

AUDIT REPORT

Vaccine Supply Chain Management processes
2021



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1. Executive Summary

1.1. Audit opinion

Gavi's Immunisation Supply Chain Strategy (iSC strategy) was approved by the Board in June 2014. Supply chain improvements were a critical part of the Alliance's 2016–2020 Strategy (Gavi 4.0), identified explicitly under the objectives for the second strategic goal to 'increase the effectiveness and efficiency of immunisation delivery as an integrated part of strengthened health systems.'

The iSC strategy included five fundamentals for immunisation supply chains: (i) Supply chain leadership, (ii) Continuous improvement plans, (iii) Supply chain data for management, (iv) Better cold chain equipment; and (v) Supply chain system design.

The strategy envisioned that progress in-country across five interwoven fundamentals would lead to the transformational changes sought under Gavi's 2020 iSC vision, "*that immunisation supply chains will efficiently provide potent vaccines to all*". This vision supported the broader Alliance goal of continuing to introduce new vaccines and increasing coverage and equity, to reduce under-five mortality and improve overall health outcomes across countries.

Overall audit opinion:

Our audit procedures were designed to provide assurance to management and the Gavi Board on the design and effectiveness of the controls in the processes related to vaccine and supply chain management with a focus on the immunisation supply chain strategy.

The audit team assessed the design and operating effectiveness of controls relating to the vaccine and supply chain management processes to be as "**partially effective**," which means, "*Internal controls and risk management practices were generally established and functioning but needed improvement. One or more high- and medium-risk areas were identified that may impact on the achievement of the entity's objectives.*"

We identified two high risk issues relating to the governance and oversight over the iSC strategy; and the need to better balance the synergy and sustainability of Gavi's investments across the fundamentals.

To address the risks associated with the issues, the audit team raised ten recommendations of which five were rated as high priority. We note that most of these recommendations are already being implemented as part of the current finalisation of the 5.0 strategy and its accompanying M&E framework.

1.2. Summary of key audit issues

| Ref | Description | Rating* | Page |
|-------|---|---------|------|
| 1.3.1 | Improving governance and oversight over the iSC strategy | ■ | 4 |
| 1.3.2 | Better balancing the synergy and sustainability of Gavi's investments | ■ | 4 |
| 1.3.3 | Closing gaps in the monitoring framework for iSC strategy | ■ | 5 |

* The audit ratings attributed to each section of this report and the level of risk assigned to each audit issue are defined in annex 3 of this report.

1.3. Summary of issues

Through our audit procedures, we identified two high and two medium priority issues relating to the vaccine supply chain management processes. These are summarised below, including the last finding which regroups the two medium issues.

1.3.1 *Improving governance and oversight over the iSC strategy*

The 2015 immunisation supply chain strategy¹ was the first Gavi Alliance-wide strategy developed to address vaccine supply chain challenges. The design of the governance and oversight processes included a task force with representatives drawn from the Gavi Alliance partners.

The cascade of responsibilities associated with this strategy, across the various levels of implementation at Secretariat, regional and country levels, was not defined or tracked. This meant that: (i) strategic decisions made at the global level regarding the strategy were not linked to regional and country activities; (ii) progress was not monitored or compared across the various regions and sub-regions; and (iii) the standard package of activities was not defined. In some instances, the inter-dependencies from activities implemented by partners and/or extended partners were not realised, or other dependent activities were delayed because prior activities were not completed on time. For some countries, the in-country leadership's accountability was not sufficiently defined on supply chain matters. Annual reviews of the implementation plan were not completed, and the task force did not sufficiently focus on programmes' performance against the defined fundamentals.

Improving governance and oversight over the iSC strategy would enable the Gavi alliance to demonstrate accountability for and/or achievement of iSC strategic goals.

1.3.2 *Better balancing the synergy and sustainability of Gavi's investments*

By the end of 2020, Gavi had invested approximately US\$435 million in Partners Engagement Framework (PEF)/Targeted Country Assistance (TCA) support and a further US\$230 million directly via the cold chain equipment optimisation platform. Additional HSS investments supported other iSC focus areas including supply chain, data, leadership and programme development.

