

AUDIT REPORT

Gavi's transition processes
June 2024



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Conclusion

Our audit procedures were designed to provide assurance to management and the Gavi Board on the design and effectiveness of the controls and processes related to transition.

Central to the Gavi model is its unique approach to sustainability, the mobilisation of domestic public resources for vaccines, and the transition process away from Gavi support. To ensure such transitions are systematically and purposefully prepared for, the Gavi Alliance plans for early national engagement, sequencing of activities and prioritisation of appropriate technical support for countries identified for transition. The Alliance also planned to institutionalise some targeted, catalytic and time limited support for post-transition countries to ensure they can sustain their immunisation performance.

Based on this review, we identified four high risk issues relating to governance, accountability and monitoring processes supporting transition and the institutionalisation of post-transition support.

To address the risks associated with these issues, the audit team raised 13 recommendations of which six were rated as high priority. We note that some of these recommendations are already being implemented as part of the current finalisation of the Gavi 6.0 strategy.

Summary of key audit issues

Ref	Description	Rating*
	Governance, accountability and monitoring processes in support of transition.	■
1.1	Gavi's transition model needs a comprehensive strategy and operational framework	■
1.2	Ownership, coordination and oversight of the transition process need to be streamlined and better defined	■
1.3	The role of Gavi Alliance partners at central, regional and country level may not be aligned to the phase of transition	■
1.4	Improvements are required in monitoring of transition in countries	■
	Transition assessment and planning	■
1.5	Governance, oversight and implementation arrangements at country level need to be enhanced	■
	Institutionalisation of post-transition support	■
1.6	Post transition engagement support needs to be reviewed to support sustainability	■

* 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 [Annex 3](#) of this report.

1. Summary of issues

Through our audit procedures, we identified four high and two medium priority issues relating to transition processes and made 13 recommendations. The high-risk issues with high-risk recommendations are summarised below. While the summary below focuses on the opportunities for improvement within the current transition process, the details of challenges, complexities, including ongoing initiatives by management are provided in section 3 of this report. In addition, there are ongoing discussions related to further evolution of the transition model in the 6.0 strategic period that had not been approved/concluded at the time of reporting. During the audit, the team noted several achievements and good practices in relation to: co-financing and Gavi's model, alignment with the policy framework, and increased transition engagement with countries in accelerated transition, as well as middle income countries. Several of these achievements and good practices are further described in section 3.11 of this report.

1.1 Gavi's transition model needs a comprehensive strategy and operational framework

The current framework for Gavi funding to countries, funding policies and guidelines¹ do not provide sufficient and timely guidance on transition planning and programming.

Given the challenges across countries, different approaches were taken as they approached transition, with the Gavi Board approving specific strategies for particular countries². In parallel, some countries have recently requested a review of their eligibility status due to changes in their macro-economic environment, some of which are line with Gavi's updated Eligibility and Transition policy³. The Programme Policy Committee (PPC) also requested⁴ Gavi management to consider a holistic approach to transition.

To address known transition challenges, since 2023 Gavi has encouraged the development of country roadmaps for some accelerated transition countries with an aim to finalise such roadmaps for all countries in accelerated transition, ideally with the endorsement of their senior Government leadership.

Currently, there is a risk that countries currently in accelerated transition may not be successful after transitioning out of Gavi support.

Implementing a comprehensive strategy and operational framework, with defined responsibilities for Gavi, partners and Governments (Ministries of Health) would support the development and completion of activities and facilitate continuous accountability during the transition process. Further, beginning the transition planning during the preparatory transition phase would enable timely planning. This would help to achieve Gavi's sustainability goal, by empowering countries to be more invested in the future continuation of their immunisation programmes. The framework would also support the development and completion of country transition roadmaps.

The issues highlighted in this audit illustrate the challenges of helping countries establish robust, sustainable immunisation programmes, in anticipation of transition from Gavi support. Not all of these challenges can be resolved using Gavi's existing funding levers. Therefore, when developing its transition strategy and operational framework, Gavi should be clear on what is the Board's risk appetite for managing transition processes.

¹ Eligibility & Transition Policy Co-Financing Policy and Health System & Immunisation Strengthening (HSIS), Programme Funding Guidelines and Budget Eligibility Guide

² Countries like Nigeria, India and Papua New Guinea have received special Board approved strategies.

³ Countries like Timor Leste, Angola, Congo Brazzaville

⁴ PPC October 2021

1.2 Ownership, coordination and oversight of the transition process need to be streamlined and better defined

Within the Gavi Secretariat, the management and coordination of transition processes was not consistent across various departments, including mechanisms over accountability and oversight. Recent activities include monitoring transition preparedness, as well as the conduct of joint missions involving different teams engaged on transition roadmaps. Efforts have also been made to better define roles and responsibilities. While handbooks with defined roles and responsibilities exist, an improvement in the level of intervention and coordination between Country Programmes Delivery (CPD), Immunisation Financing & Sustainability (IF&S) and Health System and Immunisation Strengthening (HSIS) is required, for those countries nearing the end of their preparatory or accelerated transition, in order to improve alignment with the maturity model being developed as part of 6.0. Although initial steps have been taken to integrate transition processes into Gavi's grants through the Full Portfolio Planning (FPP) process, this needs further refinement as the audit team observed gaps in the transition planning in several of the countries' FPP applications⁵.

To ensure a consistent approach, the roles and responsibilities of Gavi Secretariat teams with respect to transition processes need to be streamlined, including establishing the required level of intervention for CPD, IF&S and HSIS with countries during preparatory and accelerated transition, as part of the operational excellence project and in preparation for the Gavi 6.0 strategic period. Furthermore, a robust oversight mechanism within the Secretariat should be established to ensure that the implementation of Gavi's transition strategy and operational framework is effectively monitored.

1.3 The role of Gavi Alliance partners at central, regional and country level may not be aligned to the phase of transition

Gavi Alliance partners' roles are not differentiated across the "transition continuum", with partners frequently maintaining substantial involvement in programme management and implementation throughout. Many countries which are in accelerated transition or receive post-transition support, including Health System Strengthening (HSS), experience their Gavi funding being channelled through the partners. While work to channel funding through government has been initiated, implementation remains slow. Additionally, technical assistance (PEF TCA) support does not significantly evolve following a country's entry into the accelerated transition phase and in some instances can result in diverting key expertise away from the Expanded Programme for Immunisation (EPI), thus undermining sustainability.

Clarification on guidelines encouraging the rechanneling of Gavi funds through Government and aligning technical assistance at the end of the preparatory transition phase with national ownership, will ensure that the immunisation programme is increasingly managed by the government before support is fully transitioned.

1.4 Improvements are required in monitoring of transition in countries

The Gavi Secretariat has reviewed different tools for their suitability. Whilst a number of different health system performance indicators exist, none give a complete picture, with most measuring a specific element of health systems. Also, no single, comprehensive tool exists to collect the various data points and information.

It is recognised and accepted by the Gavi Alliance that gross national income (GNI) as the main measure used for eligibility to Gavi support, is a useful indicator of the ability to pay, without portraying the country's actual level of health investment. Similarly, the coverage and cofinancing indicators only provide a snapshot of performance at national level, whereas to get a more complete picture of the health systems' performance via an equity lens, it is necessary to review performance at least at a regional level, particularly in countries where health is devolved and where such inequities exist.

⁵ For example, Kenya and Laos

There are ongoing efforts to incorporate programmatic capacity, as a component contributing to monitoring transition (alongside GNI). The ongoing strategic discussions on Gavi 6.0 provide an opportunity to address known programmatic transition challenges, and to define and establish other suitable indicators for measuring countries' performance during accelerated transition.

Transition roadmaps should be completed for all accelerated transition countries and promptly introduced when the country enters this final phase. Such roadmaps should remain streamlined, in order to support monitoring. In addition, they should be aligned to the maturity model, which is to be defined as part of the transition operational framework.

1.5 Governance, oversight and implementation arrangements at country level need to be enhanced and sustainable

While governance and oversight concerns go beyond transition processes, the transition period represents an opportunity to evaluate and potentially enhance the country's governance framework, in preparation for longer-term sustainability of the immunisation programme. However, the Gavi principle of country ownership is not always apparent during transition planning and assessment, in particular in respect of Inter-agency Coordinating Committee (ICC) arrangements and consideration of the impact of programme implementation arrangements.

The structure, composition and scope of many ICCs revolve around overseeing Gavi grants, rather than spanning the wider immunisation programme. None of the five accelerated transition (AT) countries reviewed by the audit team, had sufficiently determined that their governance and oversight arrangements were fit for purpose beyond transition. Furthermore, beyond their transition at least two of the self-financing countries reviewed experienced significant challenges, such as protracted vaccine stock-outs, due to changes in their implementation arrangements.

Gavi should encourage transitioning countries to redefine and consolidate the Ministry of Health's governance structures and bodies, for a holistic view over immunisation and health systems, rather than structures whose purview is limited to alignment with Gavi requirements.

1.6 Post transition engagement support needs to be reviewed to support sustainability

In the past, Gavi's post transition support did not always address programmatic challenges for transitioning countries, and no assessments were conducted to obtain insights into lessons learnt. Additionally, there were no progress assessments to assess which activities were successfully completed, in order to serve as a foundation for subsequent next steps and to guide the implementation of the Middle-Income Countries (MICs) approach.⁶

The design of the MICs approach primarily focuses upon introducing PCV, rotavirus, and HPV vaccines into national immunisation programmes – if not already the case – rather than addressing countries' programmatic gaps. This applies both to countries which have transitioned, as well as never Gavi-eligible countries. While the MICs approach has been expanded to provide technical assistance in addressing any potential backsliding in former Gavi-eligible countries given the impact of Covid-19 on immunisation, it is recognised that this assistance does not fully address programmatic needs, and as a consequence some gaps may persist jeopardising the sustainability of the immunisation gains achieved.

The Secretariat should ensure that any learnings from the current MICs approach are documented and presented to the Board for 6.0 deliberations. Gavi should also document and align its risk acceptance with the Board's risk appetite, in recognition that certain programmatic issues present in both accelerated transition and MICs countries will not be addressed through the existing design and technical assistance provided.

⁶ Programme audits in Angola, Vietnam and Indonesia demonstrated sustainability gaps in their Gavi post-transition engagement support.

2. Objectives and scope

2.1 Audit objectives

The objective of this audit was to provide independent assurance on the adequacy of the design and the operating effectiveness of the key controls related to transition processes.

2.2 Audit scope

The audit team assessed the various processes and management arrangements governing Gavi's transition processes to assess the effectiveness of governance, accountability and monitoring, for processes related to transition, transition assessment and planning, and institutionalisation of post-transition support.

Our review covered the implementation period between 1 January 2016 and 31 December 2023. We also considered ongoing work in the development of the Gavi 6.0 strategy. A sample of thirteen countries was selected for detailed review: two in preparatory transition (Congo-Brazzaville and Pakistan), five in accelerated transition (Djibouti, Kenya, Laos, Nigeria, and Papua New Guinea) and six self-financing countries (Angola, Bolivia, Cuba, India, Indonesia and Vietnam).

Specific areas covered under the country reviews included: grant applications and renewals, PEF TCA applications, joint appraisal reports, grant performance framework, as well as other relevant reports. This was to examine how transition needs are identified, whether there is alignment of country gaps with the strategic objectives, and how strategic results were tracked across countries, including the extent to which the transition results were achieved. We also referenced to various prior findings from programme audits undertaken in Angola, Indonesia, Kenya, Laos, and Vietnam.

The audit did not cover the eligibility and co-financing aspects of the Gavi sustainability model as these processes were reviewed as part of the 2021 internal audit of Gavi's "eligibility, co-financing and transition policy".

2.3 Audit 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 with the audit area. This audit was conducted through interviews, observations, documentation review, process walkthroughs, assessing the design and operating effectiveness of key controls and assessing the governance and risk management processes.

The audit placed reliance on several past reviews including:

- Cambridge Economic Policy Associates evaluation of Gavi's eligibility, transition and co-financing policies (October 2019);
- Gavi's funding policy review (2019);
- Gavi internal audit of eligibility, co-financing and transition policy (October 2021);
- Mid-term evaluation of Gavi's 2021-2025 strategy (ongoing); and
- Relevant programme audits.

The recommendations from this audit focused on processes that Gavi can influence. Some additional risks and challenges that may be out of Gavi's control are identified in section [3.9](#).

3. Background and Context

3.1 The history of eligibility and transition at Gavi

When Gavi was created in 2000, it offered five years of support for pentavalent and yellow fever vaccines to eligible countries. Eligibility was determined based on a Gross National Income (GNI) per capita below US\$ 1,000, a criterion met by 75 countries at the time. As GNI levels for four countries surpassed the US\$ 1,000 threshold within the initial years, Gavi ceased support to them⁷. By 2005, the anticipated reduction in the cost of the pentavalent vaccine had not materialised, and the Gavi Board recognised that countries needed additional time to assume responsibility for vaccine financing. Therefore, the Gavi Board made a commitment to continue vaccine support for the remaining countries (later known as the ‘GAVI73’)⁸ until 2015. This period was meant to allow for sustainable country-owned programmes and market shaping, given the importance of predictability of vaccine funding.

In 2009, following a review of the eligibility policy, the Board re-set the eligibility threshold at US\$ 1,500 GNI per capita and decided that countries above the eligibility threshold would be called “graduating countries”. Support for such countries would be phased out under “graduation procedures” which ensured that countries surpassing the threshold would continue to receive ongoing vaccine support until 2015, albeit without the opportunity to apply for new vaccines.

In 2010, as a basis for the graduation and co-financing policy, fiscal space analyses were undertaken and confirmed that phasing out of Gavi support over a five-year period, with annual increments in co-financing was viable for the initial cohort of graduating countries. The eligibility, graduation and co-financing policies became effective in 2011 with sixteen Gavi countries having GNI levels above US\$ 1,500 and Gavi started gradually phasing out its support to these countries. The co-financing policy was approved up to 2015, with a request from the Gavi board that the policy be reviewed in 2014 to assess the experience with implementation, particularly for graduating countries.

3.2 Evolution of the Eligibility and Transition (previously, graduation) policy

In April 2014, the Gavi secretariat initiated a review of its eligibility, graduation, and co-financing policies. In October 2014, initial insights from the review’s analysis and consultations were discussed with the Programme and Policy Committee (PPC). As a result in June 2015, the Gavi Board approved the new Eligibility and Transition policy effective 1 July 2015, which superseded the 2009 Eligibility and Graduation policies.

This new policy sets out the criteria and procedures determining which countries were eligible for Gavi support, as well as defining the transition pathway through which such support is phased out, ensuring that Gavi funding is aligned with its mission to focus support on lower-income countries. The policy underwent three revisions on 23 June 2016, 7 June 2018 and 1 January 2023 and utilises GNI per capita (p.c.) to determine eligibility for Gavi support. In 2023, the eligibility threshold for Gavi support was US\$ 1,730 GNI p.c. The threshold is updated annually, using the World Bank’s annual inflation adjustments of income categories. GNI p.c. is used to delineate the three successive phases of support to Gavi-eligible countries (transition phase): initial self-financing, preparatory transition and accelerated transition:

- A country remains in the initial self-financing phase while its GNI p.c. is equal to or below the World Bank’s low-income threshold, i.e. US\$ 1,085 for 2023.
- Thereafter, a Gavi-eligible country remains in the preparatory transition phase once its GNI p.c. is above the World Bank’s low-income threshold, up until it enters the accelerated transition phase.
- A country enters the accelerated transition phase when its three-year average GNI p.c. as well as its most recent GNI p.c. are above the eligibility threshold, and the country is co-financing at least 35% of vaccine

⁷ Albania, Bosnia & Herzegovina, China, and Turkmenistan

⁸ East Timor and South Sudan were added when these countries gained independence.

costs. From that point on, the duration of the accelerated transition phase is eight years, during which period the country remains eligible to apply for new vaccine support in any year.

- Countries which have transitioned out of Gavi-eligibility, i.e. after they have left the accelerated transition phase, are known as ‘fully self-financing’ or ‘former Gavi-eligible’ countries.

3.3 Gavi’s strategy and sustainability approach (2016-2020)

In June 2014, the Gavi Board endorsed a five-year strategy termed Gavi 4.0, covering the period 2016 to 2020. The aim of this strategy was to advance sustainable programmes and fulfil Gavi’s mission of safeguarding children’s lives and enhancing public health through the equitable distribution of vaccines in lower-income countries. Comprising four distinct goals, each aligned with Gavi’s overarching mission, the strategy aimed to:

1. Accelerate the equitable uptake and coverage of vaccines (vaccine goal);
2. Enhance the effectiveness and efficiency of immunisation delivery as an integral component of strengthened health systems (systems goal);
3. Improve the sustainability of national immunisation programmes (sustainability goal); and
4. Influence markets for vaccines and other immunisation products (market shaping goal).

The objectives of sustainability goal #3 include:

- a) Enhance national and sub-national political commitment to immunisation;
- b) Ensure appropriate allocation and management of national human and financial resources to immunisation through legislative and budgetary means; and
- c) Prepare for sustained performance in immunisation after graduation (*i.e. transition*).

A strategic performance framework was also designed as part of the strategy, to evaluate countries and ensure they progressed towards transition, by measuring the percentage of countries in the accelerated transition phase that were on track. Being on track is defined as, if:

- a) at least 75% of predefined transition activities (such as a having a functional national regulatory agency) have been completed on time;
- b) DTP3 coverage increased over the last three years (if a country had already achieved at least 90% DTP3 coverage, this level should have been sustained for three years); and
- c) the country met its co-financing obligations and did not default on payments in the previous year.

Gavi’s own target was for 75% of accelerated transition countries to be on track towards successful transition by the end of 2020. By the end of 2018, 56% of such countries had achieved this, indicating challenges in meeting this transition target.

In June 2015, as part of the approval of the Eligibility and Transition Policy, the Gavi Board adopted a vision for successful transition – that “*Countries have successfully expanded their national immunisation programmes with vaccines of public health importance and sustain these vaccines post transition with high and equitable coverage of target populations, while having robust systems and decision-making processes to support the introduction of future vaccines.*”⁹

In May 2016, under the PPC’s guidance, a more comprehensive sustainability approach was adopted as part of operationalisation of the 2016-2020 strategy. It outlined a series of investment principles, laying out how Gavi investments should be designed and implemented to achieve the sustainability vision. It also called for the development of a framework defining more specifically “*what Gavi hopes countries will achieve at the point of transition*”, based on the goal-level indicators of the strategy, as well as “*a package of sustainability tracers*” to assess “*how countries will be able to sustain these programmatic achievements*”.

⁹ Based on 2015 Eligibility and Transition policy.

As a result, in 2017, a sustainability tracer framework was developed and approved to provide a shared, common vision of sustainable programmes to inform the Alliance’s engagement and discussions with countries. The framework included a set of key enablers, namely (i) financing, (ii) data, (iii) supply chain, (iv) demand promotion and (v) leadership, management and coordination, which are derived from the strategy. This framework is built upon an approach that identifies (1) specific outcomes that countries should be striving to achieve in these key areas before the end of Gavi support, as well as (2) a sub-set of programme elements (or “tracers”) whose achievement is deemed critical for the sustainability of programme results.

In 2019, the Gavi Secretariat also started the process of developing a healthy transition framework (HTF) with the objectives of:

- Developing a common understanding of what successful transition looks like—both the endpoint and steps to get there.
- Defining a differentiated approach to strengthening country health systems with Gavi support.
- Informing means to monitor and measure progress towards healthy transition.
- Informing alignment of country investments towards common goal (long-term)—sustainable transition

This process was not completed and no HTF was developed, due to re-prioritisation in response to the Covid-19 pandemic.

3.4 Gavi’s strategy and sustainability approach (2021-2025)

In June 2019, the Gavi Board approved a new five-year strategy (“Gavi 5.0”) with a vision of “*Leaving no one behind with immunisation*” and a mission to save lives and protect people’s health by increasing equitable and sustainable use of vaccines. Building on successes of the previous strategic periods, Gavi 5.0 has several key shifts to deliver on its mission, including: a) a core focus on reaching “zero-dose” children and missed communities, with equity as the organising principle; b) more differentiated, tailored and targeted approaches for Gavi-eligible countries; c) an increased focus on programmatic sustainability; and d) providing limited and catalytic support for select former and never Gavi-eligible countries.

The 2021–2025 strategy has four goals, each of them supporting Gavi’s mission to save lives and protect people’s health by increasing equitable and sustainable use of vaccines. The four goals are:

- 1) Introduction and scaling-up coverage of high-impact vaccines in eligible countries will continue to be at the heart of the Gavi strategy (The vaccine goal)
- 2) Strengthen health systems to increase equity in immunisation (the equity goal)
- 3) Improve sustainability of immunisation programmes (the sustainability goal)
- 4) Ensure healthy markets for vaccines and related products (the healthy market goal).

Programmatic and financial sustainability remains central to the Gavi 5.0 strategy. The objectives of the sustainability goal include:

- a) Strengthen national and subnational political and social commitment to immunisation: This will include, for example, further sharpened approaches and tools to build national and subnational political will and working with civil society organisations to ensure strong social commitments of communities for immunisation.
- b) Promote domestic public resources for immunisation and primary health care to improve allocative efficiency: The Alliance will refine on-going approaches to secure domestic public resources for immunisation and more broadly for primary health care, recognising that immunisation services reach children most sustainably when embedded into strong PHC. Gavi will also maintain the approach of increased country ownership through co-financing of vaccines.
- c) Prepare and engage self-financing countries to maintain or increase performance: To ensure systematic and purposeful preparation for transition, the Alliance will continue to engage early on transition, ensuring appropriate sequencing and prioritisation of support. While most transitioned countries are maintaining immunisation performance, some countries have gaps in programmatic capacities or in vaccine

introductions. For these countries, the Alliance will institutionalise some targeted, catalytic and time limited for post-transition countries and will further explore such support for never Gavi eligible MICs.

3.5 From Gavi 5.0 to Gavi 5.1

Operationalisation of Gavi 5.0 commenced following the June 2019 Board endorsement¹⁰. This operationalisation phase focused on reviewing and transforming Gavi's policies, strategic approaches, processes, and tools in order to align them with the revised strategic focus, including a structured process with six main workstreams¹¹.

Thereafter, and in response to the Covid-19 pandemic, Gavi chose to recalibrate its strategic priorities as a basis for its revised strategy "Gavi 5.1"¹². This recalibration is summarised in the December 2020 Board paper Strategy, Programmes and Partnerships: Progress, Risks and Challenges.¹³ While acknowledging that leaving no one behind with immunisation and Gavi's strategic goals and objectives for the next strategic period were more relevant than ever, the Alliance adopted the following recalibrated priorities for the 2021-2025 strategic period:

- Maintaining, restoring, and strengthening routine immunisation, including preventing backsliding and catching up on missed children who missed their timely vaccinations because of disrupted services;
- Reaching zero-dose children and missed communities to advance Gavi's ambitious equity agenda; this priority is even more urgent following the Covid-19 pandemic, which has increased the numbers of individuals facing deprivation, exacerbating inequities and gender disparities;
- Supporting delivery of Covid-19 vaccines to priority populations; and
- Safeguarding domestic financing for immunisation in a fiscally constrained environment.

3.6 Transition and post transition support

As already noted, successful country transition and sustainability are at the heart of Gavi's model. At its April 2017 retreat, the Board undertook an in-depth review of the risks to countries in transition. One key risk identified was that countries stagnate or decline in performance post-transition, with the Board acknowledging there could be further opportunities for vaccine introduction in some of these countries. The Board asked the Gavi Secretariat to explore how the Secretariat might continue engagement with countries post-transition to mitigate these risks. The Board also identified five countries¹⁴ that were at higher risk of failure to successfully transition and asked the Secretariat to consider tailored strategies for these countries.

3.6.1 Post transition engagement support

To address the Board request, the Gavi Secretariat developed an approach to post-transition engagement building on an initial discussion from the June 2017 Board meeting. The approach assumed that countries would continue to fully self-finance their existing vaccine programmes and that routine health system strengthening support and technical assistance would end at the point of transition. It outlined a spectrum of options for post-transition engagement and catalytic support based on countries' specific needs and risks. These options started from a minimum of continued non-financial engagement with transitioned countries to monitor performance, advocate for immunisation and facilitate sharing of lessons learned and best practices.

In November 2017, the Board approved a budget allocation of up to US\$ 30 million, in support of continued engagement with transitioned countries until 2020.

¹⁰ [June 2019 Board decision](#)

¹¹ [Dec. 2019 Board Section C: Operationalisation of Gavi 5.0.](#)

¹² [Gavi 5.1 strategy](#)

¹³ [Strategy, Programmes and Partnerships: Progress, Risks and Challenges.](#)

¹⁴ Angola, Congo-Brazzaville, Nigeria, Papua New Guinea, and Timor-Leste.

In 2018, the Board decided that Congo-Brazzaville would regain eligibility from 1 January 2019. Thereafter as of January 2024, the country re-entered accelerated transition phase. The Board also allotted an additional US\$ 30 million for post-transition support to Angola and Timor Leste up until end of 2023, funding which was approved in June and November 2018, respectively. This support to Timor Leste was subsequently extended up until to 2025.

3.6.2 Tailored strategies for transition

Similarly, in response to the Board's request, tailored strategies for Nigeria and Papua New Guinea were developed in 2018 and 2019.

At that time, Nigeria was in a particularly fragile situation, with poor health outcomes and very low coverage rates (2016 coverage with three doses of pentavalent vaccine was 33%), a constrained macroeconomic environment, multiple outbreaks (measles, yellow fever, meningitis, cholera, monkeypox, lassa fever), one of the three remaining polio endemic countries, persisting vaccine hesitancy, and insecurity in large parts of the North. Substantial bilateral and multilateral support had been provided to increase coverage but with little tangible effect. Nigeria would therefore not be on track for successful transition, due at the end of 2021. On the recommendation of the PPC, the Board approved engagement with Nigeria in line with a set of agreed principles to develop an exceptional and time-limited programmatic and financially sustainable transition strategy ("Nigeria Transition Plan"). The country developed its own strategy (the National Strategy for Immunisation and PHC System Strategy (NSIPSS) 2018-2028) under the leadership of the National Primary Health Care Development Agency (NPHCDA), including robust partner and donor engagement at all levels. In May 2018, this tailored strategy was recommended by the PPC and approved by the Gavi board in June 2018.

Papua New Guinea (PNG) entered accelerated transition phase in 2014 (GNI was \$1,570 in 2014) and its final year of Gavi support was meant to be 2020. The Gavi Board met on 26-27 June 2019 and considered a set of proposed parameters, for an extension of support to PNG beyond the December 2020 transition date. After weighing up the benefits and risks of extending Gavi's engagement, the Board approved a specially tailored strategy that extended PNG's accelerated transition phase and eligibility until December 2025. Thereafter, in May 2023 as part of the tailored strategy, the Government of PNG requested the Gavi Board to approve a two year no-cost extension up until to December 2027. The Board exceptionally approved the extension and requested that an external review of the Papua New Guinea strategy be conducted by December 2026.

3.6.3 Gavi's approach to engagement with former and never-eligible middle-income countries (MICS)

As noted in section [3.4](#), in June 2019, the Gavi Board recommended that the Gavi Alliance institutionalise its support to former Gavi-eligible countries. The Board noted that while most former-Gavi countries successfully transitioned from Gavi support, some had gaps in programmatic capacities creating a risk of backsliding in vaccine coverage. The Board noted that besides jeopardising the legacy of Alliance investments, such backsliding disproportionately impacts the most vulnerable, exacerbating intra-country inequities.

Several former-Gavi countries lagged in their introduction of critical vaccines, presenting a threat to inter-country equity. Of 19 former-Gavi countries, 6 were missing pneumococcal conjugate vaccine (PCV), 8 were missing rotavirus vaccine, and 9 were missing human papillomavirus (HPV) vaccine. Recognising these challenges, the Board requested the Secretariat develop an approach to support former-Gavi countries to prevent backsliding in their coverage and to introduce key missing vaccines.

The Board also noted that despite higher immunisation investments on average, several never Gavi-eligible countries with comparable income levels to former Gavi countries also lagged on key vaccine introductions. Specifically, 71% of never-Gavi Lower Middle-Income Countries were missing PCV, rotavirus and/or HPV vaccines. In some of these countries the vaccines were only available in the private sector, placing them out of reach for the poorest and most vulnerable. Given Gavi's goal to *'leave no-one behind with immunisation'*

and in the era of the Sustainable Development Goals, the Board considered such inequities impossible to ignore, and requested the Gavi Secretariat to explore how certain never Gavi eligible countries could be supported in introducing these three vaccines, by finding new ways to engage and catalyse their domestic resources towards this objective.

In response to the Board's requests, the Secretariat developed the Middle-Income Countries (MICs) approach which was approved by the Gavi Board in December 2020. This approach seeks to address intra- and inter-country inequities in former- and select never-Gavi eligible countries. The MICs approach has two overarching objectives: (i) to prevent backsliding in vaccine coverage in former-Gavi eligible countries; and (ii) to drive the sustainable introduction of key missing vaccines (PCV, Rotavirus, and HPV) in both former- and select never-Gavi eligible countries.

In view of the Covid-19 pandemic, the Board approved a phased implementation and the MICs approach initially focused on preventing and mitigating backsliding in former-Gavi eligible countries. As of June 2022, the focus of the MICs approach has broadened, to also include a proactive effort to drive new vaccine introductions.

3.7 Access to appropriate pricing for transitioned countries

As countries transition away from Gavi financial support to full self-financing, there is a perceived risk that they face significantly higher prices for some vaccines (specifically PCV, rotavirus and HPV), if certain conditions linked to demand predictability and materialisation, product selection and choice of procurement channel are not met. Similarly, it has been demonstrated that self-procuring non-Gavi Middle Income Countries have routinely procured certain vaccines for which there is less price visibility and a broad range of prices on offer. Highly priced doses could jeopardise the financial sustainability of immunisation programmes after Gavi financial support ends, also taking into account the fact that countries experience rapid increases in financing their vaccines during accelerated transition, and prevent or delay the subsequent introductions of new vaccines.

At the January 2015 Gavi replenishment pledging conference, several manufacturers committed to provide transitioned countries with access to Gavi prices or to freeze prices for certain vaccines (notably PCV, rotavirus and HPV vaccines) based on certain conditions, for a period after they no longer received Gavi financial support. The manufacturers' commitments were ad hoc and required countries to continue procuring through the UNICEF Supply Division (SD) or the PAHO Revolving Fund, and generally did not cover vaccines that were introduced by countries using their own financing. Countries were also likely to face challenges accessing committed prices because of payment challenges¹⁵, primarily due to barriers in their ability to procure via external agencies such as UNICEF SD¹⁶.

In May 2015, the Gavi Secretariat sought and received PPC approval for the Alliance's approach to ensuring access to appropriate pricing for transitioned countries by:

- Continuing to seek appropriate and sustainable prices through market shaping activities, consistent with Gavi's Vaccine Supply and Procurement Strategy;
- Allowing transitioned Gavi countries to be included in UNICEF tenders; and
- Providing a catalytic investment of US\$ 5 million towards the capitalisation of UNICEF's Vaccine Independence Initiative (VII), a revolving fund which provides timely financing for countries to meet payment terms.

¹⁵ This includes legislation that limits the ability to pre-pay for vaccines (i.e., paying in advance of delivery), a requirement of UNICEF SD; limited access to hard currency; and administrative issues preventing timely fund release).

¹⁶ "GAVI SUPPORT FOR ACCESS TO APPROPRIATE PRICING FOR GAVI GRADUATED COUNTRIES" Report to the Programme and Policy Committee 4-6 May 2015

The 2015 manufacturers' price commitments provided some clarity on countries' potential financial requirements in the future and allowed for better planning, at a time when Gavi-eligible countries were relying on a limited range of vaccines mostly sourced from higher priced International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). Currently in 2024, with an expanded vaccine portfolio and supplier base, as part of the MICs approach there is no intention to renew or expand these commitments. Instead Gavi aims to secure supply and sustainable pricing for MICs, using market shaping roadmaps and UNICEF procurement strategies.

The MICs approach currently supports access to PCV, rotavirus, and HPV vaccines, by shaping the conditions under which manufacturers are able to offer affordable prices, in collaboration with UNICEF Supply Division and other partners. There are three key levers that can be deployed by the Alliance partners in conjunction with countries to achieve optimal pricing: 1) improving demand predictability and the timely procurement of forecasted demand; 2) increased diversification of products at different price points and helping countries select the most cost-efficient product options, thereby facilitating competition amongst suppliers; 3) leveraging a pooled procurement mechanism (e.g. managed by UNICEF SD or PAHO) which pools demand, and by helping reduce the barriers that countries commonly face in accessing such mechanisms.

3.8 Funding Policy Review (FPR)

In 2019, the Gavi Secretariat initiated the Funding Policy Review (FPR) to align Gavi's two funding policies and the associated framework to the aims of Gavi 5.0 and beyond: 1) Eligibility & Transition Policy; 2) Co-Financing Policy; and 3) Health System & Immunisation Strengthening (HSIS) Support Framework. The objectives of the review were to reduce complexity, and strengthen the core principles of equity and sustainability, thereby improving predictability for governments and providing greater flexibility to respond to evolving country contexts.

An initial set of decisions were approved by the Board in December 2019, before the FPR was paused in April 2020, as part of a re-prioritisation to respond to the Covid-19 pandemic. The review was restarted in late 2021, with guidance provided by the Programme and Policy Committee (PPC) in October 2021 on key issues to steer the development of the updated Eligibility & Transition and Co-financing policies. Given the complexity and potential scale of changes, the Secretariat extended the timelines to December 2022 for the FPR to accommodate further guidance, more detailed analysis, and effective stakeholder engagement.

The review noted that there remain institutional and programmatic deficiencies that present a risk to successful transition and its sustainability. The cohort of countries currently in or entering accelerated transition (AT) is quite different from those that had previously transitioned: 1) their GNI per capita is 27% lower; 2) their vaccine coverage rates are lower¹⁷; 3) they are going through transition at a time of economic uncertainty and low growth; and 4) their vaccine portfolios are larger. Further, given the current fiscal and economic environment, some AT countries may be at risk of unsuccessful transition. For example, Lao PDR, Sao Tome & Principe, and Solomon Islands had requested an extension of Gavi support due to the fiscal and economic challenges. Four¹⁸ countries entered accelerated transition at less than 20% co-financing and face an exponential ramp up in co-financing over the next five years in a fiscally challenging environment.

The FPR also noted that questions had previously been raised around whether Gavi should reconsider the use of Gross National Income (GNI) as its eligibility criteria. However, the Secretariat did not believe that it was the right time to do this given the enormous impact this could have on the Gavi 5.0 strategic period, potentially bringing new countries into Gavi eligibility, thus stretching, or requiring new resources for Gavi 5.0. Current Gavi-eligible countries could also have found themselves suddenly outside of Gavi eligibility, with funding ceasing unexpectedly. The proposal was to bring new coverage and equity criteria into decision making around

¹⁷ As measured by DTP3 coverage below 85%: 38% of current countries have three doses of coverage below 85%, vs. 25% of previously transitioned countries.

¹⁸ Bangladesh, Cote d'Ivoire, Djibouti and Kenya entered accelerated transition at less than 20% co-financing.

transition and allow Gavi to work to ensure that countries transition from Gavi support with stronger and more sustainable health systems. The Secretariat noted that any future country needs would be supported through Gavi's middle-income country (MICs) approach which had a specific objective to support former-Gavi countries to prevent backsliding in vaccine coverage.

In May 2019, the Secretariat pointed out that if there was interest from the PPC and Board to review Gavi's eligibility threshold of GNI, this could be further explored going into the next strategic period, in tandem with replenishment discussions. The Secretariat developed three potential coverage and equity thresholds that would identify an AT country as being in scope for an extension. Coverage and equity levels for countries either already in AT, or expected to enter AT by 2025, were analysed against the three options to identify which countries would be at risk of unsuccessful transition under each. The results of the analysis reflected the impact of Covid-19 on country immunisation programmes, as several countries identified to be at risk would not have been had pre-Covid 2019 levels been used. For these countries, and indeed all others, the extent to which coverage and equity are set to recover is still to be seen.

Worth also noting that previously in October 2021, the PPC expressed its support for the already anticipated move to extend the duration of "accelerated transition" for countries identified to be at risk of unsuccessful transition, moving away from ad-hoc decision making towards a consistent policy approach.

3.9 Inherent challenges in transition

During Gavi's strategic period (2016–2020), 16 countries¹⁹ transitioned out of Gavi support, resulting in 57 Gavi-eligible countries remaining at the end of 2020 (down from 73 indicated in [Section 3.1](#)).

During this current strategic period (2021–2025), three²⁰ countries have transitioned out of Gavi support in 2022 and none in 2023 (in part due to the Board's December 2022 decision to lengthen the accelerated transition phase from five to eight years). At present 54 countries remain eligible for Gavi support.

Among the 10 countries presently in accelerated transition phase, these include: Lao People's Democratic Republic and Solomon Islands due to transition 31st December 2025; Sao Tome and Principe due to transition 31st December 2026; Papua New Guinea due to transition in December 2027; Nigeria due to transition 31st December 2028; Bangladesh, Côte d'Ivoire, Djibouti, Ghana and Kenya due to transition 31st December 2029.

All the countries reviewed in the audit have significant challenges which may hamper successful continuation of the immunisation programmes, including prevention of backsliding. Four examples are highlighted below:

- Laos, which is two years away from transition, does not have a roadmap and accountability framework to track its transition milestones. The country's FPP review report indicated that the in-country FPP and TCA plan was submitted prior to a final transition roadmap, and without reference to previous drafts. Thus, it was difficult to assess whether Gavi's last tranche of funding will enable the country to attain its transition priorities. The Gavi programme audit in March 2024 also noted that the country faces health financing challenges, since the Ministry of Health has continued to receive the same annual allocation from the Ministry of Finance each of the last five years, with no comprehensive visibility over the national immunisation financing.
- In November 2023 during a Gavi high level mission, Nigeria raised concerns about its current transition timeline and requested that Gavi revise these, given the adverse impact of the pandemic on the country's financial and programmatic resources. The country noted that: a) its pentavalent 3 coverage is still low at 57%; b) There are still 2.2 million zero-dose children in the country (highest in the world); c) The fiscal space has not improved sufficiently to allow Nigeria to routinise all vaccines that Gavi introduced; d) the

¹⁹ Angola, Armenia, Azerbaijan, Bhutan, Bolivia, Congo-Brazzaville, Cuba, Georgia, Guyana, Honduras, Indonesia, Kiribati, Moldova, Mongolia, Sri Lanka, and Timor Leste.

²⁰ India, Nicaragua and Vietnam.

- country is fulfilling its co-financing obligations through the use of World bank loans, as opposed to domestic financing; e) additional vaccines recently introduced have exacerbated the fiscal space challenge, in comparison to when the Gavi board approved the current transition strategy in 2018, before new vaccines including Malaria, were introduced. Nigeria has one of highest incidences of Malaria in the world.
- Papua New Guinea (PNG), part of Gavi’s fragile and conflict segment, has been in accelerated transition since 2016. Despite its status as a lower middle-income country, the pentavalent 1 and 3 coverage rates in PNG are significantly below the mean of other countries in accelerated transition and are the second lowest globally. The country’s health systems remain weak and health outcomes poor. For most of its provinces (14 out of 22 or 63.6%) there are fewer than one health facility per 10,000 population, making access to basic health services a major challenge. As already noted under section [3.6.2](#), the country has a tailored strategy for which Gavi approved a no-cost extension until December 2027, but there are concerns that the strategy targets as stated in the accountability framework will not be met.
 - For Kenya, although it entered into accelerated transition in 2022, the country has not yet completed its transition road map, nor an immunisation accountability framework. Its current FPP submission does not sufficiently reflect aspects related to transition, since the planning process did not adequately consider other health sector donors’ own transition plans and timelines. This includes The Global Fund for example, an important health sector donor from which the country is also transitioning from by the end of 2030. Thus, although a high-level Kenya Health Sector transition roadmap was developed for the period 2022-2030 specific to the donor’s three diseases (HIV, TB and Malaria), this excluded immunisation. While other key health sector donor inputs have been aligned for PNG and Nigeria, this has not been done for Kenya.

Successful transition requires careful management of several inherent challenges. The reduced levels of Gavi funding as countries transition limits the leverage and influence that Gavi has in the national dialogue to address these challenges. Most factors contributing towards a positive transition are country-led, and as such, it is critical that the Board, the Secretariat and Gavi Alliance partners, and civil society organisations work together with the Government to ensure success.

While multi-stakeholder engagement is a critical success factor, it is important to also consider these two factors:

- ***Political willingness for key programmatic, financial and institutional changes to accelerate immunisation coverage or maintain high immunisation coverage rates:*** A country’s political willingness impacts key programmatic, financial and institutional changes that are essential for successful transitions. Eligibility for Gavi support considers the economic capacity of countries to optimise the investment of financial resources. Thus, countries with greater economic capacity, particularly upper middle-income countries and lower middle-income countries, are expected to have a greater ability to finance their health programmes. However, ability to pay does not necessarily translate into a willingness to prioritise investments in the health sector, including immunisation.
- ***Limits to Gavi’s mandate in ability to address health sector wide challenges:*** Gavi's mandate to engage with countries is defined by the framework for Gavi funding to countries, there are clear limitations to how Gavi can support countries post-transition or support for wider health sector gaps when the country is still eligible for Gavi support. It is therefore critical to define Gavi’s overall risk appetite for unsuccessful transition.

3.10 Development of the Gavi strategy 6.0

Gavi’s programmatic and financial sustainability model will continue to be a core opportunity for impact in 6.0. During this audit, in March and April 2024, the Gavi Secretariat was in the process of developing the Gavi strategy and implementation plan for the next strategic period (2026-2031).

Various proposals are being considered to potentially change Gavi's sustainability model. While the draft proposals were shared with the audit team during our review in early 2024, these documents were still under discussion and are not yet approved.

3.11 Key achievements and good practices in Gavi's transition processes

- a) **Transition and sustainability are embedded in Gavi's model and strategy:** Gavi is one of the few development organisations with sustainability embedded in the operating model by requiring co-financing and ultimately transition out of Gavi support promoting country ownership and sustainability. 16 countries transitioned out of Gavi support in the strategic period (2016-2020) and three countries in the current strategic period (2021 -2025).
- b) **Policy framework to guide transition processes:** Gavi's Eligibility, Transition and Co-financing (ELTRACO) policies provides a starting point to transition and co-financing. Various revisions have been done to the policies to refine them further and adapt them to the current context.
- c) **Alignment of ELTRACO policies to Gavi strategy:** Broadly, the ELTRACO Policies are well aligned with Gavi's 4.0 and 5.0/5.1 Strategic direction and principles. This has increased both transparency and predictability for countries that are likely to transition.
- d) **Engagement with middle income countries:** The Gavi Board approved a new approach to engagement with middle-income countries in the Gavi 5.0 strategic period (the "MICs Approach") which serves as a key tool for addressing threats to the equity and sustainability of routine immunisation programmes in former-Gavi eligible countries and never-Gavi eligible lower middle-income countries (LMICs). Through the MICs Approach, Gavi provides support to address systemic issues that commonly stand in the way of sustainable and equitable new vaccine introductions, as well as shared risk factors for backsliding in vaccine coverage.
- e) **Recent efforts in countries in accelerated transition to develop transition roadmaps:** There has been increased engagement since 2023 to work with countries in accelerated transition to develop transition roadmaps. At the moment, two countries (Djibouti and Sao Tome) have transition roadmaps and accountability frameworks with formal acceptance at PM level and a third, Ghana has a transition roadmap endorsed at Ministerial level.

4. Annexes

Annex 1 : Acronyms

AT	Accelerated Transition
CPD	Country Programmes Delivery
EPI	Expanded Programme for Immunisation
FPP	Full Portfolio Planning
FPR	Funding Policy Review
GNI	Gross National Income
HPV	Human papillomavirus
HSIS	Health System and Immunisation Strengthening
ICC	Inter-agency Coordinating Committee
IF&S	Immunisation Financing and Sustainability
ISF	Initial Self Financing
MICs	Middle Income Countries
NPHCDA	Nigeria Primary Health Care Development Agency
NSIPSS	National Strategy for Immunisation and PHC System Strategy
PAHO	Pan American Health Organisation
PCV	Pneumococcal conjugate vaccine
PHC	Primary Healthcare
PNG	Papua New Guinea
PT	Preparatory Transition
PPC	Programme and Policy Committee
TCA	Targeted Country Assistance
UNICEF SD	United Nations Children's Fund Supply Division

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 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 be adhered to as applicable to guide operations. In addition, A&I staff will 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 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 – 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
<p style="text-align: center;">High</p>	<p>At least one instance of the criteria described below is applicable to the finding raised:</p> <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. • Fraud and unethical behaviour including management override of key controls. <p>Management attention is required as a matter of priority.</p>
<p style="text-align: center;">Medium</p>	<p>At least one instance of the criteria described below is applicable to the finding raised:</p> <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. <p>Management action is required within a reasonable time period.</p>
<p style="text-align: center;">Low</p>	<p>At least one instance of the criteria described below is applicable to the finding raised:</p> <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. <p>Corrective action is required as appropriate.</p>