JSI RESEARCH & TRAINING INSTITUTE, INC.

# Evaluation of the Cold Chain Equipment Optimization Platform

## Baseline Cross Country Report

December 26, 2018

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

JaRco Consulting

Research And Development Solutions

SVI STAT VIEW International

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.

JSI
1616 North Fort Myer Drive
16th Floor
Arlington, VA 22209

# CONTENTS



## TABLES AND FIGURES

# ACKNOWLEDGEMENTS

The baseline cross-country report of the Cold Chain Equipment Optimization Platform (CCEOP) rollout in Guinea, Kenya, and Pakistan is a collaborative effort between the evaluation team and the core CCEOP team in each country.

In each country, we appreciate the guidance and support of Ministries of Health, UNICEF, CHAI, Program Management Teams, National Vaccine and Initiatives, and other stakeholders. We extend our gratitude to all respondents at the national, regional, district and health facility levels who gave up their time to contribute to our evaluation with critical information. Respondents who contributed to the evaluation at the global level for the market shaping evaluation included Gavi, UNICEF Supply Division, and other international partners.

We are thankful to the data collection teams for their coordination and participation. Additionally, we thank all key informants for their critical contributions to our evaluation. We extend great appreciation for the evaluation's in-country partners JaRco Consulting in Kenya, Research and Development Solutions (RADS) in Pakistan, and Stat View International in Guinea. We would also like to thank the Gavi secretariat for its feedback and advice throughout the evaluation.

The CCEOP evaluation team was led by Dr. Soumya Alva, with support from Ms. Alexis Heaton who led the market shaping component, Ms. Wendy Prosser, and Ms. Nicole Aspros. The Guinea country evaluation was led by the Guinea team lead, Ms. Lea Teclemariam and the StatView International team led by Mr. Aliou Barry. The Pakistan country evaluation was led by the Pakistan team lead, Dr. Elizabeth Bunde and the RADS team led by Dr. Adnan Khan. The Kenya country evaluation team was led by Ms. Emily Stammer and the JaRco Consulting team led by Mr. Yirgalem Mekonnen.

# 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 |
| **LTWG** | logistics technical working group |
| **MCV** | measles-containing vaccine |
| **MOH** | Ministry of Health |
| **NVIP** | National Vaccines and Immunization Program |
| **ODP** | operational deployment plan |
| **PMT** | project management team |
| **PQS** | performance, quality, and safety |
| **RTMD** | Remote Temperature Monitoring Device |
| **SBP** | service bundle provider |
| **SDD** | solar direct drive |
| **TCO** | total cost of ownership |
| **WHO** | World Health Organization |

# SUMMARY

## BACKGROUND

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, 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 was 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 the market for CCE is healthy and that optimal yet durable and high-performing products are being procured with Gavi funding.

This prospective evaluation of CCEOP being conducted between 2018 and 2020 in three countries, Kenya, Pakistan, and Guinea, 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 understanding 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 any achievements made in promoting healthy markets and improved optimal market conditions while also considering 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 baseline assessment from this evaluation which includes (1) assessing the baseline situation prior to CCEOP distribution of equipment in three countries, and (2) evaluating the procurement landscape and planning process for CCE pre-CCEOP. These baseline findings will serve as a comparison point to assess progress at midline and endline stages of the CCEOP evaluation.

## COUNTRY CONTEXT

All three countries, Kenya, Pakistan and Guinea 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 and when available the equipment often do not meet established performance, quality, and safety (PQS) standards and have 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.

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. Year 1 will focus on replacing equipment in all facilities with equipment gaps in the 17 original health systems strengthening (HSS) grant funded counties and 30 other counties followed by the expansion of geographic scope in subsequent years. In Year 1, 1,004 pieces of equipment will be deployed between June and October 2018. Two service bundle providers (SBPs), Sanica Limited and Total Health Solutions, will provide delivery, installation, maintenance, and repairs for up to two years.

Pakistan received approval for CCEOP in the amount of $47.7 million in November 2016, with the cost split equally between Gavi and the Government of Pakistan. Data from a 2016 inventory of cold chain and related infrastructure guided the plan to upgrade CCE in facilities. Seventy-five percent of all facilities in Pakistan were selected to receive replacement refrigerators over the course of three years, of which approximately 25 percent will receive additional fridges to expand their storage capacity. In Year 1, 6828 refrigerators were deployed between May and October 2018. Vest-Frost, represented by Capri medicals in Pakistan, will provide delivery, installation, maintenance, and post-installation repairs for two years.

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. Because Guinea is a self-financing country, at least 20 percent of the funding comes from a joint investment from the country. The country will start deployment in November 2018 prioritizing CCE installation in all health posts with no CCE, followed by health centers with non-functioning equipment, those with more than 10-year-old equipment, and those non-PQS compliant and less than 10-year-old refrigerators located in all eight regions and 38 districts of the country. Haier and SOGUIMAP will provide delivery, installation, maintenance, and repairs, with the SOGUIMAP contracted to provide assistance through an extended 10-year warranty period which is considerably longer than the two-year warranty period in Kenya and Pakistan.

## DATA AND METHODS

The evaluation seeks to understand the differences between areas receiving and not receiving new equipment through CCEOP in the three countries. The baseline assessment focuses on understanding the situation before CCE installation under CCEOP. It also aims to document any pre-existing differences between the health 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).

The evaluation used a mixed-methods case-control research design that is largely prospective involving key informant interviews at multiple levels of the health system, health facility assessment, document reviews, direct observation (as and when possible), key informant interviews (KIIs) at different levels of the health system, 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

The table below summarizes findings on the CCEOP planning process by country in relation to the evaluation questions examined in the baseline.

| | Kenya | Pakistan | Guinea |
|---|---|---|---|
| **RELEVANCE OF CCEOP** | | | |
| **IN RESPONSE TO COUNTRY NEEDS** | | | |
| **Finding 1:** The CCEOP application was based on country priorities, using information from available data through information systems and from cold chain inventory | X | X | X |
| **TRANSPARENT PROCESS AND STAKEHOLDER ENGAGEMENT** | | | |
| **Finding 2:** The project management team (PMT) plays an active role in CCEOP deployment and coordination | X | X | |
| **Finding 3:** High level of stakeholder engagement but limited role beyond the national level | X | X | X |
| **Finding 4:** Complex application process in some countries with lack of clarity on cost, clearance, warranties, and other issues | X | | |
| **ALIGNMENT WITH GAVI GUIDELINES AND OTHER DONOR/PARTNER SUPPORT** | | | |
| **Finding 5:** CCEOP application was closely aligned with Gavi guidelines | X | X | X |
| **EFFECTIVENESS** | | | |
| **PLANNING FOR IMPLEMENTATION** | | | |
| **Finding 6:** Concern that facility staff are not well prepared to handle the new equipment | X | X | X |
| **Finding 7:** Mixed feelings and confusion about the SBP approach, especially in lower levels of the health system | X | X | X |
| **Finding 8:** Changes to the deployment plan | | X | |

| | Kenya | Pakistan | Guinea |
|---|---|---|---|
| **EXPECTED OUTCOMES** | | | |
| **Finding 9:** Expectations of improved efficiency of equipment and of the cold chain system, especially of temperature-monitoring systems | X | X | X |
| **OVERALL** | | | |
| **Finding 10:** Need for overall system strengthening | X | X | X |

More specific details on these findings are listed below:

- Overall, in all three countries, the CCEOP application process was made using multiple data sources including the most recent EVM assessment or cold chain inventory, in keeping with the country's needs, and with an effort to develop and strengthen the country's immunization systems, including the cold chain throughout the health system.
- In all three countries, the PMT, one of the requirements of the CCEOP application, was established to manage decisions and coordinate the implementation process. In Kenya and Pakistan, the PMT has started to play a very active role. In Guinea, because of delays in CCEOP deployment, the team, though formed, was yet to be formalized at the time of the baseline assessment, resulting in poor communication and information-sharing. Even after the establishment of the PMT after the completion of the baseline assessment, not much information circulates among the members and CCEOP committee meetings are only called on an emergency basis. There was a high level of stakeholder engagement but with a limited role beyond the national level. The CCEOP planning process was found to be transparent, but mainly at the national level.
- In Kenya in particular, there were mixed views on the complexity of the application process. The model of using consultants at the national level to support the application process was seen as very successful, especially in Pakistan, in helping participants understand the processes, requirements, and documentation.
- Review of the operational development plan (ODP) and the CCEOP applications in all countries indicates a high level of alignment with Gavi guidelines and fit with country strategies.
- A general concern in all countries is that health workers will possibly face difficulty in following equipment manuals and, as a result, handling equipment. Difficulty in following training materials may also impact their ability to provide preventive maintenance for equipment.
- Overall, there are mixed feelings about the SBP approach, citing the expense which reduced the total quantity of equipment a government could procure, the possibility of undermining government ownership of the equipment and the process, and a lack of clarity on the roles and responsibilities of the SBPs both during and post-warranty,

especially below the national level. Questions remain on whether maintenance training will be provided, on how the equipment will be maintained by the SBPs in the first two years, and on maintenance after the two-year warranty period.

- In Pakistan, in particular, there were considerable changes to the deployment plan However, these changes did not have a substantial impact on deployment. This issue will be addressed in greater detail in the midline assessment. Overall, there is much optimism among country-level stakeholders on the expected outcomes from installation of CCEOP. Although CCEOP equipment has not been fully deployed, stakeholders anticipate several positive outcomes—an improvement in the overall efficiency of the system, reduction in the need for corrective maintenance, and eventual improvement in immunization coverage.
- CCEOP is effective in addressing the CCE fundamental of Gavi's immunization supply chain (iSC) strategy; however, the overall system must also be strengthened in terms of, for example, a maintenance plan that is funded and is functional, human resource knowledge and skills on temperature-monitoring and vaccine management practices, and a distribution system that is effective.

### MARKET-SHAPING

Given the early stage of implementation, early findings relate to the initial strategy effectiveness (to date), design, and relevance of CCEOP.

- CCEOP has significantly increased attention to the CCE market, generating high levels of country awareness of and demand for better technology from countries and rapid market response from CCE suppliers. Now there are seven ice-lined refrigerators (ILRs) and solar direct drive (SDD) manufacturers of platform-eligible equipment, with more models available in all size segments.
- Despite early achievements on product innovation and availability, progress toward price reduction targets for equipment has been less rapid. While CCE prices have decreased by 3.5 percent overall since the launch of CCEOP, decreases have not been consistent across all suppliers.
- There seem to be barriers to entry for newer suppliers in a market that prior to CCEOP was dominated by two manufacturers and in a context where criteria such as brand awareness matter. Suppliers are also required to have a network of local partners, which favors more established suppliers.
- Information flow and transparency among partners, countries, and manufacturers have made progress under CCEOP. Gavi, UNICEF (Supply and Programme Division), and World Health Organization (WHO) have all been cited by stakeholders for their efforts to coordinate and improve information-sharing among themselves, countries, suppliers, and SBPs.
- The effects of market-shaping activities typically take several years, if not longer, to fully understand. The challenges with the market-shaping strategy seen to date seem to be well understood by many stakeholders. Already changes have been made to the country

application process and UNICEF tendering process, which should positively affect future market outcomes.

## RECOMMENDATIONS

A general recommendation is to recognize that beyond just CCEOP, the overall system beyond purchase of CCE and its installation needs to be strengthened. This recommendation addresses but is not limited to training for health care workers on temperature monitoring/how to use Fridge Tag, CCE maintenance and the resources (i.e., vehicles, fuel, per diem, available spare parts) required to ensure maintenance is carried out, regularly updated CCE inventory, clear standard operating procedures for CCE maintenance, a reliable distribution system that ensures vaccines are available at the facility level, and financial flows that are reliable and consistent. CCEOP is designed to contribute to all five fundamentals of the Gavi strategy, but is more advanced in its implementation than others such as leadership, data for management and system design. CCEOP can act as a catalyst for many system-strengthening activities. It is important to continue to support the fundamentals as a way to ensure performance of CCE.

Specific recommendations to the PMT in countries include the following:

- Involving stakeholders from all levels of the health system should continue to be an important aspect for all program activities beyond CCEOP application and deployment. Identify processes for engagement of all stakeholders and areas to strengthen stakeholder involvement.
- Consider the processes established by and for the PMT and how to incorporate those into regular monitoring and management of the supply chain through the logistics technical working group (LTWG).
- Annual planning and proposal preparation should support the entire system, including a reliable and funded CCE maintenance system, reliable and efficient vaccine distribution, and an updated inventory of trained and competent facility staff.
- Continue providing feedback to Gavi and UNICEF Supply Division on experiences with SBP.
- Ensure the deployment plan is accurate with the most up-to-date information available.
- Continue to monitor performance of the equipment and its impact on the overall cold chain system and immunization program.

Specific recommendations to Gavi include the following:

- Provide greater orientation on the process from proposal development to implementation and on the different actors to be involved.
- Consider adding another layer of required review to the application process by sub-national levels.
- Work with UNICEF Supply Division to assess the capability of SBPs more thoroughly before selection.

- Consider how to strengthen the LTWG through the PMT for long-term on-going monitoring.
- Continue to emphasize the link to other supply chain fundamentals and continue to support efforts in those areas.
- Learn from the SBP model and incorporate feedback into the future design of the SBP, taking into account alternative approaches.
- Continue to support country-led systems to monitor equipment performance to enable the feedback loop to manufacturers for improved technology.
- Continue to support and monitor maintenance systems across all CCE once the role of SBPs comes to an end.

Recommendations based on initial review from the market-shaping evaluation are the following:

- Determine how Gavi and UNICEF can balance the CCEOP market-shaping goals of market diversification with the commitment to country choice. This effort includes promoting market entry or selection of multiple/new suppliers for countries that may be hesitant to switch from a brand they are familiar with.
- Consider different options for the service bundle mandate depending on the context especially with some concerns of excessive costs and decreased government ownership. Options may be to delink procurement of equipment and service bundles, to waive the service bundle requirement if certain criteria are met, or to promote the use of domestic service bundle providers for on-going CCE maintenance and installation.
- Promote better and earlier cost estimates for both CCE and service bundle costs, as well as improved comparison of total cost of ownership (TCO) over expected equipment lifespan, to allow better country decision-making, in alignment with on-going efforts to strengthen performance tracking via the IMPT and WHO-PQS initiatives.
- Determine how to gather data on field performance over the longer term and incorporate these data into the CCE selection process. It may be appropriate to benchmark, in addition to product and service price, performance, product characteristics, or estimated TCO. This benchmarking, coupled with actual performance feedback, can help to demonstrate the true cost of the product over its lifespan.
- Update the CCE market assessment and incorporate a market sustainability approach that monitors trends on whether the number of suppliers expands or contracts and whether there is some optimal equilibrium which Gavi and others should be working to maintain. It is also important to consider the state of the market post-CCEOP in the absence of Gavi funding.