Sustainability and scale-up measures were not embedded within some iSC investments. For example, the investment in cold chain equipment Investments focused on replacing or adding additional cold chain units rather than considering the longer term, centred around principles of efficiency, sustainability and optimisation of the supply chain. While regular maintenance of cold chain equipment was needed in order to assure proper functionality over useful economic life, there was little visibility over how countries discharged their cold chain maintenance responsibilities. While most countries sampled for our review provided a maintenance plan, in practice there was no documentation or KPI to demonstrate that routine maintenance was done.

Long-term sustainability measures could help to demonstrate the return on investments over time and how they contribute to overall strategic goals, as reflected in the iSC fundamentals. For example, reengineering supply chain processes centred around a dynamic logistics system that considers country challenges such as reliable internet and electricity can enable vaccines to be managed more efficiently, while reducing transaction and handling costs.

Investments in training faced challenges as the Ministries of Health's abilities to maintain and sustain their human capital, including individuals trained using Gavi resources, were often eroded due to high levels of staff attrition and mobility. Reductions and turnover in human resource capabilities affected several countries' ability to sustain such iSC activities.

¹ ['Strengthening the Immunisation Supply Chain'](#), May 2016

Synergies across different Gavi investments and other implementing partners' activities were not always leveraged. For example, activation of immunisation modules in existing logistics management systems where possible would improve Gavi's catalytic investments. Furthermore, Gavi's investment focus needs to rebalance and emphasise the linkages cross-cutting between ISC fundamental areas.

Balancing synergies and addressing known sustainability gaps would improve the long-term value for money from such investments.

1.3.3 Closing gaps in the monitoring framework for the iSC strategy

The measurement framework for the supply chain strategy was developed and finalised as part of the process to establish indicators and targets for the Gavi 2016-2020 strategy (Gavi 4.0). However, information provided through the Effective Vaccine Management (EVM) assessments was varied in timing, and expected improvements were not reported accurately or consistently. Indicators included in the country Grant Performance Framework (GPF) did not provide accurate information to Gavi. Data generated in-country and reported by different sources was not linked within Gavi to provide complete and accurate information on the availability, potency and efficiency of vaccines across countries.

Headline indicator definitions kept changing over the strategic period with no linkages to previous definitions in addition to changes to fundamentals' target definitions leading to fragmented reporting and difficulties in assessing the achievements of the ISC strategy.

Closing the gaps in the monitoring framework would enable measurement through consistent indicators and enable measurement of progress against approved indicators.

Gavi management agrees with the recommendations made in the audit. We will continue to work with management to ensure that these audit issues are addressed and required actions undertaken. The status of implementation of recommendations will be reported to Gavi's Audit and Finance Committee.

Audit and Investigations

2. Objectives and Scope

2.1 Audit Objective

The objective of this audit, as approved by the Audit and Finance Committee (AFC) in 2020, was to assess the adequacy and effectiveness of the controls relating to vaccine supply chain management processes, with a focus on Gavi's 2016-2020 immunisation supply chain strategy (ISC).

2.2 Audit Scope and Approach

Our audit approach was risk based, informed by our understanding of Gavi's business, governance, risk management processes and internal control systems, as well as our assessment of the risks associated in this area.

Our approach included:

- Review of relevant documentation to understand and walkthrough the key processes, risks and mitigations;
- Assessment of the design of the key processes/controls that manage the key inherent risks;
- Testing (on a sample basis) the operationalization of key processes;
- Assessment of the quality of implemented governance and risk management process; and
- Reporting on any observations, good practices and opportunities for improvement.

