INTERNAL AUDIT REPORT

Cold Chain Equipment Optimisation Platform (CCEOP) March 2023



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Conclusion

Our audit procedures were designed to provide assurance to management and the Gavi Board on the design and operating effectiveness of the key controls in the processes related to Cold Chain Equipment Optimisation Platform (CCEOP) including the cold chain equipment market shaping strategies.

Gavi established the Cold Chain Equipment Optimisation Platform (CCEOP) in June 2015 as a strategic and targeted approach to address the challenges of improving the vaccine cold chain with higher performing Cold Chain Equipment (CCE). Functional CCE is a critical input to strengthening immunisation supply chains and immunisation programmes and contributes to supporting the Alliance's coverage and equity goal, ultimately reaching more children with lifesaving vaccines, and protecting them against deadly diseases. The initial CCEOP programme was a \$250 million co-investment funding scheme over the 2016-2020 Gavi strategic period (with 2017-2021 as the procurement period) and aimed at improving the availability and installation of high-performing CCE in Gavi-supported countries, particularly for health facilities. CCEOP addresses the supply and demand for optimal CCE, generation of demand by countries for technologically innovative and appropriate CCE, and stimulation of the market to respond to that demand with affordable and accessible equipment. The success of the CCEOP in improving countries' cold chains has led to the continuation of the CCEOP platform into the 2021 – 2025 Gavi strategic period ('Gavi 5.0').

We noted that management has well understood the risks associated with the CCEOP processes and implemented necessary controls to mitigate them. Some of the key controls include well defined policies and procedures to govern the CCEOP and market shaping processes, defined healthy market framework, market shaping roadmap, market shaping action plan tracker, CCEOP forecasts, and independent and multi-year evaluation of CCEOP investment among others.

However, we identified some medium risk rated issues related to delays in the process from CCEOP application approval to deployment. Other medium risk rated issues are summarised below.

Summary of Key Audit Issues

Ref Description	Rating*
1.1 Time taken from CCEOP Application Approval to Deployment in-Country	
Enhance the monitoring of lead times from CCEOP application submission, review and approval, sourcing to final deployment in-country to promptly identify and address the root causes of delays in the process.	
1.2 Performance Monitoring and Reporting	
Enhance CCE performance monitoring and data feedback loops at both country and global level.	
1.3 Clarity of Roles and Responsibility	
Define a roles and responsibilities matrix for all stakeholders involved in the CCEOP processes.	
1.4 Monitoring of the Market Shaping Roadmap	
Consistently monitor the Ice-lined Refrigerators/Freezers (ILR) and Solar Direct Drive (SDD) roadmaps.	

^{*} The audit ratings attributed to each section of this report, the level of risk assigned to each audit finding and the level of priority for each recommendation, are defined in annex 2 of this report.

1. Summary of issues

Through our audit procedures, we have identified four medium risk issues relating to the CCEOP processes as summarised below:

1.1 Time taken from CCEOP Application Approval to Equipment Deployment in-Country

Enhance the monitoring of lead times from CCEOP application submission, review and approval, sourcing to final deployment in-country to promptly identify and address the root causes of delays in the process.

We selected a random sample of 11 CCEOP applications processed under Gavi 4.0 from the CCEOP milestones tracker. The average number of days taken from application approval (decision letter) to purchase order placement was 255 days. From the sample, the average number of days taken from application approval to completion of CCE deployment was 635 days for a 1-year, 2-year or 3-year grant.

Although there are various reasons for delays in the CCEOP process, monitoring of lead times from application submission, review and approval, sourcing to final deployment in-country needs to be enhanced.

Delayed delivery of CCE in country may result in delays in achieving programmatic objectives.

1.2 Performance Monitoring and Maintenance of Deployed CCE

Enhance CCE performance monitoring and data feedback loops at both country and global level.

UNICEF, in collaboration with Partners, has developed a Post Installation Inspection (PII) Protocol to measure the quality of installation and the functionality of Cold Chain Equipment. The inspections are geared towards looking at equipment Deployment, Installation and Functionality, Temperature Monitoring Devices (TMD), Training and Availability of User Manuals. Gavi has developed the Intelligent Maintenance and Planning Tool (IMPT) which leverages real time temperature monitoring data to understand performance of equipment already deployed in countries. Beyond the PII reports and with IMPT still in development, we observed that there was limited CCE performance monitoring and maintenance data to inform decision making at the Secretariat level.

For instance, we were unable to obtain any updates and data on the CCE inventory in-country and the functional status, the CCE maintenance history and procedures, and the CCE warranty coverage. The Market Shaping and HSIS teams have identified performance monitoring as a priority and area of improvement under Gavi 5.0.

Programmatic objectives may be negatively impacted by failure to implement a robust process for monitoring the performance, functional status, and maintenance data of the CCE equipment to ensure that the equipment is always operating optimally.

1.3 Clarity of Roles and Responsibility

Define a roles and responsibilities matrix for all stakeholders involved in the CCEOP processes.

The CCEOP team has defined the CCEOP processes from grant application to CCE deployment at a high level and detailed the processes that are Gavi-led and those that are UNICEF-led. Additionally, the market shaping team has within the Icelined Refrigerators/Freezers (ILR) and Solar Direct Drive (SDD) roadmap action plan detailed out the teams or partners that are responsible for or are supporting the various market shaping activities. Although these roles have been broadly defined in the MOU and market shaping roadmap action plan, additional clarity needs to be provided on roles and responsibilities within end-to-end CCEOP processes. We recommend that management prepares role matrices for all stakeholders that clearly define who is Responsible, Accountable, Consulted, and Informed in the Cold Chain Equipment Optimisation Platform processes.

Failure to establish clear roles and responsibilities in complex processes such as CCEOP (which cut across various teams and organisations) may lead to delays and inability to establish responsibility and accountability for key KPIs.

1.4 Monitoring of the ILR and SDD Market Shaping Roadmap

Consistently monitor the ILR and SDD roadmaps.

Gavi's market shaping roadmap is a foundational tool of the Alliance's market shaping strategies for vaccines and immunisation-related products (including cold chain equipment). It articulates the long-term view of how the Alliance would like to see the market evolve. The ILR and SDD market shaping roadmap summarises the Alliance's market shaping strategy for ILR and SDD refrigerators/freezers market. It includes the market shaping objectives and target outcomes, and the set

of Alliance partner agreed upon interventions to reach these objectives and target outcomes. We noted that the ILR and SDD roadmap action tracker used to monitor implementation of the interventions is carried out on an annual basis. However, some items within the tracker are not consistently updated.

Failure to implement a robust process for tracking key actions of the ILR and SDD roadmap may lead to undue implementation delays thereby impacting the achievement of market shaping objectives.

2. Background

The Gavi Cold Chain Equipment Optimization Platform (CCEOP) was established in recognition that functional cold chain equipment (CCE) is a critical precondition to strengthening vaccine supply chains and ultimately, to achieving the Alliance's immunisation equity and coverage goals, yet it was a gap in many countries.

In 2015, the Gavi Board approved CCEOP and included a specific market shaping component to improve the availability and installation of high-performing, innovative CCE. Through CCEOP, Gavi pledged \$250 million dollars over five years (Gavi 4.0, 2016 to 2020) to be jointly invested with countries to support 55 countries to upgrade and expand their CCE footprint. In support of this, Gavi launched a CCEOP market shaping strategy to stimulate the market for optimal CCE while generating the demand in Gavi-supported countries to rapidly replace obsolete cold chain equipment and expand immunisation services.

The success of the CCEOP support in improving countries' cold chains led to the continuation of the CCEOP platform into the 2021 – 2025 Gavi strategic period ('Gavi 5.0'). An additional \$150M investment in CCEOP was pledged bringing the total CCEOP investments from 2016-2025 (Gavi 4.0 and Gavi 5.0) to \$400M.

Implementation of the CCEOP under Gavi 4.0 commenced in early 2016 with the first country applications recommended for approval in March and November 2016 and procurement began in September 2017. UNICEF SD is the procurement agency for the CCEOP.

CCEOP has significantly increased attention to the CCE market - generating high levels of awareness of and demand for better technology from countries and rapid market response from CCE suppliers. As of 2022 there were seven suppliers with platform eligible fridges/freezers (ILRs and SDDs) namely: B Medical, Haier Biomedical, Vestfrost A/S, Dulas Limited, Coolfinity, Godrej (using SureChill technology), and Aucma. CCE suppliers with the largest market share based on CCE units procured are B Medical (38%), Haier Biomedical (31%) and Vestfrost A/S (24%).

As at 31 December 2022 UNICEF (for the period 2017 to 2022) had procured 74,080 refrigerators and completed 65,315 installations at a total investment of \$244M. The breakdown of refrigerators procured included 31,192 Ice Lined Refrigerators (mains generators) and 42,888 Solar Direct Drive (SDDs).¹

Under Gavi 5.0, some aspects of CCEOP have been redesigned. These include; CCEOP applications integrated into full portfolio planning; use of new application kits to streamline requirements from countries; use of the 3-preference procurement approach to move towards meeting cold chain technical and program requirements; and stronger emphasis on mobilisation of non-Gavi resources at country level.

3. Objectives and Scope

3.1 Audit Objective

The audit focused on assessing the design and operating effectiveness of key controls in the processes related to CCEOP (including the cold chain equipment (CCE) market shaping strategies).

3.2 Audit Scope and Approach

We adopted a risk-based audit approach informed by our assessment of the system of internal controls. Our audit approach included:

- Review of applicable policies and guidelines including Gavi market shaping strategy, CCEOP market shaping
 framework, CCEOP market shaping roadmap and supporting documents, Gavi Application Process Guidelines, CCEOP
 budget template, CCEOP Operational Deployment Plan, CCEOP Technical & Target Requirements, CCE Technology
 Guide, Guidance on Procurement of Vaccine & CCE, Gavi Procurement Policy, Gavi Procurement Manual, Board
 papers and Board minutes. The audit assessed whether the current design and processes with regards to CCEOP
 processes met the expectations and requirements set out in these documents.
- Review of relevant documents for a sample of Gavi countries.
- Interviews with market shaping team members including Senior Manager, Strategy Development & Tenders
- Interview with HSIS team member CCEOP focal point
- Interviews with Finance team members including CCEOP finance support

¹ UNICEF GAVI KPI Q4 Report

Process areas explicitly carried out by UNICEF were not in scope. The following areas were excluded from the audit scope (i.e., either they have been covered in other audits or have a distinct risk profile):

- CCE procurement and supply to countries.
- Process of developing and finalizing operational deployment plans.
- Service contract management.
- COVAX cold chain equipment related applications, review, and approval processes

We will continue to work with management to ensure that these audit issues are adequately addressed and required actions undertaken.

We take this opportunity to thank all the teams involved in this audit for their on-going assistance.

Head, Internal Audit

Annex 1 - Methodology

Gavi's Audit and Investigations (A&I) audits are conducted in accordance with the Institute of Internal Auditors' ("the Institute") mandatory guidance which includes the Core Principles for the Professional Practice of Internal Auditing, the Definition of Internal Auditing, the Code of Ethics, and the International Standards for the Professional Practice of Internal Auditing (Standards). This mandatory guidance constitutes principles of the fundamental requirements for the professional practice of internal auditing and for evaluating the effectiveness of the audit activity's performance. The Institute of Internal Auditors' Practice Advisories, Practice Guides, and Position Papers are also adhered to as applicable to guide operations. In addition, A&I staff adhere to A&I's standard operating procedures manual.

The principles and details of the A&I's audit approach are described in its Board-approved Terms of Reference and Audit Manual and specific terms of reference for each engagement. These documents help audit staff to provide high quality professional work, and to operate efficiently and effectively. They help safeguard the independence of the A&I's staff and the integrity of their work. The A&I's Audit Manual contains detailed instructions for carrying out its audits, in line with the appropriate standards and expected quality.

In general, the scope of A&I's work extends not only to the Secretariat but also to the programmes and activities carried out by Gavi's grant recipients and partners. More specifically, its scope encompasses the examination and evaluation of the adequacy and effectiveness of Gavi's governance, risk management processes, system of internal control, and the quality of performance in carrying out assigned responsibilities to achieve stated goals and objectives.

Annex 2 – Definitions: Audit rating and Prioritisation

Issue Rating

For ease of follow up and to enable management to focus effectively in addressing the issues in our report, we have classified the issues arising from our review in order of significance: High, Medium, and Low. In ranking the issues between 'High', 'Medium' and 'Low', we have considered the relative importance of each matter, taken in the context of both quantitative and qualitative factors, such as the relative magnitude and the nature and effect on the subject matter. This is in accordance with the Committee of Sponsoring Organisations of the Treadway Committee (COSO) guidance and the Institute of Internal Auditors standards.

Rating	Implication
High	At least one instance of the criteria described below is applicable to the issue raised:
	Controls mitigating high inherent risks or strategic business risks are either inadequate or ineffective.
	The issues identified may result in a risk materialising that could either have: a major impact on delivery of organisational objectives; major reputation damage; or major financial consequences.
	The risk has either materialised or the probability of it occurring is very likely and the mitigations put in place do not mitigate the risk.
	Management attention is required as a matter of priority.
	Fraud and unethical behaviour including management override of key controls.
Medium	At least one instance of the criteria described below is applicable to the issue raised:
	Controls mitigating medium inherent risks are either inadequate or ineffective.
	The issues identified may result in a risk materialising that could either have: a moderate impact on delivery of organisational objectives; moderate reputation damage; or moderate financial consequences
	 The probability of the risk occurring is possible and the mitigations put in place moderately reduce the risk.
	Management action is required within a reasonable time period.
Low	At least one instance of the criteria described below is applicable to the issue raised:
	Controls mitigating low inherent risks are either inadequate or ineffective.
	The Issues identified could have a minor negative impact on the risk and control environment.
	The probability of the risk occurring is unlikely to happen.
	Corrective action is required as appropriate.