The next stage of the evaluation will involve conducting the midline assessment in the countries to better understand the CCEOP implementation process and early results on the post-implementation effects of CCEOP. For the market-shaping evaluation, the JSI team will use the next wave of procurement data through Q4 2018/Q1 2019 and additional partner and supplier

interviews to add to this initial analysis of market outcomes and develop a comprehensive report in mid-2019.

# BACKGROUND

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 with the objective of increasing effectiveness and efficiency of immunization supply chains and increasing the sustainability of immunization program achievements related to coverage and equity. At the country level, CCEOP provides phased support to selected countries for up to a maximum of five years. The initial support phase aims to address the most urgent CCE needs for the first one to two years (e.g., where there are the highest risks to vaccine stocks or greatest bottlenecks to coverage and equity) and the second scale-up support phase aims to allow the country additional time to further elaborate and fine-tune its long term CCE needs over the following three to five years. CCEOP addresses both the supply and demand side for optimal CCE, generating demand for technologically innovative and appropriate CCE and stimulating the market to respond to that demand with affordable and accessible equipment.

Through CCEOP, the Alliance pledged $250 million dollars 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 with improved data use. 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. Countries have moved the other fundamentals forward with varying degrees of success. 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 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 a baseline analysis as part of this evaluation and includes (1) assessing the baseline situation prior to CCEOP distribution of equipment in three countries, and (2) evaluating the procurement landscape for CCE pre-CCEOP. These baseline findings will serve as a comparison point to assess progress at 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 Survey[1] (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 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, with counties (which do not store vaccines) being 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 implementation of planned activities (Gavi 2017).

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

## 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. The country is responsible for financing 50 percent of the support ($4,115,870), the majority of which will come from health systems strengthening (HSS) funds provided by Gavi. The CCEOP rollout strategy follows a phased approach, with the ultimate goal being to equip all current and future immunizing facilities with optimal equipment. According to the revised January 2018 operational deployment plan (ODP), Year 1 will focus on replacing equipment in all facilities with equipment gaps in the 17 original HSS funded as well as 30 others counties in the country. Year 2 will expand the geographic scope to include all facilities with equipment needed throughout the country as a whole. Year 3 will contain a cold chain inventory to determine additional need. The ODP states that 1,004 pieces of equipment will be deployed in Year 1 (between June and October 2018), including 690 refrigerators to health facilities and 314 refrigerators to sub-county depots in all 47 counties. Approximately half (504) of the equipment deployed in Year 1 will be solar-powered, with the remaining 500 being powered by electricity. Two service bundle providers (SBPs), Sanica Limited and Total Health Solutions, will provide delivery, installation, maintenance, and repairs for up to two years.

## 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 having 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 as 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 level 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. While the capacity of some provincial stores met requirements for existing vaccines, it will likely be insufficient as newer vaccines, such as those for rotavirus and inactivated polio vaccine, are introduced.

## CCEOP IN PAKISTAN

Pakistan received approval for CCEOP in the amount of $47.7 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 with an aim 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. Deployment for Year 1 was carried out between May and October 2018, and included the distribution and installation of 6,828 refrigerators. One SBP, Vest-Frost, which is represented by Capri Medicals in Pakistan, will provide delivery, installation, maintenance, and post-installation repairs for two years.

## GUINEA

Having one of the lowest health and human development indicators, Guinea 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 2016 World Health Organization (WHO) and UNICEF revision, and the 2016 Multiple Indicator Cluster Survey have confirmed consistently low rates of DTP3 and measles immunization, with only 37 percent of children being fully immunized (INS, PNLP and ICF 2017, INS and ICF 2012, WHO 2016). The supply chain for vaccines in Guinea is organized in 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 need 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 involve electricity-powered central stores that, in the case of power outages, individually depend on a single backup generator. Other inadequacies 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 is scheduled to start in mid-November 2018 and includes the distribution and installation of 848 refrigerators in health facilities across all eight regions and 38 districts of the country, covering all health posts in Guinea. Two SBPs, Haier

and SOGUIMAP, will provide delivery, installation, maintenance, and repairs, with the latter contracted to provide assistance through an extended 10-year warranty period.

Using information from the CCEOP grant application, related documents, and UNICEF monitoring of deployment activities in the three countries, Table 1 outlines the timing of CCEOP-related activities, including the deployment dates.

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

| Activity | Kenya | Pakistan | Guinea |
|---|---|---|---|
| CCEOP application submitted[1] | Sept 2017 | Sept 2016 | Sept 2016 |
| CCEOP application revised[2] | NA | Oct 2016 | Nov 2017 |
| CCEOP application approved[3] | March 2017 | Nov 2016 | March 2018 |
| Service contract completed[4] | March 2018 | Feb 2018 | Aug 2018 |
| First lot of CCE delivered[5] | June 2018 | May 2018 | Nov 2018 |
| Expected deployment completion date[6] (as of Nov 8 2018) | Dec 31 2018 | Oct 31 2018 | May 2019 |
| **Total time** | **15 months** | **25 months** | **32 months** |

Note: Data sources for 1,2,3 are CCEOP grant application materials from each country and 4,5,6 are from the CCEOP milestones sheet shared weekly by UNICEF Supply Division.

## GLOBAL CONTEXT

CCEOP includes a specific market-shaping component to improve the availability and installation of high-performing CCE, underscoring the need to ensure the market for CCE is healthy and that 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 to 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 goals 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. These changes include early learnings and programmatic adjustments to CCEOP from Gavi and the UNICEF Supply Division, including the expected release of a revised Supply and Procurement Roadmap for

CCE and changes to the country application processes and tendering process implemented by the UNICEF Supply Division in 2018. The results of these updates are expected to be seen in current and forthcoming tendering in late 2018. Additionally, in early 2018, UNICEF Supply Division commissioned McKinsey to conduct an analysis of tendering results. The summary findings from this study were shared with Gavi and JSI and the agreement was to build upon these results rather than potentially duplicate this work. Activities and milestones related to CCEOP market-shaping at the global level are outlined in Table 2.

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

| Activity/Milestone | Date |
|---|---|
| Ice-lined refrigerator (ILR) and solar direct drive (SDD) Supply and Procurement and Roadmap published | August 2016 |
| First CCEOP PO placed (Haiti) | September 2017 |
| McKinsey tender diagnostic results presented | February 2018 |
| UNICEF Industry Consultation held | March 2018 |
| Market Shaping “Light Touch” Summary Report submitted | July 2018 |
| First new CCEOP tender for 2018 awarded | September 2018 |
| Revised CCE Supply and Procurement Roadmap expected (as of Nov 8 2018) | TBD |

# 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 in order to ensure that a prospective evaluation could be conducted with the baseline assessment prior to the start of CCEOP implementation.

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 take that into account when possible as part of the evaluation design. 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 any achievements made in promoting healthy markets and improved 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 |
|---|---|
| • Determine the **relevance** of the CCEOP support with respect to alignment with existing government processes and the identified needs and priorities in Kenya.<br>• Assess the **effectiveness** of the platform in achieving the objectives of the CCEOP investment.<br>• Identify the comparative **efficiency** of the CCE over time, from pre-CCEOP through Phase 1 implementation, as well as the efficiency in management of the CCEOP investment.<br>• Determine to what extent the CCEOP has improved cold chain management and processes and immunization **outcomes and results**.<br>• Determine the nature and extent to which the CCEOP has contributed to the **sustainability** of the cold chain and immunization program in Kenya.<br>• Identify the lessons learned from the rollout of CCEOP, including the challenges and how they were overcome. | • Determine the **relevance** of the CCE market-shaping strategy and the market-shaping monitoring and evaluation.<br>• Determine the extent to which market shaping activities are **implemented** as planned.<br>• 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.<br>• 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 listed in Table 4 below. This baseline assessment asked only those questions marked with an ‘x’ in the ‘Baseline’ column.

Table 4: Research Questions at Each Stage of the Country Evaluation

| Research Question | Baseline | Midline | Endline |
|---|---|---|---|
| **RELEVANCE** | | | |
| • To what extent was there a transparent, government-led process to apply for and implement the CCEOP support? | x | x | x |

| Research Question | Baseline | Midline | Endline |
|---|---|---|---|
| • 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 |
| • To what extent did the CCEOP respond to country needs for improved CCE as part of improved immunization supply chains? | x | x | x |
| • 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.)<br>○ What are the main reasons for these results? | x | x | x |
| • To what extent did the revised CCEOP application guidelines (if any during the evaluation period) reflect lessons over time? | x | x | x |
| • 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?<br>○ What were the incentives/criteria for equipment selection? | x | x | x |
| • Does CCEOP replace other funding sources or fill a gap? | x | x | x |
| EFFECTIVENESS | | | |
| • To what extent was the implementation of the platform support in each country conducted as planned[2] (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.?<br>○ What are the main reasons for these results? | | x | x |

[2] As per the country application, operational deployment plan, strategic operational plan, procurement plan, etc.

| Research Question | Baseline | Midline | Endline |
|---|---|---|---|
| • 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 |
| • To what extent has the CCEOP investment achieved (or is on track to achieve) its objectives as planned?<br>  ○ 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** | | | |
| • 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 |
| • 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/RESULTS[3]** | | | |
| • 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 |
| • 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 |

[3] 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 |
|---|---|---|---|
| • To what extent has the CCEOP contributed to appropriate stock availability of potent vaccines (measured by full stock availability, stocked according to plan)? | | | x |
| • To what extent has the CCEOP contributed to decreased vaccine wastage? | | | x |
| • To what extent has the CCEOP contributed to improvements in access and utilization of immunization services in an equitable way? | | | x |
| • 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 |
| • 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 |
| • What have been unintended (positive and negative) consequences of the CCEOP for countries, the Gavi secretariat, and Alliance partners? | | x | x |
| **SUSTAINABILITY** | | | |
| • To what extent has the CCEOP contributed to the financial and operational sustainability of the cold chain and/or wider immunization program (considering other investments and support)? | | | x |
| • To what extent has managing the CCEOP strengthened the PMT/National Logistics Working Group and contributed to country ownership? | | x | x |
| • To what extent have the SBPs built the capacity of technicians for maintaining CCE? | | x | x |
| • To what extent are the outcomes/results achieved through the CCEOP financially and operationally sustainable?<br>  ○ What main factors contributed to these results? | | | x |

For the market-shaping component, the summary of findings in this report reflect the initial market impact as of Q1-Q2 2018 in expectation of the completion of a more comprehensive market-shaping evaluation report once the revised Supply and Procurement Roadmap is available and there are additional tender outcomes from 2018 and Q1/Q2 2019 to complement the preliminary market analysis. The findings discussed here reflect a point in time analysis; 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. This report summarizes findings from global level key informant interviews (KIIs) conducted from May 15–June 30, 2018, with stakeholders who were part of the design or early implementation of the market-shaping strategy. The summary relies on, in addition to KIIs, secondary data related to initial procurement experience and results and CCE pricing provided by Gavi and UNICEF Supply Division. The KIIs and data analysis included data collection on many of the initial questions of effectiveness, relevance, implementation, and sustainability of the market-shaping efforts. Given the early stage of implementation, much of the early findings in this summary relate to the initial strategy effectiveness (to date), design, and relevance.

## 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 for the market-shaping components.

### COUNTRY LEVEL

Drawing on the expected processes involved in CCEOP design, planning, installation and maintenance, the CCEOP results framework and the performance framework, we have developed an evaluation framework to guide the country evaluations (see Figure 1). 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 are aligned 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, namely Gavi, procurement organizations, manufacturers, SBPs and technical assistance providers, who will both 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 as well as 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 takes into account provision of CCE to new sites as well 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 in its effect on more efficient immunization supply chain, and in the longer term, vaccination coverage, but the

development of a long-term sustainable system which countries have interest 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 various linkages in the proposed pathways to understand where blockages may have occurred in achievement of expected outputs and outcomes, or reasons why the process may have been successful in selected areas. By undertaking data collection at multiple time points, before CCEOP installation in countries and two years after, changes can be observed over time. This evaluation takes into account the country context, the supply chain distribution system in the country as well as the coordination with other development partners that 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 presented in Figure 2 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 were the catalyst for creating the CCEOP and how the platform achieved the desired outcomes. Specific details of the market-shaping outcomes and objectives as outlined in the Gavi Supply and Procurement Roadmap for ILR & SDD CCE are presented in Annex A. The evaluation will gain a better understanding of the overall market health, market changes, and unintended consequences, both positive and negative. The market-shaping component will use both quantitative and qualitative metrics to provide insight into the overall health outputs and impact and with each data collection time point, will evaluate how well the CCEOP has achieved its goals to date and how well it is set up to continue to achieve its goals.

