INTERNAL AUDIT REPORT

In-country Governance Mechanisms May 2025



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1. Conclusion

Our audit procedures were designed to review the adequacy, effectiveness, and sustainability of in-country governance mechanisms for Gavi-supported immunisation programmes, and provide assurance on the Gavi Secretariat's impact and influence on them.

Over the last six years, the Gavi Alliance has consistently identified Country Management Capacity – which includes governance – as a top risk to achieving its objectives. Similarly, Gavi's 2024 annual risk and assurance report highlights how Leadership, Management and Coordination (LMC) support helps to enhance countries' EPI management capacity and mitigate the associated risks. Hence, Gavi's investments in LMC initiatives are considered a strategic enabler.

From our audit, we identified two high risk issues, firstly, the need for Gavi's governance interventions to be better targeted and differentiated within a comprehensive operational framework, and secondly that sustainability considerations be embedded into in-country governance arrangements. In addition, three medium risk issues were also identified.

To address the risks associated with the audit issues, the team raised seven recommendations of which two were rated as high priority.

1.1 Summary of Key Audit Issues

Description	Rating*		
Effectiveness of Gavi's support at strengthening countries' governance mechanisms.			
1.1 LMC needs to be integrated into the organisation's HSS strategy and operational guidelines			
Sustainability of in-country governance arrangements			
1.2 Embed sustainability into country coordination forums for post transition success			
Adequacy and effectiveness of in-country governance arrangements			
1.3 Inter-agency Coordination Committees (ICCs) are not appropriately structured to fulfil their coordination mandate			
1.4 EPI departments are not appropriately structured and resourced			
Gavi's monitoring arrangements over in-country governance mechanisms.			
1.5 In-country governance mechanisms are not adequately monitored			

^{*} The audit ratings attributed to each section of this report, the level of risk assigned to each audit issue and each recommendation, are defined in <u>Annex 3</u> of this report.

2. Executive Summary

2.1 Key achievements and good practices

Gavi's LMC approach helped strengthen national immunisation programmes' institutional capacity. As noted in Gavi's 2024 annual risk and assurance report, progress was observed in mitigating country management capacity risks, driven by the LMC support enhancing EPI management capacity in several countries, to develop solution-focused plans to increase absorption capacity, to improve financial reporting, to provide targeted interventions addressing backsliding in former Gavi eligible countries and Middle-Income Countries (MICs) fragility support.

In-country governance is embedded within Gavi's Programme Funding guidelines: Governance, policy, strategic planning, and programme management are all aspects demarcated in Gavi's Funding guidelines, which offer countries a menu of options to choose from.

Country Liaison Officers have been embedded within countries reflecting significant EPI management challenges. Approximately 20 Country Liaison Officers are currently appointed, typically functioning in a bridging role facilitating exchanges and communication between Gavi and EPI management. This allows LMC service providers to focus on building in-country capacity.

2.2 Summary of issues

Through our audit procedures, we identified five issues (two high and three medium significance) and developed seven recommendations to address areas where management can do more. The significant issues are summarised below.

2.2.1 Leadership, Management and Coordination (LMC) needs to be integrated into the organisation's HSS strategy and operational guidelines

Gavi's current guidance on LMC is not sufficient to address the full range of countries' needs. Some of these needs include: bridging gaps in management capabilities, managing change processes associated with decentralisation and health reform, or navigating the transition process.

The menu of LMC options developed in 2015 has not been consistently deployed. Moreover, because funding for LMC initiatives is spread across multiple Gavi funding levers, this prevents a concerted analysis and understanding of the overall focus, magnitude and impact of investments to date, including how governance arrangements were strengthened.

As a consequence, LMC initiatives may not achieve intended results, due to the lack of consistency and coherence across their design and their use of funding sources, depending on how countries' requests are framed. To date, LMC funding has primarily focused on strengthening the Expanded Programmes on Immunisation (EPI), with significantly less emphasis on improving institutional governance capacity. Furthermore, there is a lack of clarity regarding what qualifies as LMC, and its criteria and definition.

2.2.2 Embed sustainability into country coordination forums (typically an ICC) for post-transition success

The scope of Inter-agency Coordination Committees (ICCs), as the primary immunisation governance mechanism, is often quite narrow with their focus being on reviewing and approving Gavi grant applications. Hence few ICCs are linked or anchored within broader health sector committees. In addition, the audit team

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noted that frequently governance arrangements for the immunisation programme post-transition were not considered by stakeholders as part of the measures to prepare and plan for the migration of the programme fully under national leadership.

The ICC concept was originally designed in the context of polio programmes and early self-financing countries. Gavi's leveraging of the mechanism has sometimes resulted in the ICC becoming closely associated with Gavi support, which can result in the governance function being put at risk, after disruptive events such as health reform, or following transition resulting in the ICC being considered redundant.

