, KIIs at the facility level showed that equipment operators (vaccinators) had limited awareness of the warranty agreement and the responsibilities of the SBP; and some facilities had attempted repairs themselves.

Given this situation, the federal EPI is planning a detailed training at the national level that will include preventive and curative maintenance of the equipment, proper use of Fridge Tag, difference between ice packs and water packs, and warranty time and conditions as provided by the SBP.

Guinea

National-level key informants in Guinea, including MOH representatives, indicated that they were not familiar with the details of the warranty, outside of what had been explained to them by the SBPs. They did not have access to the contract, terms of reference, or any other official documentation pertaining to the terms of the warranty, which could potentially contribute to miscommunication or misalignment of expectations in the future.

At health posts, SBP training during equipment installation focused on routine preventive maintenance for users who manage the CCE, namely health post heads. SBPs also posted their contact information on the CCE, in case of any problems. Despite this, respondents at health posts were unclear about the protocols for maintenance during the warranty period, with some understanding that they should contact the SBP for corrective maintenance, whereas others referenced the protocol for existing CCE, escalating the issue to the higher level within the health system, such as the district.

ALIGNMENT WITH GAVI GUIDELINES AND OTHER PARTNER SUPPORT

Finding 4: The CCEOP is coordinated with other donors and partners for overall system strengthening, although better documentation could improve coordination and planning (i.e., deployment of World Bank/other donor-funded refrigerators and cold rooms, and limited information on where old fridges were moved).

Finding 5: Respondents were satisfied that the CCEOP application and ODP adhered to Gavi guidelines, used available systems and cold chain inventory data, and responded to country priorities.

Although CCEOP planning was a data-driven process using information from a cold chain inventory that had been conducted, there was evidence of equipment being received from other sources with limited coordination in Kenya and Pakistan.

Kenya

In Kenya, the general understanding is that CCEOP funding would equip health facilities and sub-county stores, whereas other funding mechanisms, like the World Bank, would equip facilities and stores at all levels. There were other deployments from other sources, such as Global Good. In addition to the concurrent deployment of equipment funded by the World Bank equipment, it was also found that the installation of new equipment in some facilities resulted in shuffling of old equipment from those facilities to others. As a result, there was incomplete documentation on what equipment was located where.

Although the ODP was generally found to be appropriate, SBPs noted a few cases in which contact information for the facility in-charges was out of date. A general drawback of the ODP was that it was a dated document, based on data from 2016/2017 and that systems were not in place to update it in real time.

“ The other thing that could be done better in the ODP is being able to have a more accurate inventory update to avoid what happens when you are taking a fridge to a facility and you find another one already there, so that we are able to have a more accurate deployment plan. That could only happen if we have that data for cold chain coming in at any given time a facility receives a fridge from whatever source. The inventory is automatically upgraded so that when doing the deployment plan you know very well that when you are going to a facility there is no equipment there or the type of equipment to be shifted is rightful for that place. “ –National partner

Pakistan

Although there was general satisfaction with the application and planning process, lack of coordination was a concern. As in Kenya, Pakistan faces a situation where equipment is being received from other donors, but the process is not always coordinated. For example, the People Primary Healthcare Initiative (PPHI) manages 1,178 facilities across Sindh. Both the Federal EPI and PPHI confirmed that PPHI was not included in any discussions about CCEOP or the planning and implementation of CCEOP, even when their facilities received CCE from the grant.

Guinea

The CCEOP investment was efficiently managed in Guinea. The Gavi CCEOP application process, in addition to Gavi’s technical assistance and continued support from WHO and UNICEF in CCEOP planning and preparation, helped ensure adequate preparation and risk management planning. The development of the ODP, in particular, was very helpful in ensuring an efficient implementation process.

At the national level, EPI used all of the opportunities (forums such as the health sector development plan coordination meeting, and assessments such as the Joint Assessment) to provide information on the importance of CCEOP and need for the Ministry to secure funds to cover the customs clearance fee.

During the planning and implementation of CCEOP, community engagement was emphasized, and EPI had conducted a number of sensitization efforts. This was especially evident in communities’ active contribution to rehabilitating health posts (widening doors and reinforcing roofs in some cases). On the other hand, there was inconsistency across districts in terms of equipping facilities with stock and data management tools, and synchronizing supervision during the CCEOP process.

“The internal and external factors that contributed to the success of the implementation of the deployment plan include the preparation of field workers, awareness raising in the communities, participation of the prefect, sub-prefects, mayors and district presidents. The

installation teams were welcomed with open arms throughout the districts by people that were cheering.”

—District Health Staff, Boké Region

There were challenges encountered prior to and during deployment. The information provided by the MOH—including the list of health posts where CCE was to be installed with data pertaining to geographic location, conditions of the roof and structure, access and state of roads, and time of year when it would be more or less difficult to access each site—was invaluable to SBPs. However, several key informants at the national level mentioned that the renovation of the health posts, led by the MOH and UNICEF, proved to be very costly and time-consuming, and this was underlined as a lesson learnt for future deployment.

EFFECTIVENESS

SBP IMPLEMENTATION

Finding 6: Respondents at all levels were mostly satisfied with the installation and commissioning of the equipment by the SBPs, with some areas for improvement, such as clarity on roles and responsibilities and warranty coverage.

Overall, in all three countries, respondents expressed general satisfaction with the equipment received and the role of the SBP in the deployment process. As mentioned earlier, there were some issues regarding SOPs for SBPs and a better understanding of warranty that needed to be conveyed to staff at all levels of the health system where equipment was being deployed through CCEOP.

Kenya

Facilities and sub-county stores in Kenya were predominantly pleased with the equipment they had received, especially in cases where solar-powered equipment replaced gas-powered equipment. Advantages of using the SBPs mentioned by respondents included the rapid time-frame for delivery and installation, the quality of installation, the reliability of SBPs, the documentation of deployment (which allowed for national-level monitoring) and the reduced burden on the ministry for delivery and installation, especially among engineers and technicians responsible for installing World Bank-funded equipment.

“What worked well is the distribution, since the fridges were taken directly to the facilities. If we would have had to involve our engineers, it would have been hell on us.” —Homa Bay Sub-county official

“The fact that it takes a lot of headaches out of our mind, we know that this a service that has been paid for and will most likely be rendered at the highest quality that is possible, we do not have to worry about various differing messages or any inconsistencies that may

arise. [...] So the peace of mind that is borne by the service bundle associated activities has been quite useful.” –National Partner

Pakistan

Despite a few remaining concerns, there was overall satisfaction with the equipment installed through CCEOP. The main reasons for this were better storage capacity and ability to maintain temperature. The new equipment was a source of relief for a number of facility personnel, who would travel a long distance to acquire vaccine supplies. They were now able to store a considerable quantity of vaccine typically sufficient for a month. Working through SBPs also moved the responsibility of proper installation and repairs from the federal EPI to a third party they could monitor.

Some of the concerns raised were:

- 1) The lag in responses to questions on maintenance and repair by the SBP especially in Sindh, one of the provinces of focus of the evaluation team.
- 2) The quality of the equipment manufactured by Sure Chill.
- 3) The problem with non-working stabilizers in areas with very low voltage and erratic power supply.

Guinea

Per UNICEF/Copenhagen’s request, UNICEF Supply Division (SD) met with and vetted the SBPs (SOGUIMAP and Menerga) before they signed contracts with their respective manufacturers. Although deployment was not completed by the time of the midline assessment, all national level key informants expressed high praise for the SBPs, whom they described as “open, available, and competent.” Clear and timely notifications from UNICEF/SD about the location and status of the equipment made it easier for SBPs to take charge of equipment at the port and transport it to central or regional stores before delivering and installing in health posts. Building rapport with regional and district staff eased further communication with the regional and district health offices and accelerated the deployment process for the SBPs.

The installation process was smooth. An equipment delivery team transported the equipment to the designated health posts, and a separate installation and training team installed the CCE, ensured functionality and trained health post staff—typically the head of the post and the EPI officer—in preventive maintenance. Facility staff commended the promptness of the SBPs, highlighting that there was little to no lag time between delivery and installation.

MOH INVOLVEMENT IN IMPLEMENTATION

Finding 7: The robust system of monitoring and documentation established for equipment deployment was effective at tracing equipment and ensuring accountability from the SBPs.

Finding 8: The few deviations were effectively handled locally, with no reported additional costs incurred. Accurate deployment plans must also include a level of flexibility, especially at lower levels, to respond efficiently and effectively to on-the-ground situations in a timely manner.

Finding 9: The PMT played an active and effective role in CCEOP deployment and coordination, demonstrating ownership and strategic thinking, although documentation could be improved (also linked to sustainability).

In all three countries, the deployment process was coordinated and monitored successfully on an ongoing basis by the PMT. Although the reality on the ground did not always fit with the ODP, they worked successfully with the SBP to ensure timely deployment. In all three countries, despite delays at earlier timepoints of the CCEOP process, deployment was conducted as envisaged over a 4–6-month period.

Kenya

In addition to contributing to the development of the application and the ODP, the PMT played a key role in monitoring the deployment process. Although the PMT in Kenya was originally expected to meet every month, meetings took place on a more ad hoc basis, with interim communications between members over WhatsApp and email. At the national level, the PMT coordinated the training of the county biomedical engineers by the SBPs. They also developed forms, such as a CCE Installation and Certification Checklist, Certification of Installation, Commissioning and User Training for Electric & Solar Fridges, and a Protocol Deviation Log for CCE Deployment, to monitor deployment activities.

Originally, deviation requests were channeled to the PMT for approval. However, after a period of deployment, the process became more flexible, and the PMT agreed that county-level officials could make decisions about deviations with the signature of the SBP and the county EPI logistician for approval. This flexibility in the deviation protocol at the county level improved the deployment process. Overall, deviations were minimal. Of the 1,004 pieces of equipment procured through CCEOP, approximately 3.5 percent were deviated from the intended facility originally outlined in the ODP.

“At the very beginning [the procedure for] deviations was not very good. The approval process was very lengthy as we had to get it from the Ministry of Health and UNICEF. It was agreed in the PMT meeting that we needed to simplify the deviation document to make it easier and for us to respond quickly in case we get deviations. For the first two clusters [of deployment], we had some deviations and in some cases we had to bring the refrigerators back here [to Nairobi] while we were waiting for approval, but after the issue

was resolved, from cluster three moving forward, we were able to just communicate with the county logistician and get approval on real time basis [...] it was much more effective.” –SBP Representative

Pakistan

In Pakistan, the PMT was responsible for planning and overseeing completion of CCEOP-related tasks, organizing activities to achieve desired targets, leading the decision-making process at each stage of the project, monitoring progress, determining the causes of deviations, making appropriate corrections, and communicating among stakeholders. The PMT’s role was also to manage maintenance, repair, and training issues. The national PMT made major decisions regarding the selection of facilities and the choice of equipment, while the provincial PMT monitored the deployment process and reported to the national PMT.

The PMT was able to identify many challenges during deployment and to rectify them. This included challenges in facility staff training, stabilizers, and the sustainability of grant support. In the case of stabilizers especially, because of the issues faced, the PMT decided that the stabilizers for the next phase (Year 2) would be customized to function at the voltage of 100 instead of 170.

With regard to deviations, the ODP experienced some deviations, as some of the equipment had to be revised to address problems with availability of electric power. In other instances, space limitations within health facilities required changes. Deviations also occurred due to other reasons, such as delay in receipt of the international shipment and elections in Punjab during the deployment period. SBPs specified that deviations occurred in every district, but they were minimal, and were covered by the SBPs themselves, although respondents mentioned additional transportation cost as an issue.

In general, SBPs initially worked with the provided plan to arrange deployment in a district. They then coordinated with the province and district levels to install equipment within the districts.

Then, because our equipment and cars had reached there, so instead of doing nothing, we did it with the coordination of province and district.”

–SBP, Islamabad

Guinea

The PMT played an active role in monitoring the deployment process in Guinea. SBPs sent progress reports to the PMT on delivery and installation of CCE on a weekly basis, detailing the number of CCE that had been delivered and/or installed and highlighting any issues that were encountered during the journey. For urgent matters, SBPs communicated issues via phone with the PMT and awaited a final decision from the latter before moving forward. SBPs also attended PMT meetings periodically to present updates about their progress in person.

At the time of the midline evaluation, 646 CCEs out of the total of 848 had been delivered, of which 490 had been installed and commissioned. Deviations from the ODP were minimal, below the 5 percent deviation threshold projected in the plan. On the whole, facilities had adequately prepared for the arrival of the new CCE by widening their doors, cutting trees, and prepping a clean, spacious, and airy corner for equipment installation. Most of the deviations took place in Faranah, where in three sites, the SBP arrived to find that the health posts were still under renovation, though they had been labeled as ready. All deviations to the ODP were communicated by SBPs promptly and directly to the PMT which, in consultation with regional and district officials, made final decisions.

COORDINATION AND COMMUNICATION

Finding 10: Respondents were generally satisfied with the deployment and installation process, although relevant information on deployment schedule did not always uniformly extend to all key stakeholders.

As mentioned earlier under Finding 6, there was overall satisfaction in the deployment process in general. The role of SBPs was appreciated and systems put in place to make adjustments on the ground based on the situation. However, there were some difficulties, both in terms of coordination between the national and lower levels, and in transfer of information from the lower levels to the national level.

Kenya

Although deployment was managed in a timely manner, better communication between parties could have made the deployment even more efficient. For example, one of the SBPs, Sanica, explained that they thought the counties and sub-counties had been informed by the national government that they were scheduled to receive equipment and explained that they worked with county EPI logisticians. All three county logisticians who were interviewed reported that they had been in close communication with the SBPs throughout the deployment process, suggesting that while some communication took place, even if it did not reach all relevant parties.

Communication between all parties, but specifically between the SBPs and sub-national entities, during the deployment, was problematic. While the SBPs were in contact with the county EPI logisticians, communications were lacking among SBPs, the installation sites, and other county-level officials.

“From what I have seen, a lot of issues have come down from failure to communicate, be it from [SBPs] failing to communicate to the counties prior to deployment, or from the PMT

not communicating their desires correctly to the [SBPs], or the [SBPs] not being prompt enough for the responses on the deployment limitations.” –National Partner

Pakistan

The SBPs worked with the federal and provincial EPI and UNICEF personnel to ensure efficient deployment planning to reduce costs of travel and other expenses. In reality, it was the provincial EPI that enabled communication and coordination between the SBP and districts to ensure timely and efficient deployment.

National and provincial respondents indicated that all information about the planning and deployment stages was shared at all levels, from the PMT at the national level to stakeholders at the provincial and district levels. National stakeholders described holding many formal and informal or ad hoc meetings to discuss deployment issues in real time. However, there was less communication with districts, leading to some deviations.

Guinea

As in the other two countries, although the implementation process was generally inclusive and participatory, communication lines were not always clear and transparent. The PMT and the team’s periodic meetings were instrumental to sharing pertinent information, debating and deciding on pressing issues, and ensuring that all partners were on the same page. However, there was lack of clarity and communication on several issues. National-level key informants, including MOH representatives, indicated that they were not familiar with the details of the warranty, outside of what had been explained to them by the SBPs.

“If we hold on to information, it can ruin the whole process. We need to know all the terms and procedures related to paying the clients, paying the SBPs. It can save us time and enable us to plan ahead. This is for our own benefit.” –National partner

The SBPs, SOGUIMAP and Menerga, had not received payment from the manufacturers since the time they signed their contracts in November 2018, although they had sent all appropriate documentation to both the manufacturers and the PMT. This resulted in a major disruption for Menerga, which ultimately led them to halt all deployment in early February 2019, resulting in delays. The main reason was that the manufacturer had not received payment from UNICEF, which was waiting for the national level to independently confirm deployment.

SBPs were also affected by the need to delay deployment in a few instances because some health posts were still under renovation, though the sites had been labeled as ready. This information had not been communicated up the channel, partly because the local communities who took initiative to renovate the health posts were unaware of the strict ODP timeline.

EFFICIENCY

SBP IMPLEMENTATION

Finding 11: Satisfaction with the efficiency and quality of work of SBPs is generally good, but varies by SBP and facility preference on equipment.

Finding 12: Although the MOH was capable of installing CCE and procuring additional CCE units, respondents at the national level recognized the trade-off between the speed and effectiveness of SBPs deploying CCE and value for money.

Satisfaction with the deployment process and the role of the SBP was outlined earlier under Finding 6. However, there were some concerns. Although the MOH valued the role of the SBP, cost came up as a major concern, especially in Kenya. However, respondents in all three countries valued the expected benefits from the use of the new CCE and recognized its impact on the immunization system in general, although it is too early to be able to quantify this effect.

Kenya

Overall, the country recognized the advantages of using the service bundle model and expressed satisfaction with the role played by the SBPs in deployment. However, there were differences in the way the deployment process took place. One of the SBPs had an in-house transport system, which resulted in a lower lag time between delivery and installation, making the coordination process easier. The SBPs also followed different models of communication before delivery. In some cases, the facilities were directly contacted. In others, the county EPI logistician was aware of the delivery, but those at the sub-county level were not always informed. At the next phase of deployment, some of these learnings can be emphasized. At the same time, there was a missed opportunity for government engineers to build their own capacity by performing installations.

Another issue, not covered as part of this evaluation, but observed by the CHAI assessment, is the quality of installation. Especially in the case of SDD installation, it is particularly important to assess SBP deployment in terms of the quality of the installation, and whether standard pre-determined procedures were followed.

Despite satisfaction with SBP-led processes, and recognizing the decreased responsibility of the MOH with regard to deployment, maintenance and repair, the cost of the service bundle model came up as a major concern among key stakeholders. They felt that the increased cost of service bundles limited their ability to purchase additional equipment to meet the country's needs.

You see the strength of the CCEOP was that the service bundles gave a peace of mind. But at the same time, service bundles have been a weakness in its share of volume. When it comes to World Bank deployments, the cost of it has been a lot better because it has allowed us to procure a lot more equipment, of the same quality and technology as

the CCEOP equipment.” –National Partner

Pakistan

The decrease in operational costs as a result of the new CCE was recognized in Pakistan. Some facility personnel reported that their electricity bills had diminished after new CCE became operational. However, because of the relatively short time period since deployment and installation, it is too early to determine any of the improvements in operational cost witnessed thus far can be sustained over time.

There have been immediate and important improvements in efficiencies in terms of time. Many respondents stated that since the installation of CCE, their work performance had improved, as the new and functional CCE at the facility was a significant timesaver for vaccinators, and transportation costs have declined. The greater storage capacity of the new CCE also resulted in fewer re-stock trips (usually only one per month).

“Regarding the savings, the previous CCEs were small in which there was no or less space for the quota of the whole month. Obviously, (the vaccinators of) those EPI centers with small CCE had to come to our office twice to take the vaccines because of the incapability to keep vaccines of the whole month. They used to come after every fifteen days to take the vaccine. Now they take vaccine of the whole month by coming just once. In this way, it’s the saving of their time and obviously of petrol’s cost required for the vaccine’s transportation...” –Tehsil Health Officer -Site Town, Sindh

The main concern raised in Pakistan was the SBPs’ response to repair and maintenance requests, particularly in Punjab.

Guinea

Given the lack of CCE in health posts in Guinea, there was considerable interest at all levels to ensure timely and efficient deployment. Some health posts needed to be renovated prior to installation, and communities were engaged to provide resources to make the space in the health posts ready for installation, such as enlarging health post doors and, where necessary, providing cement for the installation of the solar panels poles.

Stakeholders valued the efficiency of the CCEOP planning and implementation process as a result of support from Gavi, WHO, and UNICEF. However, they did find the planning process to be more expensive than they had expected, because they had not taken many costs into account when they initiated the activity.

“It’s really a cost [referring to the evaluation for the sites to assess preparedness]. To do all this coming and going, it takes a cost. Go to health center, go to health post, without funding, see what it does. So, it’s really...it’s also been a part that the state has paid for

the evaluation to be done. As part of the CCEOP, there are many calls that need to be made. ...Unfortunately, there is no budget line dedicated to communication.”

—Ministry of Health Official

Although the country did not explicitly bring up the costs of involving SBPs in CCEOP deployment in the country, they were aware of the costs, though respondents also knew that the Ministry did not have the capacity to handle such a deployment themselves.

Overall, respondents from health centers and health posts expect the installation of CCE to result in time and cost savings, reducing vaccine wastage and decreasing the fuel cost and the burden on health post workers to provide outreach vaccinations.

SUSTAINABILITY

COUNTRY OWNERSHIP

Finding 2: Stakeholders do not fully understand all of the details of the warranty, type of corrective maintenance/repair that is covered, and how to access those services.

Finding 9: The PMT played an active and effective role in CCEOP deployment and coordination, demonstrating ownership and strategic thinking, although documentation could be improved.

CAPACITY FOR CCE MAINTENANCE

Finding 13: SBPs provided insufficient training to facility staff. Training needs are insufficiently defined or understood by facility staff to ensure long-term maintenance of CCE.

Finding 14: For longer-term sustainability, technicians currently have insufficient capacity for corrective maintenance. Countries are not implementing a maintenance plan at national and sub-national levels.

This evaluation examined long-term sustainability as measured in terms of the country's interest and ownership of the CCEOP process and its ability to sustain the improvements made to the cold chain system. As mentioned earlier in the section on MOH involvement in implementation, despite following the service bundle approach, the PMT played a very active role in the implementation of CCEOP in both Kenya and Pakistan, including monitoring progress.

However, concerns were expressed on the quality of the training and the ability of health facility staff and technicians to handle problems in the future. An associated concern was the ability of the MOH to handle maintenance and repair in the long term, beyond the warranty period.

Kenya

The PMT's involvement in CCEOP planning and implementation was evident. With a high level of overlap with the National Logistics Working Group (NLWG), the role played by the PMT speaks to greater involvement and long-term ownership of the NLWG that oversees supply chain activities in general in the country.

There were challenges in the country's ability to build capacity to maintain the new CCE in the long term. As discussed earlier under Findings 2 and 3, there were two levels of training in Kenya, one at the national level and another at the health facility during installation. At the national level, cold chain technicians and up to two biomedical engineers per county attended a week-long training session covering topics such as installation, usage of equipment, safety, and preventive maintenance measures. Other topics mentioned by Total Hospital Solutions were the process for checking faults, monitoring of temperature, adjustment of the thermostat and proper care and cleaning, as well as the warranty and claims procedure. The biomedical engineers attending the SBP training were largely satisfied with the training provided and the components they covered.

However, given potential problems arising post-warranty, some respondents wished that more technicians and engineers had been included in the training offered by the SBPs.

“So far no maintenance has been done to the equipment but my fear is that our biomedical engineer is not trained so we will still depend on the two trained engineers at the county level.” –Homa Bay Sub-county Official

At the facility level, staff were trained on how to operate the equipment, how to read and monitor the temperature, and when and how to conduct routine maintenance. Other than a sticker on the equipment with basic information about routine maintenance, and the equipment's operations manual, facility-level staff did not receive any additional resources for the equipment. Most facility and sub-county respondents acknowledged receiving some training, but many felt that the training was insufficient and requested more formalized training sessions. It is not very clear whether facility staff were aware of the extent to which they would use their training and what aspects would be essential to maintain the equipment.

National level training was provided to technicians and biomedical engineers. However, to ensure that everyone is clear about roles and responsibilities, and especially to ensure continued maintenance after the SBP warranty ends, there is a clear need to develop a maintenance plan that provides information specific to the newly procured CCE, the roles and responsibilities of different individuals regarding maintenance, and an SOP for whom to contact when there is a problem with the equipment. This information needs to be disseminated to the sub-national level. .

Overall, technicians' ability to carry out corrective maintenance was insufficient. This was identified as a weakness in the country's maintenance plan and identified as a challenge in the 2013 EVM assessment.

Pakistan

In Pakistan as well, both the federal- and provincial-level PMTs represented by key stakeholders played an active role in overseeing and monitoring the deployment process. Although an active NLWG does not exist in the country, the active engagement of this group is relevant.

However, we found similar dissatisfaction with the quality of training at the facility level and with long-term maintenance of CCE in Pakistan. The training was provided in Urdu, but the accompanying written material was in English. Some facility staff were also not fluent enough to understand Urdu, and SBP personnel did not always speak the specific local language. After the completion of deployment, the SBP has now translated their manual into Urdu, but this will not be used till the next phase of deployment. Overall, this has implications for the long-term maintenance of the new equipment,

Facility staff were also apprehensive about the use of Fridge Tag and the manuals, though training was held in some districts. As a result, a national-level training is planned for April 2019, to include preventive and curative maintenance of the equipment, proper use of Fridge Tag, difference between ice packs and gel packs, and warranty time and conditions as provided by the SBP.

“The training that we are talking about is an orientation that can be given to personnel by any manufacturer of the equipment. If you go to any store to purchase a fridge, even they can tell you how to operate it and that it must be placed on a stool for ventilation from the bottom etc. If you call all of this as training, then this is incorrect. I believe this is just an orientation.” –**Provincial EPI, Punjab**

“We didn’t have such training (regarding preventive maintenance) but they (i.e. SBPs) did give us instructions and gave us a booklet, but no proper training.” –**Medical In-charge, Sindh**

The country has a long-term maintenance plan that needs to be translated to the sub-national level. Recognizing long-term maintenance needs, the country has made some effort to keep the choice of models to a minimum so that workers are better trained in using and maintaining the one model that they are using. However, the maintenance plans do not reflect a long-term training plan. Additionally, the EPI teams both at the federal and provincial levels mentioned that since the SBP would take care of maintenance and repair in the first two years, EPI did not plan to train any personnel on it just yet.

Guinea

The PMT worked closely with the two SBPs in Guinea to monitor the deployment process based on regular updates and meetings, and made decisions about deviations in a timely manner.

Combined with this oversight and leadership, community engagement was an integral part of the CCEOP deployment at the lowest levels of the health system.

“The involvement of authorities at all levels and communities has been a determining factor that has contributed to the success of the installation of the new CCE. As an example, in one of our districts, it is the community that has committed itself and took charge of the construction of the premises where the fridge was installed. It is this combination of administrative and community participation that has been the basis of the success of the facility.”

—Health Center Head, Faranah

However, challenges in the long term include maintenance of equipment. Some facility staff expressed reluctance to start using the new equipment because they had not received what they considered adequate or formal training in maintenance or cold chain management. Guinea also experiences several factors that could affect the country’s ability to handle consistence maintenance. These include challenges in coordination at the national level, implementing a maintenance plan, lack of resources for existing maintenance technicians, and understaffing. So far, the PMT’s collaboration with the Ministry of Health’s Infrastructure, Equipment and Maintenance Directorate (Direction des Infrastructures, de l'Equipement et de la Maintenance or DIEM) has been limited, and their maintenance technicians have not been involved in CCE installation.

“The collaboration with the DIEM was for the choice of equipment. But I have to admit normally, we should strengthen our collaboration with the DIEM, because they have maintenance technicians. Normally, for maintenance, they are the ones who oversee that for the country. So, we are aware that we must strengthen our collaboration with the DIEM.”

—EPI official

OVERALL

SYSTEMS STRENGTHENING

Finding 15: There is no reported plan for decommissioning equipment.

Finding 16: There is a need for an updated inventory using existing information systems and automated processes.

Finding 17: Some facility personnel are not well oriented about the shift to using cool packs (instead of ice packs) for outreach activities. This indicates the challenge of ensuring that policy changes are fully communicated and implemented, not only specific to CCEOP, but also to the overall system.

Finding 18: Currently there is no clear mechanism for monitoring CCE performance over time (after installation check) and providing feedback to manufacturers. With warranty

processes unclear in many places, it is uncertain if SBPs or the UNICEF Country Office would report breakdowns to UNICEF SD.

Findings indicate that several procedures are needed to ensure long-term sustainability and strengthening of the overall immunization supply chain system. This is true for both monitoring systems and communication of national policies and procedures to the sub-national level, so that equipment through CCEOP is installed and used effectively, and the system works efficiently.

Kenya and Pakistan

As new equipment is being installed, there is an effort to draft a decommissioning plan for older equipment or equipment that is malfunctioning, to improve the efficiency of the system. However, no formal plan or procedure is in place in Kenya or Pakistan.

As mentioned earlier under Finding 4, due to support for CCE equipment by other donors, and movement of equipment between facilities, there is no clarity on the current inventory of equipment in the country and where equipment is located. There is no clear system for documenting these changes consistently and conveying the information to the national level for planning purposes. In the case of Kenya, a decision has been made to conduct new inventory before the next phase of deployment.

After equipment deployment, neither country has a clear system for providing feedback from the PMT to UNICEF SD on how the equipment is working, the extent of repairs, and how well the warranty procedures are being followed. In Kenya, UNICEF SD has indicated that communication should funnel through the Country Office, but this does not seem to be happening in practice. A representative from UNICEF SD noted that the original terms of reference had been recently updated to clarify the communications and feedback processes among countries, SBPs, the UNICEF country office and UNICEF SD.

Policy changes are not trickling down to the sub-national level. The new equipment installed through CCEOP is all freeze-free, recognizing that the current guidelines discourage freezing of ice packs for vaccines and instead recommend the use of cool packs. However, there is some dissatisfaction at the sub-national level with the new equipment because of its inability to freeze the ice packs. Some facility personnel are not well oriented about the shift to using cool packs for outreach. Considering CCEOP within the overall system, this finding indicates gaps in facility-level knowledge. It is not a reflection on the CCEOP training, but on the overall system.

Guinea

Aligning the supply chain fundamentals is key to strengthen and sustain the vaccine supply chain performance in the long term. Long-term improvements in immunization require the coordination of many components of the system beyond availability of equipment. These include ensuring a clear knowledge of inventory of CCE, implementing the maintenance plan so that the CCE is functioning well, strengthening the capacity of its supply chain managers at the sub-national levels, and putting in place a mechanism for continuous improvement. Currently

systems are not in place in Guinea to provide accurate information on the availability of CCE in health centers and health posts through an inventory or how to provide preventive or corrective maintenance to equipment during and after the warranty period.

Also, as in Kenya and Pakistan, there are no systems in place for providing feedback to UNICEF SD/country on the current status and working condition of recently deployed CCEs and what repairs/maintenance may be needed during the warranty period.

SUMMARY OF PRELIMINARY MARKET-SHAPING FINDINGS

The global market-shaping goal is to incentivize a market where CCE is available at an optimal TCO and ultimately, to create a market where high performing equipment and services are available from a solid supplier base at sustainable prices. This is supported by four strategic objectives.³

1. Stimulate supply to meet demand for higher-performing, cost-effective, high-quality products.
2. Achieve fair and sustainable prices for both devices and commissioning service bundles.
3. Continuously innovate high-performing, optimal TCO CCE products.
4. Information sharing to better connect supply and demand.

The findings to date are organized around the initial questions of effectiveness, relevance, implementation, and sustainability of the market-shaping activities, with the market-shaping strategic objectives informing the assessment of outcomes to date (see Table 6).

Table 6: Global Level Market Shaping Findings

RELEVANCE
MARKET-SHAPING STRATEGY DESIGN
MS Finding 1: The original market-shaping strategy relied heavily on the market-shaping experience with vaccines and other single-use products; more attention is needed to evaluate elements and unique approaches for durable equipment and the service bundle.
MS Finding 2: Many of the risks related to the existing market dominance of two suppliers and the complexity of the service bundle were raised in the initial procurement and supply roadmap for CCE, but the mitigation plans may not have been robust enough at the outset to sufficiently address them.

³ See Annex 1 for target outcomes by strategic objectives, as laid out by the Gavi in 2016 Supply and Procurement Roadmap for ILR and SDD Cold Chain Equipment (Restricted Version)

IMPLEMENTATION

TENDERING FOR CCE AND SERVICE BUNDLES

MS Finding 3: Despite changes to the process and attempts to shorten the overall timeline, which takes over a year for country application approval, the time required for each step, including ODP development and implementation and tender release and award, have continued to challenge efforts to shorten timelines. This meant that the CCEOP tender calendar (and procurement volumes) has shifted significantly from month to month.

MS Finding 4: Suppliers, particularly those not seeing significant procurement volumes, feel that the tender award process is opaque and is not currently rewarding investments already made in product innovation and lower TCO options. Suppliers would like UNICEF to provide more timely feedback on expected award dates and feedback on tender outcomes.

MS Finding 5: Limited data on longer-term CCE field performance, and limited ability to compare across a wide set of features, makes it difficult to accurately assess for various contexts and compare value for money or TCO in selecting equipment.

MS Finding 6: Questions and concerns persist regarding tendering and CCE selection processes and the role of country preferences. For the suppliers who had not seen significant volumes of purchase orders (POs) as of Q3 2018, there was a particular sense that the practices and outcomes to date were at odds with the CCEOP market-shaping goal of promoting innovation, competition, and value for money.

EFFECTIVENESS

STIMULATING SUPPLY TO MEET DEMAND

MS Finding 7: The original market-shaping goal was to ensure two platform-eligible suppliers of ice lined refrigerators (ILRs) and SDDs per size segment. The supply of CCE continues to expand with 9 of the 18 CCE segments tracked exceeding the original goal. As of September 2019, there were seven suppliers of platform-eligible ILRs producing 23 different platform-eligible models up from 20 in July 2018 (15% increase). For SDDs there were eight platform-eligible suppliers producing 36 different platform-eligible models, up from 33 models in July 2018 (9% increase).

MS Finding 8: Procurement has not kept pace with the initial annual forecasts for CCE that were shared with suppliers at the outset of CCEOP, due to delays in implementation. As of Dec 2018, POs had been placed for ~20k units of CCE, roughly 43% of the 46k units forecast to be procured by end of 2018. Tenders for the first 25 countries (including Year 2 procurement) have skewed towards two suppliers based on country preferences, undermining the CCEOP MS objectives to create a healthy market.

MINIMIZE COSTS OF DEVICES AND SERVICES BY PROMOTING HEALTHY COMPETITION

MS Finding 9: The MS objective of reductions in weighted average prices for ILRs and SDDs has not been prioritized, possibly de-emphasized in favor of the MS objective for innovation and the principle (to date) of fully respecting country preference.

MS Finding 10: The service bundle mandate is the greatest source of conflicted feedback. Global and national stakeholders feel that it has complicated price negotiations and efforts to ensure value for money. Countries, specifically national-level stakeholders, value the service provided but are concerned that the added costs of SBPs on top of CCE limit their ability to obtain the number of CCE they need. Suppliers appreciate the opportunity to ensure that their CCE is properly installed, but feel that they are bearing all of the risk and uncertainty. Some suppliers feel the service bundle mandate forces them into a service area outside of their core competency. Most suppliers indicated that the cost benchmarks provided during the negotiation process were unrealistic.

PROMOTE CCE INNOVATION

MS Finding 11: Although initial target product profiles (TPP) targets for SDDs and ILRs were achieved ahead of schedule, the lag in procurement volumes to date and the preference for obtaining CCE from two suppliers is limiting additional investments in technology from other suppliers.

INFORMATION SHARING TO BETTER CONNECT SUPPLY AND DEMAND

MS Finding 12: Information flow and transparency among partners, countries and manufacturers have made progress under CCEOP. Stakeholders cited Gavi, UNICEF (Supply and Programme Division), and WHO for their efforts to coordinate and improve information sharing between themselves, countries, suppliers, and SBPs.

MS Finding 13: Delays in implementation and procurement trends to date have raised questions about the credibility of CCEOP demand forecasts, which may undermine ongoing decisions by suppliers to produce or innovate for this market.

MS Finding 14: There has been progress in improving price transparency through the UNICEF SD websites, but information is not updated regularly. Also, it is not clear how the UNICEF reference prices relate to CCE prices in the CCEOP budget template, or to actual prices paid via country-specific tender awards.

SUSTAINABILITY

MARKET DYNAMICS

MS Finding 15: Suppliers raised concerns about the sustainability of the CCE market, given procurement outcomes to date. Many expressed concern that it could not sustain the current number of suppliers, without more direct market intervention on the part of Gavi and UNICEF.

Details on these findings as they relate to the evaluation questions and market-shaping objectives below are provided below.

MARKET SHAPING STRATEGY RELEVANCE

The relevance of the market-shaping strategy was evaluated in the July 2018 Market Shaping summary report. At that point it was clear that elements of the initial strategy needed adjustment, based on early outcomes. Despite some signs of progress, in assessing the relevance of the strategy design, challenges have been identified about the scope of the strategy, the relative importance of the strategic objectives, price reduction targets, the role of country product selection and preference in achieving healthy market outcomes, and the effect of the service bundle on market-shaping outcomes. Since then an updated strategy has been in development. Therefore, the evaluation team will await the revised strategy and assess relevance in the next comprehensive market-shaping report.

MARKET-SHAPING STRATEGY DESIGN

Input gathered through KIIs and review of different market-shaping strategy documents showed that the market-shaping strategy for CCE relied heavily on experience with vaccine market shaping. Though aspects of Gavi market shaping are relevant and can be adapted from the success of vaccines and other pharmaceuticals, the difference between a consumable product

(vaccine) and a durable product (CCE) may not have been sufficiently explored in the strategy design. The market-shaping hypothesis was that, like with vaccines, pooled volumes and certain funding would drive supplier price discounts while simultaneously making the market attractive for innovation and investment. However, for suppliers already dominant in this market, there has been limited movement to lower prices, and country preferences are influenced by brand recognition/product experience and concerns about switching costs, neither of which are typically part of vaccine selection. Further, the service bundle component also meant that suppliers needed to have a network of local service providers to partner with to be competitive, which created an additional cost for some suppliers.

The results of the first 25 CCEOP tenders indicate a number of design aspects that may require further consideration to foster competition and lower prices. Primarily, linking equipment manufacturing to the ability to provide custom service bundles in a wide variety of contexts inherently privileges established suppliers, and places newer manufacturers without strong networks in many of these countries at a disadvantage. The incumbent manufacturers can draw on experience in countries to respond more competitively to bids, whereas this is a barrier to entry for less established suppliers. This potentially undercuts the opportunity for competition on price and performance, in favor of country familiarity and existing market footprints.

Many of the risks related to the existing market dominance of two suppliers and the complexity of the service bundle were raised in the initial procurement and supply roadmap for CCE. However, the mitigation plans may not have been robust enough at the outset to sufficiently address them. Given the complexity of the market-shaping strategy, it seems reasonable to expect course correction. Stakeholders interviewed acknowledged that the outcomes from the first round of country applications and procurement provided important learning and are informing changes to future processes. These are expected to be addressed in the revised market-shaping strategy, and the next market-shaping report will assess the strategy's relevance more comprehensively.

IMPLEMENTATION

Implementation of the market-shaping strategy has proceeded, but overall delays in CCEOP across the 56 countries have impacted timelines for some activities, and procurement outcomes reflect those delays. CCEOP launched in 2016, but delays in the overall process and readiness of country Operational Deployment Plans meant that the first CCEOP-funded equipment was not procured until 2017, and a significant proportion of that not until December 2017. However, in recognition of the causes of these delays, changes to the process have been implemented to reduce the average time from application approval to deployment. By the end of 2018, deployment of equipment for six countries was completed, and was in process for another seven countries. POs for CCE for the next 12 countries have been placed with first deployments for these countries, expected to commence in Q1/Q2 2019. In total, by the end of 2018, POs for 23 countries, plus an additional two year-two procurements (Haiti and DRC), had been placed for 20,194 units of SDDs and ILRs.

Despite changes to the process and attempts to shorten the overall timeline, delays in applications, development and implementation of ODPs, and tender release and award process have continued to challenge the efforts to shorten timelines, and meant that the CCEOP tender calendar (and procurement volumes) has shifted significantly from month to month.

SUPPLIER FEEDBACK ON TENDERING PROCESS

Many suppliers interviewed expressed frustration at the tendering process in terms of the amount of time it took to prepare bids and the lag in response/awards from UNICEF. They acknowledged the changes made to the process in 2018, including the increase in bidder response time to six weeks, and the adjustment so that any bidder could respond to a country tender, not just the suppliers that a country has indicated as preferred. Most appreciated these changes and felt that the opportunity to bid on any tender helped make their products more visible and competitive. However, the smaller suppliers in particular were wary of the time and resource investments required to respond to a tender, especially when the outcomes continued to favor the already established suppliers. Some of the smaller suppliers understood the competitive benefit of being able to respond to any tender, but also appreciated the notion that with a smaller pool, they could focus their limited resources on the opportunities where they might be more competitive.

Given the time it takes suppliers to prepare a bid, several also voiced frustration that tenders are not better leveled over the course of the year. The experience in 2017 and 2018 was that the RFPs come out in batches – that is, there would be no tender activity for months and then several tenders released in one week. Respondents said that this affects the ability of suppliers to respond, especially smaller ones, even with the extended response time.

All of the suppliers were critical of the lack of clarity on the timing of awards or even “notional” deadlines for tender responses. All would like to see UNICEF provide more timely feedback on expected award dates and tender outcomes. At the point of the interviews in Q3 2018, several suppliers were frustrated that zero awards had been made yet for the year, even though several were open and many more expected. Further, suppliers expressed concerns that countries that had been listed on earlier versions of the 2018 tender calendar dropped off in later versions with no explanation. These changes can be challenging for companies to plan resources, and some may have made decisions to supply equipment based on an earlier version of the tender calendar and expected POs.

Suppliers also desired more feedback on the specific tender outcomes. Many said that the process is opaque, and they do not fully understand how tenders are evaluated and awarded. They expressed uncertainty on how pricing is incorporated and how the service bundle component is evaluated. There was a general feeling that CCEOP was favoring a certain type of supplier, but that UNICEF was not sharing information on why this was happening. Several suppliers that are newer to working with UNICEF also felt that their lack of experience was hindering their performance with the UNICEF tender process, and they desired feedback on their bids. Respondents indicated that more, specific feedback on the awards and decisions

would be beneficial. One supplier mentioned that pre-CCEOP UNICEF would conduct public bid openings, which allowed everyone to see awards, understand which companies were winning, prices, and the equipment purchased. The supplier indicated that this allowed manufacturers to better assess where they stood with the competition, and could help them respond more competitively for future bids.

For the suppliers who had not seen significant volumes of POs as of Q3 2018, there was a particular concern about the tendering process and the role of country preferences in selection and tender awards. Most felt that this was at odds with the CCEOP goal of promoting innovation, competition, and value for money. Several cited the fact that outcomes to date continued to benefit higher-priced CCE, even as newer, less expensive technology was available for the same type and size segments of CCE. They were frustrated that countries appear to choose what was in their application regardless of tenders, product specifications, and value for money. As one supplier put it, “They [UNICEF] say they want lower prices but are buying more expensive equipment – it just doesn’t add up. Some players have raised prices in recent years and they are still winning tenders.”

FEEDBACK ON EQUIPMENT PERFORMANCE AND ASSESSING TCO

Related to this concern, one of the market-shaping innovation-related objectives was to implement a functional feedback loop on equipment performance once deployed, in order to ensure robust products are available at both facilities and in the marketplace. This would also help provide data to inform value for money assessment and enable better comparisons across products. To date, this initiative has proven difficult to operationalize, but several approaches are expected to roll out later in 2019. There are two distinct functions anticipated – post-market monitoring (PMM) and post-installation inspection (PII). PMM is led by WHO PQS and will entail collecting data via sentinel surveillance sites, which will provide insight to the frequency and reasons for equipment failure. This will inform PQS specifications and verification protocols, while also feeding into timely feedback to manufacturers to enable corrective and preventative actions. The intent of PII is to better differentiate the performance and reliability of CCE provided through CCEOP. UNICEF is leading the PII activity, and the vision is that it will replace the commissioning that was initially part of the SBPs responsibility. UNICEF will use an ISO sampling framework to follow up on installation quality and early product performance approximately six months after installation. The rationale is that it will save money on the SBP while also providing more meaningful performance feedback on CCE; and will allow identification of both unique instances of issues and trends, and wider dissemination of that information. New CCE equipped with RTMDs also will provide a source for performance data, if data sharing agreements can be negotiated with all suppliers.

An early success of the PII is the recent alert to WHO PQS on performance concerns with specific Vestfrost models. Based on reports from PII data collection and subsequent follow-up, as of September 2019, eight (8) models of Vestfrost refrigerators were suspended and removed

from CCEOP platform eligibility while WHO and Vestfrost investigated to determine the exact root cause of the reported freezing in these fridges.⁴

UNICEF SD has supported price transparency for CCE with reference prices by equipment model and by year made available on the UNICEF website,⁵ as well as through the CCEOP budgeting tool.⁶ However, it is unclear how closely the reference prices align with actual country-specific award prices, or how accessible actual pricing information is to different stakeholders at both the global and national levels. Further, in many cases, the prices listed in the Gavi CCEOP budget template differ significantly from the reference prices on the UNICEF website, and it is not readily apparent when each was updated. And the UNICEF reference prices are often presented in ranges, which may cause uncertainty for budgeting and comparison purposes. Prices on the UNICEF website also do not include SBP costs, which will likely affect budget decisions on product selection; and the SBP cost estimates included in the budget tool seem to vary widely from actual experience. Lastly, it does not appear that the price list on the UNICEF website is routinely updated to reflect newer price data and includes newly eligible CCE, which limits informed decision-making and the overall goal of transparency.

EFFECTIVENESS

The overarching 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. At the highest level, CCEOP has been effective in significantly increasing attention to the CCE market and generating high levels of country awareness of and demand for better technology. The initial version of the Supply and Procurement Roadmap for Cold Chain Equipment (2016) and stakeholder action plan focused on two types of CCE, ILR and SDD equipment; this summary is aligned with that focus. The evaluation team looked at preliminary results by each strategic objective as set out in the roadmap. Conversations with stakeholders in early 2018 indicated that the roadmap was under revision to address and respond to early learnings from the market-shaping outcomes, but as of February 2019, this revision had not been released to include in the CCEOP evaluation.

STIMULATING SUPPLY TO MEET DEMAND

On the supply side, over the past year the number of platform-eligible models has increased (Table 7), but there has been no change in the number of platform-eligible suppliers for ILRs and SDDs. As of September 2019, there were seven suppliers of platform-eligible ILRs (Aucma, B Medical, Dulas, Godrej, Haier, Vestfrost, Zero) producing 23 different platform-eligible models, an increase from 20 models in July 2018. For SDDs there are eight platform-eligible suppliers

⁴ See WHO PQS Issues of Concern as of June 24, 2019 and update as of October 24, 2019. Available at http://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/

⁵ Available here - https://www.unicef.org/supply/index_81828.html

⁶ Available here - <https://www.gavi.org/support/process/apply/cceop/>

(AUCMA, B Medical, Dulas, Godrej, Haier, SunDanzer, , Vestfrost, and Zero) producing 36 different platform-eligible models—an increase from 33 models in July 2018.

Table 7: Number of CCEOP-Eligible Models per Size Segment over Time

Type of CCE	Size Segment	Number of Platform Eligible models			
		Feb-16	Jul-18	Feb-19	Sep-19
ILR without freezer	< 30 L	4	1	1	2
	30-<60 L	6	3	3	4
	60-<90 L	2	3	4	4
	90-<120 L	5	4	4	3
	> 120 L	8	8	8	6
ILR with freezer compartment	30-<60 L	1	1	2	3
	60-<90 L	1		1	1
On grid freezer	90-<120 L	1	1	2	2
	> 120 L	7	7	7	6
LT passive device	< 30 L	0	1	1	1
SDD without freezer	< 30 L	2	7	7	7
	30-<60 L	3	6	7	6
	60-<90 L	2	2	2	3
	90-<120 L	4	4	4	3
	> 120 L	4	3	3	3
SDD with freezer compartment	< 30 L		2	1	1
	30-<60 L	1	4	6	6
	60-<90 L	1	1	1	1
	90-<120 L	3	2	2	2
SDD freezer	30-<60 L		1	2	2
	60-<90 L		1	1	1

Overall, through the end of 2018, POs were placed for 20,115 units of ILRs and SDDs with Gavi’s CCEOP funding. Over the two-year period, the procurement split is almost 50/50 between the two types of CCE, shifting from a higher number of ILRs procured in 2017 to a greater proportion of SDDs procured in 2018. The total 2 year procurement volume of ~20k units falls short of the initial UNICEF short-term demand forecasts (24k units in 2017 and 22k in 2018) by over 26k units. According to UNICEF SD this is due to programmatic delays with applications, approvals, and development and implementation of ODPs, particularly in a few high-volume countries, that affected the overall procurement volumes and schedule. UNICEF SD indicates that they are still on track to reach 65,000 units of CCE procured in total by December 2020, including both CCEOP and HSS-funded procurements, aligning with the end of the current Gavi program cycle. Estimates for additional CCEOP procurement continue into the next Gavi planning cycle for 2021, which would result in ~85,000-90,000 SDD/ILR units

procured in total under the CCEOP program and with HSS funds. To keep pace with the forecast of 65k units by end of 2020, UNICEF will need to procure an additional ~40,000 units of CCE over 2019 and 2020.

Despite the notable increase in the availability of platform-eligible CCE models across all suppliers, procurement outcomes continue to be dominated by two primary suppliers. Over the first two full years of CCEOP-supported procurement, these two suppliers received 80 percent of all orders for ILRs and SDDs placed. However, whereas in 2017 these two suppliers made up 96 percent of procurement, in 2018, there were some shifts in market share, as a few other suppliers were awarded larger tenders. The example of Guinea, and the MOH's decision to accept 25 percent of their CCE from an unfamiliar, but less expensive supplier, is an indication of how market-shaping might continue to shift procurement outcomes in the coming years.

MINIMIZE COSTS OF DEVICES AND SERVICES

As noted in the July 2018 market-shaping summary, the CCEOP market-shaping objective of reducing the weighted average prices for both ILRs and SDDs appears to be complicated and hindered by a number of competing factors. In general, the expectation that increased procurement would result in lower equipment costs, while also incentivizing innovation, may not be realistic. To expect CCE manufacturers to both continuously invest in product improvements and innovation, and provide immediate volume-based price reductions is potentially unrealistic. Further, as procurement to date has skewed to two well-established manufacturers, not necessarily to lower-priced CCE, there is limited evidence that equipment prices are influencing decision-making or creating competition in this market at all.

The price reduction targets have also been complicated by the service bundle inclusion. Many interviewees at both global and national levels expressed concern about the additional costs added by linking the service bundle to the supplier bids; yet these interviewees assumed that the suppliers are profiting considerably from these arrangements and unnecessarily driving up costs. This warrants further exploration. There was also no indication that suppliers were entirely supportive of the service bundle component being a mandated part of the CCEOP program. In fact, most of the suppliers interviewed expressed mixed feelings about the service bundle component. Many understood the value of including it with CCEOP and welcomed the opportunity to ensure that their equipment was properly and expediently distributed and installed. Several also felt it was a good opportunity for capacity building and bolstering the local market for CCE maintenance for their equipment, as well as generally.

However, many raised the concerns about the cost and complexity the service bundle was adding to their bids. Others felt that they were being forced into a service area when they would prefer to focus on their core competency of manufacturing cold chain technology but instead needed to spend time developing a network of local service providers to partner with to be competitive. This, in turn, has created additional costs, particularly for less established suppliers, who may need to make additional investments to build this type of network in CCEOP-supported countries. All supplier representatives mentioned the high level of effort the

service bundle required up front to develop an informed and competitive bid for a given country, without any assurance that they would receive any business. Several mentioned that the service bundle was not a money-maker for them; that it adds no profit to their contracts, just additional costs, requiring additional resources to prepare a bid and then, if awarded, manage. Many expressed concern that this arrangement meant that suppliers are taking on all of the risk to do service bundles, when that risk should be shared with UNICEF and the recipient countries.

UNICEF has provided country-specific benchmarks for the SBPs, but suppliers expressed uncertainty and skepticism about the source and validity of these benchmarks. Several had the perception that UNICEF was using these unfairly – that it was not a good practice to be negotiating with information whose rationale only one side understands. Several said that for SDDs, the UNICEF benchmarks are below cost and do not include pole mounting; others said it was unclear what the benchmarks did and did not include. Multiple suppliers mentioned that it would be better to receive the benchmarks before the bids were placed, not after, since this information should inform the bidding, not the negotiations. Others felt that the benchmarks were undermining their efforts to put their best bid forward in the tender process.

PROMOTE INNOVATION

As new models of CCE achieved platform eligibility, some suppliers introduced additional capabilities and features. However, it is unclear if advances in technology will continue at the same pace over the remaining CCEOP timeframe. Suppliers were concerned about investments they had made based on the opportunity CCEOP presented, only to find that they were not being rewarded with sales.

Suppliers expressed concern that CCEOP did not have the intended effect on innovation. Initial signs of a market for 20k+ units of cold chain equipment annually prompted investments in business teams, research and development (R&D), and manufacturing, but lags in procurement and an emerging duopoly is dis-incentivizing continued investments in production and innovation. In particular, there was concern with the TPPs, and that the long cycles to implement new TPPs were actually undermining competition. That is, if a supplier had a product that was innovative and met future target product profiles, the two-year TPP cycles gave other suppliers two years to catch up with the innovation before it became a requirement for platform eligibility. Another supplier mentioned that they had expected their early readiness of equipment meeting future TPP requirements to make their product more competitive, and built up inventory in anticipation of demand, but the orders never materialized, reinforcing the idea that innovation is not rewarded.

Others mentioned investments made specifically for the CCEOP market based on the Gavi CCEOP Technology Guide, yet with no orders to date, these were now posing risks to their overall business viability. Several considered this “false promise” of CCEOP to be damaging to innovation, as manufacturers now hesitate to make further investments. At least two manufacturers said they were holding back on developing more innovative products based on lack of confidence in the CCEOP market. One mentioned that energy harvesting and RTMD

could easily be incorporated into their products, but that they cannot justify the investment without more security of demand and orders. Suppliers, especially those not yet seeing much procurement from CCEOP, struggle to reconcile the push from UNICEF and Gavi for lower prices alongside innovation; several said they will take a “wait and see” approach to understand demand before making any further investments.

INFORMATION SHARING TO BETTER CONNECT SUPPLY AND DEMAND

Information flow and transparency among partners, countries, and manufacturers have made progress under CCEOP. Stakeholders cited Gavi, UNICEF (Supply and Programme Division), and WHO for their efforts to coordinate and improve information sharing between themselves, countries, suppliers, and SBPs. In particular, suppliers mentioned appreciation for the efforts made by UNICEF SD to increase transparency and the flow of information.

However, one of the major market weaknesses that CCEOP was meant to address through improved information flow was the mismatch of supply and demand based on weak forecasts, unpredictable demand, and fragmented funding. The certainty of funding and better forecasts were thus meant to provide suppliers with the assurance needed to invest in and produce better technology. During the KIIs with suppliers in Q3 2018, the suppliers uniformly praised the initial efforts by Gavi and UNICEF SD to create and share demand forecasts with industry. The forecasts shared at the beginning of CCEOP generated interest and excitement, and helped guide production planning, resource allocation, and investments. However, as procurement through 2018 has not kept pace with the short-term demand forecasts, suppliers also voiced concern that the numbers lack credibility, and this was affecting their ongoing business decisions.

They pointed out that actual demand has varied from the original forecasts in both the type and segment of CCE requested. In particular, several smaller suppliers mentioned investments made based on an expectation of receiving at least a proportion of the initial estimates given the UNICEF tender process, yet as demand has not materialized at the levels expected, they now consider the forecasts more damaging than helpful. Even the larger, better-established suppliers who are receiving CCEOP POs acknowledged their concern when forecasts far exceed actual POs placed. One supplier mentioned that they had three models of a particular type of CCE in the pipeline but, based on earlier CCEOP forecasts, stopped development of two of these. Now as the tenders come out, demand has shifted towards this type of CCE. The supplier is very skeptical of the forecasts now, but has limited other information to use for business decisions.

Suppliers also mentioned the CCEOP Technology Guide as an important resource for conducting their internal planning and understanding what was in the product pipelines. Several suppliers suggested using the guide in conjunction with the forecasts to better understand what other suppliers are doing, and to assess market opportunities. For instance, one said that if there is a CCE segment with a high volume of expected procurement, but only two current suppliers, they will explore it as a strategic opportunity. Conversely, if there are lower forecasted

quantities and already multiple PE suppliers, they may decide that an investment in that segment may not be warranted.

Over the course of CCEOP implementation, suppliers felt generally that UNICEF SD had improved communications and transparency about their own processes and constraints, and voiced their appreciation for this improvement. In particular, they cited the industry consultations, monthly updates of the tender calendar, and sharing of market notes as positive changes and points of interaction. Many noted this as a change from past interactions with UNICEF, and felt that this increased transparency improved suppliers' understanding of the challenges with CCEOP implementation and reasons for delays in procurement.

However, suppliers said that there was still opportunity to improve—specifically mentioning the information shared on the country tenders. Several suppliers indicated that it would be more useful to see the volumes for upcoming tenders broken down by type of equipment (SDD vs ILR) to better assess the market opportunity in advance, especially in the absence of other demand information at the country level. Almost all said that more country-specific data would be useful to have sooner to enable them to build a business case on more credible demand information. Several also expressed surprise at the lack of connection between suppliers and Gavi. They felt that they had opportunity to provide feedback on processes to UNICEF, but fewer direct opportunities to interact with representatives from Gavi.

SUSTAINABILITY/RESULTS

Market-shaping activities typically require several years, if not longer, to fully understand the effects on the market. For CCEOP, given that market engagement effectively began to play out with procurements conducted in late 2017, it is early to be evaluating the impact on sustainability, but there are a few trends worth flagging to monitor over the coming years. The early results indicate an emerging or perpetuated duopoly of two suppliers, but most global-level stakeholders feel that changes made in late 2018 and early 2019, including the differentiated tender approach will help address that. However, questions remain on what the “right” number of CCE suppliers is in this market – two is generally regarded as too few, but seven or eight may be too many. Further, as demand across size segments becomes clearer, supplier targets may need to vary by CCE type and segment. It will be important to watch trends in this area to see if the number of suppliers in this space expands or contracts and if there is some optimal equilibrium which Gavi and others should be working to maintain.

SUPPLIER PERSPECTIVES ON MARKET DYNAMICS FOR CCE

Suppliers measure success in POs placed. The delay in CCEOP start-up had a number of consequences, one of which is that several suppliers went two years without a single PO from UNICEF. This, depending on size and business model, is discouraging at best and devastating at worst. As one supplier representative said, “Small companies cannot last long enough with no orders”. Across the board, the suppliers interviewed mentioned the concern about unintended

consequences of the CCEOP market shaping approach and outcomes to date. For 2017–2018, the original short-term forecast indicated that 46k units of CCE would be purchased; over this period POs for 20k units were placed, less than 50 percent of what suppliers expected. Credible demand forecasts were expected to promote innovation, stimulate competition, and ultimately reduce risks and costs on all sides. Suppliers changed plans, made investments, and produced equipment based on this information. But to date, forecasts have not been credible, and suppliers are feeling the effects. Some produce to order, some have already produced equipment that is taking up limited space in warehouses. Regardless, very few feel that CCEOP has so far lived up to its promise and this has tempered interest in this market.

Many suppliers interviewed, particularly four that are not part of the duopoly, were concerned for the future of the CCEOP market if Gavi does not change course significantly, and soon. As one said, “Gavi said CCEOP would improve the market, it has actually made it worse because POs are not coming at all.” Others questioned how interesting this market is, for those who have alternatives. In the words of one supplier who had received limited POs to date, “Our only incentive is to work harder to find other markets.” They also cautioned on the longer-term effects of the duopoly – if one or two suppliers are too dominant, the others will drop out, and there will be no way to control costs. There was a common feeling that while country preferences were driving much of the decision-making, given that the CCEOP had a specific market-shaping strategy, UNICEF and Gavi were choosing to perpetuate this duopoly by not intervening; and that if these trends continued, the market outlook for several of the suppliers was bleak.

However, many suppliers also cited their original and continued commitment to this market for social and humanitarian good. Most indicated that they felt there was still time to turn things around, but moving towards achievement of the original market-shaping objectives would require rapid, concerted intervention by Gavi and UNICEF to correct some of the early market dynamics created by CCEOP. In general, suppliers did not feel that they had a clear understanding of Gavi’s market-shaping strategy.

CHANGES IN TENDERING PROCESSES

In acknowledgement of some of the delays and the time required to conduct and respond to tenders, which has created challenges and administrative work for all stakeholders, CCEOP will employ a differentiated tender process starting in 2019. These changes are being implemented to respond to experience to date, improve competition, and ensure that diverse suppliers are represented in support of near- and long-term market health, based on the Gavi healthy markets framework (HMF). With these changes, all manufacturers will be invited to bid for the high-volume CCEOP countries (i.e. ~ 11 forthcoming country applications exceeding \$6M Gavi CCEOP contribution). A more restricted list of suppliers will be invited to bid on the remaining ~ 40 Gavi-eligible country tenders, for which lower volumes of CCE will be procured.

To build on the push for greater efficiency, Gavi and UNICEF are also considering a return to the service bundle LTA process. Allocations against service bundle LTAs will be guided by country preferences, manufacturer performance, prices, and healthy market principles as per

HMF. Invitations to submit proposals by the service bundle LTA holders will therefore be restricted, and the proposals received will be evaluated against established service bundle price points, per a benchmarking process. This process could be informed by feedback to date on SBP and supplier performance in countries that have gone through an initial deployment to better inform comparisons and value for money evaluations before new awards are made.

Based on the current 2019 tender calendar, there are approximately 3,600 units of CCE tendered in 2018 to be awarded in 2019 under the previous process and another ~15,000 units that would be tendered for high-volume countries under the differentiated process in 2019. In 2019, procurement outcomes will also include those procured with Gavi HSS funds.

With the release of the revised Supply and Procurement Roadmap in June 2019, it will be critical to communicate changes to manufacturers and partners closely monitor implementation and outcomes to assess impact on the market and the consequences of the change, intended or unintended.

RECOMMENDATIONS

COUNTRY LEVEL

Recommendations for the PMT, Gavi and UNICEF based on the midline assessment findings by country appear in Table 8. In some cases, a single recommendation is aligned with a number of findings. Thus they are organized according to the broad themes used to categorize the evaluation findings addressed in the midline assessment. Where relevant, findings and recommendations based on country-level implementation, yet related to market shaping outcomes, have been included here.

Table 8: Country Level Recommendations from the Midline Evaluation Findings

	Market Shaping	Kenya	Pakistan	Guinea
PMT INVOLVEMENT AND LEADERSHIP				
Finding 2[†]: Stakeholders do not fully understand all of the details of the warranty, type of corrective maintenance/repair that is covered, and how to access those services.	X	X	X	X
Finding 3: Many respondents were unclear on SBP terms of reference and what they were/were not contracted to do to set expectations for performance.	X	X	X	X
Finding 4: The CCEOP is coordinated with other donors and partners for overall system strengthening, although better documentation could improve coordination and planning (i.e., deployment of World Bank/other donor-funded refrigerators and cold rooms, and limited information on where old fridges were moved).		X	X	X

	Market Shaping	Kenya	Pakistan	Guinea
Finding 7: The robust system of monitoring and documentation established for equipment deployment was effective at tracing equipment and ensuring accountability from the SBPs.		X	X	X
Finding 8: The few deviations were effectively handled locally, with no reported additional costs incurred. Accurate deployment plans must also include a level of flexibility, especially at lower levels, to respond efficiently and effectively to on-the-ground situations in a timely manner.	X	X	X	X
Finding 9: The PMT played an active and effective role in CCEOP deployment and coordination, demonstrating ownership and strategic thinking, although documentation could be improved (also linked to sustainability).		X	X	X
<p>Recommendation: Assessment of the deployment in these three countries identified several best practices for the PMT to be continued in Kenya, Pakistan, and Guinea, and to highlight for other countries to learn from. Two areas that need to be addressed (and are also captured under the systems strengthening component) are developing a systematic way to update CCE inventory; and to update the maintenance plan to provide details on the warranty of new equipment and the services provided by the SBPs. Reported deviations were few, which may indicate an unclear understanding of the deviation protocol as required by Gavi, but also indicates the flexibility and resourcefulness of the SBPs and the MOH to resolve necessary changes. Regular review of SBP activities should also be incorporated into ongoing monitoring activities done by the PMT and other stakeholders.</p> <p>PMT Recommendations:</p> <ul style="list-style-type: none"> Engage stakeholders at all levels of the system to review and update the ODP at the beginning of the deployment year to ensure that it is as accurate as possible and minimize deviations. Continue to strengthen the Logistics Technical Working Group to regularly monitor and manage the supply chain, to support long-term sustainability. Circulate the PMT meeting minutes to stakeholders from all levels of the system, including those outside of CCEOP deployment. Continue regular meetings of the PMT to monitor the progress of CCE installation, SBP performance, and CCE performance throughout the warranty period. Incorporate additional processes to ensure that data on deployment and installation are captured and incorporated into regular review processes. Clarify deviation protocol with SBPs and sub-national stakeholders who are most directly involved during deployment and installation; ensure a level of flexibility of the deviation protocol to respond to changing needs. Update the maintenance plan to incorporate the details of the warranty and the services provided by the SBPs. Develop a systematic way to update the cold chain inventory within the regular monitoring system of the immunization program. This is particularly timely after installation of CCEOP equipment, but should also be part of the regular system to reduce the burden typically required of data collection for updating inventory. All coordination with other stakeholders should take into account the planning and deployment process for CCE from CCEOP and other donors. <p>UNICEF Recommendations: Following contracting with the SBP, suppliers should ensure that SBP contractual agreements and terms of reference are shared with the MOH, including SOPs and warranty agreements. Involve the MOH from the outset in discussions of implementation with the SBPs to better set expectations, and as an opportunity to increase MOH ownership. Coordinate with the MOH to plan for the subsequent equipment deployment to ensure that the country is ready. Develop a mechanism to receive country feedback on the implementation of the SBP contract for installation and on the warranty and process for repairs. Ensure that this feedback on SBP performance flows back to UNICEF SD to inform future awards.</p>				

	Market Shaping	Kenya	Pakistan	Guinea
<p>Gavi Recommendations: As part of the CCEOP, consider including a requirement for an updated inventory after each year of equipment deployment, encouraging a system that builds on current resources (i.e., LMIS, regular reports and processes). It could also build on lessons learned from this initial evaluation, such as the strong documentation requirements put into place for the SBPs; could that be extended beyond new CCE to capture where other equipment is shifted to?</p>				
SBP APPROACH				
<p>Finding 6: Respondents at all levels were mostly satisfied with the installation and commissioning of the equipment by the SBPs, with some areas for improvement, such as clarity on roles and responsibilities warranty coverage.</p>	X	X	X	X
<p>Finding 11: Satisfaction with the efficiency and quality of work of SBPs is generally good, but varies by SBP and facility preference on equipment.</p>	X	X	X	X
<p>Finding 12: Although the MOH was capable of installing CCE and procuring additional CCE units, respondents at the national level recognized the trade-off between the speed and effectiveness of SBPs deploying CCE and value for money.</p>	X	X	X	NR
<p>Finding 13: SBPs provided insufficient training to facility staff. Training needs are insufficiently defined or understood by facility staff to ensure long-term maintenance of CCE.</p>	X	X	X	X
<p>Recommendation: The SBP approach achieved what Gavi was aiming to accomplish to ensure efficient, reliable, and effective installation of CCE. Respondents were satisfied with the process with a few exceptions, the main ones in Kenya being the cost and the MOH's preference to use their own technicians for installation in order to have more funds for equipment procurement. Pakistan stakeholders had suggestions for improving and fine-tuning the SBP process, but did not express a preference as to who would be responsible for installation. The quality of installation can be evaluated over time with the performance of the equipment, and should be part of a feedback loop to UNICEF/SD and to manufacturers. Training requirements need to be defined for the different target audiences. MOH technicians should certainly be trained on the technical aspects of the equipment for installation and corrective maintenance. Installation can also be an opportunity to reinforce the preventive maintenance that HCWs already provide, and to fine-tune for the new equipment. MOH stakeholders and SBPs adapted well to minor deviations, and were able to react and adjust with no additional costs charged to the MOH.</p>				
<p>UNICEF Recommendation: Clarify training details with manufacturers and SBPs; engage MOHs in development of the SOPs so that SBPs can build ownership, and to clarify expectations about installation standards. Clarify deviation procedures and expectations to prevent surprises in the future. Ensure that quality checks of installation are included as part of PII plans and feedback on quality flows back to UNICEF SD, to inform future SBP awards. Consider strengthening the current feedback system to ensure that equipment is robust, and is used.</p>				
<p>PMT Recommendations: Develop a training plan with SBPs to ensure a high level of satisfaction with training provided to each cadre of health worker; clarify SOPs of SBPs and expectation about standards for communication and installation; continue to closely monitor activities of SBPs. Maintain the high level of flexibility and adaptability for minor changes in the ODP, and for delegating responsibility to sub-national levels to respond to changes and deviations. Consider incorporating feedback on CCE performance from facilities and on the SBP to UNICEF/SD into a regular process, such as including the feedback with updates on the CCE inventory (as one idea).</p>				

	Market Shaping	Kenya	Pakistan	Guinea
<p>SBP Recommendations: Clarify training and installation expectations and SOPs with MOH; training should include processes for reporting maintenance issues, agreed upon with MOH. Training and supporting materials and equipment manuals should be in local languages when feasible, and available at all facilities. Clarify warranty and process to report any maintenance issues with healthcare workers upon installation. Ensure high levels of communication and transparency with sub-national level stakeholders, and particularly facility-level staff, to coordinate installation and any necessary changes to the ODP. Maintain the high level of flexibility and adaptability for minor changes in the ODP.</p>				
<p>Gavi Recommendations: If reconsidering the structure of the SBP approach, any revisions must take into account the effectiveness of the SBP approach along with the specific complaint of it being too expensive and reducing the number of pieces of equipment that can be procured. Some countries may have the technical capacity to install a large volume of CCE, yet the system to support that process may not be as robust as necessary to achieve the efficiency and reliability desired by SBPs. For countries that have sufficient capacity, consider different models for service bundle requirement – tiered levels of support (full service, basic, etc.) or opportunity to choose from an a la carte menu (e.g., outsourcing distribution/transport of equipment to facilities, SDD installation versus ILR “plug and play” equipment, etc.) based on the most prominent need of the country; also consider allowing 3rd-party bidding (one SPB for all CCE suppliers in a given country, not supplier-relationship dependent).</p>				
COORDINATION AND COMMUNICATION				
<p>Finding 10: Respondents were generally satisfied with the deployment and installation process, although relevant information on the deployment schedule did not always uniformly extend to all key stakeholders.</p>	X	X	X	X
<p>Recommendation: Before deployment, the PMT should develop a communications plan to ensure that all relevant individuals at the sub-national level are aware of where and when delivery will take place, and by whom. Contingency plans and processes should be clarified for any potential deviations. Additionally, guidance should be provided to all stakeholders on the role of the SBP and MOH (including sub-national level) in maintaining repair and equipment, clarifying steps to follow in case of breakdown during the warranty period or even after the period ends.</p>				
<p>UNICEF Recommendation: Clarify the details of the warranty with manufacturers and SBPs; ensure that country-level stakeholders understand the warranty and requirements. The warranty coverage should also be clearly explained during the product selection process to ensure that country stakeholders are not over-valuing the extended maintenance periods offered for by a few suppliers on select models.</p>				
<p>PMT Recommendation: Develop communications plan for installation process; develop contingency plans and processes for deviations.</p>				
SUSTAINABILITY AND SYSTEMS STRENGTHENING				
<p>Finding 2[†]: Stakeholders do not fully understand all of the details of the warranty, type of corrective maintenance/repair that is covered, and how to access those services.</p>	X	X	X	X
<p>Finding 14: For longer-term sustainability, technicians currently have insufficient capacity for corrective maintenance. Countries are not implementing a maintenance plan at national and sub-national levels.</p>		X	X	X
<p>Finding 15: There is no reported plan for decommissioning equipment.</p>		X	X	NR

	Market Shaping	Kenya	Pakistan	Guinea
Finding 16: There is a need for an updated inventory using existing information systems and automated processes.		X	NR	X
Finding 17: Some facility personnel are not well oriented about the shift to using cool packs (instead of ice packs) for outreach activities. This indicates the challenge of ensuring that policy changes are fully communicated and implemented, not only specific to CCEOP but also to the overall system.		X	X	X
Finding 18: Currently there is no clear mechanism for monitoring CCE performance over time (after installation check) and providing feedback to manufacturers. With warranty processes unclear in many places, it is uncertain if SBPs or the UNICEF Country Office would report breakdowns to UNICEF SD.	X	X	X	X
<p>Recommendations: Continue efforts to strengthen the entire system to ensure that CCE is efficient and reliable for years to come. These recommendations build on the other supply chain fundamentals related to capacity building and leadership, and to establishing policies and procedures for long-term planning, sustainability, and country ownership.</p> <p>PMT Recommendations:</p> <ul style="list-style-type: none"> • Develop a decommissioning plan for old, unusable equipment when such a plan is not available. • Develop a systematic way to update CCE inventory regularly. • Update the country's maintenance plan to consider the current warranty and a transition plan for the best way to maintain CCE after the warranty ends; this may be useful when considering operationalization of the national maintenance plan for sub-national level implementation. • Consider developing an optimum staffing structure within an HR immunization supply chain (iSC) assessment to prepare for long-term maintenance of all CCE. • Possibly through supportive supervision, clarify with all facility staff the policy of using cold packs (instead of ice packs) for outreach activities where it is a policy; this may help with better understanding as to the choice of equipment without freezers. This can most likely be applied to other policies as well. <p>UNICEF Recommendations: Ensure that countries are well aware of all details on warranty procedures, so that they can take ownership and build systems to coordinate maintenance and repair as issues arise, Ensure that the "Decommissioning and Safe Disposal of Cold Chain Equipment" document is available and accessible to country-level stakeholders; provide guidance on applying. Ensure that the "HR Rapid Assessment for iSC" is available to country-level stakeholders; and provide guidance on applying. Following rollout of post-installation inspection, ensure that there is also a parallel process for country programs to report on use of warranty coverage and concerns with CCE performance, to identify any patterns of equipment breakdown.</p> <p>Gavi Recommendations: As previously mentioned, consider requiring an updated CCE inventory as part of the ongoing process of CCEOP, encouraging a systematic way of collecting information on CCE that leverages current resources and processes and does not require a survey that is often done with a high level of effort. Consider financially supporting transition planning, updating maintenance plans, and longer-term HR capacity building for CCE technicians.</p>				
OPTIMIZED COLD CHAIN EQUIPMENT				
Finding 1: At the macro level, the CCEOP responds to country priorities and needs, although some manageable specifications still need to be addressed.	X	X	X	X

	Market Shaping	Kenya	Pakistan	Guinea
<p>Recommendations: Ensure that CCE is meeting all health facility needs and ensure transparency as to CCE choices. Continue to monitor equipment performance to track expected efficiencies.</p> <p>PMT Recommendations: Arrange trays/baskets for the CCE to ensure optimal use of the equipment. Continue to monitor use of the equipment, tracking costs, utilization rates, and the link to coverage. Ensure healthcare workers understand the rationale behind the equipment without freezer capability.</p> <p>UNICEF Recommendations: Clarify stabilizer expectations/local voltage levels with the MOH during the application and product selection process to ensure clear communication of requirements to manufacturers. Explore the possibility of including trays/baskets with the equipment. Continue to provide feedback to the manufacturers on the performance of the CCE.</p>				
ALIGNMENT WITH GAVI GUIDELINES				
<p>Finding 5: Respondents were satisfied that the CCEOP application and ODP adhered to Gavi guidelines, used available systems and cold chain inventory data, and responded to country priorities.</p>		(not stated in Kenya but came out in baseline)	X	X
<p>Gavi Recommendations: Use the Gavi guidelines for CCEOP to incorporate more system strengthening activities, such as developing a systematic approach to updating inventory or updating the maintenance plan.</p>				

*NR - Not reported but still applicable

†Applicable across multiple evaluation objectives

MARKET SHAPING

Recommendations for Gavi and UNICEF SD, based on findings from the global level aspects of the evaluation and informed by some of the country level findings, are summarized in Table 9. In some cases, a single recommendation is aligned with a number of findings. Thus they are organized according to the four market shaping strategic objectives for CCEOP.

Table 9: Recommendations for Global Level Market Shaping

1. STIMULATING SUPPLY TO MEET DEMAND FOR HIGH-PERFORMING, COST-EFFECTIVE AND QUALITY PRODUCTS
<p>MS Finding 7: The original market-shaping goal was to ensure two platform-eligible suppliers of ice-lined refrigerators (ILRs) and SDDs per size segment. The supply of CCE continues to expand with 9 of the 18 CCE segments tracked exceeding the original goal. As of September 2019 there were seven suppliers of platform-eligible ILRs producing 23 different platform-eligible models up from 20 in July 2018 (15% increase). For SDDs there were eight platform-eligible suppliers producing 36 different platform-eligible models, up from 33 models in July 2018 (9% increase).</p>
<p>MS Finding 8: Procurement has not kept pace with the initial annual forecasts for CCE that were shared with suppliers at the outset of CCEOP, due to delays in implementation. As of Dec 2018, POs had been placed for ~20k units of CCE, roughly 43% of the 46k units forecast to be procured by end of 2018. Tenders for the first 25 countries (including Year 2 procurement) have skewed towards two suppliers based on country preferences, undermining the CCEOP MS objectives to create a healthy market.</p>

MS Finding 13: Delays in implementation and procurement trends to date have raised questions about the credibility of CCEOP demand forecasts, which may undermine ongoing decisions by suppliers to produce or innovate for this market.

MS Finding 15: Suppliers raised concerns about the sustainability of the CCE market, given procurement outcomes to date. Many expressed concern that it could not sustain the current number of suppliers, without more direct market intervention on the part of Gavi and UNICEF.

Recommendation:

UNICEF SD - Work closely with Gavi to monitor development of and changes to ODPs and ensure tender calendar stays on track as much as possible to maintain expected procurement volumes for 2019; when the schedule slips communicate the reasons for changes to suppliers; ensure that new differentiated tender approach results in healthier distribution of POs across eligible suppliers.

Gavi - update longer term CCE demand forecasts, reassess the optimal number of suppliers, and evaluate these against the supply capacity in the CCE market, with a more nuanced analysis by CCE type and size segment. These should be used to refine the market shaping strategic objectives and stakeholder action plan.

2. ACHIEVE FAIR AND SUSTAINABLE PRICES FOR BOTH DEVICES AND COMMISSIONING SERVICE BUNDLES

MS Finding 1: The original market-shaping strategy relied heavily on the market shaping experience with vaccines and other single-use products; more attention is needed to evaluate elements and market shaping approaches for unique challenges posed by durable equipment and the service bundle.

MS Finding 2: Many of the risks related to the existing market dominance of two suppliers and the complexity of the service bundle were raised in the initial procurement and supply roadmap for CCE, but the mitigation plans may not have been robust enough at the outset to sufficiently address them.

Recommendation: The differentiated tender approach that will be implemented at the beginning of 2019 and revised Supply & Procurement Roadmap for CCE are expected to address some of the limitations observed from the original strategy and early procurement outcomes; **UNICEF SD and Gavi** should closely monitor implementation and ensure actual outcomes are aligning with expected outcomes, potentially offering incentives to try out small quantities of CCE from alternative suppliers to become familiar with the brand and performance in the first year procurement, with additional incentives for future procurement years.

MS Finding 9: The MS objective of reductions in weighted average prices for ILRs and SDDs has not been prioritized; potentially de-emphasized in favor of the MS objective for innovation and the principle (to date) of fully respecting country preference.

Recommendation:

UNICEF SD and Gavi -Review price reduction targets and determine if these are still realistic given current market conditions and objectives to increase innovation and procurement of optimal, high-performing CCE. If price reduction targets are prioritized, ensure tender awards reflect this prioritization.

Gavi - Provide countries with better tools and estimates to compare models, features, and fully-installed costs (including service bundle) to better incorporate equipment cost (rather than just purchase price) in product selection.

MS Finding 10: The service bundle mandate is the greatest source of conflicted feedback. Global and national stakeholders feel that it has complicated price negotiations and efforts to ensure value for money. Countries, specifically national-level stakeholders, value the service provided but are concerned that the added costs of SBPs on top of CCE limit their ability to obtain the number of CCE they need. Suppliers appreciate the opportunity to ensure that their CCE is properly installed but feel that they are bearing all of the risk and uncertainty. Some suppliers feel the service bundle mandate forces them into a service area outside of their core competency. Most suppliers indicated that the cost benchmarks provided during the negotiation process were unrealistic.

Recommendation:

UNICEF SD - Provide SBP benchmarks earlier in tender process, provide more guidance and information on benchmark data sources; provide country MOH partners with better estimates up front in application process and consider opportunity to select tiered levels of SBP support (also see related country level recommendation); involve MOH earlier on in the SBP contract start up to build country ownership, increase transparency, and improve understanding of SBP activities and value add (compared to costs).

Gavi - Consider different models for service bundle depending on local capacity and needs – offer tiered levels of support (white glove, basic, etc.) or options to choose services from an a la carte menu (e.g. distribution, SDD-installation, etc.); also consider allowing 3rd-party bidding (one SPB for all CCE suppliers in a given country, not supplier-relationship dependent). Ensure past performance of suppliers and SBP management is included in future award criteria.

3. CONTINUOUSLY INNOVATE HIGH PERFORMING, OPTIMAL TCO CCE PRODUCTS

MS Finding 5: Limited data on longer-term CCE field performance, and limited ability to compare across a wide set of features, makes it difficult to accurately assess for various contexts and compare value for money or TCO in selecting equipment.

Recommendation:

Gavi, UNICEF, and WHO - Following pilots and implementation of PMM and PII, ensure that there is a clear feedback mechanism and data sharing platform so that this information can be accessed and analyzed by a variety of stakeholders to inform future decision-making. Document success of PII in identifying performance issues with CCE, and how it might be expanded upon.

UNICEF SD - Consider implementing a mechanism for feedback from countries on supplier and SBP performance, including the number of times SBPs respond to warranty requests by supplier and/or model, to understand prevalence of CCE problems within the warranty period.

MS Finding 6: Questions and concerns persist regarding tendering and CCE selection processes and the role of country preferences compared to product specifications and performance. For the suppliers who 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.

Recommendation:

Gavi and UNICEF - Provide suppliers with clearer understanding of the product selection process; as the differentiated tender process is implemented, provide specifics on how countries indicate preference, and for those for whom an allocation will be recommended, clarify the criteria that will be used.

UNICEF SD - Provide suppliers with increased feedback on tender awards, as possible within procurement policies. Work with suppliers on options to introduce different “promotional” methods to build interest in new equipment, such as trial periods or bonus pieces of equipment of under-selected brands that are appropriate to the country context. Consider product demonstrations or other opportunities to share experiences with CCE performance across countries.

MS Finding 11: Although initial TPP targets for SDDs and ILRs were achieved ahead of schedule, the lag in procurement volumes to date, and the preferences for obtaining CCE from two suppliers, is limiting additional investments in technology from other suppliers.

Recommendation: Gavi and UNICEF - Revisit role of bi-annual (every two years) updates to TPPs in market-shaping strategy and overall objectives to determine if changes are warranted more frequently, and to ensure that platform eligibility also reflects potential for programmatic value. Update CCE equipment guides and other sources reflecting platform-eligible CCE and tools for product selection tools more frequently to show where there have been advances in technology (and associated programmatic value of such advances); consider publishing a regular annual or twice yearly addendum to the CCEOP Equipment guide to highlight innovations and new platform-eligible CCE, without requiring a full update to the document.

4. INFORMATION SHARING TO BETTER CONNECT SUPPLY AND DEMAND

MS Finding 3: Despite changes to the process and attempts to shorten the overall timeline, which takes over a year for country application approval, the time required for each step, including ODP development and implementation and tender release and award, have continued to challenge efforts to shorten timelines. This meant that the CCEOP tender calendar (and procurement volumes) has shifted significantly from month to month.

MS Finding 4: Suppliers, particularly those not seeing significant procurement volumes, feel that the tender award process is opaque and is not currently rewarding investments already made in product innovation and lower TCO options. Suppliers would like UNICEF to provide more timely feedback on expected award dates and feedback on tender outcomes.

MS Finding 12: Information flow and transparency among partners, countries, and manufacturers have made progress under CCEOP. Stakeholders cited Gavi, UNICEF (Supply and Programme Division), and WHO for their efforts to coordinate and improve information sharing between themselves, countries, suppliers, and SBPs.

Recommendation: UNICEF SD should continue to organize regular forums for information exchange between UNICEF, Gavi and suppliers. These forums should be used to share updates on MS approaches, demand forecasts, innovation targets; this will be particularly important following the release of the updated MS strategy; consider regular schedule of monthly emails, quarterly calls, and face to face meetings as needed to provide updates on forecasts, tender schedules, and awards.

Gavi should participate in these regular touchpoints and share updates on the market-shaping strategy and outcomes from their perspectives, and make time to gather input from individual suppliers. Consider opportunity for country stakeholder (MOH/EPI and SBPs) to participate and share feedback from deployment experience.

MS Finding 14: There has been progress in improving price transparency through the UNICEF SD websites, but information is not updated regularly. Also, it is not clear how the UNICEF reference prices relate to CCE prices in the CCEOP budget template, or to actual prices paid via country-specific tender awards.

Recommendation: UNICEF SD should update the CCEOP PE model list and prices more regularly, based on actual prices from country tender awards, to improve transparency and potential use of this data; **Gavi and UNICEF SD** should align on prices so that they are consistent across CCEOP-related information sources (e.g. UNICEF website and Gavi CCEOP budget template). Ensure that these reflect actual prices from recent contracts and include updates for SBP cost estimates based on actual costs from existing contracts.

NEXT STEPS

A progress report covering all three countries, Guinea, Kenya and Pakistan will be drafted in December 2019. This report will focus on the changes in characteristics of the health facilities sampled in the HFA, emphasizing supply chain and immunization outputs and outcomes. The endline evaluation will be conducted in April 2020, with findings to be shared in July-August 2020.

For market shaping, the evaluation team will continue to monitor procurement outcomes and the trajectory of the types, quantities, and brands of CCE procured via CCEOP, especially in light of changes ensuing from the differentiated tender award process being implemented. The team will also coordinate closely with Gavi on the availability of the revised market-shaping strategy

within the updated Supply and Procurement Roadmap to determine the optimal timing for the next comprehensive market-shaping report, likely in Q3/Q4 2019. This full report will further explore many of the questions raised by early trends observed around the market shaping outcomes: pricing (both CCE and the service bundle), the risk of the duopoly to the supplier landscape, the impact of procurement decisions to-date on future innovation, and the longer-term sustainability of the CCE market. The team will continue to follow these trends and the CCEOP trajectory toward the revised market-shaping objectives, incorporating new perspectives from another full round of KIIs, document and data review, and inputs from the Kenya, Pakistan, and Guinea experiences.

Any country level findings that are relevant to the market-shaping evaluation will be incorporated into this report.

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ANNEXES

ANNEX 1: MARKET SHAPING OBJECTIVES AND TARGET OUTCOMES

Source: *Gavi, Supply and Procurement Roadmap for ILR & SDD Cold Chain Equipment, December 2016, Public Summary*

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Supply and Procurement Objectives and Target Outcomes

Strategic Objective 1: Stimulate supply to meet demand

Based on the current 18 month demand forecast for Gavi countries, CCE demand is expected to increase up to five-fold with the implementation of the CCEOP. Gavi aims to ensure that sufficient supply of high-performing CCE is available to meet total Gavi demand through two market shaping target outcomes:

- 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-country logistics and service landscape.

Strategic Objective 2: Achieve fair and sustainable prices for both devices and commissioning service bundles

Costs must be reduced long-term to ensure optimal total cost of ownership and country sustainability, especially as countries transition from Gavi support. Gavi should seek competitive prices for high-performing ILR and SDD products that meet platform-eligibility and can achieve economies of scale through pooled volume procurements, as well as allocate supply to manufacturers offering the best value for both product and services that are tailored to local service delivery landscapes. This results in four market-shaping target outcomes:

- 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.
- Cost-effective models for local service provision and maintenance incentivized.

Strategic Objective 3: Continuously innovate high-performing, optimal TCO products

High-performing CCE should reach platform-eligibility with time bound lead times and have the following two characteristics:

- 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.

Strategic Objective 4: Information - a cross-cutting objective and strategic enabler for all CCE

Specific to ILR and SDD products are two targeted outcomes:

- 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.

ANNEX 2: MARKET SHAPING EVALUATION QUESTIONS

This midline intermediate assessment report uses information from each country midline evaluation covering only those questions marked with an 'x' in the 'Midline' column.

Research Question	Baseline	Midline	Endline
RELEVANCE			
<ul style="list-style-type: none"> To what extent was there a transparent, government-led process to apply for and implement the CCEOP support? 	X	X	X
<ul style="list-style-type: none"> To what extent did the process ensure the CCEOP was aligned with and complementary to other support from Gavi (HSS, vaccines, technical assistance, etc.), other partners, or government? 	X	X	X
<ul style="list-style-type: none"> To what extent did the CCEOP respond to country needs for improved CCE as part of improved immunization supply chains? 	X	X	X
<ul style="list-style-type: none"> 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.) <ul style="list-style-type: none"> What are the main reasons for these results? 	X	X	X
<ul style="list-style-type: none"> To what extent did the revised CCEOP application guidelines (if any during the evaluation period) reflect lessons over time? 	X	X	X
<ul style="list-style-type: none"> 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? <ul style="list-style-type: none"> What were the incentives/criteria for equipment selection? 	X	X	X
<ul style="list-style-type: none"> Does CCEOP replace other funding sources or fill a gap? 	X	X	X
EFFECTIVENESS			

Research Question	Baseline	Midline	Endline
<ul style="list-style-type: none"> To what extent was the implementation of the platform support in each country conducted as planned⁷ (considering timing, quality of implementation, participatory approach, and timely flow of funds) across each component of the CCEOP, such as the application, ODP, SBP, and equipment selection, etc.? <ul style="list-style-type: none"> What are the main reasons for these results? 		X	X
<ul style="list-style-type: none"> 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 development of the application and implementation? 	X	X	X
<ul style="list-style-type: none"> To what extent has the CCEOP investment achieved (or is on track to achieve) its objectives as planned? <ul style="list-style-type: none"> What are the main reasons for these results (considering contextual factors including environmental, policy, political, financial, information and monitoring, human resources, macroeconomic)? 		X	X
EFFICIENCY			
<ul style="list-style-type: none"> To what extent has the Alliance, country (Ministry of Health), procurement agent (headquarters, regional offices) and SBP managed the investment efficiently (defined in terms of cost and time), across each component of the CCEOP and time? 		X	X
<ul style="list-style-type: none"> 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? 		X	X
OUTCOMES/RESULTS⁸			

⁷ As per the country application, operational deployment plan, strategic operational plan, procurement plan, etc.

⁸ CCEOP contribution to outcomes/results should not be assessed in isolation; other factors, including government, external considerations, and Gavi support should also be considered.

Research Question	Baseline	Midline	Endline
<ul style="list-style-type: none"> To what extent has the CCEOP contributed to extension of the supply chain, replacement (i.e., rehabilitation), and expansion of CCE at national, regional, district, and health facility levels? 			X
<ul style="list-style-type: none"> 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)? 			X
<ul style="list-style-type: none"> To what extent has the CCEOP contributed to appropriate stock availability of potent vaccines (measured by full stock availability, stocked according to plan)? 			X
<ul style="list-style-type: none"> To what extent has the CCEOP contributed to decreased vaccine wastage? 			X
<ul style="list-style-type: none"> To what extent has the CCEOP contributed to improvements in access and utilization of immunization services in an equitable way? 			X
<ul style="list-style-type: none"> To what extent has the CCEOP improved routine cold chain management (corrective and preventive maintenance, temperature control, functionality) at the national, county, sub-county, and health facility level? 			X
<ul style="list-style-type: none"> 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? 			X
<ul style="list-style-type: none"> What have been unintended (positive and negative) consequences of the CCEOP for countries, the Gavi secretariat, and Alliance partners? 		X	X
SUSTAINABILITY			
<ul style="list-style-type: none"> 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)? 			X

Research Question	Baseline	Midline	Endline
<ul style="list-style-type: none"> To what extent has managing the CCEOP strengthened the PMT/National Logistics Working Group and contributed to country ownership? 		X	X
<ul style="list-style-type: none"> To what extent have the SBPs built the capacity of technicians for maintaining CCE? 		X	X
<ul style="list-style-type: none"> To what extent are the outcomes/results achieved through the CCEOP financially and operationally sustainable? <ul style="list-style-type: none"> What main factors contributed to these results? 			X

ANNEX 3: MARKET SHAPING KEY INFORMANT INTERVIEWS (BY ORGANIZATION) TO DATE

Overall, 24 key informant interviews were conducted between May 15th and October 3rd, 2018 with representatives currently or previously working with the following organizations. In addition, representatives from the SBPs for each contracted supplier in Kenya, Pakistan, and Guinea participated in key informant interviews as part of the country data collection. To validate findings and understand changes expected or underway with the CCEOP market shaping approaches, a few further information interviews were conducted in early 2019

- Aucma
- Bill & Melinda Gates Foundation, current and former employees
- B Medical
- Clinton Health Access Initiative
- Dulas
- Gavi Secretariat, current and former employees
- Haier
- PATH
- UNICEF Programme Division
- UNICEF Supply Division
- SunDanzer
- Sure Chill
- Vestfrost