Figure 1: CCEOP Country Evaluation Framework, Based on the Gavi CCEOP Theory of Change

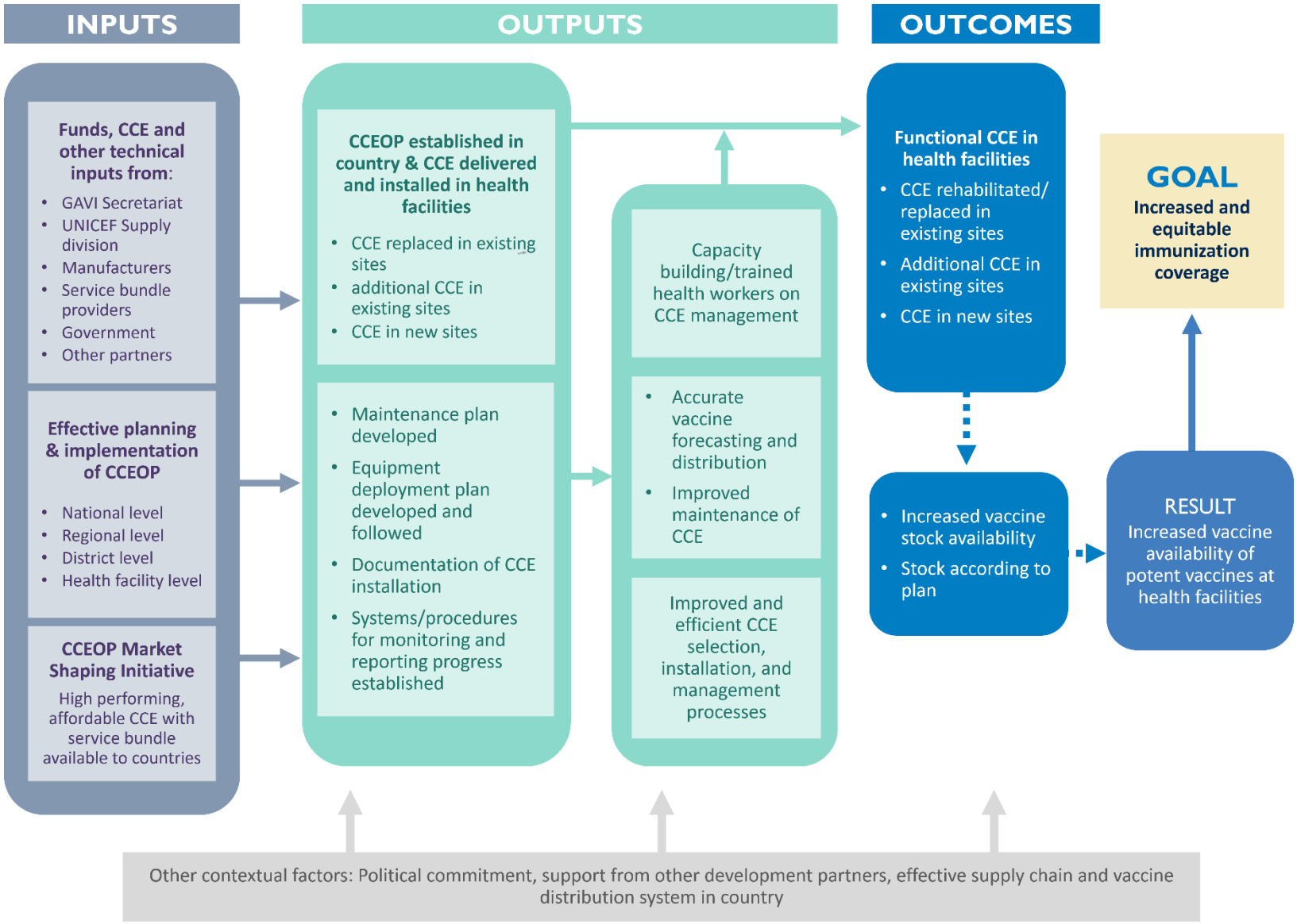
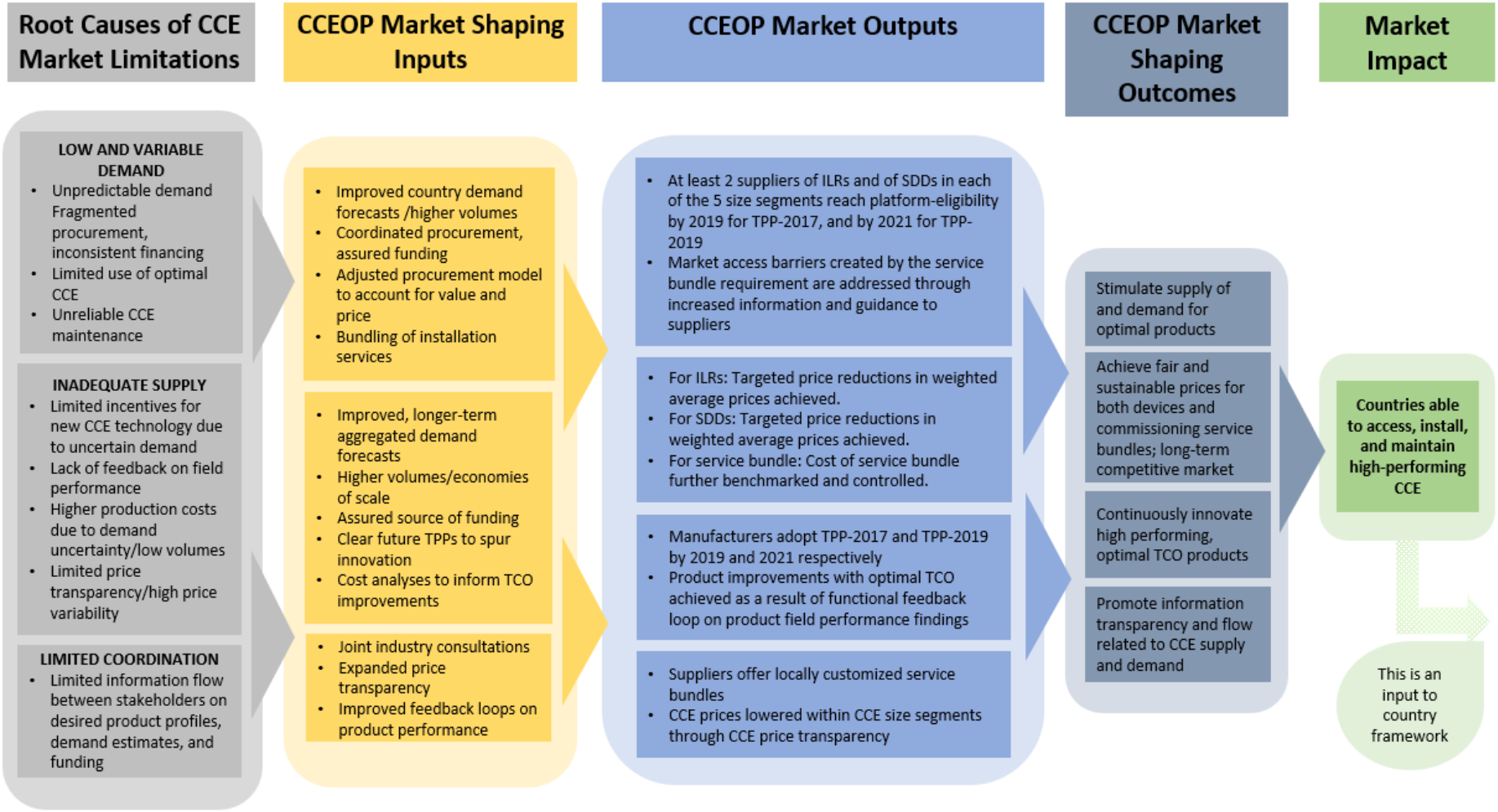


Figure 2: Gavi's Market-Shaping Evaluation Framework, Based on the Gavi CCEOP Theory of Change



# DESIGN AND METHODS

## COUNTRY EVALUATION

### DATA SOURCES AND METHODOLOGY

As described in the country evaluation protocols, the country level baseline assessments followed a mixed-methods approach including data collection from a variety of sources including document review, direct observation of the CCEOP planning and implementation planning process (when possible), 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 issues 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. 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 baseline assessment. National-level respondents were asked about proposal development, identification of cold chain gaps, development and plans for implementation of the ODP, selection of CCE and the role of SBPs. Interviews with SBPs focused on market-shaping and the SBPs' role in ODP development. Interviews at the county levels and below asked respondents about their role in CCEOP, but focused more on the current state of CCE in the county/sub-county or facility, frequency of CCE routine maintenance and repairs, and selection of health facilities and CCE type.

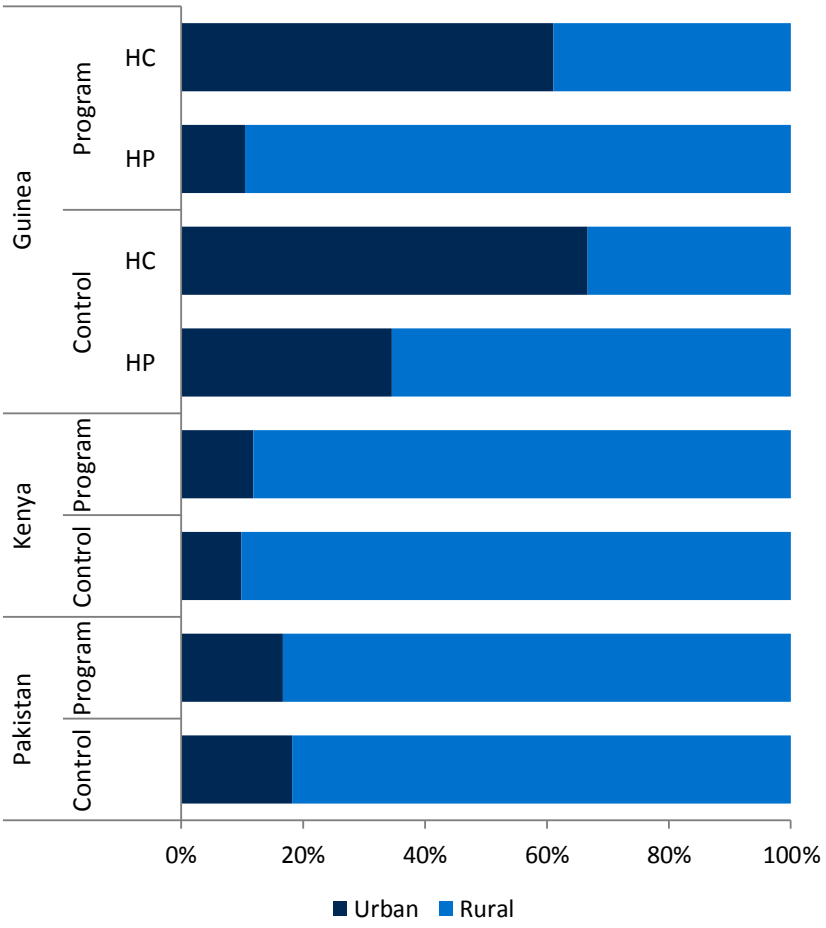
The quantitative component was an HFA in selected facilities in the sampled districts. The purpose of the HFA was to establish a baseline measure of indicators at health facilities and sub-county/district stores/depots, including frequency of immunization services provided, CCE inventory and functional status, maintenance history and procedures, stock history and stock-on-hand of two tracer vaccines, pentavalent and measles, and staff training on stock management and CCE maintenance.

### SAMPLING

The sampling approach is somewhat consistent across the three countries in order to enable 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 baseline 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 (Figure 3). In Guinea, with the further disaggregation of health facilities into health centers and health posts, slightly more than 60 percent of health centers in both arms were in urban areas while health posts were predominantly rural. In all countries, 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, 6 percent among program facilities and 14 percent in control facilities, which were privately owned.

Figure 3: Percent of Urban/Rural Facilities by Study Arm and Country




More specific details on the data, sample and methodology are available in the country evaluation protocols.

## 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 will be addressed. The baseline assessment focuses on understanding the situation before CCE under the CCEOP was installed across the three countries 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 that are not scheduled to receive equipment in Year 1 (comparison or control facilities). It is possible that some of the facilities in the second group may receive CCE at a later time. Effort was also made to align the sample based on data on deployment of CCE procured through other funding sources, based on the data available during sample selection. At subsequent data points, including the midline and endline, we will examine change over time and note any trend differences between the two groups.

Data from the HFA will be analyzed throughout the evaluation to demonstrate these changes and how they relate to CCEOP implementation in the country. The analysis will also document aspects of the CCEOP application process, including the transparency of the application process, alignment of CCEOP with the country's needs, use of data to inform the application process, and alignment of the application with Gavi guidelines and investments made by other donors. The midline assessment will focus more on the implementation process, and the endline will focus on the effects and expected outcomes.

For the baseline, 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 level and below focus on current CCE, breakdowns, maintenance, and any role in the selection of sites for CCEOP equipment. Examples of themes developed at the national level relate to the CCEOP application and planning process, including roles and responsibilities in the planning period, ODP development as well as site and equipment selection.

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 region to make regional-level comparisons between all program facilities and control facilities. Results from the HFA were triangulated with responses from the KIIs to ensure consistency and accuracy and to provide further explanation as needed.

## STAKEHOLDER CONSULTATIONS

An inception report and country-specific research protocols outlining the evaluation approach were drafted in the early stages of the evaluation. A stakeholder consultation was conducted at the inception phase of the evaluation in each country to share information with all partners on the evaluation approach. Country-level baseline assessment results were later shared in Kenya and Pakistan with the National Vaccines and Immunization Program (NVIP) in Kenya and federal EPI in Pakistan as well as the PMT in both countries and feedback noted. The dissemination of the baseline assessment report will be held in early January in Guinea.

Subsequent phases of the evaluation will have this continued engagement with all stakeholders. The evaluation team at the country level is also in continuous contact with the PMT as the progress in deployment is being reviewed.

## MARKET SHAPING EVALUATION

The market-shaping piece of the evaluation is both retrospective and prospective in order 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 baseline report presents the procurement situation for CCE pre-CCEOP, and will serve as a comparison point to assess progress at midline and endline, looking at changes observable from the data collected and the perspectives shared by key informants. This work builds on the analysis of the CCE tender process conducted by McKinsey for UNICEF Supply Division in early 2018, in so much as access to their data and findings were available to work with and complement our CCEOP evaluation data collection efforts. 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.

### DATA SOURCES AND METHODOLOGY

Built on the foundation of the Healthy Market Framework (developed by Gavi, UNICEF, 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 manufacturers, countries, and SBPs. Each country adapted these data sources and data collection tools according to their country context.

## STRENGTHS AND LIMITATIONS

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

### STRENGTHS

- This evaluation follows a prospective design that provides the ability to understand the entire process of CCEOP planning and implementation and its effect on relevant outcomes at different stages. It provides the ability to follow the same health facilities over time to examine changes taking place in real time over a two-year period.
- The mixed methods approach followed uses 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 provide relevant 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 case-control design of this study provides the ability to compare the above-mentioned changes over time in selected health facilities that have been exposed to CCEOP to a greater extent and those that have been less exposed or have delayed exposure to the effects of CCEOP.

## 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 necessarily provide sufficient information on changes in key immunization outcomes within this timeframe.
- 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 district-level HMIS/LMIS data, whose quality are not guaranteed, are used.
- 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
- In some countries such as Kenya where other donors such as the World Bank are also providing CCE, the evaluation will attempt to separate out the specific effect of CCEOP but may ultimately be limited by the country's deployment strategy. The evaluation will also try 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 group that acts as a 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 will also affect the design of the study and result in changes in facilities sampled at later times.
- The expansion of the analysis to cover remote temperature monitoring device (RTMDs) is restricted based on availability of current data and how it fits with the evaluation design.
- Limited cost effectiveness analysis examining expenditures on CCE will be conducted in Kenya after the midline evaluation and sharing of result. 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. We also do not calculate TCO but use estimates provided[4].

- 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.
- There were challenges in accessing relevant HMIS and LMIS data in all three countries. Data accessed could not be triangulated with HFA data at baseline as planned because they were of poor quality.
- 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 and on missed opportunities etc. are beyond the scope of this evaluation and will not be conducted. Some of this information will however be captured when data on stocks are compiled. The analysis also excludes other program-specific detailed implications, and is unable to 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 in consultation with the MOH. It compares CCEOP deployment through SBPs and deployment of World Bank-funded CCE directly by the MOH. While there are many areas of overlap, their approach from the information received appears to be a little different from this CCEOP evaluation. 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 specific countries such as Guinea. Because deployment is just starting in Guinea at this point, a decision was made to move the midline assessment to February 2019. This move affects the timing of cross-country analysis of midline data for the three countries. Furthermore, the need to share results from the midline assessment with Gavi in February/March has necessitated advancing data collection for the midline in the other two countries, Kenya and Pakistan. 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 planned.

[4] This cost analysis will be conducted only if a similar analysis also proposed by the Clinton Health Access Initiative will not be conducted. The decision on whether to conduct the cost analysis will be made in 2019.

With regard to market-shaping, there are similar delays in the release of the new Procurement and Supply Roadmap for example, that have affected the completion of evaluation activities as originally planned. While the original market-shaping evaluation design and specific questions around the relevance, implementation, effectiveness, and sustainability are still valid and relevant. It will be important to align with Gavi once the revised Procurement and Supply Roadmap is released to ensure the evaluation is able to capture any changes to the market-shaping strategic objectives and specific outcomes at both the global and country level. In particular, it will be important to confirm that the data collection and analysis are aligned with these changes and there is agreement on how progress towards both the original and revised objectives will be assessed.

# KEY FINDINGS AND LESSONS LEARNED

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

i) Descriptive information on the current status of immunization and CCE in the sampled areas in each country[5]. These data provide context for the qualitative findings from this baseline assessment. These indicators will also be monitored over time at the midline and endline assessments to better understand changes over time.

ii) Process indicators that include stakeholder observations and experiences with the CCEOP planning and initial stages of the implementation process aligned with the evaluation questions that were addressed in the baseline. Stakeholder perceptions on anticipated improvements to efficiency and outcomes as a result of CCEOP are also captured in this section.

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

## BASELINE STATUS OF CCE

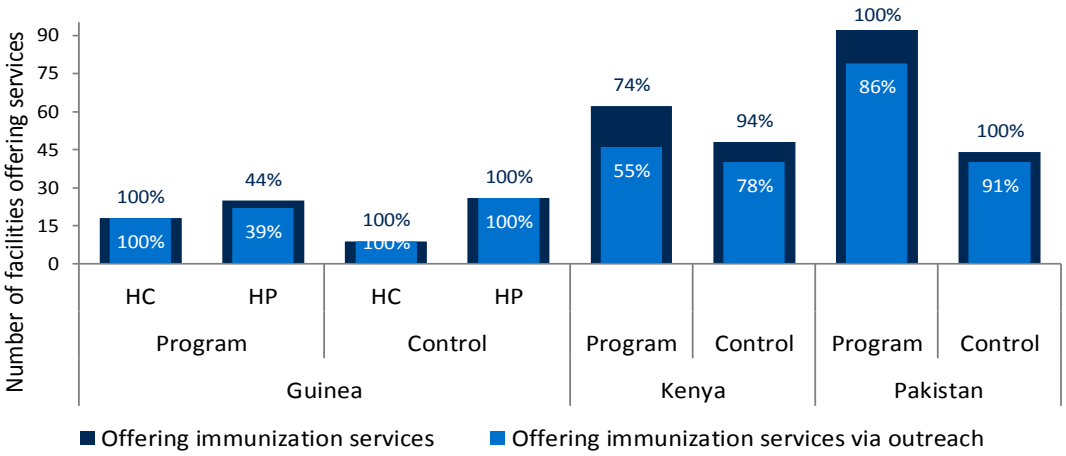
### IMMUNIZATION SERVICES OFFERED

All facilities in Pakistan offer immunization services with a large proportion (86 percent in program and 91 percent in control) also offering immunization services via outreach (Figure 4). In Guinea, all of the health centers surveyed, in both program and control arms, offer immunization services directly and via outreach. This is true for health posts in the control arm too. In the program study arm, however, only 44 percent of facilities offer immunization services with even few offering immunization services via outreach. A larger proportion of control

[5] These results are presented separately in health centers and health posts in Guinea given the large differences in these two types of health facilities. They are also presented separately for sub-county/district stores/depots.

facilities offer immunization services and immunization services via outreach in Kenya (94 percent and 78 percent respectively) while only 74 percent and 55 percent of program facilities offer these services via outreach.

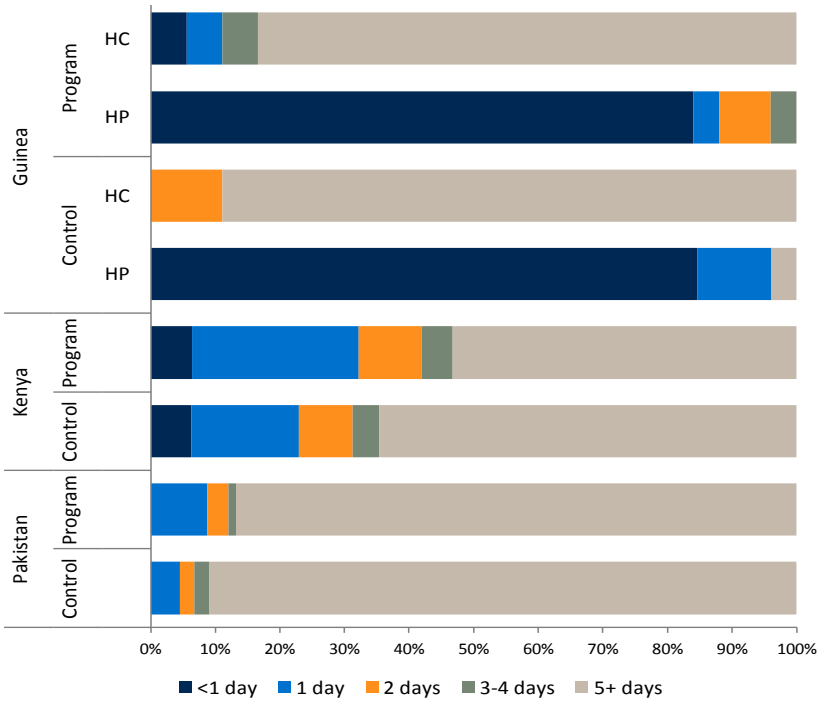
Figure 4: Number and Percent of Facilities Offering Immunization Services by Study Arm and Country




In Pakistan and Kenya, more than half the facilities surveyed provide immunization services five or more days per week (Figure 5). In Guinea, with the health center and health post disaggregation, 85 percent of health centers offer immunization services five or more days per

week. On the other hand, 85 percent of health posts offer immunization services less than 1 day per week. Kenya program and control facilities offer greater variation in frequency of immunization services offered per week compared to the other two countries.

Figure 5: Frequency of Immunization Services Offered by Study Arm and Country



## EXISTING CCE AT BASELINE

Most of the facilities surveyed in both program and control arms have at least one piece of CCE at baseline except in Guinea where an overwhelming majority of health facilities, especially health posts (which represent 75 percent of all sampled health facilities)) do not have any pieces of CCE, thus limiting their provision of immunization services (Figure 6). Of the existing pieces of CCE observed at facilities, 64 percent of the equipment was a refrigerator (Figure 7). The second most common piece was a refrigerator and freezer (24 percent). Only 12 percent of facilities had a stand-alone freezer. Freezers were observed throughout Kenya and Pakistan but were only observed at the district depots in Guinea. The overall number of pieces of CCE was much less in Guinea compared to Pakistan and Kenya, especially among health posts in both program and control arms.

Figure 6: Number of Pieces of Equipment by Study Arm and Country

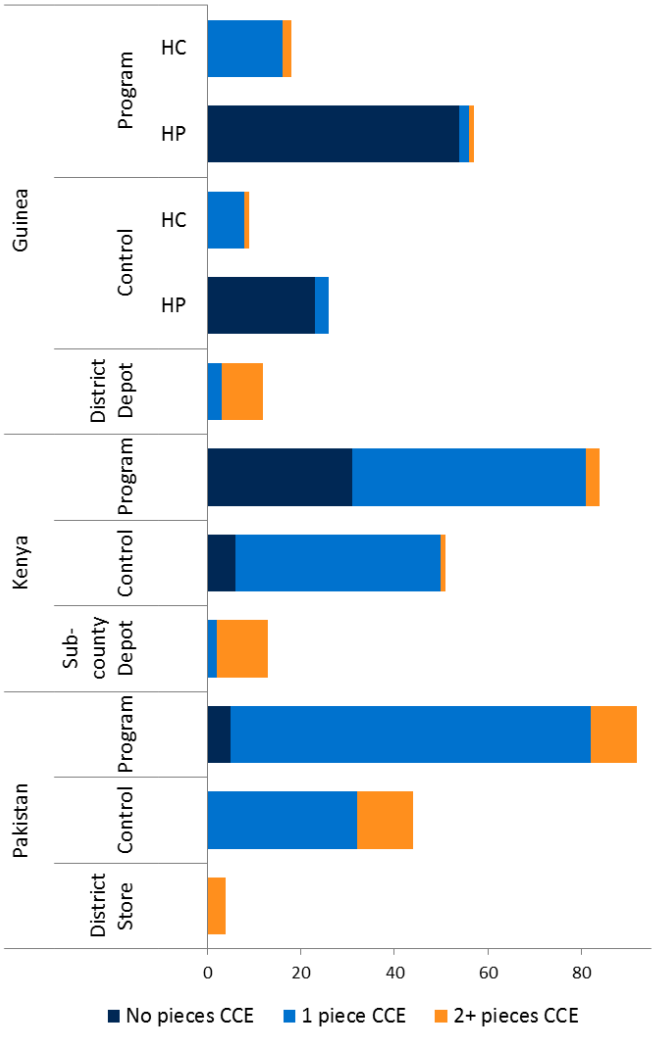
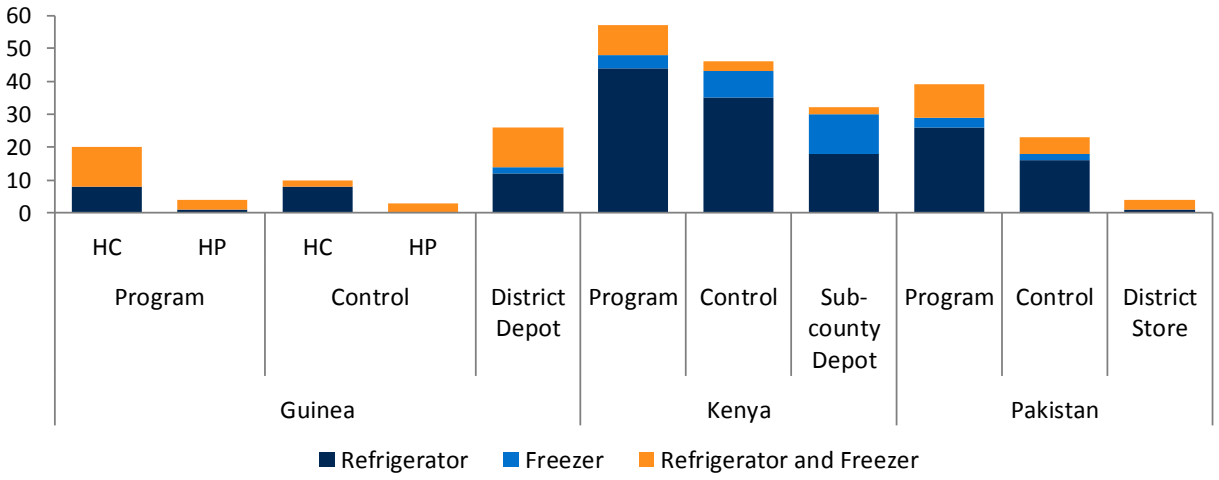
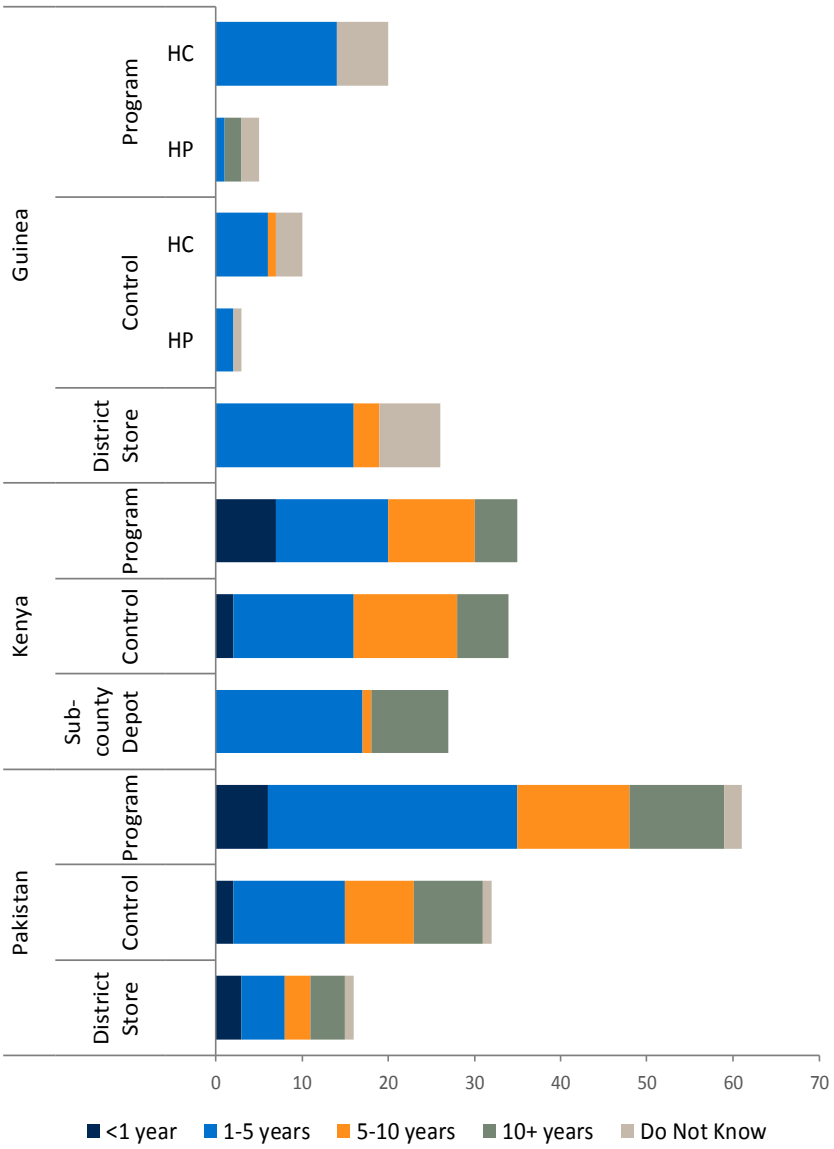


Figure 7: Type of CCE in Health Facilities by Study Arm and Country




Kenya and Pakistan had some pieces of equipment installed less than one year prior to the time of the survey (Figure 8). However at least half the equipment across the countries was installed between one-five years ago with some equipment installed over 10 years ago. It is possible that the equipment in facilities is older if they were provided from higher level facilities that had received newer equipment.

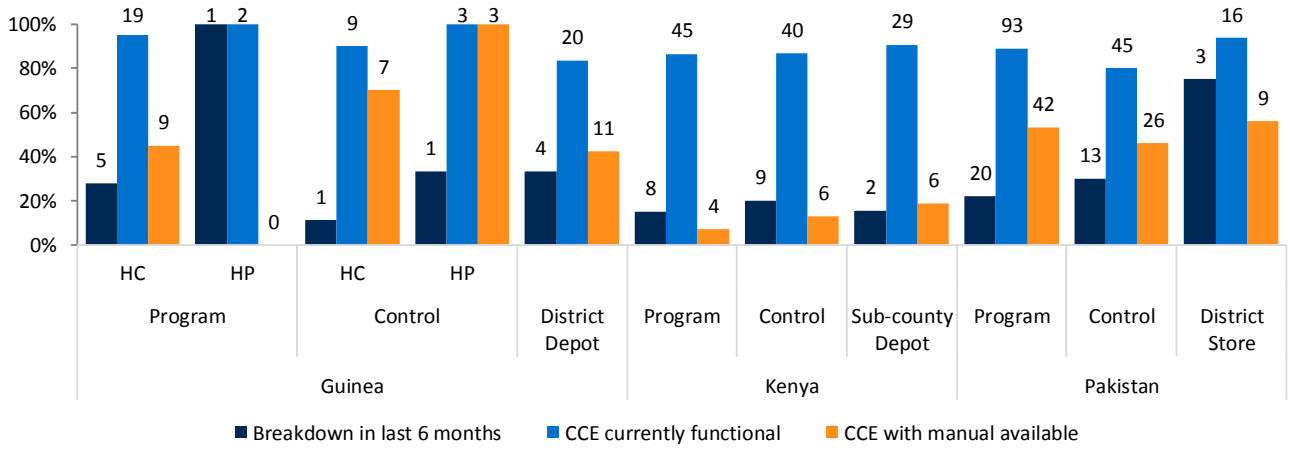
Figure 8: Years Since CCE Installation in Health Facilities by Study Arm and Country




## MAINTENANCE AND BREAKDOWNS OF CCE

More than 80 percent of facilities in all countries had currently functional CCE. However, up to 40 percent of facilities in some areas had reported a breakdown in the last six months with some variation across countries (Figure 9). Breakdowns were higher in program health posts in Guinea though the number of CCE in health posts is very small. District stores in Pakistan experienced breakdowns but data show that a majority that went into repair were fixed within two weeks. The presence of a CCE manual was especially low in Kenya as compared to the other two countries.

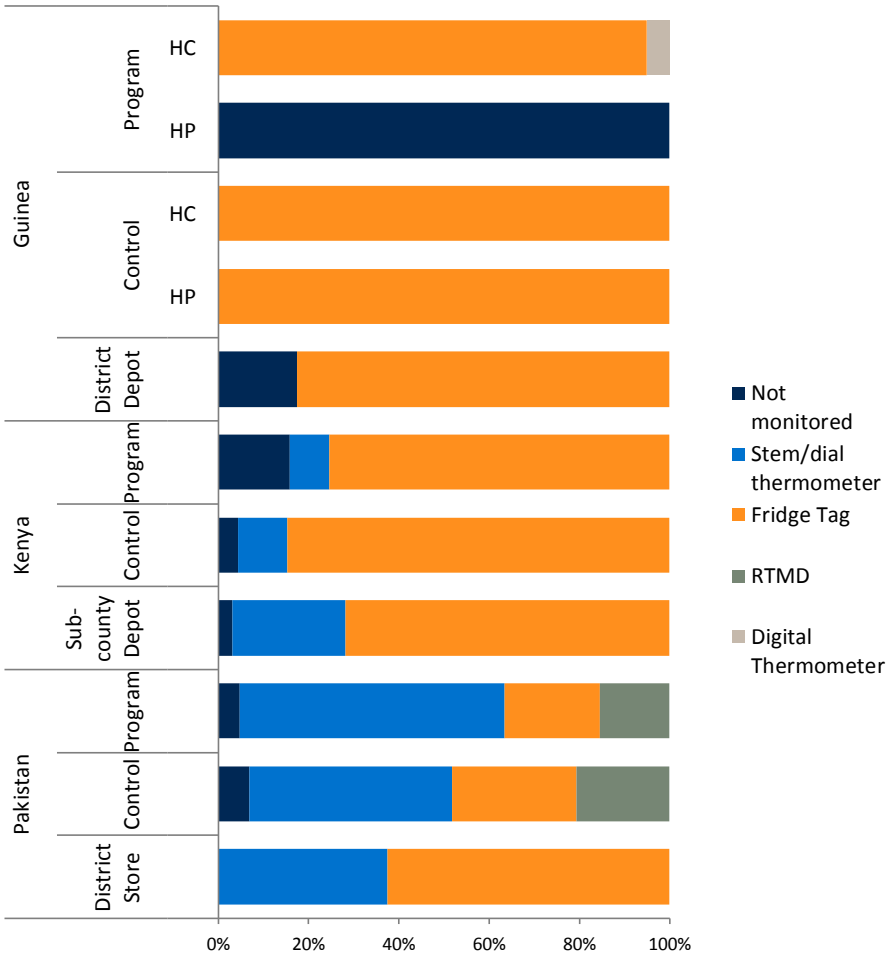
Figure 9: Maintenance and Breakdown Characteristics of CCE in Health facilities, by Study Arm and Country




## TEMPERATURE MONITORING

The most common temperature monitoring device observed across countries was a Fridge Tag (Figure 10). The next most popular device was the stem/dial thermometer covering up to half the facilities in Pakistan, fewer in Kenya and none in Guinea. Digital thermometers were only observed in some facilities in 20 percent of facilities in Pakistan and a few in Guinea. On average, 60 percent of facilities across program and control study arms had an updated temperature monitoring chart.

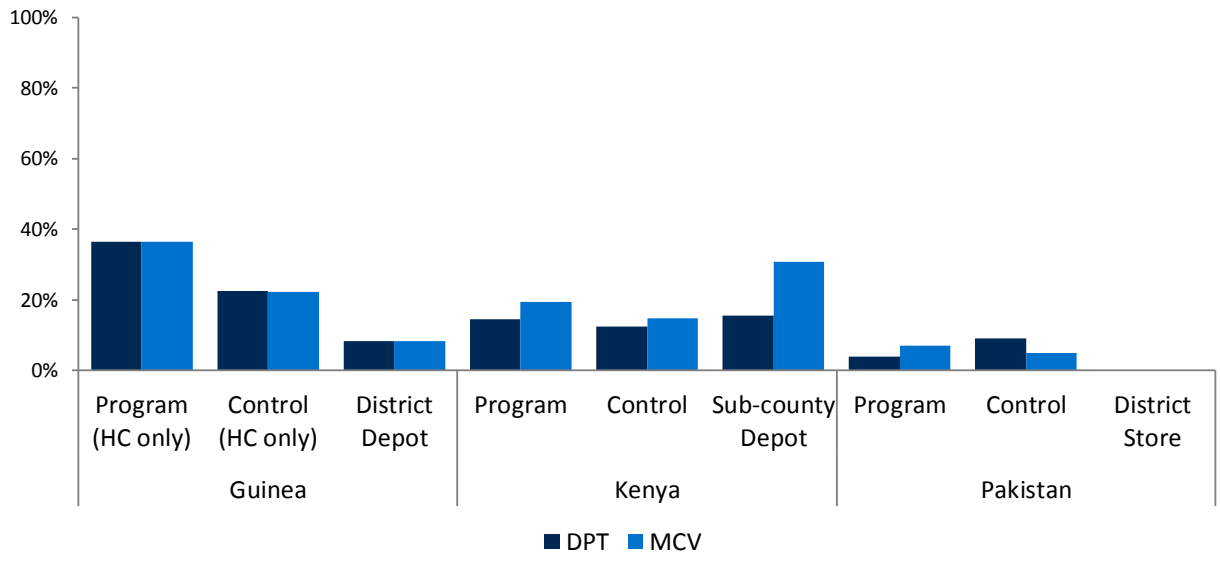
Figure 10: Details of Temperature Monitoring of CCE in Health Facilities, by study arm and country



### STOCK MANAGEMENT

Over three quarters of all facilities surveyed across the three countries reported on the following outcomes: well organized CCE; updated diphtheria, pertussis, and tetanus (DPT) stock ledgers; and updated measles-containing vaccine (MCV) stock ledgers. Health posts are not included in Guinea as they did not maintain stocks. Stockouts in the last six months were observed for both DPT and MCV, but more so in Guinea and Kenya as compared to relatively low levels in Pakistan (Figure 11). Across all three countries, stockouts of DPT and MCV vaccines were generally higher in program facilities as compared to control facilities and almost 40 percent in

Figure 11: Stockout of DPT and MCV in Health Facilities in the Last Six Months by Study Arm and Country




program health centers in Guinea). The difference was most substantial in health centers in Guinea. While the district store/depot had low percentages of stock out in Guinea and Pakistan, this was not the case in Kenya; more than 30 percent of sub-county depots in Kenya had experienced an MCV stockout, primarily because of the stockouts in one county, Kitui.

## PROCESS INDICATORS

This section addresses the process indicators highlighting the CCEOP application process, the stakeholders involved, and the expected outcomes. The majority of these questions focuses on the relevance of CCEOP to the three countries. Table 5 below outlines the key findings with regard to the relevance of CCEOP and the planning process. They are described in further detail below.

Table 5: Key Findings by Country

| | Kenya | Pakistan | Guinea |
|---|---|---|---|
| **RELEVANCE OF CCEOP** | | | |
| **IN RESPONSE TO COUNTRY NEEDS** | | | |
| **Finding 1:** The CCEOP application was based on country priorities, using information from available data through information systems, and from cold chain inventory | X | X | X |
| **TRANSPARENT PROCESS AND STAKEHOLDER ENGAGEMENT** | | | |
| **Finding 2:** The PMT plays an active role in CCEOP deployment and coordination | X | X | |
| **Finding 3:** High level of stakeholder engagement but limited role beyond the national level | X | X | X |
| **Finding 4:** Complex application process in some countries with lack of clarity on cost, clearance, warranties and other issues | X | | |
| **ALIGNMENT WITH GAVI GUIDELINES AND OTHER DONOR/PARTNER SUPPORT** | | | |
| **Finding 5:** CCEOP application was closely aligned with Gavi guidelines | X | X | X |
| **EFFECTIVENESS** | | | |
| **PLANNING FOR IMPLEMENTATION** | | | |
| **Finding 6:** Concern that facility staff are not well prepared to handle the new equipment | X | X | X |
| **Finding 7:** Mixed feelings and confusion about the SBP approach, and especially in lower levels of the health system | X | X | X |
| **Finding 8:** Changes to the deployment plan | | X | |
| **EXPECTED OUTCOMES** | | | |
| **Finding 9:** Expectations of improved efficiency of equipment, and of the cold chain system, especially of temperature monitoring systems | X | X | X |
| **OVERALL** | | | |
| **Finding 10:** Need for overall system strengthening | X | X | X |

# RELEVANCE OF CCEOP

## IN RESPONSE TO COUNTRY NEEDS

### Finding 1: The CCEOP application was based on country priorities, using information from available data through information systems and from cold chain inventory

Overall, in all three countries the CCEOP application process was made using data from multiple sources including the most recent EVM assessment or cold chain inventory. The application was made with an effort to develop and strengthen the country's immunization systems, including the cold chain, throughout the health system. Regional-, district-, and health center-level staff in all three countries were involved in the collection of data to inform the ODP development.

#### *Kenya*

In Kenya, the CCEOP funding mechanism responded well to country needs; CCEOP deployment reflected the needs and gaps identified. Deployment also fit well within the strategy outlined in the country's Cold Chain Expansion and Replacement Strategy, developed in 2016. The Cold Chain Inventory in Kenya provided the foundation for the country's Cold Chain Equipment Expansion and Replacement Plan that informed the CCE selection and facility prioritization process for the CCEOP application. County and sub-county level health officials confirmed the use of data to drive decision-making in the CCEOP application, indicating that they were responsible for collecting facility-specific information and providing it to the PMT.

The 2013 EVM assessment and the 2016/2017 cold chain inventory were used as a basis for identifying needs and gaps that informed the generation of the CCEOP operational deployment plan (ODP). Gavi also accepted this as a valid foundation upon which to base the proposal, ensuring that planning for CCEOP deployment reflected the needs and gaps identified by the country. The CCE funded by the World Bank is unlikely to overlap with CCEOP-funded equipment in health facilities in the three counties sampled. However, overlap is likely in the sub-county stores. According to the Ministry of Health, Year 1 of CCEOP deployment will focus on equipping all facilities (public, private, and faith-based) in the 17 original HSS grant funded counties that have equipment gaps and need extension, as well as facilities in 30 other counties that need extension. Year 2 will focus on replacing equipment in all facilities where there is a need, targeting the entire country. Year 3 will include a cold chain inventory to determine if expansion is possible or equipment needs replacing.

> *"… [CCEOP] came at an opportune time for us because we were already planning to meet that gap. In fact, within HSS, which is again support from GAVI, we had actually put money in there to respond to the gaps. So when CCEOP came, it was a double opportunity for us because as a country we are co-financing 50/50."* ***(Kenya MOH Official)***

#### *Pakistan*

In Pakistan, although some CCE was replaced through a World Bank grant in 2013 and additional cold chain equipment procured in 2016/2017, significant needs and gaps remained. The current CCEOP grant responded well to country needs that were identified through the

EVM assessment undertaken in 2014, a follow-up cold chain inventory in 2016, and informal feedback from field personnel.

Provincial EPIs also used the EVM assessment to provide lists of facilities and their equipment needs to the federal EPI to finalize locations for CCE installation. Provincial authorities worked with district health authorities to confirm the accuracy of the EVM assessment and cold chain inventory data and ensure that facilities were ready to receive new equipment. Combined, this information provided high-quality data used in grant development to obtain the Gavi grant and guide planning and deployment processes. Coordination between partners and stakeholders was well-organized. Management was directed by program management teams formed at the federal and provincial levels. However, the time gap between planning and implementation and changing demands from the field were the major reasons for deviations from the deployment plan.

> *"In the allocation of equipment to the districts, the districts should be taken on board. Many times there is an issue of space but the planning is done at the federal level. The better way is that the planning should be done at the grass-root level and things should go up from there." (**EVM Coordinator, Punjab, Pakistan**)*

The Gavi grant will replace nearly all CCE across Pakistan with priority given to facilities that did not have the capacity to meet current vaccine demands. Seventy-five percent of all facilities across Pakistan were selected to receive replacement fridges. Of these, approximately 25 percent would receive additional fridges to expand their existing storage capacity. Facilities identified for CCEOP had non-WHO pre-qualified equipment and/or had 10+-year old equipment. Under the current deployment plan, 11,686 of the current 15,418 refrigerators in 8,710 facilities will be replaced or allocated with new equipment over the course of the grant, expected to run three years.

> *"The whole CCEOP project and grant was not something done by one partner. There was UNICEF and Gavi at headquarter level that engaged with the government who agreed to the project as a whole and aspects of the project that needed to be taken care of. So each of the partners had a lot to play and I think it is going well, which is why we are at this stage of implementation." (**Focal person, UNICEF country office, Pakistan**)*

### *Guinea*

Guinea's CCEOP application was also well-aligned with the country's 2016-2020 national comprehensive multi-year strategic plan to increase accessibility of vaccination services and thus significantly improve immunization coverage. The MOH's principal objective is to gradually replace all of the non-PQS equipment in the country and extend the cold chain coverage, equipping all health posts in the country by 2021. CCEOP would allow the country to expand its immunization services by increasing the number of fixed posts, bringing vaccines closer to its hard-to-reach populations in a more sustainable way. Under the Gavi CCEOP grant, the country's plan is to primarily install in the health posts with no CCE, followed by health centers with non-functioning equipment, those with more than 10-year-old equipment, and those with non-PQS and less than 10 years old refrigerators. Equipment was chosen based on several

criteria such as decreased breakdown and easier maintenance, robustness for future storage capacity given the introduction of new vaccines, and service life estimate of 10 years.

In Guinea, regional health directors coordinated the data collection. District health staff collected information on health posts, specifically assessing the area where the equipment is planned to be installed.

## TRANSPARENT PROCESS AND STAKEHOLDER ENGAGEMENT

### Finding 2: The PMT plays an active role in CCEOP deployment and coordination

Gavi has developed a guidance document with information on the PMT, one of the requirements of the CCEOP application, including its roles and responsibilities (Gavi 2017a). In all three countries, the PMT was established to manage decisions and coordinate the implementation process. In Kenya and Pakistan, the PMT has started to play a very active role. In Guinea, because of delays in CCEOP deployment, the team, though formed, is yet to be formalized.

#### *Kenya*

The PMT in Kenya is comprised of key stakeholders from the NVIP, UNICEF, and the Clinton Health Access Initiative. The PMT in Kenya has been involved in many activities including facility prioritization processes and engaging with county and sub-county officials to obtain facility-specific information. It has worked hard to align CCE donated from different sources in the country, particularly equipment donated in large numbers across multiple counties from entities such as Global Good and the World Bank. Alignment with the World Bank has been particularly successful in the planning phase. The PMT has developed installation templates to monitor progress on installation by the SBP.

#### *Pakistan*

In Pakistan, the PMT was formed both at the federal and provincial levels. At the federal level, it includes the federal EPI, UNICEF, and WHO. Occasionally national experts, representatives of vendors, and others including the provincial EPI were invited to participate. The PMT meets as needed: during application development, several times a month, sometimes even twice a day. During the period leading up to arrival of the new equipment, it met two-three times a month. Minutes were taken at every meeting and shared to ensure transparency. The provincial PMT includes representatives from the provincial EPI and individual districts. Problems encountered in districts were communicated to the provincial PMT. Issues that cannot be resolved are communicated to the federal PMT, which has the power to make a final decision.

Based on the ODP, the national PMT-developed estimates were given to the provincial EPI, which worked with facility lists that had been verified by the district managers and used these verified estimates to determine facility allocations. The estimates were communicated to the provincial PMT through provincial EVM coordinators, who used these lists to prioritize which facilities would receive equipment in which of the grant years. The PMT also tracks and communicates changes in the work schedule to relevant partners.

When the equipment arrived in-country, provincial PMTs were expected to get information from districts on any specific issues and readiness to receive the equipment (site readiness and if installation plans needed revision). The PMTs were responsible for coordinating, facilitating, and monitoring the entire implementation process, including ensuring that the contractor installed equipment correctly and that staff were trained as planned. Thereafter, the PMT is to continue monitoring equipment functionality.

> *"The PMT is fully authorized to make any changes as we are able to take the district and vendor on board and through multiple meetings with the vendor we are able to tell them what we want."* ***(EVM coordinator, Punjab, Pakistan)***

### *Guinea*

A CCEOP coordination committee (equivalent to the project management team) was constituted in Guinea at the national level but is waiting to be formalized. Meanwhile, the committee's terms of reference and membership list have been submitted to the Minister. This committee is led by the National Deputy Director for Epidemiology and Disease Control, who confirmed the group meets regularly to follow up on the CCEOP action items. A more interdisciplinary team was involved in the preparation of the ODP, specifically in the selection of the CCE, and included representatives of the National Pharmacy, and Laboratories Directorate (Direction Nationale de la Pharmacie et des Laboratoires), National Logistics Management Unit (UGL), UNICEF, Division Infrastructures Equipement et Maintenance (DIEM), and a representative of Family Health and Nutrition (Santé Familiale et de la Nutrition).

## Finding 3: High level of stakeholder engagement but limited role beyond the national level

The CCEOP planning process was found to be transparent, but mainly at the national level.

### *Kenya*

In Kenya, MOH officials reported making an effort to extend the planning process for CCEOP to the county level. It is possible that these efforts varied across counties; discussions show that that county involvement was less prevalent in the three counties selected for this analysis. The PMT consulted county-level officials for input on the cold chain inventory, but county-level officials were not included in other key planning activities, such as equipment selection. The role of county and sub-county government health officials in the planning phase in Kenya mainly focused on responding to PMT requests for information about existing CCE, power source, and roof materials (readiness for solar equipment) in their facilities.
SBPs also had a limited role in the planning process. They were not involved in developing the ODP, but reported that they developed their own ministry-approved deployment proposal with more specific information on equipment deployment and installation.

National-level NVIP and partner organizations spoke about their roles in the CCEOP application and planning process, while respondents at the county level and below were unfamiliar with it. While some respondents at the county level knew that Gavi is providing CCE, they were not familiar with any of the specifics, including the type of equipment, when they could expect to

receive it, or that SBPs would be responsible for maintenance for two years following installation.

### *Pakistan*

In Pakistan, a provincial level PMT was formed in addition to a national PMI. The federal EPI and the PMT led grant-planning, development, and implementation, viewing the engagement of a range of stakeholders as critical for identifying district-level needs and developing criteria for facility improvement prioritization. The federal EPI and WHO, with support from UNICEF's consultant, developed the grant in collaboration with a Gavi focal person to ensure that it conformed to Gavi guidelines. Provincial staff were involved to some extent. The federal PMT met several times a month and conferred with provincial counterparts in monthly formal meetings. In turn, the provincial PMTs consulted with district officials regularly to confirm and/or update EVM findings. The PMTs also contacted district officials during ODP development to identify which facilities would receive which equipment. The entire process was well-documented in PMT meeting minutes and email trails, ensuring transparency at all levels.

> *"In the allocation of equipment to the districts, the districts should be taken on board. Many times there is an issue of space but the planning is done at the federal level. The better way is that the planning should be done at the grass-root level and things should go up from there."* ***(EVM coordinator Punjab, Pakistan)***

This district-level information was incorporated at appropriate levels of planning. At a later stage of implementation planning, SBPs were included in PMT discussions to streamline installation. UNICEF was present at all meetings and provided technical support through its consultant and procurement team. However, equipment selection and facility identification processes were done by a small group of experts comprising federal and provincial EPI CCEOP focal persons, UNICEF, and WHO.

### *Guinea*

The level of involvement of different stakeholders was consistent in the beginning in Guinea and, in the case of lower level stakeholders such as regions and districts, rather limited. Some relevant MOH departments were involved after the proposal development but in time to provide their feedback before the proposal was finalized. Regional, district, and health center level staff were mainly involved in the collection of data to inform ODP development.

> *"We work at the regional level, we are not at the operational level, but we get back information about the CCE from the lowest to the highest level of the health system. We have the CCE inventory. During the national immunization days, we ask managers of health facilities to provide the status of the CCE (in their facilities)."* ***(Regional Health Office, Faranah, Guinea)***

## Finding 4: Complex application process in some countries with lack of clarity on cost, clearance, warranties, and other issues

There were mixed views on the complexity of the application process. The model of using consultants at the national level to support the application process was seen as very successful in helping participants understand the processes, requirements, and documentation.

### *Kenya*

National-level partners and NVIP staff in Kenya noted that the CCEOP application process in Kenya was lengthy and complex. While both groups were grateful for Gavi's communication and responsiveness, they would have liked an orientation to the proposal process that included a larger group of stakeholders, instead of relying on a few representatives to relay the information.

**Cost**: There were several areas of confusion on cost of CCE in Kenya. The total cost of equipment was unclear for national-level respondents. Additionally, costs for things like clearance, shipping, and the UNICEF procurement services handling fee after equipment selection had taken place came as a surprise and resulted in a final equipment cost that was much higher than expected. Moreover, the overall cost of equipment changed between the time of authorization to submission because of the selection of more expensive SDD refrigerators/freezers, addition of shipping costs, currency fluctuations between U.S. dollars and euros, and the addition of an 8.5 percent UNICEF procurement services handling fee.

The PMT originally selected lower-priced equipment (for example with the capacity to refrigerate only, instead of a mix of refrigeration and freezing) so it could purchase a larger quantity. Between the submission of the application in September 2016 and the approval in May 2017, the PMT decided that freezing capacity was essential, and selected new, more expensive equipment. The dollar amount of the support from Gavi had been set by that point, based on equipment selected earlier in the process and could not be changed, resulting in a shortfall of funds.

**Warranty**: Information on warranties was unclear during the equipment selection process. Clearly stated information about warranties would have helped them make more-informed decisions when selecting equipment at the outset. For example, some equipment was initially excluded from consideration due to the high cost, but was added when decision-makers realized that it came with a 10-year warranty as opposed to the shorter warranties that came with other equipment.

### *Pakistan*

In contrast, federal EPI managers in Pakistan reported that working with Gavi was easy and logical. Involving a wide range of stakeholders from the start and throughout the application and proposal process not only captured a variety of perspectives that helped improved the planning process but also mitigated any potential political, financial, or logistical challenges in developing and processing the grant. In part, the role played by the full-time consultant hired by UNICEF to facilitate the application process was helpful. The consultant helped provide a single point of contact through which to coordinate the processes and stakeholders. The PMT was also an important coordinating and communication mechanism. Despite these mechanisms in place, communication between federal EPI and Gavi was still a learning process for both sides. A

number of other coordination mechanisms were also used, such as face-to-face meetings, Skype calls, and emails.

### *Guinea*

WHO and UNICEF provided technical assistance through an international consultant in Guinea to support EPI in developing the CCEOP application. This support was highly valued by MOH staff. With this support, they did not report any apprehensions about the CCEOP application process. Partners' support provided valuable information at each stage of the CCEOP implementation.

> *"Support from donors and partners has helped tremendously at different stages of the CCEOP process. Recently, the partners shared information on customs clearance, specifically Togo's case of exemption letter."* ***(EPI Official, Guinea)***

## ALIGNMENT WITH GAVI GUIDELINES AND OTHER DONOR/PARTNER SUPPORT

### Finding 5: CCEOP application was closely aligned with Gavi guidelines

Review of the ODP and the CCEOP applications in all countries indicate a high level of alignment with Gavi guidelines and fit with country strategies.

### *Kenya*

As noted earlier, the HSS application prioritized 17 counties in Kenya. These counties were identified as bottlenecks in the cold chain; in addition, immunization coverage was low and exhibited geographic and gender inequities. All 17 of these counties are slated to receive equipment through CCEOP, although how they will be prioritized has not been stated. Other counties would receive equipment at later stages.

Gavi guidelines also suggest that countries should "systematically use data and evidence to inform planning of Gavi support and [to] monitor implementation." The cold chain inventory and coverage data from the national HMIS in Kenya have been key to developing the ODP. Additionally, the PMT is working to develop installation templates to monitor SBPs. Efforts have also been made to coordinate with other donor sources of equipment so there is little overlap. As a result, World Bank funds in Kenya have been used to purchase equipment not included in the CCEOP application.

### *Pakistan*

Alignment with Gavi guidelines largely fell under the scope of the UNICEF consultant, who developed the grant in collaboration with a Gavi focal person, and was responsible for ensuring it conformed to Gavi guidelines. The consultant drew from both published Gavi guidelines as well as emails and direct calls with Gavi. The specific Gavi guidelines used were not explicitly expressed by EPI stakeholders in Pakistan, but the use of guidelines was felt to be an implicit part of the overall process. In their view, the CCEOP guidelines provided clear guidance on equipment selection. Federal EPI along with stakeholders such as UNICEF and WHO, as well

as the UNICEF consultant who drafted the proposal, worked closely with the Gavi focal person both formally and informally to ensure that the entire proposal conformed to Gavi guidelines on every level including type of equipment, procurement, disbursement, documentation, etc.

### *Guinea*

Country staff in Guinea also did not feel challenged by the effort to align with Gavi guidelines. The support received from WHO and UNICEF was very useful in clarifying any requirements of the CCEOP application guidelines and provide directions and necessary documentation. At the same time, the value of better orientation on the process from proposal development to implementation and on the different actors to be involved was felt to be important. Better orientation would mean less of a burden on the country, given the number of components involved in preparing the application and the ODP.

## EFFECTIVENESS

### PLANNING FOR IMPLEMENTATION

#### Finding 6: Concern that facility staff are not well prepared to handle the new equipment

All three countries rely on the SBPs for delivery, installation, and maintenance of the CCEOP equipment including provision of post-maintenance training during the warranty period. However, they have concerns about SBPs in the post-implementation period. A general concern in all countries is that health workers may face difficulty following equipment manuals and handling the equipment. Difficulty in following training materials may also impact health workers' ability to provide preventive maintenance for equipment.

### *Kenya*

In Kenya, most health care workers do not currently know how to read or record temperature data generated by Fridge Tags. They will need training to use the monitors as designed as specified in the Maintenance and Repair Strategy.

### *Pakistan*

Vaccinators in health facilities have had difficulty using Fridge Tags in the past. These staff are unable to read and record the temperature, find the highest and the lowest temperatures in the measurement period, and identify if any alarms have been set off during the day. There is also a fear that instructions for the equipment, if not available in Urdu or other regional languages such as Saraiki or Pushto, will be hard to follow. A related concern is that training will prove difficult if the instructions include many technical terms

### *Guinea*

Stakeholders in Guinea noted that job aids on equipment management and temperature monitoring would help facility staff better understand this aspect of their job once equipment were installed. They welcomed the role of SBPs, given the lack of current in-country capacity to manage installation and maintenance of such a large number of CCE. They also planned to engage a consultant for assistance post-implementation for further training and development of standard operating procedures.

*"The only intervention on the international level in maintenance services is the training and then the development of the SOP (standard operating procedures. We'll have a consultant to develop these standard operating procedures, make them available to each level and support those who are coming back from Benin to train service technicians."(**MOH Official, Guinea**)*

One concern is the fact that the SBP Haier's service does not include temperature monitoring and that Haier has not installed a model of the CCE for the ministry to test.

### Finding 7: Mixed feelings and confusion about the SBP approach, especially in lower levels of the health system

Overall, there are mixed feelings about the SBP approach, citing the expense and the possibility of undermining government ownership of the equipment and the process. There is still a lack of clarity on the roles and responsibilities of the SBPs, both during and post-warranty, especially below the national level in all three countries. Questions remain on how the equipment will be maintained by the SBPs in the first two years and after the two-year warranty period. There is a question on whether it will be maintained by county/district technicians, and whether there will be training provided to facilitate this maintenance. Because of their minimal involvement in the CCEOP planning process, most health officials at the lower levels believe that their own cold chain technicians and biomedical engineers will be responsible for all new CCE. Most health officials are also not clear on the actual processes for maintenance and repair procedures.

#### *Kenya*

The current system for maintenance and repairs, which relies on county level biomedical engineers, was felt to be insufficient. However, baseline results showed that MOH staff felt that the NVIP had sufficient capacity to install and maintain the equipment, and the extra costs related to the SBP did not justify the new approach of working with SBPs.

The understanding is that SBPs will be responsible for transporting, installing and commissioning equipment and providing maintenance training to the technicians and health facility staff. Furthermore, SBPs will provide corrective maintenance in the event of equipment fault (not human error) for the two-year warranty period. However, the counties were not closely involved in the CCEOP planning process, so most county-level health officials expect that their own cold chain technicians and biomedical engineers would be responsible for all new CCE.

*"The engineer is based at the sub-county level and it's the engineer who is supposed to be moving around maintaining the fridges during routine maintenance or when they are faulty, but because of lack of funds, he cannot do that routinely the way it is scheduled. Another challenge that we are facing is that…the technical staff are supposed to be oriented or taught about simple maintenance like when this is faulty, you do like this so that they can do operation maintenance.…So the staff used to be trained on cold chain and during training, those are the things that they used to be told. That training is no longer there." **(Sub-County Official, Homa Bay, Kenya)***

### *Pakistan*

The service bundle package in Pakistan is expected to cover distribution to the various health facilities, installation, and training the health facility workers, including the lady health volunteer, and vaccinators in the use the CCE. The same concerns as in Kenya exist in Pakistan. The exact mechanisms by which technicians and facility staff will be trained on maintenance and how this will be fully operationalized has not been fully understood, especially at the district and facility levels.

> *"I support the idea. It wasn't a cheap process but am very supportive with the idea of the manufacturer being the one responsible to carry out the deployment process up to the site, confirmation and everything involving the equipment. I realized it is not an ideal solution because the cost cannot always be handled but if this first year works, we are hoping to see more of it."* ***(Partner, National Level, Pakistan)***

### *Guinea*

The MOH in Guinea is relying on SBPs for all maintenance and training activities. Guinea currently lacks the capacity to manage installation and maintenance of such a large number of CCE and has welcomed the services the SBPs are contracted to provide. They view the long-term service as an opportunity to build capacity of Ministry's technicians at the national, regional, and district level. They also view contracting SBPs as necessary for improved maintenance response time and efficiency, which have been noted as weaknesses throughout the cold chain system. Though a necessity, the cost of SBPs installing CCE and sustainability were concerns, especially after the end of the warranty period.

One concern in Guinea is the fact that MOH had little contact with the local representative of Haier, Menerga Plus, which does not bode well for the implementation process.

## Finding 8: Changes to the operational deployment plan

### *Pakistan*

Despite an inventory during the planning process, the ODP has required changes although the exact departure from the plan is not known. In some cases, these changes occurred as a result of differences between actual and reported facility readiness. In some places, the size of the health facility was too small to handle the equipment. Some facilities were not ready to bear the electricity burden involved with installation of new CCE. The lack of awareness and limited involvement of district level staff has meant that at least some facilities in both Punjab and Sindh were not prepared to receive the new CCE, leading to changes in disbursement plans and delays. This has affected the role played by SBPs to some extent.

Information available on ODP changes show that the number of sites increased considerably in Punjab, that district health office deliveries were not in accordance with the provincial revised ODP, and that shuffling of models from one site to another occurred without prior notification resulting in unnecessary delays. While this is important to note, the impact was not substantial and will be addressed in greater detail in the midline assessment.

### *Guinea*

In Guinea, facilities need upgrading, which if not completed on time will affect the deployment process. For example, prior to installation, health posts with roofs that do not support the solar panels and with doors not large enough for CCE to pass through are required to enlarge doors. For the roofs, the MOH has managed to find a solution, installing poles to support the solar panels but the work needs to be completed prior to deployment.

## EXPECTED OUTCOMES

### Finding 9: Expectations of improved efficiency of equipment, and of the cold chain system, especially of temperature monitoring systems

Overall, there is much optimism among country-level stakeholders on the expected outcomes from installation of CCEOP. Although CCEOP equipment has not been fully deployed, stakeholders anticipate several positive outcomes—an improvement in the overall efficiency of the system, a reduction in the need for corrective maintenance, and an eventually improvement in immunization coverage.

An immediate effect is access to updated CCE with better features requiring less management by users and resulting in fewer breakdowns. One MOH official said,

> *"This equipment is special in that it requires minimal user intervention. You rarely defrost them, they have pre-set control systems, and they are easy to use."* ***(National level, MOH, Kenya)***

The temperature-monitoring devices would improve the system by allowing health officials closely monitor the CCE and shorten response times if there are deviations from the norm. Other immediate benefits are the increase in storage capacity and decreased wastage, especially from open vials. Longer-term effects are the increases in immunization coverage. Greater equity in coverage is also anticipated especially in countries like Guinea where CCEOP will result in the increase in entry points to vaccination, specifically the increase in vaccination service provision from 410 health centers to an additional 893 health posts that currently do not have any CCE.

> *"So marginalized children have access to vaccination; we're going to improve immunization coverage. When we improve immunization coverage, we'll reduce the morbidity and mortality in children…. When I say marginalized, it's in terms of distance. In a rural district, there is a health center. This health center is not in the middle, it is out of the way. There is a population that is on the other side. There can be even 50 km, between a small hamlet and the central prefecture. How can we vaccinate children in these regions?"* ***(EPI official, Guinea)***

These anticipated benefits and more information about sustainability will be examined at future data points of this evaluation. Though a necessity, the cost of SBPs was mentioned as the main disadvantage of having SBPs install CCE. Although the role of SBPs is valued in the immediate future, for both training and repair and maintenance during the warranty period, sustainability once the warranty period ends is a concern.

## OVERALL

### Finding 10: Need for overall system strengthening

CCEOP is effective in addressing the CCE fundamental of Gavi's iSC Strategy; however, the overall system must also be strengthened in terms of, for example, a maintenance plan that is funded and is functional, human resource knowledge and skills on temperature monitoring and vaccine management practices, and a distribution system that is effective.

Two areas are less clear in their effect on sustainability. First, ensuring financial sustainability is not clear at this stage in the process. Regular financial support from the Government budget will be critical to ensure sustainability of an efficient, effective, and well-maintained vaccine cold chain system. Second, institutionalizing a regular maintenance process and long-term support for repairs is critical to extending the life of the equipment and ensuring that repairs are made in a timely manner. While the SBP model relies on outsourcing of maintenance and repair during the warranty period, it offers an opportunity to bring opportunities to build the capacity of engineers and technicians in the longer term, a gap noted across all three countries. However, the exact mechanism of these processes are yet unknown.

## MARKET-SHAPING

The CCE market-shaping strategy has four strategic objectives: 1) stimulate demand and supply of higher-performing, cost-effective and quality products; 2) minimize costs of devices and services; 3) promote innovation; and 4) improve information sharing to better connect supply and demand. The evaluation and interview guides used for the KIIs were designed to assess the effectiveness, relevance, implementation, and sustainability of the market-shaping efforts to achieve these objectives. However, given the early stage of implementation, much of the early findings in this summary relate to the initial strategy effectiveness (to date), design, and relevance. Further points of analysis will assess implementation and sustainability in more detail. However, this early stage highlighted questions around implementation and sustainability that will be tracked over the course of the evaluation and likely affected by expected changes to the market-shaping approach by Gavi through the updated Supply and Procurement Roadmap. Preliminary results at this early stage indicate varying degrees of progress toward the four market-shaping strategic objectives.

### RAPID INNOVATION AND INCREASE IN CCE SUPPLIERS TO TWO PER SEGMENT

CCEOP has significantly increased attention to the CCE market -generating high levels of country awareness of and demand for better technology from countries and rapid market response from CCE suppliers. Prior to CCEOP approval in 2015, there were six manufacturers

of ILRs, now there are seven with platform-eligible CCE. For SDDs, there were four suppliers, now there are seven platform-eligible equipment manufacturers. Both categories of CCE have seen sharp increases in available models in all size segments. Prior to CCEOP's launch in 2015, there were seven devices that would have been platform-eligible for both solar-driven and on-grid refrigerators and freezers, now there are over 60. The first set of desired equipment innovations set via the target product profiles for future platform eligibility was incorporated into devices on the market well before the 2019 target and suppliers continue to expand their product offerings in line with enhanced performance.

### SLOW PROGRESS ON PRICE REDUCTION TARGETS FOR EQUIPMENT

Despite early achievements on product innovation and availability, progress toward price reduction targets for equipment has been less rapid. While CCE prices have decreased by 3.5 percent overall since the launch of CCEOP, decreases have not been consistent across all suppliers. This situation reveals a tension in the strategy between the expectation for innovation alongside price reductions; if suppliers are investing in performance, it may not be reasonable to expect immediate price reductions, especially until procurements reach higher volumes. Further, the individual, country-specific tender process reduces opportunities to achieve volume-based discounts that would be anticipated through pooled procurement. Additionally, in many cases countries are selecting higher-priced products. This selection may be due to brand familiarity/current installed equipment base and/or the availability of specific characteristics, but it also reflects difficulty accurately comparing device options with different characteristics and some lack of price sensitivity on the part of countries.

### BARRIERS TO ENTRY FOR NEW SUPPLIERS

Early outcomes have also revealed barriers to entry for newer suppliers who are trying to gain a foothold in a market that prior to CCEOP has historically been dominated by two manufacturers. While new entrants' prices may be set to drive competition, country preferences are frequently based on criteria other than price, including brand awareness and the installed base of equipment already in a country. This situation is further complicated by the service bundle component, as it requires suppliers to have a network of local partners, which favors more established suppliers or may mean that less experienced suppliers are making large assumptions in their budgets, potentially inflating service bundle costs to account for uncertainty and risk.

### IMPROVED INFORMATION FLOW AND TRANSPARENCY

Information flow and transparency among partners, countries and manufacturers have made progress under CCEOP. Gavi, UNICEFSupply and Programme Divisions), and WHO have all been cited by stakeholders for their efforts to coordinate and improve information sharing between themselves, countries, suppliers, and service bundle providers. The UNICEF-led industry consultations and efforts on price transparency have improved data accessibility. Less progress has been made toward improved information flow on product performance from the field, but this is not surprising given that as of the writing of this report in mid-November 2018,

first deployments were only underway for seven countries and deployments complete in only five countries[6].

### OVERALL ON THE RIGHT TRACK TOWARD GOALS

The effects of market-shaping activities typically take several years to be fully understood.. For an undertaking of the size and scope of CCEOP, it is expected that early experience and learning will lead to course correction and programmatic adjustments. The challenges with the market-shaping strategy seen to date seem to be well understood by many stakeholders. Already changes have been made to the country application process and UNICEF tendering process, which should positively affect future market outcomes. Further, the forthcoming update to the Supply and Procurement Roadmap for CCE from Gavi is likely to address many of the initial limitations and challenges reflected in this summary. Over the three-year period of the evaluation, JSI will be following the progress of the CCEOP market-shaping strategy and updating insights based on ever-changing market dynamics. This preliminary assessment indicates that while adjustments are warranted, the overall strategy is sound and appears to be on the right track toward the overall goals.

## LEARNINGS FROM DISSEMINATION

To date, findings from the baseline reports have been shared to date in Kenya with the NVIP, and members of the PMT, the LTWG, and other members of the immunization Technical Working Group. Feedback from the group was used to clarify concepts and roles such as the role of the PMT, to confirm findings such as the involvement of the sub-national level in the CCEOP planning and implementation process, and to make changes to the midline HFA tool, (for example in clearly outlining the definition of breakdown). Some suggestions for changes in the language used in the baseline findings report were also made which will be noted in an annex to the baseline report. Feedback on the utility of the dashboard to be developed as part of this evaluation, including the availability of data on selected indicators, was also received.

# RECOMMENDATIONS

## COUNTRY LEVEL

Recommendations for both the PMT and Gavi based on the baseline assessment findings by country are proposed below. In some cases, a single recommendation is aligned with a number of findings. As such, they are organized according to the broad themes of the evaluation questions that are addressed in this baseline assessment.

| | Kenya | Pakistan | Guinea |
|---|---|---|---|
| **APPLICATION PROCESS** | | | |

[6] Deployments complete in: Haiti, DRC1, Pakistan, Djibouti, and Liberia. Deployments underway in Kenya, South Sudan, Niger, Sierra Leone, Uganda, Malawi, and Togo as of November 19, 2018.

| | Kenya | Pakistan | Guinea |
|---|---|---|---|
| **Finding 1:** The application was based on country priorities, available data through information systems, and from cold chain inventory | X | X | X |
| **Finding 3**: High level of stakeholder engagement but limited role beyond the national level | X | X | X |
| **Finding 4:** Complex application process with lack of clarity on cost, clearance, warranties and other issues | X | | |
| **Finding 5**: CCEOP application was closely aligned with Gavi guidelines | X | X | X |

The CCEOP application requirements are effective at guiding country decision-makers to analyze the true need of CCE for the country and plan the Gavi-supported equipment appropriately. No recommendation for revision of the analysis process and data required for CCE model selection and planning.

**Recommendation**: At the country level, improve the coordination mechanism and engagement approach as much as possible, recognizing the constraints of sharing information across multiple partners, layers of the health system, and geographic areas. Gavi could consider adding in another layer of required review by sub-national level stakeholders during the proposal and operational deployment plan process, demonstrated on the application itself. To more thoroughly involve stakeholders from all levels will require more level of effort and potentially more financial requirements during the application process to ensure the sub-national level is engaged in the planning and discussion of the application preparation and development of the ODP.

The model of using consultants to support the application process was seen as very successful in helping participants understand the processes, requirements and documentation, and may be encouraged. A consultant could provide two advantages. A consultant could act as a central coordinating point and does not put an added work burden on anyone else.

**Gavi Recommendation:** Consider adding another layer of required review to the application process by sub-national levels. Greater orientation on the process from proposal development to implementation and on the different actors to be involved would be very useful.

**PMT Recommendation:** Continue to involve stakeholders from all levels of the health system is an important aspect for all program activities, beyond CCEOP application and deployment. Identify processes for engagement of all stakeholders and areas to strengthen this aspect.

| APPROPRIATE OVERSIGHT THROUGH THE PMT | | | |
|---|---|---|---|
| **Finding 2**: The PMT plays an active role in CCEOP deployment and coordination | X | X | |

**Recommendation:**

The CCEOP Guidance provides clear expectations of the PMT in terms of roles and responsibilities. The PMT should continue to meet regularly to monitor progress of SBP

| | Kenya | Pakistan | Guinea |
|---|---|---|---|
| performance, CCE installation, and performance. An area to explore is how the PMT aligns with the LTWG (where available) for continued monitoring after the end of the CCEOP project as there is an overlap of roles, responsibilities and people involved in both groups. Naturally, the LTWG would continue monitoring performance of the CCE and the supply chain in general once the CCEOP deployment and the role of the PMT are complete. This expectation could be clarified during development and implementation of the CCEOP. Strengthening the LTWG through the management practices established through the PMT will contribute to the 'leadership' fundamental of the Gavi iSC Strategy.<br><br>**Gavi Recommendation:** Consider how to strengthen the LTWG through the PMT for long-term on-going monitoring.<br>**PMT Recommendation:** Consider the processes established by and for the PMT and how to incorporate those into regular monitoring and management of the supply chain through the LTWG. | | | |
| **OVERALL SYSTEM STRENGTHENING** | | | |
| **Finding 6:** Concern that staff are not well prepared to handle the new equipment | **X** | **X** | **X** |
| **Finding 10:** Need for overall system strengthening | **X** | **X** | **X** |
| **Recommendation:** The CCEOP is significantly contributing to strengthening certain components of the immunization system by procuring optimal CCE, requiring a strong PMT, and requiring a maintenance plan, as examples. However, it must be recognized that the overall system still needs to be strengthened: training for health care workers on temperature monitoring on how to use Fridge Tag; CCE maintenance and the resources (i.e., vehicles, fuel, per diem, available spare parts) required to ensure reliable maintenance; regularly updated CCE inventory; clear standard operating procedures for CCE maintenance; a reliable distribution system that ensures vaccines are available at the facility level; and financial flows that are reliable and consistent, as examples. CCEOP is designed to contribute to all five fundamentals of the Gavi strategy, but is more advanced in its implementation than others (leadership, data for management and system design, for example). This is something to be aware of—to continue to support the other fundamentals as a mechanism to ensure performance of the CCE.<br><br>**Gavi Recommendation**: Continue to emphasize the link to other supply chain fundamentals and to support efforts in those areas.<br>**PMT Recommendation**: Annual planning and proposal preparation should support the entire system including a reliable and funded CCE maintenance system, reliable and efficient vaccine distribution, an updated inventory of trained and competent facility staff. | | | |
| **STRUCTURE OF THE SERVICE BUNDLE PROVIDERS** | | | |

| | Kenya | Pakistan | Guinea |
|---|---|---|---|
| **Finding 7:** Mixed feelings and confusion about the SBP approach | **X** | | **X** |
| **Recommendation:** Consider different approaches to the SBP model that are more adapted to the country context, capability, and type of equipment to install. Adopt an approach that still maintains high expectations for quality and timeliness of equipment installation. Additionally, it is recognized that this is a new approach for manufacturers, so it is expected that the pricing of the SBP should stabilize after the initial CCEOP countries have equipment deployed. Kenya will provide an appropriate example that compares installation of CCEOP equipment done by SBP with World Bank equipment installed by the MOH. The results of this on-going evaluation will also provide insight into the successes and challenges of the SBP approach to further guide the design of CCEOP.<br><br>**Gavi Recommendation**: Learn from the SBP model and incorporate feedback into the future design of the SBP taking into account alternative approaches. Work with UNICEF Supply Division to assess the capability of SBPs more thoroughly before selection. Continue to support and monitor maintenance systems across all CCE once the role of SBPs comes to an end.<br>**PMT Recommendation**: Continue providing feedback to Gavi on experiences with SBP. | | | |
| **PREPARING FOR IMPLEMENTATION AND DEPLOYMENT** | | | |
| **Finding 8:** Changes to operational deployment plan | | **X** | |
| The guidelines for the ODP clearly state the requirement for an accurate ODP and the costs related to any deviation in the plan. Stakeholders from all countries understood this requirement and planned as accurately as possible, yet changes are inevitable.<br><br>**Recommendation:** Continue to emphasize the importance of an accurate deployment plan.<br><br>**Gavi Recommendation:** None.<br>**PMT Recommendation**: Ensure the deployment plan is accurate with the most up-to-date information available. | | | |
| **EXPECTED OUTCOMES** | | | |
| **Finding 9:** Expectations of improved efficiency of equipment, and of the cold chain system, especially of temperature monitoring systems. | | | |
| **Recommendation**: Support the country (PMT, LTWG, logisticians, etc.) to continue to monitor equipment performance to assess the reliability and appropriateness of the equipment, including the overall system and its impact on the system and the immunization program.<br><br>**Gavi Recommendation:** Continue to support country-led systems to monitor equipment performance to enable the feedback loop to manufacturers for improved technology. | | | |

| | Kenya | Pakistan | Guinea |
|---|---|---|---|
| **PMT Recommendation:** Continue to monitor performance of the equipment and its impact on the overall cold chain system and immunization program. | | | |

## MARKET-SHAPING

A word that was used consistently about CCEOP across the first phase of the evaluation from key informant interviews was “transformational.” As with any undertaking of the size and scope of CCEOP that seeks to be transformational, fine-tuning and course corrections are to be expected. This summary is meant to provide an early snapshot of the outlook in anticipation of continued learning over the next few months to reflect changes to many of the initial elements of market-shaping. This includes a forthcoming update to the Supply and Procurement Roadmap for CCE from Gavi, which is likely to address many of the initial limitations and challenges reflected in this summary. Additionally, based on changes to the country application and supplier tender/bidding process, results from the next wave of equipment tenders will yield an additional data set on procurement outcomes which may also change the preliminary findings in this report.

Later stages of the market-shaping evaluation will explore many of the questions raised by early trends observed around pricing (both CCE and the service bundle), the risk of the duopoly to the supplier landscape, impact of procurement decisions to date on future innovation, and longer-term sustainability of the CCE market. The evaluation team will continue to follow these trends and the CCEOP trajectory toward the market-shaping objectives and include experiences with the service bundle implementation and product experiences.

Based on the initial review, the evaluation team developed the following recommendations for Gavi and partners:

- Determine how Gavi and UNICEF can balance the CCEOP market-shaping goals of market diversification with the commitment to country choice. Is there a way to promote market entry or selection of multiple/new suppliers for countries that may be hesitant to switch from a brand they are familiar with? How can this be done equitably and transparently in a way that fosters competition?

- Consider different options for the service bundle mandate. The complexity and varying contexts within Gavi countries may require further assessment of the service bundle mandate, particularly if there are countries or components of the service bundle where the full “white glove” service bundle adds excessive costs and decreases a sense of government ownership. Another option is to decouple procurement of equipment and service bundles to allow suppliers to bid on one or the other or both or to waive the service bundle requirement if certain criteria are met. It is likely that a variety of approaches may be needed to address different contexts and types of CCE, but CCEOP

will need to experiment with and learn from implementation of these different approaches.

- Promote better cost estimates for both CCE and service bundle costs to allow better country decision-making. Early country experience reflected price discrepancies between CCE selected and price of what was received because of changes in the CCE prices and the service bundle costs; how can Gavi improve data flow to allow better estimates and planning?

- Determine how to gather data on field performance over the longer term and incorporate these data into CCE selection process. While the early innovation targets have been achieved, product performance appears to be de-emphasized in market-shaping monitoring. In addition to product price, it may be appropriate to benchmark on performance, product characteristics, or estimated TCO. This approach, coupled with actual performance feedback, can help to understand the true cost of the product over its lifespan. An understanding of the true cost allows the system to better take into consideration innovation and performance elements that may be reflected and justified in a higher purchase price.

- Update CCE market assessment and incorporate a market sustainability approach. Based on initial experience with CCEOP, it is important to take a more nuanced look at what the right number of CCE manufacturers is in this market—two is generally regarded as too few, but eight may be too many for all segments. 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. It will also be important to consider the state of the market post-CCEOP, in the absence of Gavi funding.

# NEXT STEPS

Midline evaluation reports will be drafted for Kenya and Pakistan by February 2019. These reports will focus on assessing the CCEOP implementation process and answering the appropriate post-CCEOP implementation evaluation questions on effectiveness and efficiency as outlined earlier in Table 4. Because of delays in deployment of CCEOP in Guinea, the completion of the midline assessment in Guinea will take place three months later than planned in February 2019 with a report finalized in Q2 2019. Endline reports in 2020 will focus on effectiveness and efficiency of CCEOP and any changes to outcomes/results. As the case with the baseline country evaluation reports, analysis presented in the midline and endline reports will rely on the same data sources used in the baseline—document review, KIIs, health facility assessment data, and routine immunization and logistics data as appropriate to answer the relevant questions. The analysis will examine any changes seen in CCE, vaccine logistics and immunization practices in relation to the CCEOP implementation.

For the market-shaping evaluation, the JSI team will use the next wave of procurement data through Q4 2018 and additional partner and supplier interviews to add to this initial analysis of market outcomes and develop a comprehensive report in early 2019. This report will cover many of the changes that have already and are expected to be implemented following the release of the revised Supply and Procurement Roadmap by Gavi. The report will include information gathered from comprehensive manufacturer interviews to ensure their experience with CCEOP is reflected. It will explore many of the questions raised by early trends observed around pricing (both CCE and the service bundle), the risk of the duopoly to the supplier landscape, impact of procurement decisions to date on future innovation, and longer-term sustainability of the CCE market. Later reports will continue to follow these trends and the CCEOP trajectory toward the market-shaping objectives and include country experiences with the service bundle implementation and product experiences.

# REFERENCES


Gavi. no date. Gavi Market Shaping Framework. https://www.gavi.org/about/market-shaping/

Gavi. 2017. “Gavi 2015–2020 Immunization Supply Chain Strategy: Mid-Strategy Review.”

Gavi 2017a. CCEOP. Operational Deployment Guideline for Countries. Available at https://www.gavi.org/library/gavi-documents/guidelines-and-forms/cce-op-operational-deployment-plan/

Institut National de la Statistique/Guinée and ICF International. 2013. Guinée Enquête Démographique et de Santé et à Indicateurs Multiples (EDS-MICS) 2012. Rockville, Maryland, USA: Institut National de la Statistique/Guinée et ICF International.

Institut National de la Statistique (INS), Programme National de Lutte contre le Paludisme (PNLP) et ICF. 2017. Enquête de prévalence parasitaire du paludisme et de l’anémie en Guinée 2016. Rockville, Maryland, USA : INS, PNLP et ICF. https://dhsprogram.com/pubs/pdf/FR332/FR332.pdf

Kenya EVM Assessment 28 October–30 November, 2013: Findings and Recommendations of the Assessment Team.”

Ministère de la Santé de la République de Guinée, Programme Elargi de Vaccination/ Soins de Santé Primaire (PEV/SSP). 2016. Plan Pluri Annuel Complet (PPAC) 2016-2020.

National Bureau of Statistics-Kenya and ICF International. 2015. “2014 Kenya Demographic and Health Survey.” Rockville, Maryland, USA: KNBS and ICF International. https://dhsprogram.com/pubs/pdf/fr308/fr308.pdf

National Institute of Population Studies (NIPS) [Pakistan] and ICF. 2018. Pakistan Demographic and Health Survey 2017–18. Islamabad, Pakistan, and Rockville, Maryland, USA: NIPS and ICF. https://dhsprogram.com/pubs/pdf/PR109/PR109.pdf

National Vaccines and Immunization Program (NVIP). 2016a. “Kenya National Cold Chain Inventory: Results and Reports.” Ministry of Health, Government of Kenya.

World Health Organization. 2015. Effective Vaccine Management Assessment Report, Pakistan.

World Health Organization. 2016. Guinea: WHO and UNICEF estimates of immunization coverage: 2016 revision- http://www.who.int/immunization/monitoring_surveillance/routine/coverage/en/index4.html- accessed on February 15, 2018.

# ANNEX 1: MARKET SHAPING OBJECTIVES AND TARGET OUTCOMES

**Source:** *Gavi, Supply and Procurement Roadmap for ILR & SDD Cold Chain Equipment, August 2016, Restricted Version*

The following are the critical issues identified in each strategy objective area arising from the Market

Overview, as well as the Target Outcomes under each objective.

1. **Balance Supply & Demand**

   **Critical Issues to Address:**
   - *Production of quality products by existing & 'new' suppliers to meet demand in product segments*
   - *Availability of quality products at site of use*

   **Strategic Objective:**

   Stimulate supply to meet demand for higher-performing, cost-effective and quality products

   **Target Outcomes:**
   a) At least 2 suppliers of ILRs and SDDs in each size segment that are PE
   b) Market access barriers created by service bundle requirement addressed in the short term through increased information and guidance to suppliers on in-country logistics and service landscape

2. **Cost of CCE**

   **Critical Issues to Address:**
   - *Leverage of volume and funded demand to achieve price discounts relative to current prices*
   - *Price optimization of PE products, especially for SDDs*
   - *Control of in-country service bundle costs*

   **Strategic Objective:**

   Achieve fair and sustainable prices for both devices and commissioning service bundles

   **Target Outcomes:**
   a) **For ILRs:** 10% or greater price reductions in existing weighted average prices achieved for ILRs

b) **For SDDs:** 15% or greater product price reductions achieved through cost and value-based negotiations
c) **For service bundle**: Cost of service bundle further benchmarked and controlled
d) Cost-effective models for local service provision and maintenance incentivized

### 3. Innovation of high performing CCE at use site

**Critical Issues to Address:**

- *Establishment of (new) product quality standards including additional functionality promoting higher field performance*
- *Insufficient industry incentives to meet future TPP standards*
- *Information on CCE field performance used to ensure robust products available at sites and in supply market*

**Strategic Objective:**

Continuously innovate high performing, optimal TCO CCE products

**Target Outcomes:**

a) Manufacturers adopt 2017/2019 TPPs by end of 2017
b) Product improvements, with optimal TCO, achieved as a result of functional feedback loop on product field performance findings

## D. Information Sharing

**Critical Issues to Address:**

- *Lack of or non-transparent flow of information on demand and supplier products*
- *Lack of information on and familiarity with logistics and technical services landscape in target countries*

**Strategic Objective:**

Share information with stakeholders

**Target Outcomes:**

a) Suppliers offer locally customized service bundles in response to information on product and service markets
b) CCE prices lowered within CCE size segments through CCE price transparency