Consequently, ICCs risk becoming non-functional once a country transitions out of Gavi support, as was the case for Vietnam. Furthermore, both accelerated transition countries that the audit team reviewed (Nigeria and Kenya) did not yet consider arrangements for their EPI's governance and oversight post-transition.

3. Background and Context

3.1 Governance

The World Health Organization (WHO) describes health systems governance as the processes, structures, and institutions that oversee and manage a country's healthcare system. This involves managing relationships between various actors and stakeholders, including government agencies, healthcare providers, patients, communities, civil society organisations, and private sector entities. Effective health systems governance helps to ensure that strategic policy frameworks exist and that these are combined with oversight, coalition-building, appropriate regulations and incentives, system design, and accountability.¹

There are several interconnected components for governance to be successful, including: (i) clarity of purpose, roles, and behaviours; (ii) defining principles underpinning frameworks, policies and procedures; (iii) clear strategic vision, leadership and decision making; (iv) effective external relationships; (v) internal relationships; (vi) transparency and public reporting; (vii) systems and structures including compliance frameworks and risk management processes; (viii) challenging whether agreed outcomes are delivered.²

Consequently, Gavi's development of in-country governance focuses on strengthening key components such as: leadership and coordination; policy and strategy; resource allocation; monitoring and evaluation; community engagement; and capacity building.³ To examine the multi-layered aspects of in-country governance mechanisms, we simplified this into three main parts, as follows: framing (legal form and regulations); coordination, oversight and relationships; and programme management (including managerial and operational aspects of governance). See Annex 4 for an illustration of the interplay of these aspects.

3.2 Governance and immunisation

Gavi's draft Health Systems Strategy (December 2024) notes that there is a strong correlation between the strength of governance, leadership, management and financing for immunisation and the equity and sustainability of immunisation programmes. This strategy is aligned with WHO's framework, with an emphasis on governance and leadership as being the core element, to which all other components are linked.

¹ Health Systems Governance - World Health Organization (WHO)

² The basics of good governance https://www.good-governance.org.uk/publications/insights/the-basics-of-good-governance

³ Leadership, management and coordination - GAVI

3.3 Gavi support for Governance – Leadership, Management and Coordination (LMC)

To achieve sustainable improvements in immunisation coverage and equity, countries must effectively plan, implement, and monitor their Expanded Programme on Immunisation (EPI), underpinned by robust national governance.

Consistently over the past six years, the Gavi Alliance has categorised Country Management Capacity risk, which encompasses governance, as a critical risk in achieving its goals. In conjunction with mitigating that risk, Leadership, Management, and Coordination (LMC) has been recognised as a key enabler since Gavi 4.0.

The LMC approach was designed by Gavi in 2015-16 to strengthen national immunisation programmes' leadership, management and coordination capacity, based on a gap assessment of the key areas which constituted a risk to achieving of the Gavi 4.0 objectives. A workshop of experts in December 2015 identified suitable interventions, with partners subsequently designing a menu of support to deliver the greatest catalytic impact on EPI delivery. Gavi's LMC support is largely provided through both core alliance and expanded partners, including via PEF TCA.

The importance of LMC was reaffirmed when formulating the Gavi 5.0 strategy. Leadership and effective management are explicitly referred to: under the Equity goal (objectives 1 and 2); and under the Sustainability Goal, given that efforts to strengthen coordination are implicit in anchoring of Gavi's work in a Primary Healthcare framework (Objective 2). In addition, there are further references to strengthening immunisation system performance management for transitioning, post-transition, and Gavi eligible Lower Middle-Income Countries (Objective 3). This underscores the fact that in many countries, governance deficiencies remain a significant risk to the achievement of Gavi 5.0 overall goals.

3.4 Inherent challenges

In-country execution risk is inherent in the Gavi Alliance mission given its ambitious objectives – supporting some of the weakest and most fragile states in immunising children, while navigating management capacity and systems challenges. Many countries continue to have difficulties managing competing EPI priorities. This includes weaknesses in areas such as leadership, stakeholder coordination, and programmatic and operational management, translating into barriers impacting upon programme delivery. Other factors – some of which are not within Gavi's control – comprise insufficient human resources for health, challenges in retaining key staff and external disruptions caused by instability, shocks or political change.

3.5 Development of the Gavi 6.0 strategy

The HSIS team is in the process of commissioning an evaluation of the Leadership, Management, and Coordination (LMC) support provided to countries during the 5.0 strategic period. This evaluation aims to identify critical adjustments to better address the evolving landscape for Expanded Programme on Immunisation (EPI) teams. It will be a retrospective review, covering the 2020 to 2025 period of implementation. It will assess LMC design elements and the operating model, with a focus on identifying key shifts needed for the 6.0 strategic period. The review will examine both positive and negative changes, intended and unintended, resulting from LMC interventions. Additionally, it will determine whether Gavi's LMC approach remains relevant in facilitating some of the key Gavi 6.0 shifts, particularly in terms of differentiation and programme sustainability.