The audit focused on the planning, implementation and reporting of the "Gavi Alliance immunisation Supply Chain strategy" as approved by the Board in June 2014. Our review covered the strategy's implementation between 1 January 2016 and 31 December 2020, and a sample of ten countries was selected for detailed reviews. These countries were: Burkina Faso, DRC, Ethiopia, Guinea, India, Kyrgyzstan, Mali, Nigeria, Pakistan, and Tanzania. Specific areas covered included a review of the countries': grant applications and renewals, PEF TCA applications, joint appraisal reports, grant performance framework, as well as other relevant reports. This was to examine the process of how vaccine supply chain needs are identified, alignment of country gaps with the strategic objectives, and how strategic results were tracked across countries, including the extent to which the ISC results achieved sustainability. We also referenced various prior findings from programme audits undertaken in Burkina Faso, DRC, Ethiopia, Guinea, Nigeria, Pakistan and Tanzania.

While this review focused on the 4.0 strategic period, the lessons learned that have been incorporated into Gavi 5.0 strategic direction were considered in the formulation of our audit recommendations.

The scope of the audit also considered prior and ongoing reviews linked to the supply chain processes. The following key areas were reviewed:

- The planning process for the immunisation supply chain strategy;
- Operationalisation and implementation of the ISC strategy including changes or shifts, since 1 January 2016; and
- Monitoring and reporting on the 4.0 strategy including roles and responsibilities of the Gavi Alliance partners with a focus on Gavi's role.

This audit also considered various aspects of Gavi's Cold Chain Equipment Optimization Platform (CCEOP), which is an integral part of the supply chain. However, the platform was not covered in detail given that it is subject to A&I review during 2022.

3. Background and context

3.1. Evolution of the immunisation supply chain strategy (2007 to 2014)

The Gavi Alliance has a shared goal of saving lives and protecting people's health by increasing equitable and sustainable use of vaccines. Ensuring that vaccines reach the intended recipients requires effective immunisation supply chains that move vaccines and other supplies from the point of manufacture to the point of administration. By 2020 Gavi-eligible countries were projected to require twice as many vaccine products as in 2010;² the volume of vaccines was projected to increase four times (from 70 to 280 cubic cm per child);³ and the number of doses was projected to increase six times.⁴ This growth would increase the annual cost of supply chains by two-and-a-half times, and the new vaccines that are being introduced were five times more expensive per dose than existing vaccines.⁵

Various analyses by WHO and UNICEF between 2007-2012 indicated that immunisation supply chains failed to deliver potent vaccines evidenced by frequent vaccine stock-outs⁶, encountered freezing temperatures in vaccine transport⁷, had storage locations that lacked refrigerators or had inappropriate equipment⁸. Most countries' systems did not meet Effective Vaccine Management (EVM) standards as per the EVM global data analysis (2009-2018). Meanwhile, new vaccine introductions continued to put more value and volume into the supply chain, with country-demand for new vaccines projected to grow dramatically by 2020. As a result, Gavi-eligible countries were projected to be required to manage four times the volume of vaccines and six times the number of doses. This would place significant, additional pressure on under-performing and under-funded immunisation supply chains. It was recognised that action was needed to address the challenges identified and improve performance, so that immunisation coverage continues to increase, equity improve, and health impacts be realised.

The need for a stronger focus on the immunisation supply chain emerged as a priority in the change process that took place in Gavi during 2012. At the beginning of 2013, a taskforce consisting of WHO, UNICEF, the Bill & Melinda Gates Foundation (BMGF) and the Secretariat was formed to carry out an analysis of the vaccine supply chain drawing on the extensive previous work across the Alliance and to map the end-to-end processes, culminating in formulation of a strategy framework.

The taskforce presented a strategy framework to the Programme and Policy Committee (PPC) in October 2013 and the resultant Gavi's Immunisation Supply Chain (iSC) strategy was approved by the Board in June 2014.

The objectives of the iSC strategy were to:

- a) ensure availability of the right vaccines and supplies;
- b) maintain vaccine potency; and
- c) use resources efficiently.

A Gavi Supply Chain Strategy Implementation Plan was developed in November 2014 covering the period 2015-2020.

² "Stock keeping units." Gavi Procurement / SDF v8; 2010: estimates based on 2009 product line-up; 2020: estimates based on 2013 forecasted product line-up.

³ [UNICEF Supply Division Annual Report 2012](#), page 16.

⁴ 2010: UNICEF Supply Division shipment data; 2020: Gavi SDFv8 forecast. Includes volume for countries which graduate during this period.

⁵ Comparison based on 2013 price; 2020 vaccines include: Rota, PCV; HPV; 2010 vaccines include: YF, Measles, DPT, OPV. UNICEF SD.

⁶ WHO and UNICEF Immunisation Summary database country profiles provide detail of stock outs.

⁷ [Freezing temperatures in the vaccine cold chain: A systematic literature review](#) Matthias Dipika et al.

⁸ [Cold supply for hot demand](#) Gavi, the Vaccine Alliance, 2018

3.2. Development and implementation of the iSC strategy (2014 to 2020)

The iSC strategy identified five immunisation supply chain focus areas or building blocks, each with goals/objectives to be achieved by 2020. These “fundamentals” were established as:

1. Supply chain leadership: By 2020, countries have dedicated and competent immunisation supply chain leaders with adequate numbers of skilled, competent, accountable, motivated, and empowered personnel at all levels of the health system to overcome existing and emerging immunisation supply challenges.
2. Continuous improvement plans: By 2020 all Gavi-supported countries have developed and are implementing a comprehensive immunisation supply chain management plan based on robust evidence and have incorporated it in their national immunisation plans, resourced it through HSS or other funding and reflected it in comprehensive Multi Year Plans (cMYPs). Target was EVM scores of 80% across all countries with no country performing below 60%.
3. Supply chain data for management: By 2020 all Gavi countries are using data to oversee and manage key aspects of their immunisation supply chain, specifically around availability of vaccines at the service delivery level, storage and transport conditions, and efficiency of stock management, and can measure improved performance.
4. Better cold chain equipment: By 2020, the right equipment is in the right place as countries have adopted new technologies that better meet their needs—providing adequate vaccine storage for current and planned vaccines, decreased maintenance requirements and lower running costs. Robust equipment management systems are in place.
5. Supply chain system design: By 2020, 10 countries have followed an evidence-based design process which has resulted in improvements in supply chain effectiveness and addresses sustainable management of vaccines and other health commodities.

The strategy’s hypothesis was that if Alliance partners supported countries to strengthen the fundamentals, then EPI programmes will better reach the strategic objectives— i.e., ensuring that potent vaccines are available and delivered more efficiently. The Alliance also noted that because supply chain redesign is challenging and requires significant investment in infrastructure and change management, the iSC strategy proposed to engage in interagency efforts in a small number of countries. Strategic advocacy would play an increasingly important role for an enabling immunisation supply chain environment.

In parallel and following the approval of iSC strategy, the Gavi Cold Chain Equipment Optimization Platform (CCEOP) was also established in 2015 (launched and approved in 2016) 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.

CCEOP was created to expand the reach of enhanced cold chain technology and thus increase the effectiveness and efficiency of immunisation supply chains and the sustainability of coverage and equity in immunisation programs. At the country level, CCEOP provides phased support to selected countries for up to a maximum of five years. The initial support phase addresses the most urgent CCE needs for the first one to two years (e.g., where there are the highest risks to vaccine stocks or the greatest bottlenecks to coverage and equity). The second scale-up support phase allows the country additional time to further elaborate and fine-tune its long-term CCE needs over the next three to five years. CCEOP seeks to address both the supply and demand side for optimal CCE, generate demand for technologically innovative appropriate CCE, and stimulate the market to respond to that demand with affordable and accessible equipment.

Through CCEOP, the Alliance initially committed US\$250 million over five years to support 55 countries to upgrade and expand their CCE footprint, while simultaneously stimulating the market to provide affordable, technologically advanced, and accessible equipment. Two further countries were added to this list later in 2019. The CCEOP approach was guided by Gavi's immunisation supply chain strategy, given it provided an end-to-end perspective of the supply chain, while emphasising the five supply chain fundamentals (namely: supply chain leadership, continuous improvement plans, supply chain data for management, CCE, and supply chain system design).

3.3. iSC mid-strategy review 2017

In June 2017, the Gavi Alliance's immunization Supply Chain Steering Committee (iSC2) initiated a mid-point strategic review to consider progress to date and make informed adjustments to the strategy for the remaining 2018-2020 period. The mid-strategy review identified three key challenges that needed to be addressed to reach the iSC 2020 targets. These were:

- a. **Insufficient linkages between fundamentals** – The fundamentals had been dealt with individually rather than as a whole, both at the global level (e.g., fundamental-specific working groups) and in-country (prioritization of fundamentals considering capacity constraints);
- b. **Gaps within fundamentals** – In addition to interdependencies, most of the fundamentals faced specific challenges that need to be addressed and some in-country stakeholders suggested additional fundamentals or pieces missing from Gavi's iSC strategy and implementation plan (e.g., demand generation, waste management);
- c. **Limitations in the ways of working** – Several factors external to the content of the iSC strategy, at both country and global levels, compound the difficulties in a) and b) These factors included national and sub-national interactions, steering committees, funding processes, the composition of the iSC2 committee itself, and the lack of a dedicated backbone organization to help manage logistics and coordinate partners.

The mid-strategy review made three key recommendations to the iSC2 committee as follows:

- **Balance across fundamentals** – Rebalance emphasis from cold chain equipment to all five fundamentals, particularly data for management (D4M) and boost the linkages between fundamentals, beginning with D4M and Leadership;
- **Enhance iSC Strategy Targets & Tracking** – Reconfirm the iSC targets amongst partners, including the approach to effectively tracking Gavi board indicators and establish on-going tracking of the iSC strategy to inform the iSC2 committee and those to whom the iSC2 committee is accountable; and
- **Focus & Coordinate Country Support**- Support country governments, based on identified need, to progress iSC gains in Data for Immunization Supply Chain (DISC), Effective Vaccine Management (EVM) action plans, and availability, potency, and efficacy.

At the end of September 2020, the Gavi Board had also approved US\$150 million for COVID 19 vaccine delivery support for AMC92 economies. This allocation of core resources was made available for CCE and TA support to the 56 Gavi-eligible countries (priority) and additional AMC92 economies (on a case-by-case basis).

3.4. Development of the Immunisation Supply Chain strategy 2.0

During the audit, the Gavi secretariat was engaged in completing its revised iSC strategy and implementation plan for the next strategic period. This was done to align the second phase, iSC 2.0 with the Gavi 5.0 strategy

and to address lessons learned. While the draft iSC 2.0 implementation plan and HSS specialists' service package were shared with the audit team near the end of our review, these documents were still under discussion and were not yet approved. Furthermore, the lessons learned from iSC1 could not be included during the current "full portfolio planning process" given that country planning under the existing Gavi 5.0 period was significantly delayed due to the Covid-19 pandemic resulting in several no cost extensions being granted to countries for their Gavi 4.0 funding. Where possible, the audit report indicates recent changes and events that were discussed, but which did not form part of our review.

4. Key achievements and good practices

Strategic focus on iSC activities: During the strategic period 2016 to 2020, Gavi dedicated 28.5% (US\$270 million) of its HSS investments to strengthening immunisation supply chains. This was a significant increase, when compared to the two prior strategic periods. For the prior period 2011-2015, comparable investments totalled US\$183 million (18.5% of HSS), and before that for 2006-2010, investments totalled US\$21 million (equivalent to 4% of HSS)⁹. In general, Gavi integrates its iSC interventions within a range of grants including HSS, CCEOP, PEF TCA and Strategic Focus Areas (SFA) funding. This demonstrates a willingness to support cross-cutting interventions that accelerate the effective implementation of healthcare services including immunisation. PEF TCA support disbursed to all ten of the countries sampled in the audit included a supply chain component aligned to the iSC strategy.

Timely and critical investment in country CCE capacity through CCEOP: The Gavi Cold Chain Equipment Optimization Platform (CCEOP) was established in 2015, recognising 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. At the global level, CCEOP includes a specific market-shaping component to improve the availability and installation of high-performing CCE, underscoring the need to ensure that the market for CCE is healthy, and that countries are procuring optimal, yet durable and high-performing products. At the country level, CCEOP provides phased support to selected countries for up to a maximum of five years. By the end of 2020, Gavi had invested approximately US\$230 million in the Cold Chain Equipment Optimization Platform (CCEOP) across 50 countries and had commissioned 53,892 pieces of cold chain equipment. These amounts exclude any additional funds invested by the country as part of their country joint investment contribution. The iSC Mid-Term Strategy Review noted that the "Better Cold Chain" fundamental was more advanced than the other fundamentals, due to the scale of the CCEOP allowing countries like DRC to move from 36% of health facilities with functioning CCE at baseline to 80% with CCEOP support. This investment was also timely, as for eight out of the ten countries sampled for this review, it was indicated that the CCEOP investments were instrumental in helping manage the influx of Covid-19 vaccines. Specific findings on Gavi's CCE investment will be reported in the separate CCEOP audit.

Activities in the iSC strategy have contributed to achieving impact in immunisation programs: Gavi investments have enhanced in-country health systems and supported implementation of immunisation interventions. The interventions conducted by countries, with support from the Gavi Alliance and its partners, increased countries' effective vaccine management (EVM) assessment scores. Across Gavi's portfolio, while all areas improved their EVM scores, notable progress was seen in storage capacity (E3) and vaccine management, knowledge, aptitude, and practices (E8) – both averaging scores above 80% (the recommended minimum threshold for optimal performance). These two areas align with Gavi Alliance's investment priorities, notably the CCEOP platform, which significantly impacted upon countries' cold chain capacity. Areas such as Infrastructure (E4) and temperature management (E2) have also seen improvement in their average score, indirectly benefiting from the investments associated with storage capacity, and concomitant better management of equipment¹⁰. We also noted that eight out of the ten sampled countries showed improvements in their composite EVM scores.

In Ethiopia, Gavi funded an expansion of the country's Health Commodity Management Information System so as to integrate the vaccine supply chain into the Ethiopian Pharmaceuticals Supply Agency (EPSA) systems. EPSA currently manages the distribution of vaccine and supplies to 96% of the country. Gavi also supported CCE maintenance training for 56 biomedical engineers from Oromia, SNNPR and Addis Ababa at the Zonal and

⁹ Presentation on "A brief introduction to Immunisation Supply Chain – May 2020"

¹⁰ Draft Gavi iSC strategy 2021-25

Hospital level, and cold chain user training for 750 immunisation providers and their supervisors from districts and health facilities from Oromia, Addis Ababa and Somali regions.

In India, Gavi funded two governmental institutes to develop the “National Cold Chain & Vaccine Management Resource Centre (NCCVMRC)” at Delhi and the “National Cold Chain Resource Centre (NCCRC)” at Pune. These two apex institutes were charged with managing all activities related to immunisation supply chain-cold chain, especially for training of various cadres of cold chain and logistics staff. Gavi also supported capacity building of critical Human Resources through the development of a cold chain handlers training module and conducted state and national level trainings. 1,800 staff were trained on cold chain management, supportive supervision, management information systems and EVM. The Electronic Vaccine Intelligence Network (eVIN) platform funded by Gavi, also formed the basis for subsequent development of the CoVIN platform used as an essential tracking tool for the national Covid-19 pandemic response, used both to register people, as well as to track and issue Covid vaccines.

In Mali, 16 EPI managers from the regions and the central level were trained from the regional institute, LOGIVAC in Benin. In DRC, two storage hubs were built at Kinkole and Kisangani.

The above interventions illustrate how the implementation of immunisation activities is often associated with the country’s delivery of health care. This was especially noted during the Covid-19 pandemic where an increase in Gavi support enabled countries to expand their capacity and manage Covid vaccines although significant capacity challenges remain.

Innovations around supply chain investment: The Strategic Training Executive Programme (STEP) is a training initiative launched in 2015 by Gavi with United Parcel Service (UPS) and supported through Leadership, Management and Coordination (LMC). It was designed as an innovative, executive training programme on leadership, targeting high-level immunisation supply chain managers in Low- and Middle-income countries. In its first phase, 171 participants from 16 African countries (and Pakistan) participated in the programme between 2015-2018. In its second phase, STEP 2.0, the programme has been outsourced and is being aligned to the Gavi 5.0 approach with a focus on the subnational level and will be delivered through partnering with regional institutions such as LOGIVAC in Benin and the Rwanda Centre of Excellence. In DRC, another innovation through Village Reach involves piloting the delivery of vaccines using drones to 25 Health Zones in the Equatorial Province with an extension being planned across two further provinces. Issues around scalability and sustainability of such innovations still need to be addressed as further detailed in section 5.2.

Countries were provided with guidance to access iSC funding: The Gavi Alliance aligned its support and processes to effectively catalyse supply chain changes in countries. For instance, Gavi’s guidance to countries on the importance of transformational supply chain investments was clarified as part of the Health Systems Strengthening (HSS) application process. Changes to country guidance were complemented with similar changes in Gavi’s policies and processes to ensure that these aligned with the iSC strategy. In May 2018, Gavi also provided revised country guidance on aligning Gavi investments with achieving immunisation outcomes¹¹. We reviewed 71 grant applications for the ten sampled countries and noted that the identification of country needs, and any gaps associated were properly aligned with the iSC strategy objectives.

¹¹ [Programming guidance - Supply Chain](#)

Annexes

Annex 1 – Acronyms

| | |
|--------|--|
| AFC | Audit and Finance Committee |
| BMGF | Bill & Melinda Gates Foundation |
| CCE | Cold chain equipment |
| CCEOP | Cold Chain Equipment Optimization Platform |
| cMYP | comprehensive Multi Year Plan |
| D4M | Data for Management |
| DISC | Data for Immunization Supply Chain |
| EPI | Expanded programme for Immunisation |
| EVM | Effective vaccine management |
| HSS | Health systems strengthening |
| iSC | Immunisation supply chain |
| iSC2 | Immunisation Supply Chain Steering Committee |
| KPI | Key performance indicator |
| LMC | Leadership, Management and Coordination |
| PEF | Partners Engagement Framework |
| PPC | Programme and Policy Committee |
| SFA | Strategic Focus Area |
| STEP | Strategic Training Executive Programme |
| TCA | Targeted Country Assistance |
| UNICEF | United Nations Children’s Fund |
| WHO | World Health Organization |
| USD | United States Dollars |

Annex 2 – 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 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.

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 our auditors to provide high quality professional work, and to operate efficiently and effectively. They help safeguard the independence of the A&I's auditors 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 Gavi 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 3 – Definitions: opinion, audit issue rating

A. Overall Audit Opinion

The audit team ascribes an audit rating for each area/section reviewed, and the summation of these audit ratings underpins the overall audit opinion. The audit ratings and overall opinion are ranked according to the following scale:

| | |
|--------------------------------------|---|
| Effective | No issues or few minor issues noted. Internal controls, governance and risk management processes are adequately designed, consistently well implemented, and effective to provide reasonable assurance that the objectives will be met. |
| Partially Effective | Moderate issues noted. Internal controls, governance and risk management practices are adequately designed, generally well implemented, but one or a limited number of issues were identified that may present a moderate risk to the achievement of the objectives. |
| Needs significant improvement | One or few significant issues noted. Internal controls, governance and risk management practices have some weaknesses in design or operating effectiveness such that, until they are addressed, there is not yet reasonable assurance that the objectives are likely to be met. |
| Ineffective | Multiple significant and/or (a) material issue(s) noted. Internal controls, governance and risk management processes are not adequately designed and/or are not generally effective. The nature of these issues is such that the achievement of objectives is seriously compromised. |

B. 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 finding raised: <ul style="list-style-type: none"> 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 finding raised: <ul style="list-style-type: none"> 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 finding raised: <ul style="list-style-type: none"> 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. |