4. Objectives and scope

4.1 Audit objectives

The objective of this audit was to review the adequacy, effectiveness, and sustainability of in-country governance mechanisms, and provides assurance on Gavi Secretariat's impact and influence on them.

The audit reviewed Gavi's investments in strengthening countries' capabilities through technical assistance and various LMC activities. It also examined other measures taken by Gavi to mitigate associated risks, including the organisation's monitoring and reporting of in-country institutional capabilities.

4.2 Audit scope

The audit team assessed:

- whether in-country governance arrangements are fit-for-purpose and effective in aiding Gavisupported immunisation programmes, to meet their programmatic objectives,
- the sustainability and resilience of in-country governance arrangements,
- the Gavi Secretariat's monitoring arrangements over in-country governance mechanisms; and
- the extent to which interventions by Gavi's partners and technical assistance providers are sufficiently targeted and differentiated to mitigate the country management capacity risk.

Our review covered the period spanning the Gavi 4.0 and Gavi 5.0 strategic periods. We also considered ongoing work in the development of the Gavi 6.0 strategy. A sample of eleven countries was selected for detailed review: two high impact (Nigeria and Ethiopia), three middle income countries (Angola, Indonesia and Vietnam), four core (Lao PDR, Congo Brazzaville, Mozambique and Kenya) and two fragile and conflict (Central Africa Republic and South Sudan).

Specific areas of in-country governance arrangement that were covered included their adequacy and effectiveness; their sustainability; effectiveness in strengthening initiatives funded by Gavi; and Gavi monitoring arrangements. We also referenced to various governance issues from past programme audits undertaken in the sampled countries.

Governance cannot be examined, nor can conclusions be applied wholesale, without considering each country's specific context. In addition, governance includes several cross-cutting and interlinked themes, including intractable issues associated with Governments' human resource constraints. We therefore limited our focus to delineating opportunities for improving in-country governance processes within Gavi's mandate. Although Gavi has no single definition for in-country governance, an illustration of what constitutes some of the main components is shown in Annex 4.

The audit did not cover aspects relating to Ministries of Health's political representation and legal form. Most cross-cutting governance components were also excluded, as well as the accountability and governance arrangements concerning civil society and the general public, which were considered beyond scope.

4.3 Audit approach

Our audit approach was risk-based, informed by our understanding of Gavi's business, governance, risk management processes, their internal control systems, as well as our assessment of the risks associated with this audit area. The audit was conducted through interviews, observations, documentation review, and by assessing the design and operating effectiveness of key controls and the governance and risk management processes.

The audit placed reliance on several past reviews including:

- Review of Gavi's Leadership, Management and Coordination approach (June 2021); and
- Relevant programme audits.

The recommendations from this audit focused on processes that Gavi can influence.

We will continue to work with Gavi management to ensure that these 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.

Director, Programme Audit

5. Annexes

Annex 1: Acronyms

CDD Country Delivery Department

EPI Expanded Programme for Immunisation

FPP Full Portfolio Planning

HSIS Health System and Immunisation Strengthening

ICC Inter-agency Coordinating Committee

IRC Independent Review Committee

LMC Leadership, Management, and Coordination

MEL Monitoring, Evaluation, and Learning

MICs Middle Income Countries

MoH Ministry of Health

PEF Partnership Engagement Framework
PPC Programme and Policy Committee

TCA Targeted Country Assistance

Annex 2: Methodology

Gavi's Audit and Investigations (A&I) audits are conducted in conformance with the Global Internal Audit Standards of the Institute of Internal Auditors. These Standards constitute 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' Global Guidance is also adhered to as applicable to guide operations. In addition, A&I staff adhere to A&I's Audit Manual.

The principles and details of 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 Audit Manual contains detailed instructions for carrying out 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 – 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
	At least one instance of the criteria described below is applicable to the finding raised:
	Controls mitigating high inherent risks or strategic business risks are either inadequate or ineffective.
High	 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.
High	 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.
	Fraud and unethical behaviour including management override of key controls.
	Management attention is required as a matter of priority.
	At least one instance of the criteria described below is applicable to the finding raised:
	Controls mitigating medium inherent risks are either inadequate or ineffective.
Medium	 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.
	At least one instance of the criteria described below is applicable to the finding raised:
	Controls mitigating low inherent risks are either inadequate or ineffective.
Low	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.

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Annex 4: In-country governance mechanisms

An illustration of in-country governance mechanisms relating to EPI programmes:

