Mid Term Evaluation of Gavi's 2021-2025 Strategy

Final report
Volume I (main report)

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Abbreviations and acronyms

AVMA	African Vaccine Manufacturing Accelerator
CCE	Cold chain equipment
CDS	COVID-19 Vaccine Delivery Support
COVAX	COVID-19 Vaccines Global Access
CPMPM	Country programme monitoring and performance management framework
CSCE	Civil Society and Community Engagement
CSO	Civil society organisation
DTP	Diphtheria-tetanus-pertussis containing vaccine
EAC	Evaluation Advisory Committee
EAF	Equity Accelerator Funding
EHG	Euro Health Group
EPI	Expanded programme of immunisation
EQ	Evaluation question
FGHI	Future of Global Health Initiatives
FPP	Full portfolio planning
G7	Group of Seven (Canada, France, Germany, Italy, Japan, the United Kingdom, and the United States)
GHIs	Global health initiatives
GNI	Gross national income
HI	High impact (countries)
HLQ	High level question
HLRP	High Level Review Panel
HPV	Human papillomavirus
HSIS	Health system and immunisation strengthening
HSS	Health systems strengthening
IRC	Independent Review Committee
KI	Key informant
KII	Key informant interview
LIC	Low-income country
LMIC	Low- and middle-income country
M&E	Measurement & evaluation
M&R&S	Maintain, restore, and strengthen (Gavi COVID-19 initiative)
MCV	Measles-containing vaccine
MI	Mission indicator

MIC	Middle-income country
MSS	Market Shaping Strategy
MTE	Mid-term evaluation of Gavi's 2021 – 2025 Strategy
MTR	Mid-term review
NIS	National immunisation strategies
NVI	New vaccine introduction
NITAG	National immunisation technical advisory group
PCV	Pneumococcal conjugate vaccine
PEF	Partners' engagement framework
PHC	Primary health care
PPC	Programme and Policy Committee
PPR	Pandemic preparedness and response
PT	Post-transition
R&D	Research and development
R&P	Respond and Protect (Gavi COVID-19 initiative)
RI	Routine immunisation
SCM	Senior country manager
SDG	Sustainable development goal
SFA	Strategic Focus Area
SG	Strategic goal
SI	Strategy indicator
SII	Strategy implementation indicator
SMART	Strategic, measurable, achievable, relevant, and timebound
TA	Technical assistance
TCA	Targeted country assistance
ToC	Theory of change
VIS	Vaccine investment strategy
VfM	Value for money
WUENIC	WHO and UNICEF estimates of national immunisation coverage
ZD	Zero Dose

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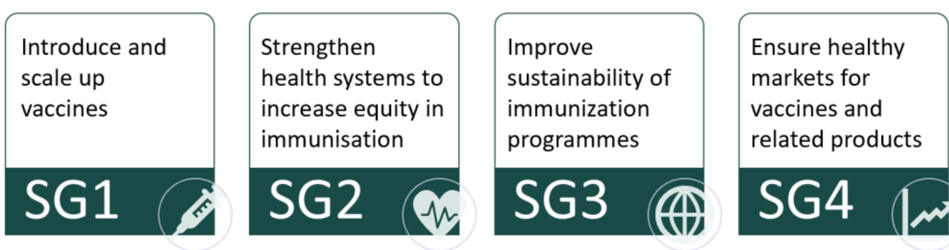
EXECUTIVE SUMMARY

Introduction

Between its creation in 2000 and 2022, Gavi helped immunise more than one billion children through routine immunisation programmes and helped deliver 1.8 billion vaccinations through preventive campaigns.[i] Millions of children are alive and healthy today because of Gavi's contribution to immunisation.

Gavi's fifth strategic plan for the period 2021-2025 (Gavi 5.0) was approved by the Gavi Board (the Board) in 2019, prior to the onset of the COVID-19 pandemic, 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. Its four strategic goals (SGs) are to:



New focus areas included:

- reaching zero-dose (ZD) children and missed communities with equity as the organising principle;
- providing more differentiated, tailored, and targeted approaches for Gavi-eligible countries;
- increasing focus on programmatic sustainability; and
- offering limited and catalytic support for select former and never-Gavi-eligible middle-income countries (MICs) to prevent backsliding of vaccine coverage and to drive the sustainable introduction of key missing vaccines.

By mid-2020, the COVID-19 pandemic had become the primary global health focus, with Gavi providing large scale support, including to post-transition MICs, through the COVID-19 Vaccines Global Access (COVAX) facility.[1] Responding to the consequent implementation delays, the Board approved a recalibration of Gavi 5.0 (5.1) in December 2022, with core priorities to catch up on coverage and reach ZD children through routine immunisation (RI). The Board also affirmed Gavi's critical role in fighting outbreaks and pandemic preparedness and response (PPR) and approved a COVID-19 strategy, alongside exploring future integration with Gavi core programming. Other initiatives included extension of the accelerated transition phase from five to eight years, a relaunch of human papillomavirus (HPV) vaccine, support for vaccine manufacturing in Africa and other regions, and support to countries and communities confronting multiple health challenges.

Gavi commissioned a mid-term evaluation (MTE) to provide the Board and the Secretariat with an independent, objective assessment of Gavi 5.0/5.1 implementation, with a focus on whether the design of Gavi 5.0 was appropriate, coherent, and implemented effectively.[2] The MTE is intended to support course correction of Gavi 5.0/5.1 and inform the development of the 2026-30 Gavi 6.0. This Executive Summary summarises the MTE methodology and provides conclusions on the strengths

[1] COVAX was also available to never Gavi-eligible countries.

[2] Since the MTE is intended to evaluate performance in the 2021-23 period and therefore encompasses at least the start-up of 5.1, we will henceforth use the term "5.0/5.1" to cover the period under evaluation.

and weaknesses of the current strategy, with supporting findings, recommendations, and lessons learned, in order to maximise strategic focus and accessibility for the Board.

Methods

We assembled substantial evidence including:

- review of more than 1,000 Gavi and external documents, 450 of which were thematically coded and analysed; and
- 184 key informant interviews (KIIs) – 104 at global-level (Gavi Secretariat, Board members, Alliance, and other connected partners), and 80 at country-level (senior country managers, country-based Alliance partners and other connected partners including ministries of health/ expanded programmes of immunisation, national immunisation technical advisory groups (NITAGs), and civil society organisations (CSOs)).

We used a range of analytical methods including:

- analysis against the elaborated Gavi 5.0 theory of change (ToC), including assumptions developed by the MTE team;
- thematic coding and triangulation of evidence, along with strength of evidence ratings;
- analysis of key drivers of observed results, using force field analyses and current reality trees;
- seven thematic studies[3] to provide a deep dive on key topics; and
- analysis against all OECD DAC evaluation criteria, except efficiency.

Strength of evidence - the findings are presented using a transparent, four-point strength of evidence rating (Table 1), reflecting the level of triangulation in the available evidence. These ratings are shown alongside headline findings.

Table 1: Robustness rating for main findings

Rating	Assessment of the findings by the strength of evidence
Strong **1**	Evidence comprises multiple data sources, both internal (e.g., Gavi Secretariat and Board) and external (good triangulation from at least two different sources, e.g., document review and KIIs or multiple KIIs of different stakeholder categories), generally of good quality. Where fewer data sources exist, the supporting evidence is more factual than subjective.
Moderate **2**	Evidence comprises multiple data sources (good triangulation) of lesser quality, or the finding is supported by fewer data sources (limited triangulation, e.g., only documents. or KIIs from one stakeholder category) of decent quality, but that are perhaps more perception-based than factual.
Limited **3**	Evidence comprises few data sources across limited stakeholder groups (limited triangulation) and is perception-based, or generally based on data sources viewed as being of lesser quality.
Poor **4**	Evidence comprises very limited evidence (single source) or incomplete or unreliable evidence. Additional evidence should be sought.

Added value and linkages to previous reviews and evaluations - The MTE builds on the findings of three recent independent evaluations commissioned by Gavi – Gavi's initial response to COVID-19, strategy operationalisation, and Gavi's contribution to reaching zero dose and missed communities (ZD). The MTE also integrates recent Secretariat analysis and reports, including EVOLVE and the 2023 mid-term review (MTR). The MTE adds value (see Box 1) by analysing aggregate data unavailable in the other evaluations, broadening, deepening, and consolidating data and findings behind the evaluations, and identifying and analysing drivers and barriers to results.

[3] Thematic studies covered the following topics: **drivers** affecting progress against Gavi 5.0 targets, **plausibility** of the Gavi 5.0 strategy contributing to SG1, 2, and 3, **innovation**, **horizon scanning**, domestic **resource mobilisation** (RM), **MICs** and **SG4**. For details see Vol II Annexes 9 – 12.

Box 1: Added value of MTE

- **Complemented data collection** – gathered and consolidated evidence unavailable to earlier evaluations to ensure a more complete picture of results and outcomes under Gavi 5.0/5.1; e.g., on Full Portfolio Planning or programme guidelines.
- **Broadened analysis** – provided a comprehensive perspective on Gavi 5.0/5.1; other processes did not do this.
- **Deepened analysis to answer the 'why' question** – explored WHY observed results occurred.

Conclusions and supporting findings

In this section, we present seven overarching conclusions, with key findings, strengths and challenges relating to Gavi 5.0/5.1 and Gavi 6.0. Many of our findings and conclusions align with Gavi's own analysis and corresponding initiatives (Annex 16). Our recommendations, presented below, reflect feedback we received from participants at a 15 February 2024 stakeholder workshop which focused on maximising utility and feasibility of implementation.[4]

Conclusion 1: During the first three years of Gavi 5.0/5.1, a period of exceptional disruption and uncertainty, the Alliance can claim some notable achievements and organisational reforms, including helping countries contain some of the backsliding in routine immunisation (RI) coverage while delivering nearly 2 billion COVID-19 vaccine doses and increasing the breadth of protection. [EQ6, EQ7, EQ9]

There was substantial growth in Gavi's scope during Gavi 5.0/5.1. This included expanding the vaccine portfolio, vaccine cohorts, and the channels needed to reach them, MICs engagement, new partnerships, programmes, and staff, while minimising COVID-19-induced major disruptions to co-financing commitments and RI supplies. Secretariat leadership initiated much-needed reforms such as Operational Excellence, EVOLVE, Full Portfolio Planning (FPP), the country programme monitoring and performance management framework (CPMPM), differentiation to reduce administrative bottlenecks and burdens on Gavi supported countries, increasing flexibility, speeding up decision making and enhancing country voice. The successful implementation of these reforms requires major changes in organisational culture throughout the Alliance – the Board, core partners, and Secretariat. Within the Secretariat, this includes clear definitions of accountability, increased delegation, prioritisation, and greater risk appetite.

Key findings[5]

2 **Finding 1.1**: Gavi is broadly on track with disbursements against the 5.0 budget, driven by vaccine-related expenditures. Performance is equivalent to the same point in time in Gavi 4.0, which is notable given external challenges and increased absorption required for COVID-19 Vaccine Delivery Support (CDS) funds. Gavi forecasts full expenditure for 5.0/5.1 although this relies on slower-to-programme

Strengths

- Gavi's action to mitigate the impact of COVID-19 on RI appears to have contributed to preventing more substantial backsliding.
- Gavi projects full utilisation of the 5.0/5.1 budget, which is remarkable in the context of COVID-19-related operational constraints. This demonstrates that with clear priorities (and in a crisis), the Gavi model can deliver exceptional results. If the efficiency and Operational Excellence drives referred to in

[4] Each conclusion is presented alongside the relevant evaluation questions (EQs) which we were asked to address in the evaluation.
[5] Finding numbers refer to the finding in the main text below (linked).

cash grants, for which disbursements are more challenging to predict.

1 **Finding 2.1**: By end 2022, as substantiated by WUENIC data, many Gavi 5.0 indicators had recovered to 2019 levels. This reflects an improvement since 2021. But, consistent with Gavi's own analysis, DTP3, geographic equity, MCV1 and ZD reduction numbers were off track. Results are not uniform across countries, with core and post-transition countries struggling more than other segments.

Conclusion 4.3 are successful, Gavi will be well-positioned to fulfil its core functions in Gavi 6.0.

Challenges

- Delivery on cash grants, which are slower to programme and harder for countries to absorb in addition to other sources of non-Gavi external funding, will be challenging during the remainder of Gavi 5.1. Constrained fiscal space and debt distress may also slow disbursements where domestic resources are needed for implementation.
- Continued results on Gavi 5.0/5.1 implementation delivered to date (and by extension for Gavi 6.0) will depend on a range of factors discussed in the following conclusions. Chief amongst these are challenges related to transition, sustainability (Conclusions 5 and 6), and responding to uncertainty in Gavi's operating environment (Conclusion 7).

Conclusion 2: Some, but not all, strategic goals (SGs) 1-3 will be met by 2025, while most SG4 targets will be achieved. [EQ1, EQ4, EQ5, EQ9, EQ12]

There are several caveats regarding our analysis of the plausibility of achieving Gavi 5.0/5.1 coverage targets. The first concerns the confidence which can be placed on the relatively small annual changes which occur in WUENIC data. Both the numerator (number of immunisations) and the denominator (target population) are subject to enumeration errors, but WUENIC data is not presented with confidence limits and does not necessarily correspond with that from household surveys. Second, there is a one-year time lag before official coverage data becomes available, with for example, 2023 coverage estimates will only be available in July 2024. Our analysis therefore reflects data only up to 2022, two years into implementation of the Gavi 5.0/5.1 strategy. Third, some Gavi strategy indicators (SIs) are lacking targets or data points. With these caveats, the likelihood of Gavi-supported countries achieving 5.0/5.1 targets, in ascending order, is depicted in Figure 1.

Figure 1: Plausibility of achieving Gavi 5.0/5.1 targets

Plausibility	Targets	Targets
Cannot predict	**M1** Under-5 mortality **S1.5** Country prioritization of vaccines **S2.4** Number of immunisation sessions **S2.5** Stock availability at facility level	**S2.6** EPI management capacity **S2.7/S2.8** Percentage of countries addressing demand and gender-related barriers with Gavi support **S3.3** Vaccine introduction in former- and never-eligible Gavi countries
Unlikely	**M4** ZD reduction **S1.2** DTP3 coverage **S2.1** Geographical equity	**S2.3** MCV1 coverage **S1.7** Timely detection and response to outbreaks
Somewhat likely	**S1.2** HPV coverage* **S1.6** Measles campaign reach	**S4.3** Number of vaccine and immunisation-related products with improved characteristics
Likely	**M2/M3** Number of future deaths /DALYs averted **S1.3** Rate of scale-up of YF and MCV2 **S1.4** New vaccine introductions **S2.2** DTP drop out	**S4.1** Number of healthy markets exhibiting healthy market dynamics **S4.2** Number of innovative products within pipeline with commercial scale manufacturers
Highly likely	**M5** Unique children immunized through RI **M6** Economic benefits generated **S1.1** Breadth of protection** **S1.2** MCV2/PCV3 coverage	**S3.1** Co-financing **S3.2** Prevention of backsliding in post-transition countries

* Pending introduction by countries such as India and Nigeria which will substantially change the overall weighted average coverage
** Flatlining in core countries

Key findings

1 — **Finding 1.2**: Most Partners' Engagement Framework (PEF) interventions are focused on SG1 and SG2, with limited focus on SG3.

2 — **Finding 1.3**: Relevant process/output-focused strategy (and strategy implementation) indicators (SIs and SIIs), CPMPM, and Balanced Scorecard indicators also reflect more progress at intervention level against SG1 and SG2 than SG3.

2 — **Finding 1.6**: Progress and assumptions hold more consistently along SG1 ToC causal pathways. Progress along SG2-SG4 causal pathways is mixed, partly due to wide variations in contexts, limited implementation on SG3, and variable progress on sub-areas within SG4. There is a mixed/negative picture on ToC assumptions related to in-country capacity and the effectiveness and sustainability of Gavi-supported interventions.

1 — **Finding 2.2**: Plausibility varies by SG (see Figure 1). The plausibility of reaching targets cannot be calculated for some

Strengths

- Based on current metrics, SG1 and SG3 are mostly on track, suggesting that Gavi is well placed in 6.0 to continue with its core mandate of sustainable access to vaccines.
- Whilst SG2 appears off track, intervention level activity suggests emphasis on ZD has translated to action within the Secretariat (see Conclusion 4 for findings on Alliance partners). This is likely a good sign for Gavi 6.0.

Challenges

- More focus is needed on sustainability, both in terms of metrics, programming, and coherence (Conclusion 6).
- With varied results – core and post-transition countries are struggling more than other segments – the need for differentiation is clear (see Conclusion 4).
- Gavi is trying concurrently to address multiple, shifting, complex priorities.
- Greater focus is needed on pre-Vaccine Investment Strategy (VIS) market shaping and demand health.

indicators, mainly because relevant targets have not been set.

2 **Finding 2.15**: The SG4 indicators are on track, minimally influenced by COVID-19.

1 **Finding 2.28**: Although the SG4 indicators will likely be met, more emphasis is needed in areas where market health remains weak.

Conclusion 3: Gavi's contribution to the 5.1 strategic goals through 5.0/5.1 programming will not be visible until mid-2025, but likely will make a positive contribution. The contribution from Gavi 4.0 appears strong but recalibrating 5.0 strategic priorities has had limited impact. [EQ4, EQ5, EQ6, EQ7, EQ8]

Measuring Gavi's contribution to the SGs is problematic due in part to issues with country and partner monitoring/reporting arrangements, the staggered nature of grant making, delays in Gavi 5.0/5.1 operationalisation, indicator choice (including lack of output indicators and the focus of SG3 and SG4 indicators) and missing data points – although resolving these issues is not straightforward. Despite recent improvements, such as the Balanced Scorecard, management systems for planning and tracking contributions to the SGs are insufficient to enable learning, course correction and prioritisation of work. There are also issues of timely access to available data, which can make it difficult for external observers to reach appropriate judgements.

Key findings

3 **Finding 1.5**: Gavi does not routinely track progress at output level and limited evidence thus exists as to whether interventions under each SG are translating into intended outputs.

2 **Finding 1.20**: Results in terms of RI, reaching ZD, rolling out COVID-19 vaccines, and protecting domestic finances are mixed, with the contribution of recalibration to results unclear.

1 **Finding 2.3**: The current contribution of the 5.0/5.1 strategy to results is unclear, given delays in operationalisation/ disbursement of key grant workstreams (FPP and Equity Accelerator Funding), the staggered nature of the grant-making process, and lags in reporting.

1 **Finding 2.4**: The contribution of Gavi 4.0 to current results has been substantial, especially in terms of vaccine introductions, cold chain equipment

Strengths

- The high degree of continuity between Gavi 4.0 and 5.0/5.1 seems set to be a positive feature of contribution to results.

Challenges

- COVID-19 impeded the first two years of Gavi 5.0/5.1 implementation, exacerbated by a range of internal factors (Conclusion 4), which are likely to continue into 6.0 without action.
- Due to reporting lags and the staggered nature of the grant-making process, the impact of Gavi 5.0/5.1 on immunisation will not be visible in WUENIC reporting until mid-2025. This is well understood, but difficult to address.
- Gavi 5.0/5.1 programming will be finalised only in 2024, with consequent overlaps into the 6.0 period. This places practical constraints on what can be done in Gavi 6.0, and goals should be set accordingly.
- Tracking progress at the level of outputs is conceptually complex and probably unrealistic. Designing SMART[6] indicators

[6] Specific, measurable, achievable, relevant, and time-bound indicators that are used in monitoring and evaluation.

improvements and helping countries contain pandemic impacts on RI.

2 **Finding 2.5**: We cannot yet estimate the future contribution of Gavi 5.0/5.1 to 2025 outcomes and beyond, but early evidence points to reaching more children with an ever-expanding number of life-saving antigens.

2 **Finding 2.20**: Increased attention to demand health was a key shift in Gavi 5.0, but lower country appetite for new vaccine uptake/product switches has limited opportunities for improvement.

for measures such as increased capacity, innovation, political commitment, and collaboration would be challenging. Measurement would be burdensome both for countries and the Secretariat and would not always translate across different contexts.

Conclusion 4: Gavi is making concerted efforts to achieve the 5.1 goals. Maintaining progress requires tackling how the Alliance influences country immunisation programming, while respecting country ownership. It also requires accelerating and deepening the ongoing, much-needed internal reforms to streamline Gavi's systems and processes. [EQ2, EQ8, EQ11]

Progress in implementing Gavi 5.0/5.1 is covered under Conclusion 2. Successful implementation for the remainder of Gavi 5.1, and by extension Gavi 6.0, will depend on implementation of the multiple ongoing reform processes described under Conclusion 1. These reforms will likely take time and will also be influenced by the grant making cycle, which in turn reflects varying country planning cycles. Therefore, it is probable that the reform process will not be fully implemented until well into the Gavi 6.0 period. As priorities, the recent evaluations of the operationalisation of Gavi's strategy and Gavi's contribution to reaching ZD children and missed communities both highlight the urgent need to reduce complexity and transaction costs for countries, simplify processes, and speed up grant approvals and disbursements.

The current operational model, involving multiple centrally determined donor requirements and funding levers, imposes burdensome administrative costs on countries, can impede country voice, and may also be incompatible with domestic budgetary systems, even when aligned with country planning cycles. This issue, while hardly unique to Gavi, requires re-examination to provide greater scope for country priorities, ensure consistency with country budget mechanisms and planning cycles, and account for different levels of need and institutional capacity. Success also depends on effective partnerships, both within the Alliance and with governments and CSOs.

Country voice and support for country priorities are underpinning principles, but there can be tensions between delivering Alliance strategic priorities and ensuring country ownership. We recognise that reform is challenging in a complex multi-country and multi-agency partnership, but the need for dynamic, data-driven, context specific solutions coupled with greater data accessibility to improve oversight on performance is urgent. We note that Gavi is acting on these important agendas, including through EVOLVE and efforts to strengthen the overall functioning of the Alliance.

4.1 Secretariat and partner capacity [EQ2, EQ8, EQ11]

Key findings

1 **Finding 1.7**: Core partners are strongly aligned behind the Gavi ZD agenda. Support for other priorities is strong in principle but, as noted in the strategy operationalisation evaluation, mixed in terms of operationalisation and prioritisation.

2 **Finding 1.8**: Alliance partnerships can work well, but there are concerns about the inconsistent capacity and accountability of core partners.

1 **Finding 1.9**: Beyond capacity constraints, core partners experience a range of challenges including unclear roles, lines of decision making, and navigating Gavi's complex and evolving funding processes; all of which can reduce trust and effective working relations within the Alliance.

3 **Finding 1.10**: Regional-level core partners play a pivotal role in pushing forward Gavi's strategy and progress towards the SGs, including in MICs, but this does not happen consistently.

1 **Finding 1.23**: There is a high degree of convergence on a set of key barriers, including timelines for application/disbursement, alignment with country priorities, data quality and weaknesses in Secretariat and partner capacity.

2 **Finding 2.21**: There is a gap in downstream/country support to evidence-informed decision-making around vaccine uptake and switches, only partially alleviated by limited resources in the Secretariat and Alliance.

Strengths

- Alliance partners play a pivotal role in the operationalisation of Gavi strategies, including ensuring Gavi can reach marginalised populations and work in fragile countries.

Challenges

- The Alliance has experienced significant headwinds during Gavi 5.0, mostly linked to the pressures from COVID-19. Efforts to "reset" Alliance relationships are commendable. Nevertheless, there is work to do going into Gavi 6.0 to mitigate tensions and ensure shared expectations around roles and responsibilities, capabilities, performance, and accountability, based on mutual trust and effective communication.
- The Civil Society and Community Engagement Framework (CSCE) provides a steer on the three fundamental pillars of Gavi's relationship with CSOs - service delivery, demand generation and advocacy. However, efforts to increase and expand CSO and non-core partner engagement have created some tensions with core partners and country governments.

4.2 Country ownership and country-level capacity [EQ2, EQ3, EQ8, EQ10, EQ11]

Key findings

1 **Finding 1.12**: Country capacity among core partners and governments may be less than optimal, exacerbated by the complexity of Gavi application processes. Country capacity to utilise Gavi funds is an issue in some countries, with many fragile countries experiencing very low utilisation during 2021-22, and some fragile and core countries struggling to utilise funds into 2023.

2 **Finding 1.14**: Tension exists between the principles of country ownership and the extent to which Gavi pushes forward priorities such as ZD and equity across diverse country contexts.

1 **Finding 2.7**: The Gavi Secretariat and wider Alliance work in a range of ways to ensure that Gavi strategic priorities are reflected in country applications and priorities; some are more effective than others.

1 **Finding 2.10**: There is strong convergence across a long list of constraints to strategic level results, also broadly consistent across SG1 and SG2, related to weak health systems, demand (including vaccine hesitancy), resource constraints, COVID-19, access, data and Gavi systems and processes.

1 **Finding 2.11**: COVID-19 has been a key barrier to achieving the Gavi 5.0/5.1 SGs, but other drivers such as complex systems predate the pandemic.

1 **Finding 2.23**: Gavi's demand health influence has been limited, due to the current co-financing policy, the country finance allocation methodology, and country control over choice of vaccine supplier and product presentation.

1 **Finding 3.6**: Country focus has long been Gavi policy, but many KIs, including Board members and country representatives, noted the tensions between "countries decide" and centrally determined global initiatives and funding levers.

Strengths

- Gavi is committed to country ownership and has taken steps in 5.0/5.1 to strengthen country engagement and capacity. These efforts have been met with some success and need to be continued into 6.0.

Challenges

- The differentiated engagement model is key but needs further refinement to ensure that it better reflects Secretariat and country capacity and needs. The approach for Gavi 5.0/5.1 and 6.0 should ensure support is available where needed, with decisions delegated to the appropriate level.
- In countries suffering from fiscal space limitations, the expanding Gavi funded vaccine programmes and presentation options warrants reconsidering the balance between country choice and market health needs.
- Delivering against Gavi's strategic priorities whilst ensuring country ownership can be challenging.

4.3 Weaknesses in Gavi's systems and processes [EQ8, EQ11]

Key findings

1 **Finding 1.11**: As found in previous evaluations and reviews, country stakeholders noted that Gavi application processes are complex and burdensome. Some see FPP as a step in the right direction, while some continue to experience substantial delays in approval and disbursement, with significant on-the ground implications. Recommendations/ outputs from the Independent Review Committee (IRC) evaluation and EVOLVE process are intended to address many of these issues.

1 **Finding 1.17**: Experience suggests that decision-making can be sped up, but this needs to be institutionalised; and more work is needed to address the timeliness of disbursements.

1 **Finding 1.23**: There is a high degree of convergence on a set of key barriers to operationalisation, including timelines for application/disbursement, alignment with country priorities, and data quality.

1 **Finding 1.24**: The root causes of these barriers are varied. Those cited most often are firmly on Gavi's radar, with work in progress and important action agendas.

1 **Finding 2.8**: The extent to which we could assess Gavi's influence on country immunisation programming intentions was limited by factors related to monitoring, accountability, and learning.

1 **Finding 2.13**: Where we could identify root causes, these are linked to how Gavi is structured and resourced and therefore more within Gavi's control. These have often been affected by the exceptional circumstances linked to COVID-19.

2 **Finding 2.16**: The SG4 corporate performance indicators are not well aligned to measure Gavi's market shaping work. Operational-level activity monitoring on SG4 indicators is not well-defined or transparent.

Strengths

- Gavi recognises that complex processes and slow decision-making need urgent resolution. The varied root causes are now largely on Gavi's radar.
- The Operational Excellence initiative provides a critical and thoughtful approach to diagnosing and identifying solutions, but at this early stage of implementation, we cannot assess the likelihood of success. These initiatives will continue to be important throughout the remainder of Gavi 5.1 and into 6.0.

Challenges

- The challenges associated with Gavi's complex systems and processes have been known since at least 2016. The measures proposed in EVOLVE and Operational Excellence (which address personnel and culture) will require effective change management efforts well into Gavi 6.0.
- Solutions to key barriers have been identified previously, including by other evaluations. These barriers have proven hard to address, in part because other issues such as COVID-19 took priority. There has, however, been little tracking of efforts to address these barriers and this is a key gap to fill in Gavi 5.1 and 6.0.
- The impetus to add new levers to support new initiatives, or resolve immediate crises, can be strong, overriding efforts to simplify processes. Reaching agreement with the Board on a revised, simplified model with clear monitoring could help reduce the internal and external drivers of complexity.
- Countries struggle to engage with Gavi processes, exacerbating existing country level capacity constraints.
- Operational reporting weaknesses may reduce accountability and transparent prioritisation, as well as opportunities for learning and course correction.

Conclusion 5: Resilient and strong health systems are essential for vaccine programme sustainability. [EQ12, EQ13, EQ14]

Gavi has a long history of investments in aspects of health systems strengthening (HSS) such as supply chain and cold storage, which have also helped strengthen primary health care (PHC). Gavi recognises that strong PHC systems are essential to ensure equitable access to vaccines, to achieve the ZD agenda (with opportunities to integrate the ZD approach into the wider PHC system), and for sustainability. Gavi is for the first time developing a health systems strategy for Gavi 6.0, an important and timely initiative, even if history suggests that implementation, requiring enhanced cooperation with partners, will be challenging. The strategy will likely recognise that a key element is to articulate how Gavi investments will strengthen health systems, and how these investments will provide more specific programmatic support. The recent Future of Global Health Initiatives (FGHI) process noted that "building greater alignment, particularly around HSS and a more sustainable global health ecosystem, is even more urgent as the world faces increasing epidemiological and demographic changes and global health inequities."[ii] Gavi can point to several recent examples of enhanced HSS collaboration with key partners such as the Global Fund and the World Bank.

The MTE found few Gavi-supported interventions to improve, for example, budget efficacy at country level (see also Conclusion 6), market intelligence on, and transparency of vaccine prices for MICs, or support to supply and procurement performance in countries nearing/after transition, despite the pivotal role of these interventions for sustainability. Without clear attention to these issues, countries may be unable to introduce new vaccines, or even sustain existing investments.

Key findings

2 **Finding 2.6**: It is unclear whether Gavi 5.0/5.1 will strengthen health systems or sustainability of immunisation investments.

1 **Finding 2.9**: There is strong stakeholder agreement on a limited set of SG enablers, including health system capacity.

2 **Finding 2.17**: Gavi's Market Shaping Strategy (MSS) 2021-2025 design is comprehensive, strategically focused, and responds to previous evaluation recommendations, barring two exceptions.

1 **Finding 3.1**: Gavi's operating environment will likely continue to be marked by turbulence and uncertainty during the remainder of Gavi 5.1 and 6.0. Gavi needs to ensure that its systems can respond to different country contexts with timely and flexible programming.

Strengths

- Gavi is developing a new health systems strategy for Gavi 6.0 which has the potential to provide clearer strategic direction, greater cooperation with partners, and mechanisms to evidence HSS results.
- Gavi's market shaping work has picked up pace in the first part of Gavi 5.0/5.1 and is set to continue through 2025. Secretariat capacity/ processes on healthy demand have been strengthened.

Challenges

- It is important to prepare and implement a holistic health systems strategy for Gavi 6.0 which, working with core partners, supports strong PHC and vaccine delivery systems, including for transition countries.
- Supporting supply and procurement performance in countries nearing/after transition and improving market intelligence data for MICs and never-eligible Gavi countries as part of a comprehensive approach to sustainability and transition.

Conclusion 6: Notwithstanding increased momentum towards 5.1 goals, there are serious concerns around transition and sustainability as some countries may again backslide during a time of increasing global social, political, and economic fragility. [EQ4, EQ5, EQ9, EQ10, EQ13]

The co-financing model created over 15 years ago to assist vaccine introductions in lower-income countries has been successful – from 2008 to 2023, Gavi countries paid approximately US$ 1.7 billion in co-financing.[iii] However, as more countries transition out of Gavi support, Gavi's footprint and impact will decline, even while large numbers of children remain unvaccinated. The Alliance recognises that it cannot reach the sustainable development goals (SDGs) and global vaccination targets, or effectively support new life course vaccines, without engaging key former and never-Gavi-eligible MICs, where a significant proportion of un- or under-vaccinated children reside.

With the increasing number of Gavi financed vaccines, additional supplier presentations, challenges balancing country product preferences with available supply, more countries moving towards transition, or already self-financing vaccines, and more countries in economic distress, the challenge is to prioritise and optimise vaccine portfolios to achieve value for money (VfM) and security of supply. The current eligibility, co-financing and transition model/pathway insufficiently addresses affordability, sustainability of RI and new introductions for low-income countries (LICs) and transitioning/transitioned countries lacking medium-term access to Gavi-similar vaccine prices, and so no longer fit for purpose.[7] In preparation for Gavi 6.0, Gavi is reviewing the Eligibility, Transition and Co-financing (ELTRACO) policies through an informal Board task force, which aims to better take into consideration countries with specific and different profiles, as well as countries with more challenging fiscal/ financial environments.

Key findings

1 **Finding 1.2**: PEF milestone data shows very limited focus on SG3-related interventions.

1 **Finding 2.1**: Results against Gavi 5.0/5.1 indicators are not uniform, with core and post-transition countries struggling more than other segments.

1 **Finding 2.1**: Co-financing remained at 100% between 2019 and 2022, waivers aside.

1 **Finding 2.2**: SG3 (The sustainability goal): The two SIs for which enough data is available (3.1 and 3.2) are respectively highly likely and likely to be achieved. There is a question, however, regarding the extent to which these are the most meaningful indicators to measure progress and set ambitions on sustainability.

1 **Finding 2.23**: Gavi's demand health influence has been limited due to the

Strengths

- Countries have maintained co-financing levels, despite economic headwinds.
- The MICs approach has proved a welcome innovation, with important learning.

Challenges

- Immunisation portfolios are becoming more expensive, while countries face constrained finances. Better financial and economic monitoring with partners is key both to identify and mitigate risks, and to monitor the broader sustainability of Gavi's model.
- Experience to date with implementing the MICs approach has identified scope for adaptation, including improving transparency in vaccine pricing, HSS support, revised transition criteria, and more defined partnership working arrangements.
- Transition for the next cohort is problematic as some countries lack the stability, health system maturity, or financial capability to sustain RI gains. We understand that Gavi is

[7] Gavi-similar prices are negotiated on behalf of transitioned countries for some antigens and for a specific duration – in theory these engagements will not need renegotiation since UNICEF tiered pricing and better market health in general should ensure access to affordable vaccines for in- and transitioned countries. However, these actions, while necessary, may not be sufficient considering the increasing financial fragility in these countries.

current co-financing policy, the country finance allocation methodology, and country control over choice of vaccine supplier and product presentation.

1 **Resource Mobilisation Study Finding:**[8] Co-financing is insufficient as an indicator of vaccine sustainability.

1 **Resource Mobilisation Study Finding:** Current manufacturer agreements to maintain access to Gavi prices for former Gavi-eligible countries, unavailable to never-eligible MICs, are currently set to expire in 2025 with no systemic solution.

1 **Resource Mobilisation Study Finding:** Gavi has never estimated the full cost of procuring and delivering vaccines in LICs and LMICs. This information is critical to inform 6.0 preparations and to ensure the sustainability of existing vaccine investments.

2 **MICs Study Finding:** There are questions about Gavi's use of gross national income (GNI) data to decide eligibility for MICs support and improve sustainability of RI, suggesting instead a composite indicator to better target Gavi resources.

intending to address these challenges in the 6.0 design process.

- The current allocation model, co-financing policy, and policies on country vaccine choice do not prioritize VfM and vaccine programme sustainability.

Conclusion 7: We agree with the Gavi analysis of the barriers to vaccine uptake during 6.0, including conflict, climate change and natural disasters, vaccine hesitancy, weak health systems, and economic disruption. The extent to which the Alliance can overcome them depends crucially on the success of current efforts to deal with longstanding barriers to operational efficiency and effectiveness. [EQ10, EQ15]

Economic, social, and political turbulence will likely be the norm, placing a high priority on streamlined processes, decision-making and accessible data. While international support for Gavi's mission remains high, the actual volume of financial support has yet to be established in the face of multiple competing priorities. Recent Board papers and evaluations have also noted the trade-offs between the "core" Gavi 5.1 agenda and further expansion and deepened engagement. These trade-offs are real, but this is not a binary choice, given rapidly shifting demands on the Alliance. It will be vital to maintain attention to implementing the core Gavi 5.1 agenda efficiently and effectively, while judiciously focusing on new initiatives and innovations which can substantially reduce the global burden of infectious disease. Balancing these trade-offs and establishing clear criteria for prioritisation between competing demands and limited resources, both in the Secretariat and in-country, as well as clear accountability within the Alliance, will be key to successful outcomes for Gavi 6.0. At the same time, ensuring that Gavi has the right systems and mechanisms to develop tailored approaches and to adapt to changes in its operating context will be critical to its effectiveness.

[8] See Annex 10 for MICs thematic study findings and Annex 11 for resource mobilisation study findings.

Key findings

1 **Finding 2.12**: Our analysis notes the likely influence of exogenous factors over which Gavi has limited control or influence, such as fragility and conflict, increases in birth cohorts, and difficulties/lack of incentives in accessing the hard to reach, especially in a context of competing priorities.

1 **Finding 3.1**: Gavi 5.0/5.1 has been marked by unprecedented disruption due to COVID-19 and economic and social shocks. Gavi's operating environment will likely continue to be turbulent and uncertain in the remainder of Gavi 5.1 and in 6.0.

1 **Finding 3.2**: International financial support is not assured for Gavi 6.0, with many competing priorities.

2 **Finding 3.3**: Vaccine nationalism and hesitancy may again feature in future pandemics, and as with COVID-19, may impede vaccine access and delivery for LICs in a future pandemic.

Strengths

- Gavi is aware of and is planning to address risks that may affect Gavi 5.1 results. Gavi's analysis of risks is comprehensive and of high quality.

Challenges

- Gavi has limited control or influence over the many exogenous factors which can affect performance. How these will affect Gavi's operations will vary across and within countries and cannot be easily predicted. Gavi's capacity to respond will depend on its business risk appetite, a "differentiated approach to materiality[9]", and to a considerable extent, overcoming internal barriers to greater efficiency and effectiveness.

Recommendations

Since many of our recommendations apply to the final stages of Gavi 5.1 and the forthcoming Gavi 6.0, they are not divided between the two strategic periods. Where recommendations are specific to either one, this is noted. Our recommendations are consistent with and build on those in the recent evaluations of Gavi's contribution to reaching ZD and missed communities, and the operationalisation of Gavi's strategy. They also reflect feedback from participants at the 15 February 2024 Gavi co-creation workshop, whom we thank for their constructive suggestions and assistance. The Alliance is already working on some of the areas covered by our recommendations and a summary of these actions can be found in Annex 16.

For each recommendation, the type of action is described using the following three terms:

- **CONTINUE**: choose to prioritise this area of existing work in Gavi 5.1 and into 6.0;
- **ADAPT:** modify existing work to respond to experience and analysis from MTE and/or other evaluations; and
- **STOP:** stop development or implementation of processes or initiatives in highlighted areas.

Recommendation	Conclusion
1 ***Build on the momentum which now exists in Gavi 5.1 to achieve Gavi's four strategic goals and continue this focus in 6.0.*** a. Since it is likely that Gavi 5.1 and 6.0 will run concurrently for a period, ensure that ongoing Gavi 5.1 programmes are not "buried" under new 6.0 initiatives when 6.0 starts in 2026. [ADAPT]	Conclusions 1, 2, 3, 7

[9] Key informant quote

<table>
<tr><th></th><th>Recommendation</th><th>Conclusion</th></tr>
<tr><td>2</td><td>To enhance Gavi's responsiveness and impact during Gavi 5.1 and in advance of 6.0, accelerate, test, and monitor organisation-wide implementation of Operational Excellence initiatives and agreed strategy operationalisation evaluation recommendations.
a. Prioritise and accelerate the reforms to operational culture identified by EVOLVE and the strategy operationalisation evaluation to reduce country transaction costs and increase responsiveness to crises and changing contexts.[10] In that context, sharply reduce the current 21.4 months (as of January 2024) duration between initiating the FPP process and disbursement.[iv] [CONTINUE/ADAPT]
b. Manage the risk that Operational Excellence is seen as a 'silver bullet' for all organisational challenges by ensuring that it outlines clear and realistic goals and benchmarks to measure progress. [ADAPT]
c. Initially, focus the Target Operating Model[11] on those reforms (e.g. simplified processes) that are particularly useful in fragile/conflict settings, and which assist implementation of strategic priorities (e.g. contracting of CSOs in support of RI service delivery, demand generation, advocacy and the overall ZD agenda). [CONTINUE]
d. Consolidate the current 17 funding levers and limit the addition of new levers to reduce country transaction costs and operational complexity. Building on analysis in the MTE, identify the internal and external drivers of multiple funding levers as well as the barriers to consolidation, and resolve issues prior to implementation of Gavi 6.0. Plan the consolidation of levers to harmonize with country processes and preferences. For example, adopt a new funding lever only if existing funding mechanisms (even when revised) would not work AND if affected countries agree that the new lever can be easily accommodated in country processes, including the FPP. [STOP]
e. Put in place change management processes[12] to ensure that Operational Excellence reforms are fully implemented before Gavi 6.0 starts, since previous organisational reform efforts have met with mixed success. Ensure sufficient processes, human and financial resources, and structures are in place to underpin implementation, and that the drivers and barriers to reforms are well understood.[13] Ensure that all relevant parts of the Secretariat (operational, country, financial) are on board. Map the potential impacts of reforms on all country segments (core, high impact, and fragile) and stress test these reforms by piloting in different settings. [CONTINUE]
f. Monitor these reform processes against agreed benchmarks and regularly inform the Board on progress and bottlenecks. [ADAPT]</td><td>Conclusions 4 (4.3), 7</td></tr>
<tr><td>3</td><td>Review the country engagement model, including the differentiated approach, so that Gavi support is better aligned with national immunization priorities and support mechanisms are sufficient and appropriate for country needs, capacity, and potential for impact.</td><td>Conclusions 3, 4 (4.1, 4.2), 7</td></tr>
</table>

[10] As previously noted, the need for operational reforms has been apparent since at least 2016.

[11] The EVOLVE Target Operating Model has identified a set of reforms including end-to-end view with differentiated paths, simplified processes, clear roles and responsibilities, automation, focus on activities that add value, rebalanced effort across the grant management cycle, data-driven decision-making, removal of duplicated work, consolidation of funding levers, and integrated platforms.

[12] E.g. covering leadership (including setting ambitious goals and sticking to agreed plans if/when challenged), planning and oversight, involvement of stakeholders, communication, training, metrics).

[13] Our mandate did not include an organisational, or governance review and the 2019 McKinsey organizational review was not shared with us. However, it is clear from available evidence and our analysis, that Gavi systems, processes, structures, resources, and governance can be better aligned - a review to ensure their coherence, and their mutual reinforcement would be strategic.

	Recommendation	Conclusion
	a. Accelerate work with countries and partners to ensure that sustainable national immunisation strategies (NIS) are in place and empower countries to align Gavi support with their NIS. In addition, develop country-level strategic goals, aligning programmes where needed with other global health institutions. [ADAPT] b. In alignment with EVOLVE proposals, differentiate country engagement based on a composite of indicators such as performance, capacity, fiduciary and programmatic risk, and potential impact, rather than by segment. For example, in a high performing country with good vaccination coverage and low fiduciary risk, empower the country to choose priorities from a menu of Gavi support. At the same time, manage tensions between country ownership and centrally determined priorities[14] through effective policy and technical advice to support and influence countries to identify relevant Gavi support (see Recommendation 3c).[15] [ADAPT] c. Delegate decision making and accountability for country programmes and priorities to the senior country managers (SCMs).[16] Empower them to take, after appropriate consultation with relevant internal and external stakeholders, effective and timely decisions on country priorities and decisions, up to agreed financial ceilings, on actions such as reallocations.[17] Identify and address internal and external barriers to decentralisation and delegated authority, and assess current competency gaps and take appropriate actions (e.g. training, talent placement, other resources) to ensure that SCMs and their teams have the necessary resources and capacity to support successful implementation of tailored country programmes.[18] [ADAPT] d. Define criteria for adoption of new initiatives which are "off-plan" (not foreseen in the country NIS) (see Recommendation 2b). [ADAPT]	
4	***Identify clear roles and accountabilities with core partners to help achieve Gavi's strategic goals, especially in challenging areas such as gender and expanded partnerships. Identify/implement suitable mechanisms to track Gavi-funded partner implementation of Gavi 5.1 and incorporate into 6.0.***[19]	Conclusions 4 (4.1), 7

[14] Giving more choice to countries would require Gavi to manage implications (in terms of reduced control over delivery against global commitments) and consider new ways to report on the portfolio of diverse country choices (see recommendation 8).

[15] We recognise that Gavi already offer countries a menu of vaccine support plus HSS and TCA grants. But we also note that centrally determined priorities form part of application review processes through both official requirements, e.g., the EAF envelope can only be used for activities that are identified as critical to reaching ZD children and missed communities, and unofficially through application materials and IRC review processes, e.g., encouraging the inclusion of ZD and gender-related activities. This creates tension between country ownership and global objectives. This recommendation seeks to address this tension by placing greater emphasis on facilitation of tailored programmes from a menu of Gavi support options.

[16] SCMs play an important role in the interface between countries and the Secretariat, but their real decision authority appears quite limited despite their senior status, in part due to the multi-layered decision/approval processes documented by EVOLVE and the consensus decision making culture within the secretariat.

[17] Currently it appears that SCMs have little financial decision-making authority as all reallocation and reprogramming must be approved by Regional Heads or senior management. We note the recent delegation of authority for programmatic approvals from CEO/CFO to the MD and Directors of CPD but argue that this authority should be delegated to the SCMs up to an agreed dollar amount.

[18] This critical change in organizational culture was also identified in the EVOLVE process.

[19] Gavi's impact depends crucially on how the Alliance partners work together. We recognize that the structure of the Alliance makes these discussions challenging, but clarity on roles and responsibilities of core partners will be very

Recommendation	Conclusion
a. Ensure appropriate governance mechanisms are in place at global, regional, and country levels to facilitate alignment, communication and coordinated action between and within Alliance partners. This could, for example, build on successful examples of engagement of regional-level core partners under the MICs approach. **[CONTINUE]** b. Agree terms of reference with core and extended partners (at each geographic level as appropriate) which specify partner roles and accountabilities to achieve the SGs and delivery of Gavi 5.1 and 6.0. These agreements should specify how individual partners will use Gavi funds to support identified strategic priorities and goals and include benchmarks to monitor progress, along with regular reporting to the Board. Ensure that the necessary partner capacity and capability exists, particularly at country level, and identify any remedial measures needed. Consider periodic independent assessment of processes and performance to identify any needed course correction. **[ADAPT]** c. Use country-led joint appraisals to monitor progress regularly in all countries. **[ADAPT]**	
5 ***In consideration of increasing fragility and vulnerability in many Gavi countries[20], revise the eligibility, transition, and co-financing model in 6.0 to enhance financial and programmatic sustainability.*** In this context: a. Focus on financial sustainability, including through ongoing work with core partners and other institutions to better understand and mitigate the impact of domestic financial constraints on achievement of Gavi 5.1/6.0 priorities and objectives. Ensure that the impact of fiscal constraints and the availability, or unavailability, of domestic resources is factored into the design of all future initiatives. **[ADAPT]** b. Ensure a comprehensive definition and approach to sustainability by factoring in key components of programmatic sustainability such as equity, gender, and regulatory/legal enabling environments at global, regional, and national levels. **[CONTINUE/ADAPT]**. c. To maximize programmatic and financial sustainability, identify criteria in Gavi 6.0 (e.g., fragility, indebtedness, PHC capacity, and legal and regulatory frameworks) to determine the speed of transition for eligible countries and eligibility for MICs support for never-eligible countries. **[ADAPT]** d. In the context of major changes in the vaccine market (e.g., expanding vaccine portfolios and higher costs), promote access to and affordability of vaccines in MICs and nearing/post-transition countries by: i) supporting supply and procurement performance (see Recommendation 9g); ii) improving vaccine market intelligence data relating to MICs and never-eligible Gavi countries; and iii) giving prominence to identifying new and innovative sources of financing (i.e. not domestic) for never-eligible MICs and transitioning countries. **[ADAPT]**	Conclusions 2, 5, 6, 7

important for the successful implementation of 6.0. We understand that there are ongoing discussions amongst the core partners which touch on these issues.

[20] See also recommendation 9a.

	Recommendation	Conclusion
6	***Design a health systems strategy in time for Gavi 6.0 describing how Gavi, with its partners, will invest in building viable country PHC systems. This is essential for equitable and sustainable immunisation and the ZD agenda.*** The strategy should reflect the recent Lusaka agreement which incorporates a programmatic sustainability objective,[21] and also reflect on past efforts (dating back at least 15 years) to harmonize partner investments in health systems, including managing the associated high transaction costs. **[ADAPT]**	Conclusion 5
7	***Build on experience in Gavi 5.1 to specify the range of Alliance technical/ advisory support to MICs to promote sustainable transition for former-eligible countries and sustainable adoption of new vaccine programmes for both former- and never-eligible countries.*** This is particularly important since the majority of ZD children live in MICs, and MICs have a high disease burden which could be reduced by vaccines in the research and development (R&D) pipeline. **[ADAPT]**	Conclusions 6, 7
8	***Establish appropriate monitoring systems for Gavi 6.0 which provide timely evidence of country progress towards the strategic goals, and Gavi's contributions to such progress. Explore whether these systems can be redesigned to be less transaction heavy for countries, while allowing Gavi access to key data to assess progress and contribution. Document rationale for configuration of internal systems, including trade-offs,[22] and periodically review sufficiency, relevance, and effectiveness of monitoring arrangements with the Board***. In this context, address two key issues repeatedly raised by external evaluations (and well-known to Gavi): a. Methodological issues on measuring results and predicting future trends. WUENIC data is the main data source to estimate coverage, but its limitations include long time lags and large data confidence limits. Consider further efforts to strengthen country health management information systems and complementary investments in survey data (including rapid surveys). **[ADAPT]** b. Strengthen monitoring of Gavi's contribution to observed and future results. This could include strengthening internal reporting mechanisms[23] including reporting by partners to track activity against plans and delivery against Gavi's ToC outputs and outcomes. It could also include portfolio-level monitoring approaches adopted by other institutions such as the World Bank. [24] **[ADAPT]**	Conclusion 3, 4 (4.2)

[21] The Lusaka agenda captures consensus around five key shifts for the long-term evolution of GHIs, including Gavi – and the wider health ecosystem – and highlights several near-term priorities to catalyse action. The five shifts are: make a stronger contribution to PHC by effectively strengthening systems for health; play a catalytic role towards sustainable, domestically financed health services and public health functions; strengthen joint approaches for achieving equity in health outcomes; achieve strategic and operational coherence; and coordinate joint approaches to product research and development and regional manufacturing to address market and policy failures in global health.

[22] There are trade-offs between comprehensive monitoring of data which enables Gavi to report on implementation and contribution to SGs and the associated transaction costs for countries and partners in comprehensive reporting on Gavi programmes. Monitoring systems nevertheless need strengthening (e.g. joint appraisals and reporting by partners on implementation) so that evidence is periodically collected against agreed country level outputs and outcomes which can be incorporated into a portfolio level overview.

[23]The importance of activity and output level monitoring is heightened in cases where Gavi interventions require a longer time to show results than a Gavi strategic cycle. The utility of the CPMPM as a tool to estimate contribution is somewhat limited since the indicators in the CPMPM do not closely match the SIs.

[24] https://scorecard.worldbank.org/en/scorecard/home

Recommendation		Conclusion
9	***Continue to improve the supply and sustainability of affordably priced vaccines by expanding efforts and overcoming constraints in areas requiring enhanced efforts and coordination across the Secretariat and partners (e.g. demand health, long horizon market shaping, and vaccine programme sustainability).*** In this context: a. Continue the effective deployment of existing market shaping tools which facilitate innovation, competition, and demand consolidation (e.g. support to Vaccine Innovation Prioritisation Strategy (VIPS) work, WHO Prequalification and national regulatory authorities, and UNICEF procurement tenders) and a partner-aligned strategic approach to market shaping (principally through the antigen roadmap process). Improve the efficiency of data sharing amongst Square partners,[25] clarify roles and responsibilities, and enhance the processes and tools used for market shaping including aligning the level of effort with expected impact and the content and timing of the output with its anticipated use. [ADAPT] b. Continue work to refine plans for the African Vaccine Manufacturing Accelerator (AVMA), while mitigating risks to achieving impact. Further design decisions would benefit from economic modelling from the perspective of individual firms targeted by the AVMA, as well as from the overall market perspective of the targeted antigens. **[CONTINUE]** c. In the context of unprecedented expansion in the menu of Gavi supported vaccine products and presentations, further strengthen/expand efforts on demand health. This should include: i) better ways of communicating vaccine choices to countries and mechanisms for supporting NITAGs with vaccine product portfolio management decisions as well as new forums for communication across the programmatic and market-shaping teams; ii) remapping of roles and responsibilities; iii) new policies related to how the market-shaping and programmatic teams work together; and iv) more cohesive demand health targets that are collectively created across Secretariat teams. [ADAPT] d. Heighten corporate attention to measurement of demand health attributes (e.g., percent of unconstrained demand met within a certain timeframe and number of product switches to more appropriate presentations) as distinct metrics. [ADAPT] e. Review the influence of the co-financing policy, budget allocation model, and policies enabling country control over the vaccine supplier and product presentation on vaccine demand materialisation, portfolio optimisation, VfM, and sustainability. Analyse the impact of a switch to a country budget ceiling allocation model and/or altering the policies on country choice of vaccine supplier and product presentation on: i) allocative efficiency at the overall Gavi portfolio level; ii) VfM decision-making at country level regarding vaccine programme choices; and iii) leverage to influence market health. Revise the co-financing policy to incentivize VfM in all countries, not just countries in transition. [ADAPT] f. Where justified by Gavi's comparative advantage and market needs, intervene with pull mechanisms earlier (in the Gavi pre-VIS to vaccine introduction cycle) to avert market failure, prepare markets for optimised programme launches, and ensure improved responsiveness and faster access to vaccines in the event of an outbreak or epidemic. [ADAPT]	Conclusions 5, 6

[25] Partnership of Gavi market-shaping partners: Gavi Secretariat, UNICEF-SD, WHO-IVB, & BMGF-VDCP (Gavi's Market Shaping Strategy 2021-2025).

Recommendation	Conclusion
g. Implement the agreed 2020 procurement and supply strategy evaluation recommendations to: i) support supply and procurement performance in nearing/post transition countries and improve vaccine market intelligence data relating to MICs and never-eligible Gavi countries; and ii) strengthen M&E of operational activities. The latter should balance transaction costs and utility (accountability and lesson learning) while addressing antigen roadmap data confidentiality by identifying meaningful, but non-sensitive measures which can be shared. **[ADAPT]**	

Lessons learned

This section details lessons[26] that Gavi could draw upon for the Gavi 6.0 strategy, based on the experience of developing and implementing Gavi 5.0/5.1, under two main headings: i) adaptability and flexibility; and ii) monitoring and tracking implementation. These lessons are based on findings from the MTE and not necessarily drawn from Gavi's own analysis.

On being able to adapt and be flexible

1. After COVID-19, it is a given that Gavi can adapt and respond fast to an emerging crisis. However, in a less crisis-driven environment, there are conflicting drivers at work. For example, the need for simplification of Gavi systems reflects country demands for lower transaction costs and less burdensome processes. However, donors, with accountability to different stakeholders, may make demands which increase complexity and transaction costs. Although there has been some progress during Gavi 5.0/5.1, in practice there has been too little reform over the past decade. Much more needs to be done to tackle the barriers which are inherent in a large, complex organization with diverse stakeholders, each reporting to separate governing bodies. Overcoming these barriers is complex and requires determined change management from top to bottom of the organisation, and explicit agreement with the Board around associated implications and/or trade-offs.
2. Rapid reprioritisation may be needed during these times of crisis, alongside appropriate adjustment of expectations. This places a premium on effective (flexible and responsive) partnerships – with core and extended Alliance partners, with country stakeholders, and within the Secretariat. Defining roles and responsibilities and aligning expectations around revised priorities based on mutual trust and effective communication is key. Sufficient resources will be needed to manage these processes, which need to be functioning in advance of the next crisis.
3. Gavi's ability to identify required changes and to execute those changes depends on the extent to which the SCMs, whose capacity may be stretched across multiple countries, have the necessary delegated authority, resources, capabilities, and partnerships in place to affect change.
4. Models that have worked for Gavi in the past may not work as well in the contexts that are likely to predominate in Gavi 6.0 – for example, fragility and conflict, both between and within countries, and the majority of ZD children living in MICs. This makes it particularly relevant for Gavi 6.0 to focus on eligibility, transition and sustainability, market shaping, and HSS.

[26] The DAC definition of a lesson requires that lessons highlight strengths or weaknesses in preparation, design, implementation; and we note, in this regard, overlap with strengths and challenges identified for each conclusion in the Executive Summary.

On monitoring progress and tracking implementation

5. Monitoring strategic implementation and results and using this information for course-correction and engagement with stakeholders necessitates high-quality systems that provide relevant, timely and publicly accessible data. Establishing the minimum set of information required and balancing this with acceptable transaction costs of collection/collation/accessibility is a difficult balancing act, involving choices and trade-offs. This is a longstanding challenge that is best addressed through explicit documentation of goals and decisions.
6. The results of implementing a five-year strategy may only be realised during the subsequent strategic period, resulting in a challenge to accountability and reporting to stakeholders on progress. Managing expectations of what can be achieved in a five-year phase is important, especially if going beyond Gavi's existing 'core business', as is the use of long-term indicators spanning multiple strategy periods.
7. Setting goals in terms of measurable targets and consistent indicators across all contexts provides challenges for country ownership, and Gavi is not alone in experiencing the resulting tensions between accountability to donors and the principle of country ownership. Gavi will need to be mindful that a move towards country ownership may weaken its ability to commit to global targets and donor-specific requirements. The next replenishment cycle should factor these challenges into its investment case and funding levers.

1 Introduction

1.1 Evaluation purpose, objectives and scope

Gavi commissioned Euro Health Group (EHG) to conduct a mid-term evaluation (MTE) of the implementation of Gavi's fifth strategy (Gavi 5.0). The evaluation focused on whether the design of Gavi 5.0 (2021-2025), and modifications to the 5.0 priorities (as reflected in Gavi 5.1)[27] were appropriate, coherent, and implemented effectively.

The primary purpose of the MTE was to support course correction in Gavi 5.1 and to inform the development of Gavi 6.0 (2026–2030). The temporal scope of the MTE covered January 2021 through December 2023, and the geographic scope included all 54 countries categorised as 'Gavi-eligible' in 2023. The main objectives of the MTE were to:

- Evaluate the status of implementation of Gavi's fifth strategy (Gavi 5.0/5.1) by end 2023 and identify the drivers and barriers that explain that status.
- Assess the extent to which implementation of the strategy on its current trajectory will plausibly result in achievement of the prioritised strategic goals (SGs) and objectives and identify areas for course correction.
- Generate a series of findings, conclusions, lessons learned and recommendations that can feed into a first course correction of Gavi 5.1 and inform the development of Gavi 6.0 (2026-2030).

To explore these objectives, the MTE addresses three high level questions (HLQs), under which sit 15 evaluation questions (EQs) shown at the top of each sub-section in Section 2, and in full in Table 2.[28] The MTE is intended to support learning, with less emphasis on accountability. The primary audience is the Gavi Board (the Board),[29] including Alliance partners, donors, country representatives and civil society organisations (CSOs), and the Gavi Secretariat.

Table 2: Gavi 5.0 mid-term evaluation questions (with links to relevant sub-sections)

HLQ1 What is the status of the implementation of Gavi's fifth strategy by the end of 2023? What are the drivers and barriers that explain that status?	
Relevance, coherence, and efficiency	**EQ1 (Section 2.1.1)** To what extent do the implementation mechanisms to operationalise Gavi's 2021-2025 (5.0/5.1) strategy align with how Gavi is expected to contribute to all its strategic goals as identified in the theory of change (ToC)?
	EQ2 (Section 2.1.4) To what extent is there alignment across key Alliance partners on Gavi's approach to implementation of the current strategy? Are there challenges for partners in playing their expected roles (e.g., for Gavi 5.1), and are these being effectively addressed?
	EQ3 (Section 2.1.5) What have country level stakeholders' experiences been of the implementation under the current strategy, including use of key operational levers ("bubbles") such as differentiated engagement?
	EQ4 (Section 2.1.3) To what extent have the implementation of Gavi's levers and mechanisms for operationalising the current strategy led to intended and unintended consequences at global or country level?
	EQ5 (Section 2.1.2) How relevant is the elaborated Gavi 5.0 MTE ToC and underlying assumptions as countries build back from the pandemic and in the context of Gavi 5.1?

[27] Since the MTE is intended to evaluate performance in the 2021-23 time period and therefore encompasses at least the start-up of Gavi 5.1, we will henceforth use the term "5.0/5.1" to cover the period under evaluation
[28] note that section 1.2 sets out the structure of this report.
[29] https://www.gavi.org/governance/gavi-board/members

	EQ6 (Section 2.1.6) To what extent did Gavi effectively and efficiently implement approaches to safeguard routine immunisation (RI) programmes and support recovery in countries from COVID-19 disruption? How flexible were these to allow rapidly adapting programmatic, administrative, or financial processes to be implemented in a timely fashion? Which approaches were most/least effective and efficient?
	EQ7 (Section 2.1.7) To what extent have Gavi's recalibrated priorities in response to COVID-19 affected (positively and negatively) the expected delivery against the strategic goals and influenced rebound from the effects of COVID-19 on routine immunisation (RI) programmes? Has operationalisation of the recalibrated priorities in Gavi 5.1 positioned the Gavi Alliance for success by 2025?
	EQ8 (Section 2.1.8) How/to what extent did Gavi effectively mitigate against and respond to failures in the ToC causal pathways and other significant barriers to operationalisation?
	HLQ2 Achievement of strategic goals and objectives – To what extent will implementation of Gavi's 2021-2025 strategy plausibly result in achievement of the prioritised strategic goals and objectives? Which areas are important for course correction?
Effectiveness, efficiency, and impact	**EQ9 (Section 2.2.1)** To what extent do Gavi's strategy performance indicators show recovery to 2019 baseline levels? To what extent will implementation of Gavi's 2021-2025 strategy on its current trajectory plausibly result in achievement of the prioritised SG1, 2, 3 and related objectives?
	EQ10 (Section 2.2.3) What were the most significant factors which affected progress against targets in the Gavi results framework? Which successes and barriers are the key ones to build on/ address?
	EQ11 (Section 2.2.2) How/To what extent has Gavi influenced countries to adjust their immunisation programming intentions related to SG1, 2, and 3?
	EQ12 (Section 2.2.4) What progress has been made against SG4 sub-strategies on healthy markets (SG4.1) and innovative products (SG4.2 and SG4.3) and to what extent has the COVID-19 pandemic compromised progress? To what extent will implementation of Gavi's 2021-2025 strategy on its current trajectory plausibly result in achievement of the prioritised SG4 and related objectives?
	EQ13 (Section 2.2.5) What has been the contribution to SG4 in relation to the following key Market Shaping Strategy 5.0 pillars? – Healthy Demand, Partnership Optimisation, Regulatory Environment, Future Supplier Base.
	EQ14 (Section 2.2.6) Is SG4 as originally articulated still relevant for the second half of the Gavi 5.0/5.1 strategy period?
	HLQ3 What are the major lessons learned and recommendations that can inform development of Gavi 6.0 (2026 – 2030)?
Sustainability	**EQ15 (Section 2.3.1)** What new and emerging themes or drivers/factors could impact Gavi's mission, and are critical to inform Gavi 6.0?

The EQs listed in Table 2 largely cover the DAC evaluation criteria.[v] HLQ1 focuses on relevance and coherence, and HLQ2 addresses impact and effectiveness. There is less focus on efficiency as the MTE scope did not include value for money (VfM) analysis, but some efficiency-related findings also fall under HLQ1 and HLQ2. Sustainability is a cross-cutting theme, reflected in findings that relate to SG3.

1.1.1 Background

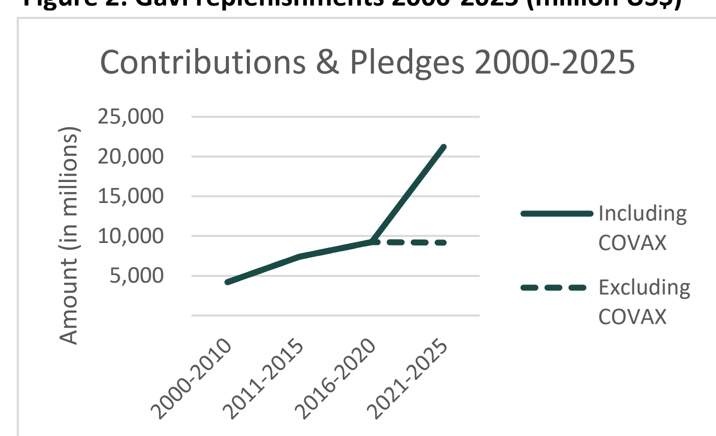
Gavi, the Vaccine Alliance, was created in 2000 as a multilateral funding mechanism to "save lives and protect people's health by increasing coverage and equitable and sustainable use of vaccines".[vi] Its main activities include supporting low- and middle-income countries' (LMIC) access to new and underused vaccines for vulnerable children through financial support, technical expertise, and

market-shaping efforts to help lower the cost of vaccine procurement. Since its creation in 2000, Gavi has helped vaccinate more than 1 billion children, preventing more than 17 million deaths.[vii]

Gavi operates on a five-year funding cycle, with a revised strategy and goals for each cycle. In addition to its role in routine childhood immunisations, Gavi was one of the lead organisations in COVAX – the multilateral effort to support the equitable global development, procurement, and delivery of COVID-19 vaccines.

From its launch through 30 June 2022, Gavi has mobilised more than US$ 23 billion (excluding funding for COVAX) from donor governments, private organisations, and individuals. Replenishments have flatlined over the past two funding cycles, excluding COVAX (see Figure 2).

Figure 2: Gavi replenishments 2000-2025 (million US$)



Source: http://d-portl.org/

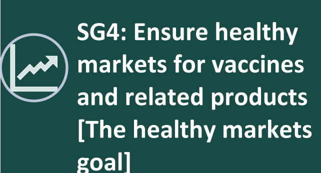
1.1.2 Gavi 5.0/5.1 and COVID-19

In June 2019, the Board approved Gavi 5.0 as part of the Immunization Agenda 2030 to leave no one behind[viii] by increasing equitable and sustainable use of vaccines. Gavi 5.0 strategic goals are shown in Table 3 and in the 5.0 theory of change (ToC) (see Figure 3).

Gavi 5.0's core focus is on reaching zero-dose (ZD) children and missed communities, with equity as the organising principle. Gavi 5.0 also includes more differentiated, tailored, and targeted approaches for Gavi-eligible countries, increased focus on programmatic sustainability, and support to former and select never Gavi-eligible middle-income countries (MICs) to prevent backsliding in vaccine coverage and to drive the sustainable introduction of key missing vaccines. 54 countries were eligible to apply for Gavi financing in 2023, based on average gross national income (GNI) per capita of US$ 1,730 or lower over the past three years.[ix]

Table 3: Gavi 5.0 strategic goals

Goal	Objectives
SG1: Introduce and scale-up vaccines [The vaccine goal]	• SG1a: Vaccine prioritisation • SG1b: Introduce & scale up coverage of new vaccines (new vaccine introductions and vaccine investment strategy) • SG1c: Enhance outbreak and pandemic response through equitable access to vaccines
SG2: Strengthen health systems to increase equity in immunisation [The equity goal]	• SG2a: Reaching under-immunised and zero-dose children (incl. SG2b, SG2c) • SG2b: Maintaining and restoring routine immunisation to prevent backsliding and catch-up missed children (in light of COVID-19) • SG2c: Working with communities to build resilient demand and identifying and addressing gender related barriers to immunisation
SG3: Improve sustainability of immunisation programmes [The sustainability goal]	• SG3a: Strengthen commitment • SG3b: Promote domestic public resources for immunisation • SG3c: Engage self-financing countries

 **SG4: Ensure healthy markets for vaccines and related products [The healthy markets goal]**	• SG4a: Market dynamics for immunisation-related products at affordable prices • SG4b: Incentivise innovation for the development of suitable vaccines • SG4c: Scale up innovative immunisation-related products

Gavi 5.0 was to be implemented by operationalising the strategy[30] through flexible and tailored application of Gavi's instruments and policies to achieve the 5.0 goals (see Box 2).[31] The Full Portfolio Planning (FPP) process provides the main mechanism through which countries access support under the 5.0 strategy, designed to promote coherence through analysis, design, consultation, and approval. The Gavi 5.0 ToC, elaborated by the MTE team (see Annex 2), is summarised in Figure 3.[32]

Box 2: Operationalisation of Gavi's strategy

Gavi's strategies are operationalised through a process described further in the strategy operationalisation evaluation. Strategies are accompanied by a set of programmatic policies, strategies, funding levers, and guidance. Through these mechanisms and additional high-level engagement, strategic priorities are reflected through country applications for grant funding. Applications are then approved through an Independent Review Committee (IRC) review process, during which they may also be encouraged to reflect certain strategic priorities. Through these mechanisms, if all assumptions hold, Gavi's strategic priorities are then reflected in immunisation programmes, and thus, contribute to progress on mission and strategic indicators.

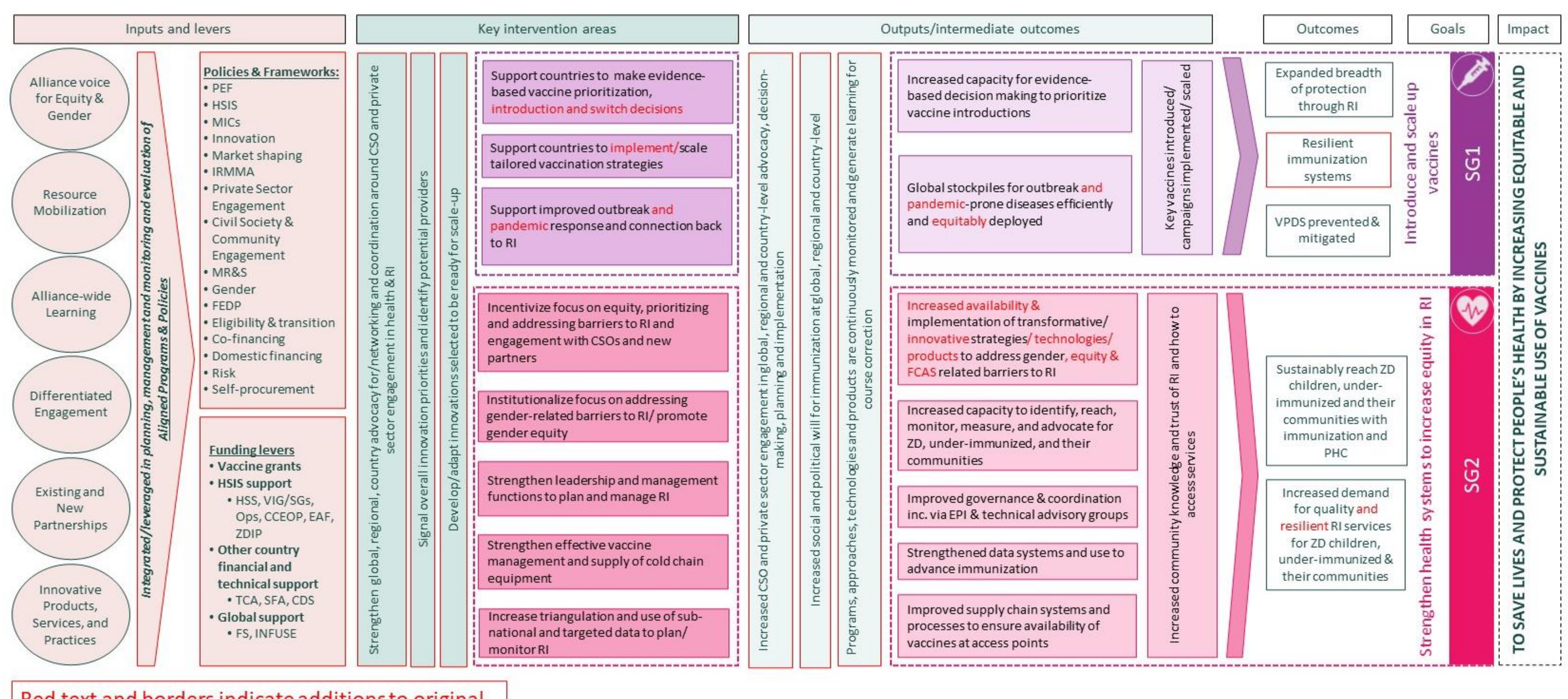
The onset of COVID-19 in February 2020 saw large drops in immunisation coverage in 2020/21 and by mid-2020 it was the primary global health focus. Gavi provided major support through COVAX (including in 15 post-transition MICs), with approximately 130 new hires along with existing Secretariat staff diverted to COVID-19.[x] In December 2020, the Board agreed that a range of priorities, such as new vaccine introductions and the new MICs approach, would be paused until the pandemic was over.

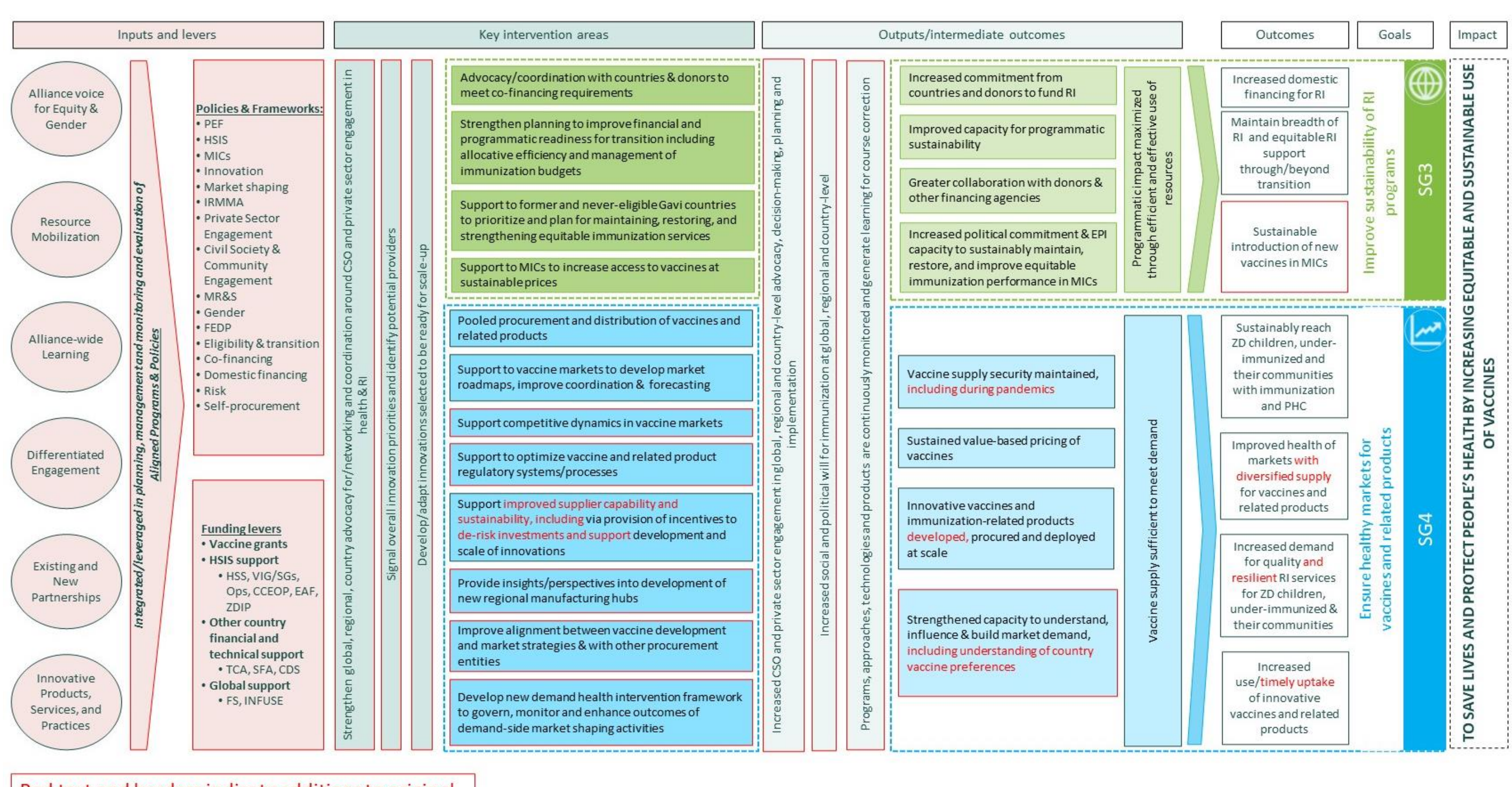
In December 2022, the Board approved Gavi 5.1, an evolution of Gavi 5.0, responding to the impact of COVID-19 and its learnings. Core priorities for the remainder of the 2021-2025 strategic period are to catch up on coverage and to reach ZD children through routine immunisation. The Board also affirmed Gavi's critical role in fighting outbreaks and pandemic preparedness and response (PPR), alongside exploring future integration with Gavi core programming. Initiatives approved in 2023 include a relaunch of human papillomavirus vaccination (HPV), US$ 1.8 billion in funding for the African Vaccine Manufacturing Accelerator (AVMA), and a US$ 500 million First Response Fund to ensure immediate financing at the start of a future pandemic.

The Gavi 5.0/5.1 strategy period has been marked by substantial exogenous disruption and uncertainty in Gavi's operating environment related not only to COVID-19, but also to economic dislocation, war, natural disasters and climate change, not all of which were foreseen when Gavi 5.0 was designed. These remain significant factors, as discussed in more detail under Section 3.1.

[30] The Operationalisation has been evaluated separately covering implementation up to December 2022 (Strategy operationalisation evaluation).
[31] For more information on Gavi's instruments and policies see https://www.gavi.org/programmes-impact/types-support
[32] A ToC for 5.1 has not been issued.

Figure 3: Elaborated Gavi 5.0/5.1 Theory of Change

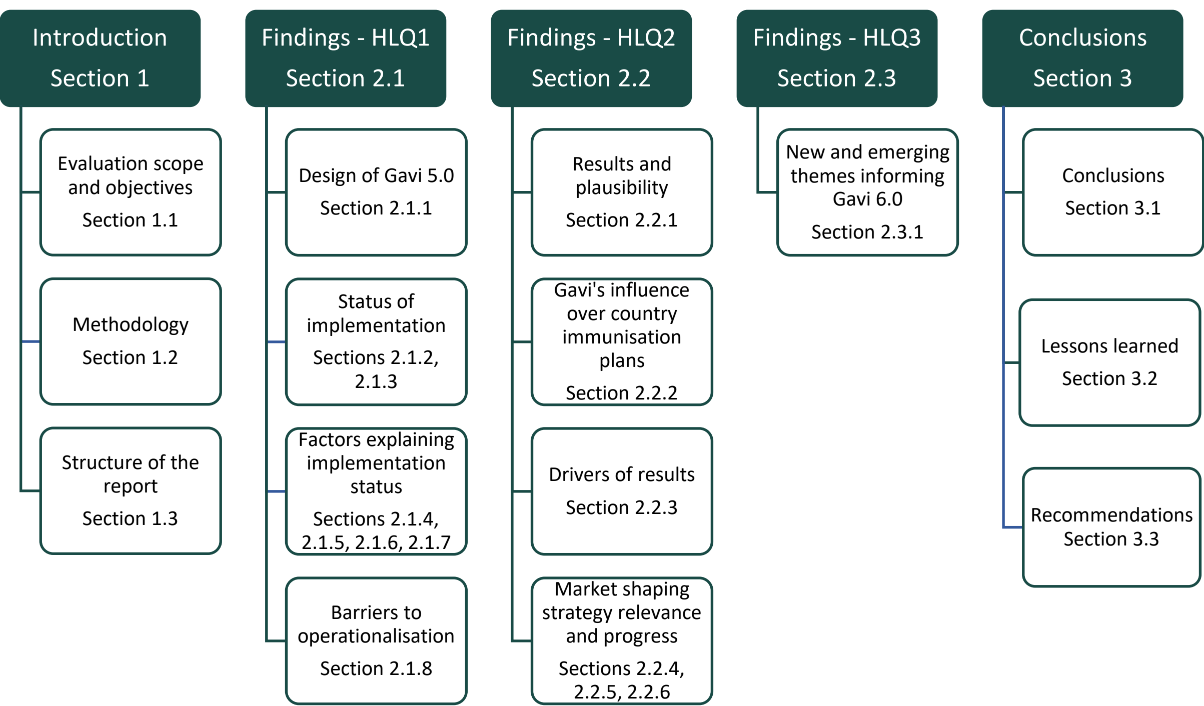



Inputs and levers
Key intervention areas
Outputs/intermediate outcomes
Outcomes
Goals
Impact
Alliance voice for Equity & Gender
Resource Mobilization
Alliance-wide Learning
Differentiated Engagement
Existing and New Partnerships
Innovative Products, Services, and Practices
Integrated/leveraged in planning, management and monitoring and evaluation of Aligned Programs & Policies
Policies & Frameworks:
• PEF
• HSIS
• MICs
• Innovation
• Market shaping
• IRMMA
• Private Sector Engagement
• Civil Society & Community Engagement
• MR&S
• Gender
• FEDP
• Eligibility & transition
• Co-financing
• Domestic financing
• Risk
• Self-procurement
Funding levers
• Vaccine grants
• HSIS support
• HSS, VIG/SGs, Ops, CCEOP, EAF, ZDIP
• Other country financial and technical support
• TCA, SFA, CDS
• Global support
• FS, INFUSE
Strengthen global, regional, country advocacy for/networking and coordination around CSO and private sector engagement in health & RI
Signal overall innovation priorities and identify potential providers
Develop/adapt innovations selected to be ready for scale-up
Advocacy/coordination with countries & donors to meet co-financing requirements
Strengthen planning to improve financial and programmatic readiness for transition including allocative efficiency and management of immunization budgets
Support to former and never-eligible Gavi countries to prioritize and plan for maintaining, restoring, and strengthening equitable immunization services
Support to MICs to increase access to vaccines at sustainable prices
Pooled procurement and distribution of vaccines and related products
Support to vaccine markets to develop market roadmaps, improve coordination & forecasting
Support competitive dynamics in vaccine markets
Support to optimize vaccine and related product regulatory systems/processes
Support improved supplier capability and sustainability, including via provision of incentives to de-risk investments and support development and scale of innovations
Provide insights/perspectives into development of new regional manufacturing hubs
Improve alignment between vaccine development and market strategies & with other procurement entities
Develop new demand health intervention framework to govern, monitor and enhance outcomes of demand-side market shaping activities
Increased CSO and private sector engagement in global, regional and country-level advocacy, decision-making, planning and implementation
Increased social and political will for immunization at global, regional and country-level
Programs, approaches, technologies and products are continuously monitored and generate learning for course correction
Increased commitment from countries and donors to fund RI
Improved capacity for programmatic sustainability
Greater collaboration with donors & other financing agencies
Increased political commitment & EPI capacity to sustainably maintain, restore, and improve equitable immunization performance in MICs
Programmatic impact maximized through efficient and effective use of resources
Vaccine supply security maintained, including during pandemics
Sustained value-based pricing of vaccines
Innovative vaccines and immunization-related products developed, procured and deployed at scale
Strengthened capacity to understand, influence & build market demand, including understanding of country vaccine preferences
Vaccine supply sufficient to meet demand
Increased domestic financing for RI
Maintain breadth of RI and equitable RI support through/beyond transition
Sustainable introduction of new vaccines in MICs
Sustainably reach ZD children, under-immunized and their communities with immunization and PHC
Improved health of markets with diversified supply for vaccines and related products
Increased demand for quality and resilient RI services for ZD children, under-immunized & their communities
Increased use/timely uptake of innovative vaccines and related products
Improve sustainability of RI programs
SG3
Ensure healthy markets for vaccines and related products
SG4
TO SAVE LIVES AND PROTECT PEOPLE'S HEALTH BY INCREASING EQUITABLE AND SUSTAINABLE USE OF VACCINES
Red text and borders indicate additions to original 5.0 ToC diagram

1.2 Structure of the report

The MTE report is in two volumes. Vol. I is structured around the HLQs and the EQs (see Table 2). Vol. II contains annexes with supporting evidence. References to the annexes and other non-essential documentation are provided as endnotes (roman numerals), whereas more essential references are provided as footnotes (numerals).

Figure 4: Structure of the report



1.3 Methodology

We highlight below key aspects of our methodology. As agreed with the Secretariat and the Evaluation Advisory Committee (EAC) at the time of our inception report, we used a mixed method approach to answering the 15 EQs in the terms of reference, comprising key informant interviews (KIIs), evidence and data from other evaluations (including in some cases, transcripts of their KIIs), document and literature reviews, and seven thematic studies to address specific questions arising from the EQs. These data were cross checked and triangulated to maximise utility. The MTE team held three in-depth analytical review workshops at key points in the process and sought additional expert review in certain cases. Additional detail, including on sampling, the evaluation matrix, and implementation of ethical procedures, is included in Annex 3 (Vol. II).

1.3.1 Data collection

We assembled a substantial evidence base through document reviews, KIIs and thematic studies, summarized in Table 4 and Annex 3.

Table 4: Data and information sources

Activity	Details
Global key informant interviews	• 104 global and regional-level KIIs (49% internal Gavi, 25% Alliance, 12% Board, 14% connected),[33] including interactions with the EVOLVE and mid-term review (MTR) teams. • Key informants (KIs) were identified by Secretariat staff, stakeholder mapping to key levers and themes, and snowball sampling, with some KIs reinterviewed to fill gaps in our understanding and analysis and to provide feedback on emerging hypotheses.[34]
Country key informant interviews	• 80 country-level KIIs (20% Gavi country focused staff, 45% Alliance, 9% CSOs, and 26% connected including ministries of health, expanded programmes of immunisation (EPI), and national immunisation technical advisory groups (NITAG). • **Country-level** perspectives were collected through thematic studies (see below) in Angola, Burkina Faso, Ghana, Ethiopia, Indonesia, Kenya, Kyrgyzstan, Madagascar, the Philippines, Sri Lanka, and Zambia[35] (see Annex 3 for selection criteria).
Evidence from other evaluations	• Evidence and reports from prior and ongoing evaluations (strategy operationalisation, COVID-19, COVAX, and ZD). This included notes from 55 KIIs undertaken by other evaluations. • Emerging questions from ongoing and recently completed evaluations were also mapped to determine areas of focus and to maximise value added by the MTE (see Annex 8).
Document review	• More than 1,000 Gavi and external documents reviewed and 450 analysed (including through thematic coding), including July 2023 WHO and UNICEF estimates of national immunisation coverage (WUENIC) data. • Documents were selected for thematic coding and analysis based on their i) pertinence to the evaluation questions (see Annex 3) and ii) adherence to the temporal and geographic scope of the evaluation.
Thematic studies	• Seven thematic studies (Table 5) to fill identified gaps in evidence not covered in prior/ongoing evaluations or in Gavi documents. • Evidence base for thematic studies collected through aforementioned global/country KIIs and document reviews.

All data was collected using piloted instruments, including a semi-structured interview guide that was revised at various stages as the evidence base and our understanding of the issues evolved (see Annex 3). Data was collected until we reached analytical saturation, i.e., when new themes were no longer arising from KIIs and documents, while having covered, respectively, all relevant stakeholder groups and document types (detailed in Annex 3).

1.3.2 Analytical methods

We used a range of analytical methods, as follows (see Annex 3 for details):

- **The Gavi 5.0/5.1 ToC** (Figure 3): We elaborated a ToC as part of the MTE process. Its underpinning assumptions provide the organising framework for analysis under HLQ1 and EQs 1-5 (Sections 2.1.1-5), and on EQ9 (Section 2.2.1 under HLQ2). See Annex 2 for original Gavi 5.0 ToC and a 5.0/5.1 ToC elaborated by the MTE team. The Secretariat has not published a separate ToC for Gavi 5.1.

[33] 'Connected' is a category of stakeholder that is involved in Gavi's work, but not inside the secretariat or Alliance, e.g. country governments, donors.
[34] Snowball sampling entailed eliciting suggested further KIs from previously identified KIs.
[35] While documents from Mali were utilised, we were not able to secure any KIIs during the data collection period (see Table 7).

- **Thematic coding and analysis of evidence to triangulate and generate strength of evidence ratings** (see Annex 3 for details): We identified findings from coded data, and triangulated evidence from different sources, including during three internal team workshops.
- **Analysis of key drivers of observed results:** We used force field analyses and current reality trees to better understand the drivers of observed results (see Annex 7 for more details).
- **Thematic studies:** We completed seven studies designed to strengthen the evidence base for MTE findings, covering drivers, plausibility, innovation, horizon scanning, resource mobilisation MICs and SG4. Four cross cutting studies (resource mobilisation, MICs, SG4 and innovation) are presented separately in Vol. II, Annexes 9-12. Findings from all thematic studies were triangulated with the rest of the evidence base and are presented across the evaluation report.
- **OECD DAC criteria:** Analysis was conducted against all OECD DAC evaluation criteria, except efficiency.

Table 5: Thematic studies and objectives

Thematic study	Purpose
Resource mobilisation	Determined the sustainability of Gavi's co-financing model and current approach to domestic resource mobilisation considering increased debt distress and fiscal constraints. Findings contributed to EQs 7, 9, 10, and 15, as well as provided context for recommendations.
Innovation	Evaluated how innovation, as a strategic priority under Gavi 5.0, contributed (or is intended to contribute) to ToC outputs.
Drivers of results under Gavi 5.0/5.1	Increased evaluability of EQ10 on drivers of observed results under Gavi 5.0/5.1, answering the 'why' question and adding value to the evaluation.
Plausibility of reaching goals under Gavi 5.0/5.1	Strengthened evaluability of EQ9 on plausibility of Gavi 5.0 contributing to the achievement of prioritised SG1, 2, 3 and related objectives.
MICs	Added to further understanding of Gavi's work under the MICs approach to date, which contributed to multiple EQs, informed how the approach contributed to relevant ToC outputs, and offered key insights into how the approach should be adapted and integrated into Gavi 6.0 (supporting EQ15 in particular).
SG4	Strengthened ToC focus and the evaluability of SG4-related EQs (e.g., EQs 12-14) given a lack of recent evaluations on market shaping.
Horizon scanning	Gathered the latest reliable information on aspects of the macro environment that are relevant to Gavi's mission to provide the context for and therefore, maximise utility of recommendations.

Strength of evidence – the findings are presented using a transparent, four-point strength of evidence rating (see Table 6), reflecting the level of triangulation in the available evidence. These ratings are shown in the headline findings in Section 2.

Table 6: Robustness rating for main findings

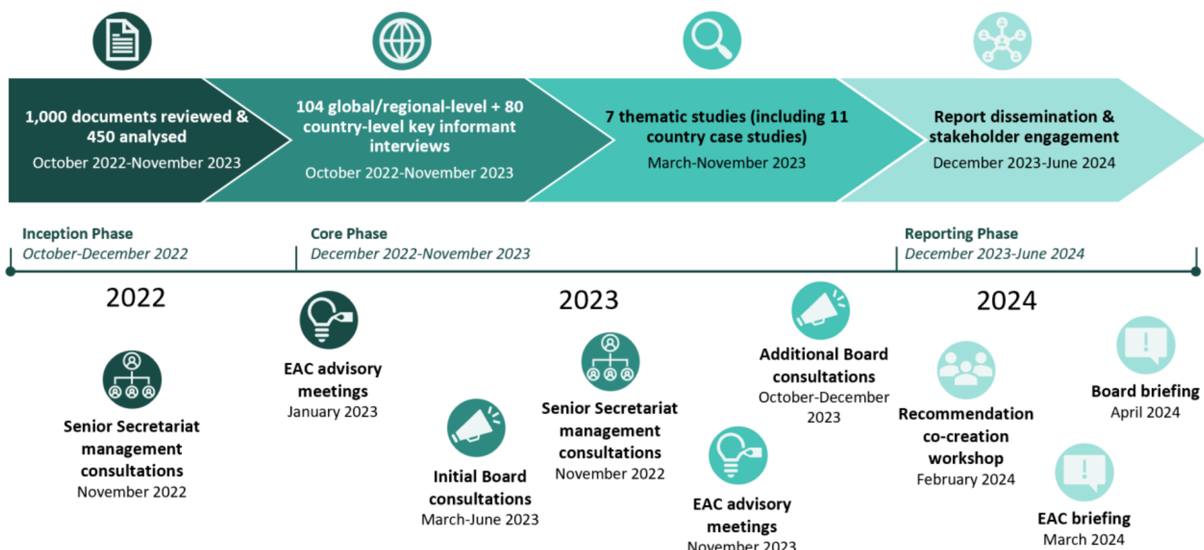
Rating	Assessment of the findings by the strength of evidence
Strong 1	• Evidence comprises multiple data sources, both internal (e.g., Gavi Secretariat and Board) and external (good triangulation from at least two different sources, e.g., document review and KIIs or multiple KIIs of different stakeholder categories), generally of good quality. Where fewer data sources exist, the supporting evidence is more factual than subjective.
Moderate 2	• Evidence comprises multiple data sources (good triangulation) of lesser quality, or the finding is supported by fewer data sources (limited triangulation, e.g., only documents. or KIIs from one stakeholder category) of decent quality but that are perhaps more perception-based than factual.
Limited 3	• Evidence comprises few data sources across limited stakeholder groups (limited triangulation) and is perception-based, or generally based on data sources viewed as being of lesser quality.
Poor	• Evidence comprises very limited evidence (single source) or incomplete or unreliable evidence. Additional evidence should be sought.

1.3.3 Approach to utilisation and stakeholder engagement

Throughout the evaluation, we prioritised interactions with key stakeholders at integral stages with a focus on increasing utility of emerging conclusions and recommendations (see Figure 5). Stakeholder consultations were integrated into the evaluation process at multiple points, including:

- engagement of Secretariat senior leadership throughout the inception, core, and reporting phases, to facilitate relevance, validity, and utility of emerging findings and conclusions;
- two meetings with the EAC to discuss key limitations and mitigations;
- interviews with Gavi Board members, as the target audience of the evaluation, at the outset and final stages of the evaluation – initial interactions framed the evaluation approach and focus, while later interactions focused on triangulating emerging findings and conclusions;
- a recommendation co-creation workshop held of 15 February 2024 with 27 relevant Secretariat and Alliance stakeholders to discuss implications of the MTE findings, emphasising validity and utility of recommendations; and
- a Board briefing prior to the April 2024 Board retreat.

Figure 5: Stakeholder consultations



For further information on how key stakeholders and partners were engaged, see Annex 13.

1.3.4 Challenges and limitations, mitigations, and departures from the TOR

Table 7 summarises the limitations and operational challenges encountered in the MTE, together with mitigating actions.

Table 7: Limitations, challenges, and mitigating actions

Limitation or challenge	Mitigation
Overlap in scope, staffing and timing with other evaluations. As planned by the Secretariat, the MTE took place concurrently with the evaluation of the operationalisation of Gavi's strategy and the first-year evaluation of the ZD programme, and soon after the completion of the COVID-19	We maintained close links with the other evaluation teams to ensure timely access to emerging data and findings, assessed strength of evidence available through these other evaluations, and used our own data collection, KIIs and document reviews to cross-check, complement and strengthen evaluability. As

evaluation, risking duplication and evaluation fatigue. There was also some overlap in staffing of the different evaluations, risking independence and confirmation bias in reaching conclusions. Finally, there was a risk that the evaluators could be overly influenced by the Secretariat in reaching its conclusions.	noted below, we were also explicit about limitations on data availability. The experience gained by MTE team members from engagement in other Gavi evaluations and processes minimised the risk of duplication and added value to data collection efforts. Independent quality control and team leadership minimised the risk of confirmation bias in reaching conclusions. We received many helpful comments and suggestions from the Secretariat and EAC, but we did not accept them all – some we rejected based on the evidence, others we incorporated following triangulation with other data sources. The findings and conclusions are therefore categorically those of the evaluators. The recommendations arising from these findings and conclusions were refined at a February 2024 co-creation workshop focusing only on the recommendations, not the findings and conclusions, attended by Secretariat and Alliance staff.
Inaccessibility, or unavailability of evidence from the Secretariat, including from KIIs.	We attempted to strike the right balance between participation and utility, minimising transaction costs for Alliance stakeholders whilst still ensuring sufficient evidence to support identification of relevant findings. We built on lessons learned from previous evaluations, cross-checking and synthesising available data and analysis. We worked in a timely way with Gavi to engage with partners (including CSOs) and government stakeholders where feasible.
Evaluation fatigue/inaccessibility of KIs resulting from multiple recent evaluations.	Since we had access to the KII transcripts from several recent evaluations, we tried, wherever feasible, not to repeat previously asked questions of an informant and instead used triangulation to cross check viewpoints. To do so, we had good access to Secretariat staff and regular touch points with members of the leadership team. Our choice of countries for the thematic studies was agreed with the Secretariat, in part to avoid countries which had been the focus of other recent evaluations. Our intention was to maximise country/CSO voice in the MTE, but even with senior country manager (SCM) assistance to facilitate contacts and our own intensive efforts, we were unsuccessful in some countries. Our efforts to hold a joint meeting with the wider CSO community were also unsuccessful, despite assistance from the relevant alternate board member.
Interface with the Board	To ensure Board views were fully reflected, we interviewed several Board members, (including the Board Chair and Vice-Chair), some twice, at the start and end of data collection. We also met twice with the EAC to receive feedback.
Methodological issues measuring results and predicting future trends including a) missing data points in Gavi strategy indicator reporting; b) lack of statistical confidence limits for WUENIC estimates; c) time lag before official coverage data becomes available; and d) methodological issues	We used the most recent global and national data and triangulated and interpreted this data based on global and country-level KIIs. We have identified gaps in the available data, for example, on domestic immunization financing.

regarding coverage, including accuracy of denominator data.[xi]	
Methodological issues estimating Gavi's contribution to observed and future results including a) delayed and staggered nature of Gavi 5.0 operationalisation and implementation – in 2023, we could only observe the plausible effects of Gavi 4.0 on 5.0 objectives and targets; and b) weak Gavi monitoring systems – e.g. lack of internal reporting mechanisms to track activity against plans, or delivery against ToC outputs and outcomes.	We have made explicit in the report where contribution cannot be quantified due to these limitations.

1.3.5 Added value of the mid-term evaluation

The MTE built on the findings of recently completed, or ongoing independent evaluations, including COVID-19, strategy operationalisation, and ZD evaluations, as well as recent Secretariat analysis and reports, including EVOLVE and the 2023 MTR. As summarised in Box 3 below, the MTE adds value by providing data which was unavailable at the time of these other evaluations, broadening and deepening the analysis and identifying the drivers behind results.

Box 3: Added value of the MTE

The MTE built on work by other evaluations, including the strategy operationalisation and ZD evaluations, in the following ways (see Annex 8 for further details):

1. **We gathered additional evidence** – to ensure a more complete picture of implementation under Gavi 5.0/5.1; e.g., on Full Portfolio Planning (FPP) or programme guidelines.
2. **We broadened analysis** – to provide a comprehensive overview on Gavi 5.0/5.1, including seven thematic studies on topics not covered by other evaluations.
3. **We deepened analysis** – to explore **why** observed results occurred, using data and methodologies unavailable to the other evaluations.

The methodologies used to achieve these are described in Section 1.3.

2 Findings

Our evidence base includes the documents and KIs listed in Annex 4

Table 4, plus KIIs from other recent evaluations such as the strategy operationalisation evaluation; analysis of the 2022 WUENIC data issued mid-July 2023; key findings from the COVAX, COVID-19 and strategy operationalisation evaluations; evidence from the draft ZD evaluation report, and interactions with the MTR and EVOLVE teams.

2.1 HLQ1 What is the status of the implementation of Gavi's fifth strategy by the end of 2023? What are the drivers and barriers that explain that status?

2	**HLQ1 summary finding:** A mixed picture. Disbursements are broadly on-track, although remaining disbursements may be more difficult to programme, requiring high country absorptive capacity. Some key priorities are not being integrated or implemented, with most concerns for SG2 [the equity goal] and SG3 [the sustainability goal], although momentum on SG2 is growing.

This Section covers design considerations – in terms of alignment of implementation mechanisms with the Gavi 5.0 ToC. Next, we look at the status of implementation against the ToC (Section 2.1.1), before analysing the factors that explain implementation status (Sections 2.1.2 and 2.1.3): perspectives of Alliance partners (Section 2.1.4), country level stakeholders (Section 2.1.5), the implications of COVID-19 (Section 2.1.6) and Gavi's response to this (Section 2.1.7). Finally, we discuss the barriers to operationalisation across the whole of Gavi 5.0/5.1 (Section 2.1.8).

2.1.1 To what extent do the implementation mechanisms to operationalise Gavi's 2021-2025 strategy align with how Gavi is expected to contribute to all its strategic goals as identified in the ToC?

1	**Summary finding:** Of the seven Gavi 5.0 ToC 'bubbles' through which Gavi is expected to contribute to its strategic goals, there has been strong integration of equity through the ZD focus into Gavi 5.0 design and operationalisation, and moderate integration of partnerships and learning. But integration of gender, resource mobilisation, and innovation is limited. The MTE reinforces evidence from the strategy operationalisation evaluation and EVOLVE process, that operationalisation of Gavi's policies and programmes is perceived as complex, with significant negative impact on the ground.

The Gavi 5.0 ToC outlines seven cross-cutting levers ('bubbles')[36] "through which the Alliance can operate to catalyse and deliver support to achieve Gavi's objectives".[xii] The bubbles are diverse, with some, such as resource mobilisation, seen as essential foundations for mobilisation of any strategy, and others of varying importance across different funding levers and country contexts. These bubbles have been integrated into operationalisation and implementation of Gavi 5.0 to various degrees. Due to the complex pathways through which these support Gavi 5.0 goals, it is not possible to assess contribution. Instead, Table 8 below summarises the extent to which each of these seven bubbles has been integrated into the design and implementation of Gavi 5.0, based on a combination of qualitative analysis of background documents and interviews, review of CPMPM[37] and Balanced Scorecard data, and summarising content from the MTE resource mobilisation and innovation thematic case studies.

[36] In the original 5.0 ToC diagram, these are referred to as "levers", but 'levers' has since been used to describe the suite of Gavi's policies and funding mechanisms. We are using the term 'bubbles' to avoid confusion over terms. Bubbles are represented on the far left side of the ToC (see Figure 3).
[37] Country Program Management Performance Metrics data – used for tracking ongoing implementation of Gavi 5.0

Table 8: Summary of integration of ToC bubbles into design and operationalisation of Gavi 5.0

Bubble	Summary of issues	Assessment of degree of integration
Aligned Programmes & Policies *(see Annex 5)*	Key programmatic policies such as Gender, Fragile, Emergencies and Displaced Populations (FED), and Health System and Immunisation Strengthening (HSIS) are well represented in the design of Gavi programmes and funding levers. However, as outlined in the strategy operationalisation evaluation and EVOLVE, challenges with operationalisation of funding levers have limited the extent to which Gavi's priorities (such as gender) have been successfully implemented. As a result, Gavi programmatic support is perceived by partners and countries to be complex rather than aligned and coherent, contributing to significant delays in application and disbursement, including for FPP and initial MICs support applications.	Limited integration
Alliance voice for equity and gender *(see Section 2.1.2, Finding 1.4 and Annex 5)*	Equity through the ZD framing is consistently integrated in the design of Gavi 5.0 funding levers and is strongly filtering through to interventions included in applications for Gavi support. These interventions appear to be broadly evidence-informed (e.g. based on efforts to improve understanding of where ZD children are and what the various demand barriers to reaching ZD are), although actual implementation is limited to date.	Good integration
	Gender is well integrated into the design of many funding levers, but operationalisation is still limited in practice, with gender-responsive or transformative interventions still poorly represented across Gavi support as a whole, and limited evidence of work actually taking place to date	Limited integration
Differentiated engagement *(see Section 2.1.5, Finding 1.13 and Annex 5)*	Evidence strongly indicates a need to refine differentiation so that application and review processes better account for the actual Secretariat resources available to manage assistance well, in addition to the relative risk of working with, and the capacity/ needs of different countries. The MICs approach of simplified processes shows promise (see Annex 10).	Limited integration
Partnerships *(see Section 2.1.4 and Annex 5)*	New and existing partnerships are seen as key to the success of Gavi 5.0 and as playing an especially important role in fragile and conflict affected countries, with emerging evidence of the value that regional core partners can play. But evidence indicates that the Secretariat has not sufficiently mitigated the inherent tension between core Alliance and newer CSO partners, or the complexity of contracting country CSOs. This has affected progress in developing new partnerships and risks the coherence and harmony of Gavi's relationship with core partners.	Moderate integration
Alliance learning *(see Annex 5)*	Learning is integrated into the Gavi 5.0 monitoring framework and there are multiple examples where Gavi has made efforts to integrate ongoing learning into its policies and processes, for example via a learning system strategy, learning agendas, and hubs. There is anecdotal evidence of learning being used e.g., to improve the effectiveness of HPV introduction in MICs. But some stakeholders question whether learning is driving decision-making and thus real improvement and change. On a more granular level, monitoring systems are not yet supporting efficient tracking of progress against Gavi 5.0 as outlined in the 5.0 ToC.	Moderate integration

Resource mobilisation[38] *(see Annex 11, Resource Mobilisation Thematic Study and Box 8)*	There have been some activities related to domestic resource mobilisation and sustainability in Gavi 5.0, primarily relating to advocacy for timely co-financing payments and transition planning, but a systematic approach to, and monitoring of outcomes related to resource mobilisation is lacking. Gavi does not track domestic resource mobilisation for immunisation aside from co-financing payments (only a proportion of overall programme costs). Evidence also indicates that this area is not highly prioritised in funding applications and activities compared to other thematic areas, such as ZD and new vaccine introductions, and that the prioritised thematic areas are not being systematically assessed for sustainability. As noted in Annex 11, advocacy activities aimed at increasing domestic resource mobilisation are not likely alone to achieve sustainability; rather, there is a need for a multi-pronged approach to priority setting with collaboration between the Alliance, CSOs, and governments.	Limited integration
Innovation *(see Annex 12, Innovation Thematic Study)*	The approach to innovation, based on six key shifts grounded in learning from previous approaches, was approved by the Board in June 2022. This included an Innovation Top Up fund to help scale proven interventions in response to country needs. Operationalisation of the approach was delayed and has been hampered by interconnected factors including de-prioritisation due to COVID-19, weak monitoring and accountability systems, differences in understanding the term 'innovation', and not having a centralised home/ lack of promised human resources. As a result, progress to date has been limited and piecemeal, teams are still working in silos (despite complementarity of design), and the approach is still not sufficiently country-driven.	Limited integration

2.1.2 How relevant is the elaborated Gavi 5.0 MTE ToC and underlying assumptions as countries build back from the pandemic and in the context of Gavi 5.1?

2 **Summary finding:** Gavi does not routinely track progress against the 5.0 ToC as a whole, calling into question the relevance of the ToC beyond a conceptual framework. Making a judgement against this question is therefore challenging.[39] However, our analysis suggests more focus and progress against SG1 [the vaccine goal], SG2 [the equity goal] (though with less progress on gender), and SG4 [the healthy markets goal] than against SG3 [the sustainability goal]. There is a mixed to negative picture around critical assumptions related to sufficiency of government capacity and the effectiveness and sustainability of Gavi-supported interventions. These assumptions are still relevant, but their failure to consistently hold is a cause for concern.

In this Section we examine progress against *interventions* outlined in the Gavi 5.0 ToC to support our analysis of whether the ToC *outputs* are being achieved (Section 2.1.3), as well as to what extent critical assumptions have held. The ToC frames and justifies the design of new levers and the content of applications, but it does not provide the framing for, or basis of, subsequent monitoring efforts at

[38] The Resource Mobilisation thematic study (Annex 11) focuses on domestic resource mobilisation, which is the area of resource mobilisation we see as cutting across the ToC from left to right. Resource mobilisation from donors is of course also key but acts primarily at the left/input side of the ToC. As the Alliance has (to date) been relatively successful at this, this was not our area of focus.
[39] A separate ToC for 5.1 has not yet been issued.

country or regional/global/strategic levels.[40] This is further complicated by around 20 separate multiple intervention-/lever-specific ToCs.[41] Together, this Section and Section 2.1.3 provide the core of our description of the status of implementation under Gavi 5.0/5.1.

2 **Finding 1.1: Gavi is broadly on track with disbursement against the 5.0 budget, driven by vaccine-related expenditures. Performance is equivalent to the same point in time during Gavi 4.0, which is notable given external challenges and increased absorption required for COVID-19 Vaccine Delivery Support (CDS) funds. Gavi forecasts full expenditure for 5.0/5.1 although this relies on slower-to-programme cash grants for which disbursement trajectories are more challenging to predict.** At its replenishment in 2020, Gavi raised US$ 10.3 billion, US$ 1 billion more than initially requested. Of this, 56% was allocated to vaccine expenditure, 35% to investments in immunisation systems and enabling infrastructure (including to partners, cash support and Gavi operations), and 5% for Board strategic investments. As of September 2023, more than halfway through the strategy period, Gavi has disbursed around 53% of its budget for 5.0.[42] Of this, 65% has been spent on vaccines, 28% on cash grants and 7% on operating expenditures (see Figure 6).

Figure 6. Gavi 5.0 disbursement status

By type, the vaccine budget is at 63% overall disbursement, cash grants at 39% disbursement, and operating expenditure at 48% disbursement. Whilst Gavi is forecasting a full utilisation of its 5.0 budget, it appears that the cash grant projections are somewhat optimistic: just under US$ 2 billion remains to be disbursed in just over two years, which will be programmed through relatively complex and slow grant management processes (Section 2.1.5) currently averaging 2.5 years from start to disbursement. The current disbursement status is similar to that at the same point of the 4.0 strategy period, and in view of disruptions in the first two years of Gavi 5.0, is a notable achievement.

[40] Although Gavi noted there is routine monitoring against the strategy objectives on the one pager, which resembles the TOC.

[42] Data received from Gavi Secretariat.

1 **Finding 1.2: Available data from the Partners' Engagement Framework (PEF) Targeted Country Assistance (TCA)/Strategic Focus Area (SFA) milestones indicates that most interventions are focused on SG1 [the vaccine goal] and SG2 [the equity goal], with very limited focus on SG3 [the sustainability goal]**. SG4 [the healthy markets goal] is discussed in Sections 2.2.4, 2.2.5, and 2.2.6. Monitoring of progress against Gavi 5.0 at the intervention and output levels is limited. Where it does exist, it is not mapped against the ToC components directly, but against, for example, programmatic areas.[43] Updated country-level workplans outlining progress at the intervention level were unavailable.

Box 4: Integration of ZD into country applications
An HSIS analysis of the 25 HSS or EAF applications approved by the IRC in 2022 and 2023 gave an average score for the extent ZD was integrated as a key shift of 2.41 out of 3. This was higher than gender and innovation and about the same score as for demand and CSO engagement. Our analysis of FPP documents showed similar findings.

Milestone reporting does exist for TCA, and rapid mapping[44] of this data provides some indication of relative level of effort at intervention level against the SGs. PEF milestone mapping of TCA milestones (2021 – mid 2023) shows that over 60% of planned milestones since 2021 have been focused on SG2 (the equity goal), and that this has increased since 2022 (although notably, gender-related milestones within this are very poorly represented). This is consistent with analysis of country applications as conducted by the strategy operationalisation and ZD evaluations and corroborated by the MTE team and analyses from the Gavi Secretariat (see Box 4 and Table 9).

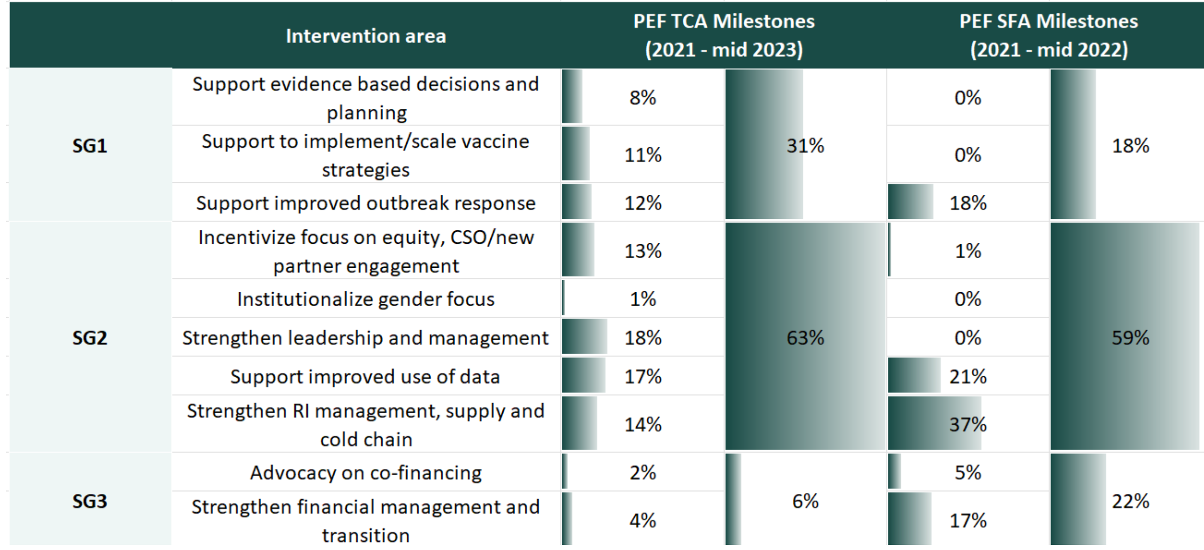
SG1 [the vaccine goal] milestones are also well represented, and it is important to note the substantial overlap/complementarity between SG1 and SG2 interventions. However, consistently there is a much lesser focus on milestones focused on SG3 [the sustainability goal] (see Table 9). We also note a relatively strong focus on outbreak response under SG1 (see Table 9), although the latter has dropped off since 2021 due to a reduction of interventions focused on COVID-19.[xiii]

PEF SFA milestones data (only available for 2021 to mid-2022) shows a more significant focus on SG3 (22% of milestones), in line with sustainable financing being a key focus area of SFA. However, SG2 is still the primary focus (60%) of milestones.

Actual progress against annual[45] TCA milestones shows that 57-62% (average 60%) were completed or on track over the whole period, but with slower progress against SG3 milestones. Progress has generally increased since mid-2022, where 53-77% (average 68%) were completed/on track – but decreased for SG3 (from 57% to 53%) (see Figure 8 in Annex 5).[xiv] Progress against annual SFA milestones varied from 63-81% (average 74%) completed, or on track, with most limited progress in SG1 (63%) and the most progress in SG2 (81%) (see Figure 12 in Annex 5).[xv] However, we cannot make judgements about progress overall, as we lack data on the implementation of previous annual milestones.[46]

[43] Such as Data, Demand Promotion, Coverage/Equity, Financial Management, Leadership, management and coordination, Supply Chain, Vaccines, Financing, Transition, Vaccines etc.
[44] Based on review of key phrases in milestone and activity descriptions relevant to the ToC components
[45] We assume milestones are set annually.
[46] Milestones that were not completed in an annual cycle do not appear in the subsequent reporting.

Table 9: Relative focus on PEF TCA and SFA milestones mapped against ToC interventions



	Intervention area	PEF TCA Milestones (2021 - mid 2023)		PEF SFA Milestones (2021 - mid 2022)	
SG1	Support evidence based decisions and planning	8%	31%	0%	18%
	Support to implement/scale vaccine strategies	11%		0%	
	Support improved outbreak response	12%		18%	
SG2	Incentivize focus on equity, CSO/new partner engagement	13%	63%	1%	59%
	Institutionalize gender focus	1%		0%	
	Strengthen leadership and management	18%		0%	
	Support improved use of data	17%		21%	
	Strengthen RI management, supply and cold chain	14%		37%	
SG3	Advocacy on co-financing	2%	6%	5%	22%
	Strengthen financial management and transition	4%		17%	

2 **Finding 1.3: Relevant process/output focused strategy (and strategy implementation) indicators (SIs and SIIs), CPMPM and Balanced Scorecard indicators also reflect more progress at intervention level against SG1 and SG2 than SG3.** This could bode well for SG2 (also noted by the ZD evaluation)[47], which is encouraging considering the poor strategy-level results presented in Section 2.2, but it is too early to say with certainty. There is an emerging picture from this evaluation, including KIIs, that more focus is needed on sustainability.

Milestone/intervention level reporting for other funding levers (HSS, Equity Accelerator Funding (EAF), Cold Chain Equipment Optimisation Platform) was not available, but review of relevant SIs, SIIs and CPMPM data allows us to make some assessment of progress at ToC intervention level. Table 10 in Annex 5 provides an overview of pertinent SIs and CPMPM indicators, mapping them against the most relevant SGs. For example:

- For **SG1 [the vaccine goal]**, seven relevant indicators show improvement since 2021, including SII A1.1 (timeliness of vaccine launches), SII A1.5 (proportion of approved measles applications upon first Independent Review Committee (IRC) review), SI 1.6 (measles campaign reach), HPV applications approved, and number of HPV launches.
- For **SG2 [the equity goal]**, five relevant indicators show improvement since 2021, including SII A2.2 (EAF and FPP applications approved), SII A2.4 (cash disbursement against forecast), SII A2.5 (proportion of grant funds utilised) and SI 2.4 (number of immunisation sessions).
- In comparison, while two out of four relevant indicators under **SG3 [the sustainability goal]** do show improvement, one of these (SII A3.3 – RI coverage in transitioned countries) cannot be attributed to MICs support as disbursement has not yet started.

Table 10 in Section 2.1.3, provides a summary assessment of progress against ToC intervention areas, based on a combination of PEF TCA/SFA milestone mapping, mapping of relevant indicators and review of qualitative data. A more detailed table with bulleted summaries of the evidence and sources of evidence is provided in Table 11 in Annex 5.

1 **Finding 1.4: Gender-responsive or transformative interventions are not well represented in SG2 programming, despite gender being a Gavi priority predating Gavi 5.0, as has been consistently noted by other evaluations and the Secretariat. The main barriers include poor**

[47] If ToC assumptions hold in most key countries, then in line with the ToC causal pathways, longer-term SG2 results should follow. Currently there are no critical failures (see Vol II, Annex 5, Figure 13).

understanding (across the Alliance) of how specific gender issues impact immunisation outcomes, together with lack of sufficient capacity and integration of gender issues in the Secretariat and the wider Alliance dedicated to ensuring a gender-lens in Gavi-supported interventions. In addition, gender is usually outside country EPI team responsibilities. More detailed mapping against the interventions as outlined in the elaborated Gavi 5.0 ToC provides further insights, such as almost total absence of TCA and SFA milestones explicitly mentioning gender or broader equity (see Table 9 and Box 5). This is despite gender being a key part of SG2 and an SFA grouping since Gavi 4.0.[xvi] It is important to note, however, that while milestone mapping indicates no gender-related SFA work taking place, SFA disbursement data for 2022-23 indicates that 5% of total funds committed and 6% of total funds disbursed were focused on gender (see Table 8 in Annex 5). There are some examples of SFA funding being used to roll out a training for Gavi staff, Alliance partners and country representatives on mainstreaming gender into immunisation programming and of some operational research on piloting gender transformative approaches. There are also examples of increased operationalisation of gender in HSS and EAF grants, with 65% of HSS/EAF applications from 2021-mid 2023 designed with some identification of gender issues (compared to only 5% under Gavi 4.0).[xvii]

Despite these laudable efforts, evidence from the MTE and other evaluations confirms that overall, there is still relatively limited focus on gender[xviii] (see Box 5).

The reasons include, in the Secretariat and among partners and countries:

- **Poor understanding of relevant gender dimensions** in immunisation, with an overfocus on sex differentials in coverage, which may discourage action as these are usually minimal, instead of a focus on addressing gender-related barriers and costs by encouraging, e.g., fathers' involvement.
- **Insufficient gender resources**. Only one person in the Secretariat focuses solely on gender (covering issues both internal and external to the Secretariat). Focal points for HSIS advocate/advise on many priority areas (in addition to gender), and there is no Gavi support allocated to core Alliance partners that can be used to fund gender-specialised positions in countries.[48]
- **Gender issues may not be within the remit of the EPI team which delivers vaccines**. Gender issues are usually the responsibility of other units in the Ministry of Health, with weak links to immunisation.

[48] By comparison, the FAO has a network of more than 200 Gender Focal Points at HQ and country offices able to dedicate 20 percent of their time to gender-related work https://www.fao.org/3/cb2401en/cb2401en.pdf. The Global Fund has a Community, Rights and Gender Department providing technical leadership, strategic and policy guidance on gender, human rights, key and vulnerable populations and community responses.

Box 5: Gavi's use of gender-responsive programming

Following the 2019 evaluation of Gavi's Gender Policy, Gavi has tried to mainstream gender through FPP processes and reallocating existing funds to ensure a stronger focus on the ZD agenda. However, evidence from a range of sources, including the strategy operationalisation evaluation country case studies, suggests that only a few countries have used a gender lens in their programming, and very few have incorporated interventions that could be categorised as gender-responsive or gender-transformative. This is consistent with the IRC observation that *"despite repeated IRC recommendations, countries are not conducting rigorous gender analyses and discussions of gender barriers, and proposals remain weak. Related gender-responsive or transformative strategies are insufficiently addressed and may not be incorporated in action plans."*[2] Gavi's HSIS team analysed 25 HSS or EAF applications approved in 2022 and 2023 to assess the extent to which gender was integrated as a key shift, with an average score of 1.8 out of 3. While sub-criteria of identifying gender barriers, addressing health workers' barriers and addressing caregivers' barriers were partially met, other sub-criteria were, on average, not met: gender coverage gaps, addressing adolescent mothers' barriers, and addressing adolescents.[3] Our analysis of FPP documents in case study countries also shows low gender integration.

1: Gavi. 2022. Report to the Board, 7-8 December.
2: IRC Report, November 2022.
3: Gavi. 2023. HSS 5.0 Key Shifts tracker

2.1.3 To what extent have the implementation of Gavi's levers and mechanisms for operationalizing the current strategy led to intended and unintended consequences at global or country level?

3 **Summary finding:** Evidence to answer this question is thin given the focus and nature of Gavi measurement and evaluation (M&E) systems (and without major changes will be challenging to address going forward). What we do know about implementation suggests more limited progress along the ToC pathways towards SG2 and SG3. Anecdotal examples of unintended consequences highlight e.g. use of GNI as the main criteria for eligibility and transition timelines and CDS funding displacing HSS funding.

Analysis of whether implementation is contributing to *intended* consequences is also included in Section 2.2.

3 **Finding 1.5: There is limited evidence on whether interventions under each SG are translating into intended outputs, as Gavi does not routinely track progress at the output level.**[49] **There are anecdotal examples of intended outputs under SG1 [the vaccine goal] and SG2 [the equity goal] being achieved. But there are also examples of outputs that have not materialised, and of some unintended negative consequences of the focus on increased CSO engagement, the use of GNI as the main criteria for eligibility and transition timelines, and of CDS funding displacing HSS funding**. Tracking progress at this level is conceptually complex and probably unrealistic for several reasons. For example, designing SMART (**s**pecific, **m**easurable, **a**chievable, **r**elevant and **t**imebound) indicators for measures such as increased capacity, innovation, political commitment, and collaboration would be challenging. In addition, ongoing measurement would be burdensome for both in-country implementing agencies (core and expanded partners and government) and the Secretariat and would likely not always translate across different contexts. Any consideration of tracking at this level would require explicit discussion on trade-offs with the Board. Our qualitative review of background documents (including Balanced Scorecard reports, CPMPM reporting and qualitative reports/narratives) and interviews mapped against the ToC indicate that,

[49] Gavi did note some exceptions, such as in the GBS programmatic module.

despite Gavi 5.0/5.1 implementation being at an early stage, there are some examples of intended outputs being achieved. The strongest progress is under SG2, however with overall limited evidence, as ToC outputs are not systematically tracked through any current indicators. A summary of progress at output level is provided in Table 10.

Table 10: Summary of progress against ToC interventions and outputs

	Intervention Area	Progress Assessment	Output	Progress Assessment
SG1	Support countries to make evidence-based vaccine decisions.	Moderate progress	Increased capacity for evidence-based decision making to prioritise vaccine introductions.	Moderate progress
	Support countries to implement/scale tailored vaccination strategies.	Good progress		
	Support improved outbreak & pandemic response and connection back to RI.	Good progress	Global stockpiles for outbreak & pandemic-prone diseases efficiently and equitably deployed.	Moderate progress
SG2	Incentivise focus on equity, prioritising/ addressing barriers to RI and engagement with CSOs/new partners.	Good progress	Increased capacity to identify, reach, monitor, measure & advocate for ZD and under-immunised.	Good progress
	Institutionalize focus on addressing gender-related barriers to RI/promote gender equity.	Limited progress	Increased availability/implementation of transformative innovative strategies /technologies to address gender, equity, and fragile and conflict-related barriers to RI.	Limited progress
	Strengthen leadership & management functions to plan and manage RI.	Good progress	Improved governance & coordination including via EPI & technical advisory groups.	Moderate progress
	Increase triangulation and use of sub-national data to plan/monitor RI.	Good progress	Strengthened data systems and use to advance immunisation.	Moderate progress
	Strengthen vaccine management & supply of cold chain equipment.	Good progress	Improved supply chain systems and processes to ensure vaccine availability.	Good progress
SG3	Advocacy/coordination with countries & donors to meet co-financing.	Limited progress	Increased commitment from countries and donors to fund RI.	Moderate progress
	Strengthen planning to improve financial and readiness for transition.	Limited progress	Improved capacity for programmatic sustainability.	Moderate progress
	Support to former and never-eligible MICs to prioritise and plan for maintaining, restoring, and strengthening equitable RI services.	Moderate progress	Increased political commitment & EPI capacity to sustainably maintain, restore, and improve equitable immunization performance in MICs.	Moderate progress
	Support to MICs to increase access to vaccines at sustainable prices.	Limited progress	Greater collaboration with donors & other financing agencies.	Limited progress
SG4	Pooled procurement and distribution of vaccines and related products.	Good progress	Vaccine supply security maintained.	Good progress
	Support to vaccine markets to develop market roadmaps, improve coordination & forecasting.	Good progress	Sustained value-based pricing of vaccines.	Good progress
	Support competitive dynamics in markets.	Good progress		
	Support improved supplier capability & sustainability, including to de-risk investments and support development/ scale of innovations.	Moderate progress	Innovative vaccines and RI-related products developed, procured, and deployed at scale.	Moderate progress
	Provide insights into development of new regional manufacturing hubs.	Good progress		
	Support to optimize vaccine and related product regulatory systems/processes.	Moderate progress		
	Improve alignment between vaccine development and market strategies & other procurement entities.	Moderate progress	Strengthened capacity to understand, influence & build market demand, including understanding of country vaccine preferences.	Limited progress
	Develop new demand health intervention framework to govern,	Moderate progress		

	monitor and enhance outcomes of demand-side market shaping.		

A more detailed summary is provided in Annex 5. Two outputs under SG2 appear to have made good progress: there were several qualitative examples of the "improved supply chain systems and processes to ensure availability of vaccines at access points" output being achieved, with either Cold Chain Equipment Optimisation Platform and/or CDS being used in support of this, including in eligible MICs. Similarly, there were several examples of the "increased capacity to identify, reach, monitor, measure, and advocate for ZD, under-immunised, and their communities" output being achieved, for example, through sub-national planning and micro-planning supporting improved identification and reach of ZD children.[xix] However, there are also examples of decisions being made that were not based on evidence (SG1 output), such as countries pausing vaccination because their preferred vaccine product was out of stock, even though an effective alternative was available;[50, xx] of vaccine/EPI coordination and governance (SG2 output) often still inadequate,[xxi] of improved capacity for programmatic sustainability not materialising (SG3 output) despite rapid economic growth,[xxii] and of issues in supply chain systems and processes (SG2 output) resulting in stockouts.[xxiii]

Some unintended consequences of Gavi support were identified, albeit with a limited evidence base for each. For example:

- CDS funds resulting in low uptake utilisation of HSS funds, partly as they were seen as easier to access;[xxiv]
- the push for increased CSO engagement resulting in increased competition for resources in some countries;[xxv] and
- the use of GNI as the main way to segment countries and define transition timelines has also had unintended consequences. For example, countries with increasing GNI have started the transition process without full consideration of other factors which may mean they are not in fact well positioned for transition (e.g., Papua New Guinea); and some MICs countries have been automatically excluded from MICs approach support based on GNI, when in fact they may otherwise be strong candidates for targeted support.[xxvi]

2 **Finding 1.6: Available evidence against the ToC indicates progress and assumptions hold more consistently along SG1 causal pathways. Progress along SG2, SG3, and SG4 pathways is mixed, partly due to wide contextual variations, limited implementation on SG3 (MICs support) and variable progress on sub-areas within SG4. There is a mixed to negative picture against critical assumptions related to in-country capacity and the effectiveness and sustainability of Gavi-supported interventions, with potentially significant implications for achievement of Gavi 5.0 goals and the design of 6.0.** Assessment of progress against the ToC towards outcome level is challenging as it is not used as an overall monitoring framework, so evidence is limited in some areas. A visual summary of progress against the main ToC pathways is provided in Annex 5, Figure 13, which includes assumptions and progress towards outcome level. The assumption that "Gavi programmes/processes support efficient operationalization" at the far left of the ToC has mostly failed to hold. However, while there is evidence that this has resulted in delays and frustrations, it has not caused a critical failure in the ToC as a whole. Some of the more critical assumptions with a mixed to negative picture are:

- **Sufficient government capacity to engage/ implement**, which varies by country, as explored under Section 2.2.3.

[50] Although this may not reflect lack of capacity, but other reasons

- **Gavi interventions are effective and sustainable:** there is limited evidence against this assumption, with some examples of optimism regarding the effectiveness and sustainability of Gavi supported interventions, but also some significant concerns (for example questioning the sustainability of the push for new vaccine introductions in MICs with limited health system capacity (see Box 6 and Annex 10 related to the MICs thematic study for details).

Box 6: Middle Income Countries

Gavi's MICs support is key to achievement of SG3 and HPV relaunch targets. MICs support is still in early implementation, but progress is promising. Stakeholders with experience of MICs operationalisation provided critical insights into potential design modifications for the future:

- Limited transparency of vaccine pricing and concerns around higher prices paid, especially by never-eligible countries, require urgent attention to avoid threats to the sustainability of new vaccine introductions.
- MICs, especially never-Gavi-eligible countries, have highly variable health system strengths and resilience. While Gavi may not be the most appropriate partner/donor to provide HSS support to MICs, stakeholders widely acknowledged the importance of ensuring that a critical level of health system capacity and strength is in place prior to new vaccine introductions.
- While a decision was previously made not to provide Gavi support to all World Bank-defined MICs, and there is consensus that supporting all MICs is not realistic, many stakeholders questioned the use of GNI data to decide eligibility, suggesting instead a composite indicator which also considers burden of disease to better target Gavi resources.
- There is a need to explicitly consider the equity trade-offs between providing support to reach MICs and regions with the largest numbers of ZD and under-immunised children, versus supporting the most vulnerable and hard-to-reach children in smaller MICs and/or harder-to-reach areas of larger MICs. This relates to the question around Gavi's future role in supporting broader RI/health system capacity in MICs, including never-eligible MICs.
- The MICs experience demonstrates cases of reduced IRC review and more streamlined and flexible application processes, while also highlighting the importance of a full dry run of processes to avoid unnecessary delays and frustrations before rolling out to countries.
- The MICs approach also offers insights into how global and regional core partners can be successfully leveraged to drive Gavi's agenda forward and support progress towards the SGs, with learning from regional successes fully supporting more effective implementation at country level.

2.1.4 To what extent is there alignment across key Alliance partners on Gavi's approach to implementation of the current strategy? Are there challenges for partners in playing their expected roles and are these being effectively addressed?

2 **Summary finding:** Despite significant hindrances during Gavi 5.0, mostly from COVID-19, Alliance alignment on 5.0 priorities is generally strong. The introduction of some new priorities created initial tensions (especially on CSO engagement) with variable operationalisation linked to capacity and accountability. Ongoing efforts to 'reset' Alliance relationships suggest optimism, but with work to do.

The following findings reflect data collected and reviewed at the time of the evaluation, including stakeholder perceptions. However, it is important to note that Gavi has recently undertaken several efforts to "reset" Alliance relations, including formation of the Alliance Partnerships and Performance Team, efforts to clarify roles and responsibilities, and introduction of a new accountability framework for PEF Foundational Support and SFAs.[xxvii]

1 **Finding 1.7: There is strong alignment among core partners behind Gavi's ZD agenda, but Gavi's push for increased CSO and expanded partner engagement has created some tensions, with some core partners at all levels questioning the rationale behind application of the concept in all contexts/countries. Partner support for other priorities such as innovation and resource mobilisation is strong in principle but mixed in terms of operationalisation and prioritisation.**

As previously outlined under Section 2.1.2, core partners play a key role in providing technical assistance (TA) to support the various SGs, with a particularly strong focus on SG2 and supporting interventions related to the ZD agenda. Evidence also confirms support for gender, although this has not been operationalised as successfully.[xxviii] Partner support for other priorities such as innovation and resource mobilisation is strong, but operationalisation is mixed across countries, depending on context. See Annex 11 [Resource mobilisation thematic study] and Annex 12 [Innovation thematic study] for further details.

A key concern cited by core partners and other stakeholder groups relates to tensions that Gavi's Civil Society and Community Engagement (CSCE) approach has introduced between CSOs and core partners. Core partners expressed concern that allocation of Gavi resources to new partners redistributed resources that would previously have been allocated to them.[xxix,xxx] This has manifested itself in cases where, for example, the 10% TCA allocation was perceived as a "maximum", with 90% of TCA allocated to core partners, and CSO partners left competing for the remaining 10% – countering the aim of using CSOs for more effective results.[xxxi] A small number of core partner informants did acknowledge the value of CSOs and expanded partners, for example in reaching ZD communities at a sub-national level where CSOs have better reach and trust,[xxxii] yet other KIs also raised concerns regarding the appropriateness of CSOs providing TA to government stakeholders. Some core partner informants in different regions and countries also felt that the push for CSO involvement is less relevant or feasible in certain contexts, e.g. in smaller countries or in MICs where there are limited or no CSOs working in health/RI.[xxxiii]

Box 7: Greater CSO involvement

In June 2021, the Board approved a new CSCE approach to ensure local partners and CSOs are better leveraged to tackle the ZD agenda.[1] This involves revised country guidance to support countries to meet the Board requirement that 10% of their combined TCA, HSS and EAF ceilings are allocated for activities undertaken by CSOs.[2,3] Additionally, guidance for PEF TCA stipulates that 30% of funds will be allocated to local partners over the course of Gavi 5.0.[4] In the previously mentioned analysis of HSS or EAF applications approved by IRC in 2022 and 2023, the average score for the extent to which CSO engagement was integrated as a key shift was 2.41 out of 3 (GREEN-meets the criteria) – higher than gender and innovation and about the same score as for demand and ZD.[5] Our analysis of FPP documents in our case study countries showed a high level of integration of CSO engagement.[6]

1. *Gavi Civil Society and Community Engagement Approach, Report to the Board, 23-24/6-2021.*
2. *ibid*
3. *Gavi Annual Progress Report 2021*
4. *Gavi Report to the Board 7-8 December 2022*
5. *Gavi HSS 5.0 Key Shifts tracker 2023*
6. *MTE analysis of FPP documents for Burkina Faso, Ethiopia, Kenya, Kyrgyzstan, Madagascar, Mali and Zambia.*

CPMPM data indicates that, overall, 23% of funds have been allocated to CSOs, although this has dropped from 29% in 2022 to 18% in 2023. EAF has the highest proportion of funds allocated to CSOs, at 31%, followed by TCA (24%) and HSS (18%). High impact (HI) countries allocate more funds to CSOs than any other segment across all three main levers. Financial data does not show whether funds are going to new or existing partners but does show an increased proportion of funds going to local CSO partners in 2023 (as opposed to international CSOs), perhaps reflecting an increase in engagement with new country partners. See Annex 5 for detailed analysis of CSO funding allocations.[xxxiv]

Other challenges were noted, in relation to Gavi systems and requirements that are not supportive of direct contracting of smaller and/or local CSOs,[xxxv] leading to sub-contracting by core partners. Some informants said this contributes to the tensions between core and newer partners[xxxvi] while others noted this could be beneficial in fragile environments.

2 **Finding 1.8: Core Alliance partners play a pivotal role in the operationalisation of Gavi 5.0/5.1, including in articulating and implementing Gavi programmes and priorities at country level, particularly in fragile countries. These partnerships can work well, but some Secretariat and Board informants were concerned about inconsistent capacity and accountability of core partners to deliver effective, sustainable country interventions in support of the SGs**. The core Alliance partners play a pivotal role in the operationalisation of 5.0/5.1,[xxxvii] including in articulating Gavi's priorities at country-level, where Gavi has no on-the-ground presence.[xxxviii],[xxxix] They play a particularly important role in fragile and conflict affected countries, where Gavi would struggle to move funds otherwise.[xl] A positive example of the core partners working well together is COVAX, which was implemented during a time of crisis.[xli] As outlined under Section 2.1.2, other than SG2, there is stronger support for SG1 among partners than for SG3.

However, there are concerns about how individual core partners are operating in some regions and countries. A recent survey noted that "*the current perception among many Alliance members is that partners do not always speak with one voice, and better alignment among partners could help to create an even more substantial local impact*".[xlii] These concerns were broadly centred around core partner capacity to provide the expected support, and core partner accountability and reporting:

- Overall there is a mixed picture in terms of core partner capacity to provide the needed technical support at the global, regional and country levels.[xliii] Specific examples cited of limited capacity were in the use of gender approaches and in behaviour change communications.[xliv] [51] Within the core partners, there is some acknowledgement of capacity constraints, more in terms of number/breadth of staff than in technical expertise of individual staff, especially in regions/countries that receive less Gavi support (e.g. Latin America and the Caribbean, and in post-transition/former-eligible and never-eligible MICs).[xlv]
- Secretariat staff at different levels and some Board members expressed concerns about core partner accountability for the quality of delivery (programmatic and financial).[xlvi] Examples referenced included lack of clarity on which partner should be held accountable for vaccine stock-outs[xlvii] or for misuse of funds.[xlviii] Resistance was also reported concerning attempts to increase programmatic accountability through introduction of (self-reported) milestone tracking on PEF funds channelled to WHO and UNICEF. Although, some countries (e.g., Nigeria) reported strong accountability mechanisms of all stakeholders,[xlix] and there are ongoing efforts to revise and improve core partner accountability/reporting frameworks. Some KIs linked poor accountability to a lack of clarity around lines of engagement within the core partners.[l] Informants also noted that the core partners may sometimes use Gavi resources to support their own resources and operational priorities, even if these do not fully align with those of Gavi, but we could not provide independent verification of this.

1 **Finding 1.9: Beyond capacity constraints, core partners experience a range of challenges including unclear roles and lines of decision making and navigating Gavi's complex and evolving funding processes; all of which can reduce trust and effective working relations within the Alliance.** Efforts are ongoing to improve core partner relations, including clarifying roles and responsibilities, but the strategy operationalisation and ZD evaluations along with other

[51] Current gender training being rolled out under an SFA has the potential to increase partner understanding of relevant issues, but its success will likely depend on whether partners have the resources to increase capacity on gender.

available evidence highlight a range of concerns. For example, some core partners felt that in response to concerns around their capacity, the Secretariat has started to *"fill some of these ga*ps" in areas such as political advocacy, which was seen by some as inappropriate and disrespectful to partners.[li] As the strategy operationalisation evaluation notes, Gavi's various processes are seen as highly complex and burdensome, a view shared by many core partners. In-country partners are spending excessive time providing guidance on country applications for Gavi support with consequent reductions in resources for TA.[lii] Variable levels of trust between partners and with Gavi were also highlighted as a concern, with some partners feeling that their role is unclear.[liii]

3 **Finding 1.10: Regional level core partners have a pivotal role in pushing forward Gavi's strategy and progress towards the SGs, for example in MICs, but this is not consistently happening.** Secretariat and core partner informants at regional and country level noted the value of engagement with regional core partners (primarily WHO and UNICEF) to drive Gavi's agenda.[liv] Various historic and current platforms exist for this, and where it works well, it is seen as helping to share valuable learning across and within regions, valuable for consensus building, and supportive of overall operationalisation at all levels.[lv] While it was mostly informants engaged with Gavi's MICs lever that referenced the value of regional partners (see MICs thematic study, Annex 10 and Box 6), the benefits were seen as going beyond MICs work.[lvi] The MICs approach was designed to engage regional core partners, which then support country partners and governments. Several stakeholders familiar with MICs regional support (across Gavi Secretariat, core partners at global, regional and country level and some government stakeholders) felt that it was valuable and was key in encouraging former- and never-eligible countries to apply for new vaccine introduction support. It had also already proven a valuable avenue for learning within regions, for example to improve the MICs application experience for Asian countries following on from challenges experienced by Indonesia; and for sharing European country experience with Kosovo as it planned HPV introduction with MICs support.[lvii] There is reportedly variable capacity among regional core partners, with some regions seen as providing highly responsive and valuable support, and others less efficient or effective support.[lviii] This may however reflect the unclear roles of regional partners[lix] - some KIs noted that due to variable capacity and understanding, these partnerships are not yet being consistently leveraged:[lx]

> *"When you have good collaboration at the regional level, down through to the country office level… when you get the partners working really well together like that, you actually get things done… [in some regions there is a] lack of coordination and visibility. As a result, I don't see us leveraging the regional offices to support country offices the same way."*
>
> - Gavi Secretariat informant

2.1.5 What have country level stakeholders' experiences been of the implementation under the current strategy, including use of key operational levers (bubbles) such as differentiated engagement?

2 **Summary finding:** Two main messages emerge from analysis of country-level stakeholder interviews: 1) Gavi systems and processes are complex and burdensome, absorbing unreasonable/unrealistic time from EPI teams and diverting attention from delivery; and 2) countries clearly understand the value of vaccines, but tension exists between the principle of country ownership and advancing Gavi priorities as set out in 5.0/5.1, exacerbated by perceived weak country voice in Gavi decision-making. Gavi is seeking to address these issues in 6.0.

1 **Finding 1.11: As found in previous evaluations and reviews, country stakeholders noted that Gavi application processes are complex and burdensome. Some see FPP as a step in the right direction, while some continue to experience substantial delays in approval and**

disbursement, with significant on-the ground implications. Recommendations/ outputs from the IRC evaluation and EVOLVE process are intended to address many of these issues. Confirming evidence from the strategy operationalisation evaluation, the ZD evaluation, and EVOLVE, country informants interviewed as part of the MTE thematic case studies noted that Gavi's application processes and procedures are complex and burdensome. Specific examples include the expectation that applicants are familiar with the ToC approach (required as part of the FPP application process for all except fragile countries).[52, lxi] Although some see FPP as a step in the right direction, others noted ongoing confusion and complexity (e.g., in relation to IRC review processes and the option to uncouple some applications from the FPP).[lxii]

> *"With FPP, the procedure has become simpler but review by IRC worse, as we are getting more and more questions and sometimes repeated questions we need to answer again and again"*
>
> \- Country government informant

Country stakeholders were particularly concerned when delays linked to application processes resulted in significant on-the-ground delays. For example, in Kenya, one of the first countries to engage in the FPP, a combination of factors led to six applications included under one FPP. They were eventually delinked into separate vaccine and cash-support applications to prioritise and speed up the process. [lxiii] However, the process still took over three years.[lxiv] Zambia (sampled as part of the MTE resource mobilisation thematic study) also experienced an extended FPP – 20 months to IRC approval and an additional 5.6 months to disbursement. Stakeholders in Zambia expressed frustrations with confusing and complex processes, compounded by country-capacity constraints, and challenges with the IRC review.[lxv] In eligible MICs, early country applicants such as Indonesia also referenced challenges with application processes and resultant delays (see Annex 10).

With other application processes, some stakeholders referenced the relative simplicity and speed of applying for CDS support,[lxvi] and stakeholders involved in more recent MICs applications felt that the process was relatively simple and flexible compared to other Gavi support,[lxvii] with some also making favourable comparisons to other donors:[lxviii, 53]

> *"Compared to Global Fund this is very easy peasy – genuine opinion. On this application, they asked us if there was anything else we wanted to highlight. The initial instructions were very clear, not complicated, and this simplified the procedure."*
>
> \- Country government informant

1 **Finding 1.12: Country capacity among core partners and governments may be less than optimal, exacerbated by the complexity of Gavi application processes. Country capacity to utilise Gavi funds is an issue in some countries, with many fragile countries experiencing very low utilisation during 2021-22, and some fragile and core countries struggling to utilise funds into 2023.** Country capacity to fully utilise Gavi processes and systems depends on the human and financial capacity of health ministries and EPI teams, institutional infrastructure such as regulatory systems, and the extent to which conflict and fragility affect the delivery of services. As previously noted, during COVID-19, countries were often overwhelmed with managing different priorities (such as COVID-19 response versus RI) with limited resources,[lxix] as well as balancing sustainability of existing vaccines with new introductions.[lxx] The evidence from the strategy operationalisation evaluation, ZD evaluation, and MTE country-level data collection indicates that country capacity, particularly of EPI teams and other staff assigned to RI remains a significant issue in many countries, even though COVID-19 pressures have subsided.[lxxi]

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[52] As we have noted previously, the Secretariat does not seem to place a high priority in using its own ToCs.
[53] See Annex 10 for the MICs thematic study.

Country capacity constraints are exacerbated, as noted above, by Gavi's perceived burdensome application processes.[lxxii] In some cases, external consultants are recruited to support the application process, but there were concerns that this still used financial resources for implementation, and still requires significant support/oversight by the government.[lxxiii]

> *"A consultant is supporting the applications but before the consultant starts working, the country needs to do a lot of preparatory work, to collect all data, and that is time consuming. The consultant is not solving everything – you need to go through the IRC, and before the IRC, usually you need to communicate with the Country Team, who also has some recommendations, comments, questions... so it's kind of an intense process."*
>
> \- Country core partner informant

There is significant variation of utilization of funds across countries.[54] Averages over country segments show no clear patterns. However, six fragile countries experienced very low (<50%) HSS utilization during 2021-23, with Sudan and Yemen at less than 20% in June 2023. This likely reflects additional capacity challenges experienced by fragile countries. It is also notable that some core countries, such as Kyrgyzstan and Ghana, have seen very low HSS utilisation in 2022 and 2023. This is potentially significant given the perception that core countries are not receiving sufficient support via the current model of differentiation and may also reflect the need for additional capacity/ support in some core countries. Use of CDS funds (see Table 11) is also low overall, with a total of US$ 621 million utilized out of US$ 1.08 billion in grant funds, compared to US$ 3.3 billion of HSS funds utilized out of US$ 5.63 billion, likely reflecting the challenges of mobilizing these funds during the midst of the COVID-19 pandemic. Utilisation rates have generally increased in 2023 compared to previous years.[lxxiv]

Table 11: Utilisation of HSS and CDS by segment, Dec 2021-Jun 2023[lxxv]

Segment	Date of Report	HSS Utilization		CDS Utilization	
		At time of reporting	Averaged	At time of reporting	Averaged
Core - EAP	Dec/21	77%	77%	24%	48%
	Dec/22	74%		59%	
	Jun/23	80%		60%	
Core - ESA	Dec/21	79%	81%	32%	52%
	Dec/22	82%		60%	
	Jun/23	83%		64%	
Core - WCA	Dec/21	75%	74%	47%	61%
	Dec/22	71%		66%	
	Jun/23	75%		70%	
Fragile	Dec/21	75%	76%	26%	50%
	Dec/22	73%		59%	
	Jun/23	80%		64%	
High Impact	Dec/21	75%	76%	45%	60%
	Dec/22	75%		69%	
	Jun/23	79%		66%	

2 Finding 1.13: Most KIs see Gavi's differentiated engagement model as inappropriate, believing that differentiation needs to be redesigned so that application and review processes account for the actual Secretariat resources needed to effectively manage country programmes, taking into account country risk, capacity and need. The simplified MICs approach

[54] It is important to note the utilization data presented covers both HSS funds approved under 4.0 and 5.0, with most funds approved under 4.0. Nevertheless, this does still reflect countries' ability to utilize funds, which is the focus of this narrative.

provides some insights. Differentiated engagement is designed to work in line with defined country segments, namely core (priority and standard), HI, and fragile and conflict, with MICs eligible for targeted Gavi support also effectively another segment. These segments were designed to be differentiated in terms of ownership, Secretariat engagement levels, degree of expected detail in FPP applications and timelines (see Annex 5 for summary).[23, i] In principle, HI and fragile and conflict-affected countries were expected to have higher Secretariat engagement, with longer approval times than core countries. However, all segments have experienced similar durations from FPP to disbursement (except core 'standard' countries which have been faster on average). In some cases, this is compounded by lack of familiarity with segments in the IRC,[iii] or some staff not adhering to segment-specific guidance due to individual concerns about risk.[33,iv] Many stakeholders felt there is a need to further simplify how differentiation works to reduce time-to-disbursement and to better take into account risk, size and need which varies within segments.[lxxvi]

Evidence from the thematic case studies[lxxvii] indicates that in some countries, government awareness of the different segments is poor. This is hardly surprising - the FPP and other application guidelines make no reference to differentiation, and government stakeholders would likely only be explicitly aware of differentiation if the SCM or a core partner mentions it.[55] There are also examples of HI countries, which are expected to provide more detail in their applications, experiencing emergencies, which made such requirements especially burdensome,[lxxviii] and country case studies in the ZD evaluation indicate that differentiation is not filtering through as expected to fragile countries.[lxxix] Country teams and core partners note that differentiation is not providing countries with the quantity or quality of needed support, with MICs and smaller countries feeling a particular burden. The EVOLVE process and IRC evaluations also identified issues with differentiation of processes and have proposed key shifts to improve differentiation (see Annex 5 – supporting evidence for HLQ1 for details).[lxxx]

2 **Finding 1.14: Tension exists between the principles of country ownership and the extent to which Gavi pushes forward priorities such as ZD and equity across diverse country contexts.** (Also see related content under SG4/demand health shaping). Country ownership is reflected in the 5.0 ToC, which outlines several cross-cutting principles including "community-owned" and "country-led/sustainable". "Coherent support aligned with country priorities and needs" is also one of the assumptions in our elaborated 5.0 ToC (see Annex 2).

Evidence from countries sampled in the strategy operationalisation evaluation, ZD evaluation and MTE indicates that there is generally strong in-country alignment across core partners for the ZD agenda, but in some countries, where ZD populations are smaller, it is seen as less relevant, with a broader equity agenda seen as more appropriate.[lxxxi] Among other country stakeholders, the degree of perceived alignment between in-country priorities and Gavi's push for ZD, equity and gender varies. For example, while countries such as Ethiopia, DRC and Djibouti have continued to build on a pre-5.0 focus on ZD by leveraging EAF funds, broader equity (including gender), as previously highlighted, was sometimes not reflected as strongly in applications, despite the High Level Review Panel (HLRP)/IRC flagging these areas as lacking.[lxxxii,lxxxiii,lxxxiv] There is acknowledgement in Gavi that the cultural realities within some countries affect the way and extent to which gender can be pushed as a priority while respecting country ownership.[lxxxv]

More broadly, there was a perception that priorities such as ZD and equity, but also other current or future Gavi priorities, need to be more clearly aligned with not just national immunisation strategies (NIS), but also primary health care (PHC) and HSS strengthening goals. For example, in Cambodia, stakeholders perceived insufficient Gavi focus on supporting PHC outcomes, despite the links

[55] Review of country presentations also indicates that they are not aware, as they were asked to present against the 9 Gavi core principles, including differentiation, but none of the content there related to differentiation by segment.

between ZD children and broader unmet PHC needs.[lxxxvi] Stakeholders from several other countries (Kenya, Angola, Indonesia, Zambia, Kyrgyzstan and regional core partners), also highlighted the importance of aligning ZD with the broader PHC agenda to improve country ownership and sustainability.[lxxxvii]

Gavi has made efforts to increase country voice and acknowledges the associated challenges, but there are suggestions that Gavi could do more at country level to respect national strategies and priorities.[lxxxviii]

> *"…It is neo-colonialist if you ask me, because whatever support we put in should be strengthening countries' national immunisation strategies…. and then emphasise within the national strategy areas that we are happy to support…this is a better and more respectful way to engage with countries than through an onerous process that takes up to two years, and by the end of that time, their strategic period has almost ended."*
>
> \- Gavi Country Teams

The strategy operationalisation evaluation noted that lack of political will may affect the extent to which Gavi's strategic priorities are reflected in Gavi grant designs[lxxxix] (a key enabler/barrier to progress, discussed under Section 2.2.3 below). Despite Alliance efforts to influence country immunisation priorities, Gavi sometimes encounters push-back from national health authorities and, in line with the principle of country ownership, usually choses not too push too hard[xc] (especially on priorities that can be perceived as more contentious such as gender). The strategy operationalisation evaluation also noted that *"Gavi's reluctance to impose demands on countries may partly explain why some strategic priority areas remain unaddressed despite repeated IRC recommendations over many years,"*[xci] a view supported by several MTE KIs. Some stakeholders (both internal and external) also noted that Gavi strategies are typically developed in Geneva, albeit with extensive consultation, and can be somewhat 'removed' from individual country realities, which may contribute to countries deemphasizing some Gavi strategic priorities.[56] There is also often a misalignment/time-lag between the timing of NIS and that of Gavi strategic cycles, which means that at best Gavi can aim to influence future NIS on the basis of current strategic priorities.[xcii] We note that influencing future NIS appears to be a direction of travel under 6.0, and that EVOLVE has proposed shifting towards using NIS as a funding framework.[xciii]

2.1.6 To what extent did Gavi effectively and efficiently implement approaches to safeguard RI and support recovery from COVID-19 disruption? How flexible were these to allow rapidly adapting programmatic, administrative, or financial processes to be implemented in a timely fashion? Which approaches were most/least effective and efficient?

1	**Summary finding:** There is insufficient evidence to establish either the effectiveness of Gavi's initial response to COVID-19, or of specific aspects of the response. However, there is evidence of varied uptake and progress in terms of speeding up decisions which offer learning. Disbursement was of greater concern, but there is optimism that this will be addressed through EVOLVE.

Gavi supported a range of initiatives to directly and indirectly safeguard RI and support recovery from COVID-19 disruption, which have evolved over time.[57] Gavi's initial response to COVID-19 was through Respond & Protect (R&P) and Maintain, Restore & Strengthen (M&R&S) initiatives, which were the focus of the COVID-19 evaluation.[xciv] Gavi subsequently introduced other initiatives that aimed to catch-up on missed children and to refocus on the goals of Gavi 5.0 in different contexts.

[56] It is noted that there is a country consultation process as part of strategy development, but nevertheless this was shared by some stakeholders.
[57] We are not explicitly evaluating COVAX but capture its contribution to 5.0 goals where relevant.

Our analysis focuses on R&P, M&R&S, and three other initiatives launched in mid-2021: the EAF (including the Zero-Dose Immunisation Programme), CDS,[58,xcv] and MICs. We also consider operational/ administrative initiatives – such as the FPP step-back, EVOLVE and revision of programme funding guidelines – designed to streamline grant management processes and speed up disbursement. Other efforts, such as the humanitarian buffer, US$ 20 million allocation to strengthen political will, and the 'Big catch up',[59] are noted but not included here.

1 **Finding 1.15: Whilst RI gains initially reversed, the extent to which Gavi initiatives contributed to subsequent rebounds, given decisions that Gavi took on tracking their implementation, is unclear.** RI coverage dropped (hitting the most vulnerable hardest)[xcvi] and then recovered as discussed in Section 2.2.1. Immunisation systems proved remarkably resilient "*stretching to deliver more vaccines than ever before in history*".[xcvii,xcviii] There is limited evidence on the effectiveness or contribution of Gavi's efforts to these trends. The COVID-19 evaluation highlights that Gavi intentionally and appropriately limited requirements of country reporting on use of the R&P and M&R&S flexibilities – in terms of delivery against key outputs and outcomes.[xcix] Monitoring data and/or evaluative judgements on effectiveness of other initiatives (such as EAF and MICs) are currently limited, given the early stages of implementation.[60] There is, however, evidence that CDS contributed to protecting and supporting recovery of RI.

1 **Finding 1.16: Implementation of initiatives designed to safeguard RI and support recovery appears to have been patchy; uptake has been slower than expected, although we note that the picture is undermined by lack of monitoring data for each.** The COVID-19 evaluation[61] found that lack of monitoring data made it difficult to be confident of implementation or uptake of flexibilities under R&P and M&R&S. For other initiatives, such as EAF and CDS, implementation did not progress as expected:[c] Although there were few EAF applications in 2022, substantially more were received during 2023. There have also been delays in country FPP applications to date (see Annex 5),[ci] an important, albeit single, measure of country capacity to secure funding for RI. Latest Secretariat data (October 2023)[cii] shows that 23 Gavi-eligible countries received IRC approval of their FPPs from January 2021-October 2023, although only approximately 12 countries are likely to receive disbursements by the end of 2023, using current averages of time from IRC approval to disbursement.[62] Another 11 countries are expected to receive IRC approval in 2024. As noted above, the MICs approach was initially approved by the Board in December 2020 with a phased approach in the context of COVID-19, initially focusing on support against backsliding in former-eligible MICs, with support for new vaccine introduction in both former- and never-eligible MICs approved in June 2022.[ciii] As of June 2023, 12 MICs applications have been received.[63]

1 **Finding 1.17: Performance in terms of timeliness and disbursement has been variable with experience suggesting that decision-making can be sped up, but this needs to be institutionalised, and more work is needed to address disbursement performance.** Improving timeliness of approval and disbursement was a key objective for R&P, M&R&S[64] and CDS,

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[58] Also discussed under Sections 2.1.3, 2.1.7, and 2.2.1
[59] Launched on 24 April 2023, the Big catch up includes joint high-level advocacy, support to develop country-specific plans, simplified and expedited processes to allow reprogramming of Gavi funding, and consideration for additional vaccine support to ensure catch-up activities can reach older cohorts that may not be covered by existing country supply in 20 focus countries. (WHO news, MTR)
[60] The MICs approach was paused in December 2020, as part of the recalibration of Gavi priorities (see Section 2.1.7 for more details); EAF received fewer applications in 2021/22 than expected as discussed in Section 2.1.1.
[61] Also noted in other Gavi docs – e.g. July 2022 Vaccine HLRP RoP final.pdf
[62] Using estimates of time from IRC approval to disbursement from CPMPM (8.9 months in October 2023).
[63] Six for backsliding support, six for new vaccine introductions
[64] Gavi set targets of 5 days for approvals and 5 days for disbursements (C-19 report, p36).

with approvals significantly faster compared to normal business.[65] But disbursement appears to have been more of a challenge under both R&P and CDS. R&P disbursements took between 1.5 and 5 months, and the COVAX report highlights that resources were not in place for the first delivery of vaccines to countries.[66] CPMPM data shows that disbursements take an average of 9.5 months.[civ] Gavi is working to improve performance in this area, including through the EVOLVE process which has assessed the activities and stakeholders involved in approval to disbursement to identify efficiencies and improve timeliness.[cv]

2.1.7 To what extent have Gavi's recalibrated priorities in response to COVID-19 affected (positively and negatively) the expected delivery against the strategic goals and influenced rebound from the effects of COVID-19 on RI programmes?

2 **Summary finding:** The rationale for the recalibrated priorities was clearly articulated, with varying results across the four priority areas: 1) maintaining, restoring, and strengthening immunisation services, 2) reaching ZD children and missed communities, 3) ensuring access to COVID-19 vaccines, and 4) safeguarding domestic financing for immunisation. The effects of recalibration are unknown, but it appears to have been useful as a signalling exercise on priorities in the face of COVID-19. Pausing or phasing some areas (MICs, innovation, new vaccine introductions and Gavi's funding policy review) was realistic. Whilst effects are difficult to ascertain, the phased approach for MICs affected progress in critical vaccine introductions such as HPV, but also allowed valuable additional time for more effective integration of learning.

In December 2020, the Board agreed to recalibrate Gavi 5.0 strategic priorities to focus on four main areas. At the same time, it was accepted that other areas of Gavi 5.0 would advance more slowly including the new MICs approach, new vaccine introductions, work on supporting innovation, and review of Gavi funding policies.[cvi] In this Section we assess the extent to which this reprioritisation has contributed to recovery of RI from the effects of COVID-19.

2 **Finding 1.18: The definition of recalibrated priorities in terms of expected results and mechanisms through which priorities would be delivered was clearly articulated.** M&R&S and ZD both focus on RI and specific risks within RI performance. Mechanisms for taking forward these recalibrated priorities were mostly already ongoing – such as through HSS and PEF TCA. Recalibration included several additions and modifications to provide emphasis and additional resourcing.[67]

2 **Finding 1.19: Results delivered through these mechanisms have been varied and it is difficult to assess whether recalibration improved results.** As discussed in Section 2.2.1, RI has largely recovered to pre-COVID levels, although we also note in Section 2.2.2 that this may not always be enough to reach the SGs. The ZD evaluation highlighted that progress is being made in operationalising the ZD approach, even if results of these efforts are yet to translate to positive results in SG indicators. COVAX distributed almost 2 billion vaccine doses to 144 countries, representing approximately 75% of low-income countries' supply of COVID-19 vaccines.[cvii] In 2020, nine out of 15 countries that applied for co-financing waivers were approved, and in 2021, six out of

[65] For example, the first CDS (early access window) application was approved within 35 days, and some others in as little as 48 hours (compared to normal performance of 3 months); COVAX baseline report. The COVID-19 evaluation also found that e.g. 5 of 8 case studies R&P applications were approved within two weeks

[66] The COVAX evaluation report also links this to issues with Gavi's mandate on funding for COVID-19 delivery (finding 38-40, 53-54).

[67] E.g., the £500m EAF was created to allow countries access up to 50% additional HSS on top of existing grant for dedicated activities to reach zero dose children and missed communities; $150m additional funds were added for the operationalisation of COVID-19 vaccine programmes; co-financing flexibilities from the COVID-19 response were extended; US$ 148 to 157 million was added to the PEF for 2021-2025, and US$ 20 million to advance the zero-dose learning agenda.

six were approved.[68] There is no counterfactual to enable judgement as to whether this performance would have been better or worse without recalibration. It is plausible to believe that pausing other strands of work created space for the Secretariat and national counterparts to focus on these priority areas. However, we do not know with certainty whether this increased efforts for RI, ZD and domestic financing agendas, or whether resources were absorbed responding to COVID-19.

2 **Finding 1.20: Recalibration of 5.0 strategic priorities was intended to act more as a signal of priorities rather than to change programming, and some Secretariat staff reported this was useful. However, the contribution of recalibration to the SGs is not clear.** The mechanisms noted under Finding 1.19 offered flexibility, TA to adapt/sharpen focus of country plans, and additional funding. There appears to be some alignment between recalibration and the major barriers to progress (described under Section 2.1.8 or Section 2.2.3).[69] We also note that recalibration did not cover all Gavi work: for example, the process and system reforms covered under EVOLVE. CDS provided resources to increase capacity of WHO and UNICEF country offices (a key barrier to progress identified in Section 2.2.3). However, the evidence suggests that recalibration was primarily about signalling and agenda setting – with an explicit Board agreement that Gavi would maintain focus on RI and address risks of backsliding. Other Gavi staff reported that this signalling was useful to focus efforts. Linkages between recalibration and SGs are not formally part of Gavi documentation. Whilst priorities on M&R&S and ZD seem to logically focus on SG1 and SG2, and domestic financing on SG3, one Secretariat KI felt that it was not possible to do this mapping.

1 **Finding 1.21: The effects of phasing/pausing MICs, innovation, new vaccine introductions and Gavi's funding policy review are difficult to ascertain, but the decision seems to have been pragmatic and realistic. In MICs, the phased approach has affected progress in critical vaccine introductions such as HPV, but it has allowed valuable additional time for more effective integration of learning.**

MICs – The Board agreed to phase the introduction of the MICs strategy, with initial engagement from January 2021 to June 2022 (accounting for up to 25% of the total MICs funding envelope) focused on support against backsliding for former Gavi-eligible countries. Subsequent support for new vaccine introductions, including in never-eligible countries, was subsequently approved in June 2022.[cviii]

Innovation – In December 2020, the Board also agreed to pause development of a formal innovation strategy, leading to eventual approval (including the creation of the Innovation Top Up Fund) in June 2022. As a result, by mid-2023, just one country (Madagascar) had applied for the top up funds. By November 2023 more countries had applied (Burundi, Chad, Eritrea, Ethiopia, Kyrgyzstan, Senegal, Syria, Tajikistan, and Zambia) but an internal assessment was still pending on commitment and disbursement rates.

New vaccine introductions – New vaccine introductions from the Vaccine Investment Strategy (VIS) were also paused with the focus on prioritising the conclusion of long-standing introductions and scale-up programs,[70] continued investment in preventive programs for diseases with outbreak potential as well as stockpile investments,[71] and pausing support for other VIS vaccines during the acute phase of the pandemic.[72]

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[68] As noted in the COVID-19 evaluation report, Gavi worked with partners to support countries to make their co-financing contributions as planned so that waivers were exceptionally used.

[69] Section 2.1.8 notes internal barriers as: application/disbursement, alignment with country priorities, data quality, lack of secretariat and partner capacity; and Section 2.2.3 notes key barriers to results as weak health systems, demand (including vaccine hesitancy), resource constraints, COVID-19, access, data and Gavi systems and processes.

[70] including measles second dose, rubella, yellow fever, rotavirus and pneumococcal vaccines along with the continued scale-up of human papillomavirus (HPV) and Typhoid Conjugate Vaccine (TCV).

[71] including endemic cholera and multivalent meningitis

[72] including rabies, Hepatitis B birth dose and DTP boosters

Funding policy review – The review of core funding policies was also paused, subsequently approved in 2022.

The effects of the above choices, which were not well outlined in Programme and Policy Committee (PPC) or Board documentation at the time of the decisions, are not easy to disentangle. Our findings suggest that:

- Work on innovation, new vaccine introductions, and review of Gavi core funding policies would have struggled in the face of the urgent COVID-19 response. In the absence of adequate surge capacity, temporarily deprioritising these areas was a pragmatic, realistic choice.
- The phased approach under MICs was also pragmatic. Country needs were acute, as they were struggling to concurrently maintain RI and respond to COVID-19. At the same time, rolling out a new initiative would have required Secretariat capacity which was already overstretched. The phasing of the MICs approach delayed support to the introduction of key vaccines including HPV (critical to achievement of SG1). However, on the more positive side, it allowed integration of learning from the initial phase, and also allowed more time to develop and ensure sufficient capacity for a comprehensive overall learning agenda (see Annex 10 for more on this).

1 **Finding 1.22: Results in terms of RI, reaching ZD, rolling out COVID-19 vaccines and protecting domestic finances are mixed, with the contribution of recalibration to results unclear.** Results for these measures are reported in Section 2.2.1. In terms of understanding the contribution of the recalibrated priorities we note that:

1. we are primarily looking at results from Gavi 4.0 given the status of implementation of Gavi 5.0/5.1 (in particular for FPP and EAF applications), as discussed in Section 2.1. This is partially attributable to the fact that Gavi countries are not required to align grant applications and activities to Gavi's strategic cycle, therefore the majority of Gavi 5.0/5.1 programming will not start implementation until early 2024 and will not be visible in WUENIC data until mid-2025; and
2. data systems within Gavi are not set up to track contribution of recalibration.

On this basis, we conclude that the contribution of recalibration is limited, or at best unclear.

2.1.8 How/to what extent did Gavi effectively mitigate against and respond to failures in the ToC causal pathways and other significant barriers to operationalisation?

1 **Summary finding:** There is considerable convergence in evaluations and internal processes on key barriers to operationalisation. Gavi is working to address these barriers to varying degrees, and whilst there is some optimism about success, addressing these barriers will continue to be an important agenda for the remainder of 5.1 and for 6.0.

1 **Finding 1.23: There is a high degree of convergence on a set of key barriers to operationalisation, including timelines for application/disbursement, alignment with country priorities, data quality, and weaknesses in Secretariat and partner capacity.**[73] The COVID-19, strategy operationalisation, and ZD evaluations, corroborated by the MTE, all note similar barriers to operationalising Gavi 5.0/5.1 which are consistent with Gavi's own documentation[cix] (see Table 12 for triangulation of barriers across key sources).[cx] We have identified, through KIIs, where there is convergence across stakeholder groups on a subset of key barriers including: slow application/disbursement timeframes, alignment between Secretariat and country/Alliance

[73] Note that the barriers identified here focus on internal constraints. More focus on country level barriers is included under Section 2.2.3 because that question is framed in terms of results at level of SGs.

priorities, data quality, appropriateness of Gavi support/policies, and lack of country capacity. There are some examples of variation between stakeholder groups - for example, government KIs gave higher priority to issues around transition and eligibility and less to data quality compared to Board and Secretariat KIs - but there is convergence on the themes mentioned above. Overall, concerns around slow disbursement and alignment with country priorities were most frequently cited as barriers across all stakeholder groups.

1 **Finding 1.24: The root causes of these barriers are varied. Those cited most often are firmly on Gavi's radar, with work in progress and important action agendas.** Table 12 summarises the barriers most cited by KIs and possible root causes for each. Many of these are linked to organisational complexity and capacity, which are currently the focus of significant internal processes (EVOLVE, Operational Excellence, Organisational Improvement), but actual progress will depend on effective change management processes and strong internal and external focus and communication. Other root causes are more external, linked to the strength of country health systems and country ownership (see Section 2.2.3), and are now under consideration in the run up to 6.0.

These root causes do not differ at operational level and so we do not present analysis by SG, however there is more nuance at the level of results (discussed in Section 2.2.3).

Table 12: Barriers to operationalisation and mitigating actions

Barrier	Details	Root causes	Mitigating actions
Application and disbursement	Average time from FPP to disbursement is 21.4 months,[74] and high transaction costs are consuming for applicants.	Complicated multi-stage, multi-activity process with multiple teams (up to 12) involved at every stage.[cxi] Fundamentally a reflection of Gavi's complex model and culture,[cxii] exacerbated by, but also exacerbating, weaknesses in Secretariat and partner capacity (see below). Complexity driven by donor accountabilities, broadening mandate, and shifting priorities.	Recommendations/outputs from EVOLVE, the IRC evaluation and Operational Excellence initiatives on restructuring, clarifying roles and responsibilities, responding to organisational survey including on cultural constraints e.g. around risk, offer some optimism.
Lack of capacity (Secretariat, Alliance and governments)	Secretariat and partners have insufficient capacity to manage processes and respond to all (competing) demands.	Increasingly complex Gavi model is time consuming to navigate (levers, teams,-decision makers). Secretariat staff has grown, but still only 20% are in Country Programmes, and some SCMs manage multiple countries (following differentiation – see Annex 5) with insufficient delegation of authority. Countries fiscally constrained, while responding to multiple donor application processes and competing health priorities.	EVOLVE seeks to simplify and reduce transaction costs. Operational Excellence and Organizational Improvement work expected to address internal capacity challenges. Issues tracked through CPMPM (EPI team capacity) and risk reporting (#1 risk in 2023). Alliance reset ongoing.
Alignment / prioritisation	Sometimes tension between Gavi and country priorities.	Gavi needs to deliver against the 5.0 SIs and respond to donor priorities not unique to Gavi. Exacerbated by limited country voice in decision making and oversight, and Secretariat capacity to understand country voice. The model	Design of Gavi 6.0 is already working towards a model that is driven by country needs. CSCE is settling in. Differentiation is a step

[74] As of 31 January 2024. Data taken from CPMPM 2.0.

		does nothing to force trade-offs that make prioritisation more explicit.	forward, albeit with some questions on design.
Data	Lack of/poor quality data affects programme design and oversight of implementation. Challenges with access to data also noted.	Longstanding data issues linked to HSS (at country level) and Gavi systems complexity (at Secretariat level). Outside MTE scope to assess drivers of weak country systems. Lack of monitoring data is driven by transaction cost concerns and conceptual challenges. [cxiii]	SFA activity reports suggest substantial activity ongoing but not possible to track effectiveness (as per Section 2.1.2). Improvements noted through the Balanced Scorecard. CPMPM and EVOLVE expected to make a difference.
COVID-19	Diverted key stakeholders from RI, including delivery system.	Outside MTE scope to analyse, but COVID-19 was reflection of ineffectiveness of global and national PPR systems, and Gavi's ability to concurrently respond while maintaining focus on RI. Links to effectiveness of HSS interventions, not just for Gavi.	Gavi 5.1 and 6.0 articulate Gavi's role in PPR and integrating COVID-19 vaccines into RI.

2.2 HLQ2 Achievement of strategic goals and objectives – To what extent will implementation of Gavi's 2021-2025 strategy plausibly result in achievement of the prioritised Strategic Goals and objectives? Which areas are important for course correction?

1	**HLQ2 summary finding:** By end 2022, many, but not all Gavi 5.0 indicators had recovered to 2019 levels. The plausibility of achieving the SG targets by 2025 is mixed: all Gavi 5.0 mission indicators are highly likely or likely to be met, except for ZD, as are nearly 50% of strategic SIs or sub-SIs (65% excluding those with insufficient data). Two of the three SG2 SIs with adequate data (S2.1 geographic equity and S2.3 MCV1 coverage) are unlikely to be met, while meeting the third (S2.2 DTP drop out reduction) is likely. Key drivers of progress at the level of SGs and indicators appear to be political support, Gavi support, health system capacity, partnerships, and advocacy. Conversely, key constraints include weak health systems, demand (including vaccine hesitancy), resource constraints, COVID-19, access to services, data and Gavi systems and processes. A limited number of these constraints are within Gavi's control. Gavi works in a range of ways to implement its strategic priorities, with advocacy seemingly key. However, limited capacity to monitor and hold partners accountable for results can reduce effectiveness in translating priorities at country level. ZD is reasonably well-integrated in country applications, albeit to varying degrees. Greater CSO engagement is also being integrated, albeit with some tensions. Other priorities such as gender-responsive, transformative and sustainability approaches are less well integrated.

Overall, the MTE finds a mixed picture on the status of 5.0/5.1 implementation (HLQ1), with particular concerns for SG2 and SG3. This Section looks at how this relates to performance in terms of the 5.0/5.1 strategic goals covering EQs on results and plausibility, Gavi's influence over country immunisation plans, and drivers of observed results. For results and plausibility, we have split our

analysis into two parts to reflect the structure of the EQs. The first part covers the extent to which Gavi's 5.0/5.1 mission indicators and strategy indicators showed recovery to 2019 baseline levels in 2021[cxiv] and 2022. The second part covers the plausibility of reaching Gavi 5.0/5.1 SG targets by end 2025 and Gavi 5.0/5.1 making a substantial contribution to that achievement.

2.2.1 To what extent do Gavi's strategy performance indicators show recovery to 2019 baseline levels? To what extent will implementation of Gavi 5.0/5.1 on its current trajectory plausibly result in achievement of the prioritised SG1, 2, 3 and related objectives?

1 **Summary finding:** By end 2022, many, but not all Gavi 5.0/5.1 indicators had recovered to 2019 levels, despite an improvement since 2021. The plausibility of achieving the Gavi 5.0/5.1 SG targets by 2025 is mixed: all mission indicators (MIs) are highly likely or likely to be met, except for ZD, as are nearly 50% of strategic indicators (SIs) or sub-SIs (65% excluding those with insufficient data). Two of the three SG2 SIs with adequate data (S2.1 geographic equity and S2.3 MCV1 coverage) are unlikely to be met, while meeting the third (S2.2. DTP drop out reduction) is likely.

2.2.2 To what extent do Gavi's SIs show recovery to 2019 baseline levels?

1 **Finding 2.1: By the end of 2022, many but not all the Gavi 5.0/5.1 indicators had recovered to 2019 levels, reflecting an improvement since 2021.[75] Consistent with Gavi's own analysis, DTP3, geographic equity, MCV1 and reducing numbers of ZD were off track. Results are not uniform across countries, with core and post-transition countries struggling more than other segments.** Based on our analysis of data reported to the PPC in October 2023 compared to 2019,[cxv] several Gavi 5.0 indicators worsened during 2020 and 2021 for a mix of reasons (discussed under Section 2.2.3). S1.2 DTP3 coverage, for example, dropped by 5pp between 2019 and 2021, signalling the worst backsliding in child immunisation in three decades.[cxvi] The number of ZD children increased by 38% during that period (from 9 to 12.4 million). At the same time, S2.1 geographic coverage, an indicator that measures how well Gavi-supported countries can increase coverage in areas with limited access to immunisation services,[cxvii] decreased by 5%.[cxviii]

Table 13 summarizes whether results had recovered to 2019 levels by the end of 2022. We provide detailed analysis for each indicator in Annex 6. We note, however, that these results are not uniform across countries with core, post-transition (PT) countries, and LICs struggling more than countries in other segments/income groups (although for core and PT countries, this might also partly be linked to these countries having better data systems than other segments). In addition, for many Gavi 5.0/5.1 indicators, we could not compare 2022 with 2019 values.

Table 13: Comparison between 2022 and 2019 baseline.

SG	Finding	Indicator (for which comparisons available)	Comparison between 2022 and 2019
MIs	The only two MIs for which this comparison is meaningful are M1 Under-five mortality, which continued to decrease during the pandemic and M4 ZD reduction, which in 2022 was still 14% above pre-COVID-19 levels.	M1 Under-five mortality	n/a for 2022 (-3.5 deaths per 1,000 live births in 2021 compared to 2019)
		M4 ZD reduction	14% above 2019 levels
SG1	All available indicators except DTP3 coverage were back to, or exceeding 2019 levels. Progress limited in core, post-transition, and low-income countries	S1.1 Breadth of protection	8pp increase compared to 2019 baseline
		S1.2 DTP3 coverage	2pp under 2019 levels
		S1.2 MCV2 coverage	6pp increase compared to 2019 baseline

[75] The year that Gavi originally expected countries to return to pre-COVID-19 coverage levels.

	compared to other segments/income groups.	S1.2 PCV3 coverage	14pp increase compared to 2019 baseline
		S1.2 HPV coverage	3pp increase compared to 2019 baseline
		S1.7 timely outbreak detection	7pp under the 2018-2020 average baseline
SG2	DTP dropout rates are back to 2019 levels, but MCV1, geographic equity, and ZD numbers have yet to recover. Performance is sub-optimal in core and post-transition countries, compared to other segments.	S2.1 Geographic equity	5pp under 2019 levels
		S2.2 DTP drop out	No decrease compared to 2019 baseline
		S2.3 MCV1 coverage	2pp below 2019 levels
		S2.6 EPI management capacity	-0.22 points below 2019 levels
SG3	Co-financing has remained at 100% between 2019 and 2022, but with 9 waivers in 2020, 6 in 2021, and 2 in 2022.	S3.1 Co-financing	No change compared to 2019 baseline

KEY: Limited recovery | Moderate recovery | Good recovery

MIs: While M1 under-five mortality continued to decrease, the number of ZD children (M4) was still 14% higher in 2022 than in 2019. Although reduced compared to the previous year, ZD numbers in 2022 were still above the 2019 baseline, especially in core (+65%) and post-transition (+42%) countries.[cxix]

SG1 [the vaccine goal]: By 2022, all available indicators other than DTP3 coverage were back to the 2019 baseline.

- S1.1 breadth of protection, a summary measure of prioritised vaccine introductions, rate of scale up of newly introduced vaccines, and S1.2 MCV2, PCV3 and HPV2 vaccine coverage, did not decrease during 2020-21 compared to the 2019 baseline.
- In 2022, S1.2 DTP3 coverage, was however still 2pp under its 2019 levels.
- Based on our analysis of country-level data on SI and MIs and of WUENIC data, differences are however visible between country segments, with core and post-transition countries among Gavi-57 and LICs struggling more than countries in other segments/income groups.

SG2 [the equity goal]: By 2022, DTP drop out was back to 2019 levels but MCV1, geographic coverage and ZD numbers were yet to recover. Performance was again found to be sub-optimal in core and PT countries compared to other segments.

- By 2022, S2.2 DTP drop out was back to 6%. Other indicators under SG2, however, were not yet back to baseline.
- S2.3 MCV1 coverage was still 2pp down overall at 79%[76] with similar patterns at portfolio level to those of DTP3.[77]
- S2.1 Geographic equity was still 5pp at 62%. In 2022, it further deteriorated in core countries compared to 2021 and 2020, while in PT countries[78] was still 3.5% under 2019 levels. On the other hand, between 2019 and 2022, it improved in HI (albeit only slightly) and in fragile countries.[79]

[76] Our analysis of SI/MI data in Oct 2023 Gavi PPC papers.
[77] Gavi. 2023. Report to the Programme and Policy Committee. Annex C: Technical report on Gavi 5.0/5.1 indicators.
[78] This includes all 17 post-transition countries (Angola, Armenia, Azerbaijan, Bolivia, Bhutan, Cuba, Georgia, Guyana, Honduras, Indonesia, Kiribati, Sri Lank, Republic of Moldova, Mongolia, Nicaragua, Ukraine, Uzbekistan).
[79] Our analysis of country level data for SIs and MIs received from Measurement and Strategic Information (MSI) team.

SG3 [the sustainability goal]: S3.1 co-financing remained at 100% between 2019 and 2022, waivers aside. The percentage remained stable at 100% between 2016[80] and 2022. Co-financing waivers were however granted to nine countries in 2020, six in 2021 and two in 2022[81]. While this is a success story, the resource mobilisation study (Annex 11) notes that co-financing is not a good indicator of future sustainability of immunisation financing (see Box 8). "*Gavi should be careful to avoid equating sustainability with self-sufficiency"* (Gavi Board member). Indicators that were used under Gavi 4.0 to measure improvements in sustainability such as countries on track to successful transition, country investment in RI, and an institutional capacity score[cxx] are no longer SIs.[cxxi]

Box 8: Domestic resource mobilisation
While SG3 is "on track" with co-financing at 100% since 2016, this indicator is a poor proxy for financial sustainability as it does not account for the substantial domestic costs of vaccine delivery (Annex 11). While Gavi countries generally meet co-financing requirements, our thematic study has demonstrated challenges in funding traditional vaccines, vaccine delivery (especially to ZD populations), and new vaccine introductions. In addition, inflation, currency depreciation and much higher vaccine prices for transitioned countries pose threats to the sustainability of Gavi's model. While there are currently manufacturer agreements in place to maintain access to Gavi prices for former-eligible Gavi countries, these are not available to never-eligible MICs and are currently set to expire in 2025 with no systemic solution. As immunisation portfolios become more expensive and more LIC and LMIC countries face constrained finances, better financial and economic monitoring with partners is very important, both to understand and mitigate risks, and to monitoring the broader sustainability of Gavi's model (see Annex 11). Gavi has never done an estimate of the full costs of procuring and delivering vaccines in LICs and LMICs, which is critical information to inform 6.0 preparation.

SG4 [The healthy markets goal] is on track, only minimally influenced by the pandemic. It seems likely that indicators S4.1 and S4.2 will be met but could be reversed if the market becomes more fragile (S4.1), or if some products are culled from the research and development (R&D) pipeline (4.2). Indicator S4.3 may be met but relies on R&D timelines which would normally be longer than a Gavi strategic period. Given that market shaping, emerging as a key area for Gavi 6.0, has not been evaluated previously during Gavi 5.0, we present our findings in Sections 2.2.4, 2.2.5, and 2.2.6, with a more detailed analysis in Annex 9.

To what extent will implementation of Gavi 5.0/5.1 on its current trajectory plausibly result in achievement of the prioritised SG1, 2, 3 and related objectives?

Table 11 in Annex 6 presents the analysis of factors that we considered to estimate the plausibility of meeting various targets by 2025. To reach a judgement, we considered:

- whether the indicator was back to/above pre-COVID levels in 2022 (where applicable)
- trends over 2021-2022
- difference with Gavi projected values for 2022
- difference with extrapolated linear targets for 2022, where Gavi yearly projections were not available[cxxii]
- status of implementation and size of relevant Gavi supported interventions (see Section 2.1)
- analysis of likely enablers and constraints over the next two years, especially fragility, the macro-economic context and long-standing health systems weakness/barriers (see Section 2.2.3)
- analysis of the extent to which and how Gavi 5.0/5.1 priorities are influencing country decisions (see Section 2.2.2)

[80] Gavi. 2019. Annual Progress Report 2019.
[81] Gavi. 2023. Co-financing 2022 – for FCDO September – ppt received from IFS team

- triangulated views of country, regional and global KIs regarding plausibility.

1 **Finding 2.2: The evaluation found the plausibility of achieving 5.0/5.1 SG targets by 2025 as follows:**

- **All MIs** are highly likely or likely to be met, except for ZD reduction (M4).
- **SG1 [the vaccine goal]:** Most SIs or sub-SIs for which enough data is available are highly likely, or likely to be met except S1.2 DTP3 and S1.7 timely outbreak detection and response (unlikely to be met), and S1.2 HPV coverage and S1.6 measles campaign reach (somewhat likely to be met).
- **SG2 [the equity goal]:** S2.1 geographic equity and S2.3 MCV1 coverage are unlikely to be met while S2.2. DTP drop-out reduction is likely to be achieved.
- **SG3 [the sustainability goal]:** The two SIs for which enough data is available (3.1 and 3.2) are respectively highly likely and likely to be achieved. There is a question, however, regarding the extent to which these are the most meaningful indicators to track to measure progress and set ambitions on sustainability.
- **Remaining indicators:** The plausibility cannot be calculated, mainly because relevant targets have not been set.

Table 14 provides a summary of our assessments on plausibility of reaching Gavi 5.0/5.1 targets by 2025 for SG1-3; SG4 is covered in Sections 2.2.4, 2.2.5, and 2.2.6. We provide detailed analysis for each indicator in Annex 6.

Table 14: Plausibility of reaching targets

SG	Summary of findings	Indicator	Plausibility
MIs	All MI for which 2022 data are available but M4 (ZD reduction) are likely or highly likely to be met. M5 (unique immunised children) and M6 (economic benefits) are highly likely to be met being ahead of schedule. MIs related to future deaths (M2)/DALY (M3) averted are likely to be met. M4 on ZD number reduction appears to be off-track and unlikely to be met.	M1 Under-five mortality rate	Cannot predict (2022 value not yet available)
		M2 Number of future deaths averted	Likely
		M3 Number of future DALYs averted	Likely
		M4 ZD reduction	Unlikely
		M5 Unique children immunized through RI	Highly likely
		M6 Economic benefits generated	Highly likely
SG1	Most SIs or sub-SIs for which enough data is available are highly likely or likely to be met <u>except</u> S1.2 DTP3 coverage and S1.7 timely outbreak detection and response, which appear unlikely, and S1.2 HPV coverage, which appears only somewhat likely to be met. Core and post-transition segments are mostly off-track.	S1.1 Breadth of protection	Highly likely
		S1.2 MCV2 coverage	Highly likely
		S1.2 PCV3 coverage	Highly likely
		S1.2 HPV coverage	Somewhat likely
		S1.2 DTP3 coverage	Unlikely
		S1.3 Rate of scale up of PCV and RotaC	Highly likely
		S1.3 Rate of scale up of yellow fever and MCV2	Likely
		S1.4 New vaccine introductions	Likely
		S1.5 Country prioritisation of vaccines	Cannot predict (Indicator has been in abeyance given the pause on rolling out the VIS 2018 vaccines during the COVID-19 pandemic)
		S1.6 Measles campaign reach	Somewhat likely
		S1.7 Timely detection and response to outbreaks	Unlikely

SG2	Two of the three SIs for which enough data is available (S2.1 geographic equity and S2.3 MCV1 coverage) are unlikely to be met while the third (S2.2. DTP drop out reduction) is likely to be met but the target is not very ambitious.	S2.1 Geographic equity	Unlikely
		S2.2 DTP drop out	Likely
		S2.3 MCV1 coverage	Unlikely
		S2.4 Immunisation sessions conducted	Cannot predict (no target specified. New indicator recently added to the WHO/UNICEF electronic Joint Reporting Form, so time trends are likely reflecting reporting completeness)
		S2.5 Stock availability at facility levels	Cannot predict (no target specified. Only value available is for 2021)
		S2.6 EPI management capacity	Cannot predict (no target specified, testing and piloting new approaches was initially paused due to COVID-19 pandemic-related reprioritisation. Reporting for this indicator to begin in 2024)
		S2.7 Percent of countries implementing tailored plans to overcome demand barriers	Cannot predict (no target specified. Indicator has been significantly changed since 2021 so values are not comparable)
		S2.8 Percent of countries addressing gender-related barriers	Cannot predict (no target specified. Only value available is for 2022)
SG3	The two SIs for which enough data is available (S3.1 and S3.2) are respectively highly likely and likely to be achieved. However, there is a question regarding the extent to which these are the most meaningful indicators to measure progress and set ambitions for sustainability.	S3.1 Co-financing	Highly likely
		S3.2 Prevention of backsliding in post-transition countries	Highly likely
		S3.3 Vaccine introductions in former- and never-Gavi eligible countries	Likely

All MIs for which 2022 data are available – except for M4 on ZD - are likely or highly likely to be met. According to our analysis based on the above criteria and presented in Table 14 above:

- Unique immunised children (M5) and economic benefits (M6) are **highly likely** to be met ahead of schedule according to both linear and non-linear projections.
- MIs related to future deaths (M2)/DALY (M3) averted are **likely** to be met.
- M4 on ZD number reduction appears to be off-track and **unlikely** to be met. This is consistent with recent Gavi projections, even under the most ambitious scenarios.[cxxiii] Our analysis of Gavi country-level data[cxxiv] suggests that core (+65% ZD children between 2019 and 2022) and PT countries (+42%) appear most off-track.

SG1 [the vaccine goal]: Most SIs or sub-SIs for which enough data is available are highly likely or likely to be met except S1.2 DTP3 and S1.7 timely outbreak detection and response, which appear unlikely and S1.2 HPV coverage, which appears only somewhat likely to be met.
According to our analysis based on the above criteria (see Table 14):

- S1.1 breadth of protection, S1.2 MCV2 coverage and PCV3 coverage, and S1.3 rate of scale up of PCV and RotaC are **highly likely** to be met.
- S1.3 rate of scale up of yellow fever and MCV2 and S1.4 new vaccine introduction (NVI) are **likely** to be met. S.1.2 HPV coverage is **somewhat likely** to be met, in view of status and a range of factors that need to fall into place to meet the Gavi 5.0/5.1 target (see Box 9). S1.6 preventive measles campaign reach is also **somewhat likely** to be met, as it was exceeded in 2022. However, there is also evidence of increased measles outbreaks and several countries not achieving (different antigen) campaign coverage.
- Two indicators or sub-indicators, S1.2 DTP3 coverage and S1.7 timely outbreak detection and response (-14pp in 2022 compared to the Gavi-projected value) are **unlikely** to be met. Our projections for S1.2 DTP3 coverage are consistent with recent Gavi scenario planning.[cxxv] According to our analysis of country level data received from Gavi,[cxxvi] segments that appear most off-track are again core (DTP3 coverage in 2022 was -6.5% lower compared to 2019) and PT countries (-3.4%).

Box 9: HPV projections

The indicator is slightly ahead of schedule according to Gavi original non-linear projections for 2022. The progress to be made in the space of 2 years for Gavi-57 countries remains, however, quite substantial (from 10% to 24% coverage – cf. the +3pp increase from 2019 to 2022). Gavi has recently expressed an ambition to nearly double the original target, thanks to enhanced efforts such as Multi-Age Cohort additional to RI, additional introductions in the Gavi-57 (including India which alone represents 40.5% of the Gavi-57 forecast) and MICs support as part of the so-called HPV relaunch.[2] Gavi projections, however, rest on many unknowns, including success of HPV campaigns in populous countries such as Nigeria (2023), Bangladesh (2023), Pakistan (2025) and India (pending decision from the government and supply availability) with vaccinations planned to start later in 5.0, given known supply challenges.[2] Evidence from KIIs and document review also suggests that barriers in terms of demand and reaching adolescent girls tend to be on average high, while recent EAF and HSS proposals have scored on average poorly in terms of meeting needs of adolescent girls[3] (see also Section 2.2.2). On this basis, the original target related to Gavi-57 is considered 'Somewhat likely' to be met.

1: Gavi (MEL/MSI). 2023. 5.0 target plausibility scenarios.
2: Gavi. 2023. HPV forecast update to the SLT. 9 October.
3: Gavi. 2023. HSS 5.0 Key Shifts tracker.

SG2 [the equity goal]: Two of the three SIs for which this can be estimated (S2.1 geographic equity and S2.3 MCV1 coverage) are unlikely to be met, while the third (S2.2 DTP drop out reduction) is likely to be met.

- S2.1 geographic equity is **unlikely** to recover and meet its +7pp target by 2025, as the indicator has been on a downward trend since 2019. This is particularly the case in core and PT countries which saw the worst drops, although values remain the lowest in fragile and HI countries at 46% and 62% respectively.[cxxvii]
- S2.2 DTP drop out reduction is the only SI that appears **likely** to be met by 2025 of all indicators under SG2 for which enough data points are available.[82]
- S2.3 MCV1 coverage, which as mentioned above tends to correlate with DTP3 and is not yet back to pre-pandemic levels, is also **unlikely** to be met by 2025. Values were lower in every segment in 2022 compared to 2019. However, this varied, as drops were higher in PT (-

[82] It's important to bear in mind that, even if the indicator was not to improve, if an increased number of ZD children were to be reached with DTP and percentage of drop out stayed the same, this would *de facto* equal to a decrease of dropouts (and children being reached with DTP3) in absolute numbers.

6.7pp) and core (-3.6pp) countries although coverage remained the lowest in fragile countries at 65.1%.

SG3 [the sustainability goal]: The two SIs for which enough data is available (3.1 and 3.2) are respectively highly likely and likely to be achieved. There is a question, however, regarding the extent to which these are the most meaningful indicators to measure progress and set ambitions on sustainability (see Box 8 and Finding 2.1)**.** Targets related to:

- S3.1 co-financing show that obligations are **highly likely** to be met. The indicator has been stable (waivers aside) at 100% since 2016.[83] Our analysis of CPMPM data available on this indicator also shows that in September 2023, 73% of countries for which information was available had at least partially fulfilled their co-financing obligations, compared to 66% in September 2022.[84] Evidence from country level KIs and from a document review also shows that governments have prioritised co-financing and increased their contribution in absolute terms (given the number of antigens is increasing and transition dates are approaching), even in face of worsening economic conditions and competing priorities.
- S3.2 prevention of backsliding in PT countries also appears **highly likely** to be met, as no further decline was registered. But, given evidence from our analysis of WUENIC data on PT countries performing more poorly in comparison to HI and fragile countries, the target appears unambitious.

Current indicators do not appear adequate to track financial sustainability (see Box 8 and Annex 11), or to gauge the prospects for programmatic sustainability, which is a key aspect of ensuring the capacity for vaccine delivery systems to run without TA from Gavi. Gavi analysis highlights barriers to, or concerns about the prospects for transition of the ten countries in accelerated transition. The current cohort has a significantly lower level of economic growth per capita than those that previously transitioned. Their programmatic capacity is also weaker and has been further stretched by the COVID-19 pandemic; more than half of the countries have DTP3 coverage levels below 85%. Consequently, only six additional countries are now expected to transition by the end of this strategic period, as opposed to ten originally forecast.

1 **Finding 2.3: The current contribution of the Gavi 5.0/5.1 strategy to results is not clear, given the delays in operationalisation/disbursement of key grant workstreams (FPP and EAF), the staggered nature of the grant-making process, and lags in reporting.** As highlighted in the strategy operationalisation evaluation[cxxviii] and confirmed by our own document review and KIIs, due to the delays in operationalisation of Gavi 5.0 and the staggered nature of the grants, as well as delays in disbursement, key activities under Gavi 5.0 are only being implemented (and only in some countries) as of the end of 2023. This has limited the contribution of Gavi 5.0/5.1 to observable results. Moreover, given that official coverage estimates are only available with a one-year delay, results of activities under Gavi 5.0/5.1 will only contribute to results reported by WUENIC[cxxix] in July 2025 and onwards.

1 **Finding 2.4: Despite measurement challenges, it appears that the contribution of Gavi 4.0 to current results has been substantial, especially in terms of vaccine introductions, cold chain equipment (CCE) improvements, and helping countries contain the effects of the pandemic on RI.** As the ZD year one evaluation annual report notes, estimation of Gavi 4.0 contribution to 2022/2023 outcomes is hampered by several factors including: *"limited strength and availability of evidence; Gavi's unique business model restricting access to critical grant implementation data; and the complexity of the Alliance and partnership system that Gavi works in"*.[cxxx] Measurement challenges are described in Section 2.1.3. Despite these and other challenges, the ZD evaluation

[83] Gavi. 2019. Annual Progress Report 2019.
[84] Our own analysis of CPMPM data received from Gavi on 31 October 2023.

concluded that *"Gavi 4.0 funds partially contributed to ZD outcomes"*.[cxxxi] Evidence from the MTE document review and KIIs (both at global and at country level) also points to Gavi having made a substantial contribution to Gavi 5.0/5.1 results through previous strategic funding. This is seen especially in terms of i) NVIs;[cxxxii] ii) CCE[cxxxiii] including COVID-19 funding (mainly CDS) contributing to geographic equity among other things; iii) helping countries containing drops in RI coverage caused by COVID-19 and other factors; iv) delivering 1.65 billion COVID-19 vaccine doses under COVAX alone;[cxxxiv] v) increasing breadth of protection and number of unique immunised children;[cxxxv] and vii) maintaining co-financing requirements during an unprecedented crisis period. This is also in line with the recent Future of Global Health Initiatives (FGHI) report which concludes that Gavi has contributed to the reduction in the global burden of vaccine-preventable diseases, with measurable wins on immunisation and improving donor coordination in this area.[cxxxvi]

2 **Finding 2.5: We cannot yet estimate the future contribution of Gavi 5.0/5.1 to 2025 outcomes and beyond, but early evidence points to reaching more children with an ever-expanding number of life-saving antigens.** We have noted above the complexity of estimating Gavi's *current* contribution and estimating its *future* contribution is methodologically impossible. Analysis of current planned activities under 5.0/5.1 (see Section 2.1.2), however, points to a strong potential to make a significant contribution in relation to NVIs and hard to reach children. Evidence from our MICs and innovation thematic studies also suggest that these approaches will likely contribute to positive immunisation outcomes once countries have had the chance to implement. On the MICs front for instance, for introduction of targeted vaccines, at least ten national vaccine introductions are expected across five countries with Gavi support by the end of 2025, with a further seven introductions across four countries possible, thus likely exceeding the target of eight to ten vaccine introductions (see Annex 10). Despite challenges with operationalisation of the innovation approach, it is being integrated as a priority, albeit only partially, in new applications, making plausible that innovation will contribute at least to some extent to Gavi 5.0 SGs (see Annex 12).

2 **Finding 2.6: It is unclear whether Gavi 5.0/5.1 will strengthen health systems, or sustainability of immunisation investments**. Some KIs questioned whether Gavi funds are substituting for domestic resources, a question raised in the recent FGHI report.[cxxxvii] KIs also expressed concerns about HSS and how much of it is strengthening versus supporting health systems. As a Board member put it "*HSS support is nominal in a way. Gavi is solving input constraints – vaccines, operational costs, staffing, incentives, campaign ops – not strengthening health systems."* Our findings also suggest that the extent to which the current approach will contribute to increased sustainability (beyond meeting co-financing commitments) is at best unclear (Annex 11). This is also consistent with Finding 1.8 regarding early indications that causal pathways may not hold against SG2 and SG3, with implications for Gavi's contribution to the achievement of these goals.

2.2.3 How/to what extent has Gavi influenced countries to adjust their immunisation programming intentions related to Strategic Goals 1, 2, and 3?

1 **Summary finding:** Gavi works in a range of ways to implement its strategic priorities, with advocacy seemingly key, but with risks associated with creating priority-specific mechanisms. As a result, ZD is reasonably well integrated in country applications, albeit to varying degrees. The Gavi 5.0 aspiration for greater CSO engagement is also being integrated, albeit with some tensions within the Alliance. Other priorities such as greater use of gender-responsive and transformative and sustainable approaches are much less integrated due to limited capacity to monitor and hold partners accountable for in country results alongside complex internal processes and country policies and systems which may not always be in accordance with Gavi priorities.

We present analysis in Section 2.1 which covers issues relating to integration of ZD, CSO partnerships, gender, Alliance working, internal capacity, and country alignment. Under Section 2.1.8, we also identify some barriers to implementation of Gavi 5.0 and overall priorities. Here we reflect on issues relating to Gavi's influence that have not already been covered elsewhere.

1 **Finding 2.7: The Gavi Secretariat and wider Alliance works in a range of ways to ensure that Gavi strategic priorities are reflected in country applications and priorities; some are more effective than others**. As highlighted by the strategy operationalisation[cxxxviii] and the ZD[cxxxix] evaluations as well as by a number of MTE KIs, Gavi's mechanisms to influence countries programming include: i) funding applications processes and guidelines; ii) earmarking of funds; iii) top-up funding, such as for innovation; iv) grant application review processes including comments by the IRC; and v) communication, advocacy and country engagement at various levels.[85] Direct country engagement, especially at the highest levels, seems to be the most effective tactic when it comes to influencing country priorities (e.g., India[cxl] and Nigeria[cxli]), while funding application documentation seems to have limited impact (albeit receiving the greatest attention from Gavi), as *"evidence suggests that country stakeholders often do not read or engage with them, due to their length and complexity"*.[cxlii] Evidence from KIIs suggests that top-ups and earmarking can prove effective to ensure allocation of funds to specific priorities, but can also drive higher levels of fragmentation and complexity (Section 2.1.5) as well as excessive rigidity when savings from one "pot" cannot be used to strengthen other areas.

1 **Finding 2.8: The extent to which we could assess Gavi's influence on country immunisation programming intentions was limited by factors related to monitoring, accountability, and learning.**

- **Structured internal assessment on the extent to which Gavi strategic priorities are being integrated is currently confined to some funding levers and assessment of progress against them is not systematic.** The IRC reviews applications and provides comment, but according to the strategy operationalisation evaluation, analysis of IRC comments over time suggests that some issues are not addressed meaningfully over many years.[cxliii] IRC comments and recommendations are recorded and communicated with countries through an Issue Resolution Tool (IRT)[86] and the Secretariat is responsible for ensuring that countries address the recommendations, but the IRT was described as difficult to use. The strategy operationalisation evaluation also noted that, while IRC comments and recommendations are communicated to countries and follow-up is tracked by relevant Secretariat focal points through the IRT, this has been described as insufficient and does not give a portfolio-level view of the extent to which comments are addressed in final grant applications.[87] We note that the HSIS team recently undertook some of this analysis[88,cxliv,cxlv] but we are not aware of similar exercises applied to other funding levers. Consequently, "*there is a lack of clarity internally on how systematically and comprehensively the IRC recommendations are addressed in practice in each country and across the portfolio. The inability to measure progress in addressing IRC recommendations means there is little incentive or accountability to do so between grant applications. As a result, little progress is made over time*"[cxlvi] A recent evaluation of the IRC also made recommendations to increase engagement with countries, technical partners, and for the IRC to improve the quality and the feasibility of its recommendations.[cxlvii] Implementation of evaluation recommendations is reportedly underway.

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[85] By SCMs, functional teams (albeit their involvement with countries is self-reported as limited), Gavi leadership and through Alliance partners with in-country presence, especially WHO and UNICEF and to some extent the WB.
[86] The issue resolution tool is a Gavi internal tool used for managing issues and action points recommended by the IRC for approved applications.
[87] While the IRC do compile key themes through high-level reports, these do not provide the specific comments on each grant application.
[88] We have referred to evidence from this analysis in Section 2.1 (see observations on ZD, CSO and gender).

- **The CPMPM is primarily focused on process measures, hence it has limited value as a tool to monitor progress against strategic objectives and ensure accountability for outcomes.** The extent to which CPMPM tracks SIs is limited. Moreover, obtaining the necessary disaggregated data can be time consuming and requires careful interpretation which is not always intuitive.
- **There is a gap in Gavi monitoring systems in relation to outputs being delivered and how/to what extent these are contributing to outcomes of interest**.[89] The issue was exacerbated by the pausing of the newly introduced Joint Appraisals during COVID-19 and their temporary replacement with more light touch multi-stakeholder dialogues.[cxlviii] We understand that Joint Appraisals have been reinstated**.**
- **Some stakeholders noted weaknesses in Gavi's learning and accountability systems, both within the Secretariat as well as the broader Alliance**. Board KIs also pointed to the lack of evidence on operational impact to exercise effective oversight and being presented only with "highly curated" information.

2.2.4 What were the most significant factors which affected progress against targets in the Gavi results framework/key barriers to address?

1 **Summary finding:** Key drivers of progress at the level of Strategic Goals and indicators appear to be political support, Gavi support, health system capacity, partnerships, and advocacy. Key barriers include weak health systems, demand (including vaccine hesitancy), resource constraints, COVID-19, access to services, data and Gavi systems and processes. A limited number of these barriers are within Gavi's control.

We analysed drivers of observed results at the level of SGs by triangulating evidence from previous evaluations (COVID-19, ZD, COVAX and strategy operationalisation), and reviewing Gavi documentation and KIIs. For KIIs we developed force field analyses and current reality trees (Annex 7) to support identification of enablers, constraints, and root causes.

Enablers

1 **Finding 2.9: Stakeholders are in strong agreement on a limited set of SG enablers, which are broadly consistent across SG1 and SG2. Gavi is aware of and taking action to maximise its effectiveness across these enablers.**[90] KIs highlighted political support, Gavi support, health system capacity, partnerships and advocacy as key enablers, of which, force field analyses (see Annex 7) stressed political support and capacity to respond as the most important. There was a high degree of convergence across stakeholder groups, although country respondents gave more weight to political support and Secretariat respondents stressed Gavi's contribution, partnerships, and advocacy. Our own analysis of variation in enablers across Gavi 5.0 strategic goals, focused on SG1-SG3 suggests that:

- **SG1:** Top enablers are capacity to respond and relevant analysis, followed closely by political will, demand/support for vaccines and economic resources.
- **SG2:** Like SG1, political will and capacity to respond are key, but resilient and high performing health systems, and campaigns are also important.
- **SG3:** Progress appears to be linked to governments recognising the clear benefits of vaccines, country resources, availability of other sources of funding, and Gavi advocacy.

[89] Beyond number of immunisation sessions and stock availability, to better capture especially HSS outputs, which is particularly challenging given their heterogeneity.
[90] The strategy operationalisation and ZD evaluations did not investigate enablers, or barriers to progress against 5.0 strategic goals

Actions to optimise the contribution of these enablers is a routine part of Gavi support. Advocacy by SCMs and Gavi senior leadership seeks, among other things, to shore up political support at country level. A major part of Gavi cash-support seeks to strengthen health systems, even though there is recognition of need/scope for a more effective and coordinated response (see Finding 2.6). Partnerships, also at the heart of Gavi's model, now include a greater engagement of CSOs for implementation, which is seen as an important step (see Section 2.1.4).

Constraints

1

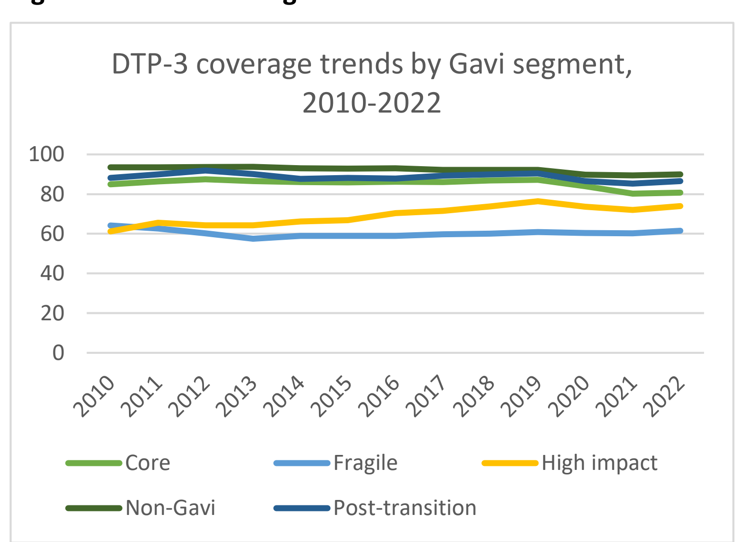
Finding 2.10: Strong convergence was noted across a longer list of constraints to strategic level results, also broadly consistent across SG1 and SG2. Informants highlighted weak health systems, demand (including vaccine hesitancy), resource constraints, COVID-19, access to services, data and Gavi systems and processes (see Table 15 for longer list). Of these, force field analyses stressed resource constraints and COVID-19 as the most important barriers (based on aggregation of stakeholder views). Whilst these issues were highlighted by the majority of key stakeholder groups, it is interesting to note that country respondents emphasised health system constraints ahead of COVID-19 and resourcing constraints, whereas Gavi staff emphasised demand barriers.

Our analysis across the Gavi 5.0 SGs suggests little variation in identified constraints across SG1 and SG2, with the exception that lack of political will and poor quality were noted under SG2, but not SG1. For SG3, indicators suggest a positive story on sustainability. However, our analysis identifies limitations with the current indicators which do not allow judgement on sustainability prospects (see Finding 2.1, Box 8, and Annex 11 for more details).

1

Finding 2.11: COVID-19 has been a key barrier to achieving the 5.0/5.1 SGs, but other drivers such as complex systems predate the pandemic. COVID-19 had a multifaceted and prolonged impact on Gavi's mission in terms of: i) lockdowns and other public health measures to contain the pandemic which caused disruption to RI;[cxlix,cl,cli clii cliii cliv] ii) Gavi capacity to operationalise 5.0[clv] which was only partly mitigated by the December 2020 recalibration of priorities; and iii) the toll on country capacity to deliver RI services[clvi]- as EPI teams were under pressure and as the number of vaccinators often remained fixed while having to deliver 3.5 times the usual doses[clvii] and to different populations; this also had an impact on country bandwidth to prepare and submit funding applications to Gavi.[clviii] However, coverage in some Gavi-eligible countries had been flatlining for some years before dropping in 2020-21[91], pointing to systemic challenges that predated and are likely to outlive the pandemic (see Figure 7).

Figure 7: DTP-3 coverage trends



1

Finding 2.12: Analysing the root causes for the above constraints is outside the scope of this MTE, but our analysis notes the likely contribution of a range of exogenous factors over which Gavi has limited control, or even influence. Gavi includes relevant analyses of root

[91] Analysis based on Gavi's country level coverage data shows that, over the period 2010-2019, DTP3 coverage flatlined or decreased in 55% of the core and of the fragile countries and in 100% of two post-transition countries (using 2023 segments). It however considerably improved in all HI countries.

causes for some of these constraints in its annual risk reporting.[clix] We also note the likely substantial contribution of exogenous factors such as: fragility and conflict;[clx] increasing birth cohorts[clxi] – vaccinations will have to outpace changes in birth cohorts if coverage rates are to increase; and difficulties/lack of incentives in accessing the hard to reach, especially in a context of competing priorities and decreasing under-five mortality.[clxii]

1 **Finding 2.13: Where we could identify root causes, these are linked to Gavi's structure and resourcing, and therefore more within its control. These have often been affected by the exceptional circumstances linked to COVID-19.** Taking a broader view (beyond the key constraints emphasised in Finding 2.10), we identified a longer list of barriers more within Gavi's control to address and for which we can identify root causes. These include constraints around **programming**, **differentiation,** and **coordination/ partnership**. We note that root causes for complexity of Gavi systems is discussed under Section 2.1.8.

- **Programming:** Three different stakeholder groups (SCMs, CSOs and Alliance partners) noted concerns about the focus of Gavi programming. This covered a range of issues, from inability to cover what is needed (e.g. lack of operations funds or lack of Gavi support for vaccines that countries would like to procure), to whom Gavi works with in government, to inexperience within the Secretariat. The root causes are likely to be multiple but are certainly linked to (un)availability of relevant skills in the Secretariat (a concern voiced by several KIs).
- **Differentiation:** As discussed in Section 2.1.5, the basis for differentiating between processes and resources to support countries has critics. Four different stakeholder groups noted concerns (SCMs, other Secretariat staff, the Board and Alliance), highlighting the importance of needs-based differentiation and providing more support to core countries and MICs, as per the recommendations of the 2019/20 organisation review (not shared with the MTE team). Gavi's capacity to monitor and evaluate progress was affected by COVID-19.
- **Coordination and partnership:** This area is covered in detail under Section 2.1.4. But stakeholder groups including SCMs, other Secretariat staff, and Alliance partners noted constraints around coordination and alignment, with competition for funding a key focus, rather than coordination on strategy. As noted above, and in recent dialogue within the Alliance, there are inherent tensions within the Alliance (in terms of funding and accountability) which were placed under greater strain during COVID-19, e.g., through undermining pre-existing coordination mechanisms.

Table 15: Identifying root causes of constraints/barriers

Constraint/barrier	Gavi influence	Root causes
Resources/ economy	Strong Gavi influence	See Annex 11
Gavi systems	Strong Gavi influence	See Section 2.1.8
Programming	Strong Gavi influence	Secretariat composition and strategy for HR recruitment (see Section 2.1.3)
Differentiation	Strong Gavi influence	As per recommendation of 2019 organizational review Implementation of approach and opportunities for learning/adaptation affected by COVID-19
Coordination/ partnership	Strong Gavi influence	Inherent tensions in Alliance, COVID-19 affected core coordination mechanisms, lack of management capacity[clxiii]
COVID-19	Medium Gavi influence	COVID-19 function of ability to identify and respond – i.e. system issue for countries and for Gavi

Weak health systems	Medium Gavi influence	Outside our remit to explain root causes
Demand	Medium Gavi influence	Outside our remit to explain root causes, but evidence suggests demand affected by presentations, social media, communications/ advocacy, culture
Costs	Medium Gavi influence	Linked to access and resources categories above
Data	Medium Gavi influence	Outside our remit to explain root causes – similar to COVID-19; data is a systems issue
Access to services	Medium Gavi influence	Outside our remit to explain root causes – like COVID-19; access is a systems issue
Exogenous	Weak Gavi influence	Outside our remit to explain root causes

1 **Finding 2.14: Responding to these constraints and barriers may be outside Gavi's control, meaning Gavi's contribution is often indirect, and reliant on others**. Poor access to services and lack of data are often symptoms of weak health systems capacity. Whilst Gavi provides substantial support to HSS, the effectiveness of this support depends on the quality of analysis and programming that underpin Gavi's grants, and on implementation of agreed interventions (by Gavi partners). Analysis of the factors that affect Gavi's operations is included in Section 2.1.8. Gavi influences demand through advocacy and focused work under SFA funding, which is also an indirect pathway to the outcomes that Gavi is interested in. Perhaps the only key constraint that Gavi has direct control over is resourcing – but even this is limited to Gavi's own contributions, and these are often limited relative to overall needs.[92]

Gavi's ability to influence COVID-19 was limited by capacity constraints; the initial response is documented in the COVID-19 evaluation. Although Gavi cannot predict future pandemics, it can influence whether country and Gavi systems are fit for purpose to support effective prevention, preparedness, detection, and response.

2.2.5 What progress has been made against SG4 sub-strategies on healthy markets (SG4.1) and innovative products (SG4.2 and SG4.3) and to what extent has the COVID pandemic compromised progress? To what extent will implementation of Gavi 5.0/5.1 on its current trajectory plausibly result in achievement of the prioritised SG4 and related objectives?

2 **Summary finding:** Data summarised in the market shaping thematic study (Annex 9) show that the SG4 indicators are on track and were only minimally influenced by the pandemic. Indicators 4.1 and 4.2 will likely be met but could be reversed if the market becomes more fragile (4.1), or if products are culled from the R&D pipeline (4.2). Indicator 4.3 relies on R&D timelines normally longer than a Gavi strategic period but may be met. Due to reduced immunization activity in countries during the pandemic and the Alliance's effective management of demand and supply, COVID-induced supply disruptions were not generally material in affecting acceptable levels of market health (indicator 4.1). There is no evidence to suggest that the pandemic influenced R&D efforts (with implied impact on 4.2 and 4.3). The SG4 corporate performance indicators are not well aligned to the emphasis of Gavi's market shaping work and operational level SG4 M&E systems are not well-defined and transparent; this may reduce accountability and transparent prioritisation, as well as opportunities for learning and course correction.

[92] And we have limited evidence on this, as noted in Annex 11.

2 **Finding 2.15: The SG4 [the healthy markets goal] indicators are on track, minimally influenced by the pandemic.** The S4.1 composite target of 10/14 (14 being the denominator of antigen markets supported by Gavi) for "healthy markets" was achieved in 2021 and 2022. The S4.2 innovation-focused indicator with a target of eight products in the R&D pipeline was also met, as of 2022. The S4.3 indicator "products with improved characteristics procured" has a target of eight by 2025 and currently stands at two. S4.1 and S4.2 are not targets that will necessarily follow arithmetic progression, that is, there can be reversal of the target number achieved if a market becomes more fragile (S4.1) or if some products are culled from the R&D pipeline (S4.2). Nonetheless, with the information available, it seems likely that S4.1 and S4.2 will be met.

S4.3 relies on R&D timelines which would normally be longer than a Gavi strategic period. However, the target figure has been derived based on the market shaping team's knowledge of the trajectories of likely improved product introductions and therefore may be met. Due to reduced immunization activity in countries during the pandemic and the Alliance's effective management of demand and supply alignment, COVID-19-induced supply disruptions were not material in affecting acceptable levels of market health (S4.1), except for contributions to compromised production capacity with Rota. There is no evidence to suggest that the pandemic may have influenced R&D efforts (with implied impact on S4.2 and S4.3).

2 **Finding 2.16: The SG4 corporate performance indicators are not well aligned to measure Gavi's market shaping work. Operational-level activity monitoring on SG4 indicators is not well-defined or transparent. Additionally, the coherence between Gavi 5.0 strategic imperatives and realisation of market shaping objectives (as measured through SG4 indicators and Market Shaping Strategy (MSS) M&E respectively) may be challenged due to the parallel strategic processes and timeframes upon which results can be observed. Finally, the combination of M&E weaknesses may reduce accountability and transparent prioritisation, as well as opportunities for learning and course correction.**

- There appears to be uneven weighting/emphasis of the three SG4 indicators in light of the relatively high proportion of Alliance effort now allocated to components of S4.1. Despite the increased emphasis on demand health (folded into the aggregated S4.1 indicator) under Gavi 5.0/5.1, it receives insufficient visibility.
- At the operational level, there is a market-shaping strategy operational plan with six components with associated activities, working groups, process, and operational indicators. However, the market shaping team reports that this plan is not being used and monitored, as priorities have changed. There is reported to be antigen roadmap activity tracking, however this does not cover all of market shaping activities and contains confidential data. Consequently, internal activity reporting linked to market shaping strategy workplans is currently weak and some of the Square[93] partners are recommending that a refresh to operational plans and targets is needed.
- The coherence between Gavi 5.0 strategic imperatives and realisation of market shaping objectives (as measured through SG4 indicators and MSS M&E respectively) is unclear due to the differing timeframes for preliminary results, as well as the largely parallel strategy operationalisation processes of the MSS and the Gavi 5.0 strategy.[clxiv]
- Weaknesses in the relevance of SG4 strategic indicators and operational level M&E systems may in turn weaken accountability, transparent prioritisation, and course correction. Improvement in internal M&E is important in the context of current 6.0 discussions around trade-offs. In addition, it is relevant to inform and increase transparency of decisions about relative effort (including that of Alliance partners) devoted to different initiatives, at the outset and during implementation.

[93] Partnership of Gavi market-shaping partners: Gavi Secretariat, UNICEF-SD, WHO-IVB, & BMGF-VDCP (Gavi's Market Shaping Strategy 2021-2025).

2.2.6 What has been the contribution to SG4 in relation to the following key Market Shaping Strategy 5.0 pillars? – Healthy Demand, Partnership Optimisation, Regulatory Environment, Future Supplier Base[94]

2 Summary finding: Gavi's Market Shaping Strategy 2021-2025 design is comprehensive and strategic, with market shaping levers effectively deployed but with mixed results to date from partner efforts. Gavi support for African manufacturing is a high priority but requires addressing several risks. The co-financing policy, country finance allocation methodology, as well as country decision making on vaccine suppliers/product presentations limit Gavi's capacity to influence demand health, despite enhanced Secretariat support. Work on the Vaccine Innovation Prioritisation Strategy has accelerated, and the Secretariat is working on the case for earlier intervention on market shaping pull mechanisms.

2 **Finding 2.17: Gavi's Market Shaping Strategy (MSS) 2021-2025 design is comprehensive and strategically focused and responds to previous evaluation recommendations barring two exceptions.** Gavi's MSS sets out three strategic pillars - demand health, future supplier base, and innovation – as well as three strategic enablers – optimising the market shaping partnership, improving regulatory efficiencies, and updating new strategic tools and processes. The operational plans within these six areas are relevant to the priority market shaping challenges and are largely reflective of recommendations made during the previous evaluation of Gavi's market shaping strategy 2016-2020[clxv], except for: i) strengthening of internal monitoring and evaluation of operational activities; and ii) helping to support supply and procurement performance in countries nearing/after transition and improving market intelligence data relating to MICs and never-eligible Gavi countries.

2 **Finding 2.18: Gavi's market shaping levers are effectively deployed, relying amongst other things, on the demand signal that Gavi can offer to suppliers - assured financing, a tendency for countries to remain with the same product, predictable birth cohorts and regular, credible forecasts. In addition, competition and supply security is facilitated through several enablers, including WHO prequalification and national regulatory authority support, UNICEF procurement tenders and exceptional use of de-risking levers**. Gavi's market shaping is reliant on an equilibrium between competition and assured demand, as strategized in the antigen roadmaps and facilitated by Gavi's continual interaction with UNICEF and with manufacturers. The "improving regulatory efficiencies" enabling pillar of the market shaping strategy involves support to teams within WHO to work on strengthening regulatory capacity in priority countries and hastening market entry of new supply, including through the WHO prequalification process. Gavi has also used risk sharing through pre-payments, or volume guarantees as exceptional levers, for example with a new entrant at a particular time with a particular product. Gavi's market shaping has been shown to produce benefits beyond Gavi countries, because it increases market transparency, enhances competition and promotes a stable supplier base.[95] Even though the levers Gavi utilises in some cases have a lead time longer than the timeframe of a Gavi strategic cycle, the fact that the S4.1 indicator on healthy markets is meeting its target suggests that market shaping levers are being effectively deployed. That said, misalignment between demand and supply is the reason why some antigens do not meet the criteria for market health; alignment could be improved if certain limitations could be removed and efforts expanded (see Findings 2.20, 2.21, 2.22, 2.23).

[94] Note that the evaluation question as originally phrased in the evaluation RfP does not correspond to the correct Market Shaping Strategy 5.0 pillars. Please see Finding 2.17 for the correct listing

[95] EXTERNALITIES OF GAVI MARKET SHAPING ACTIVITIES: https://www.gavi.org/sites/default/files/document/the-monitoring-of-gavi-market-shaping-externalities---public-summarypdf.pdf NB: Positive outcomes of Gavi's market shaping activities were identified for pneumococcal and measles-rubella supply security and manufacturer diversity for oral cholera, yellow fever, rotavirus and pentavalent. The pentavalent market also appears to have seen benefits to middle-income countries (MICs) in terms of lower prices – potentially a positive spillover effect of Gavi's market shaping work.

2 **Finding 2.19: Efforts to improve processes and tools for developing partner-aligned strategic approaches to market shaping continue, but with mixed results.** Under the MSS strategic enabler "implement updated strategic tools and processes," changes were proposed to the antigen roadmap drafting process to align the level of effort with its potential impact and to maintain relevance. Eight of 15 roadmaps have been updated during Gavi 5.0/5.1, some with a more agile format. That said, some partner misalignment remains around the appropriate frequency and format of Gavi roadmaps, including how they synergise with procurement cycles and tactics.

Under the strategic pillar "Future Supplier Base" a "criticality/capabilities" analysis was launched, recognising that vaccine markets increasingly require cross-cutting and manufacturer-centric views. This is in addition to individual vaccine market views, around which Alliance partners have traditionally been organised. The timing of this work has been delayed due to difficulties in aligning partners on the approach. Consequently, the work was pushed into the implementation stage of the market shaping strategy, instead of informing risk mitigation, or Alliance actions to be taken during the formative stages of the strategy development. Previous brainstorming efforts focusing on how to leverage these analyses have been slow to yield new ideas and KIs suggest a reconsideration of such efforts is needed to ensure a cost-effective approach.

The focus of the "partnership optimisation" enabling workstream has been to improve the efficiency of data sharing amongst the Square partners[96] and bring clarity around roles and responsibilities of the partners. The former has been challenging, hindered by confidentiality restrictions in sharing pricing data and/or differences in assumptions and use for the forecasting data.

2 **Finding 2.20: Although the need for increased attention to demand health was recognised as a major shift under Gavi 5.0, country appetite for new vaccine uptake and product switches has been smaller than expected, limiting opportunities for improvement. Demand health is also a key driver behind challenges with the four antigens experiencing unacceptable market health at present.[97]** The need for increased attention to demand health emerged in 2019/2020 due to the increase in the number of products and presentations available / soon to be available, as well as the need to mitigate risk of supply insecurity (as a function of insecure demand materialisation, poor demand predictability, or demand skewed to one presentation). There are now 19 antigens on the Gavi menu with over 50 vaccine presentations (e.g., going from two to twelve Rotavirus options, four options for PCV presentations and two schedules, plus HPV options). Another six to twelve antigens will be considered in the next VIS.

There are opportunities to realise further impact and savings by thinking through how countries can optimise their vaccine portfolios through product switches but switch activity has been limited. Secretariat KIs report that only a dozen countries have requested or have been prompted by the Secretariat to consider optimisation options, either due to Rota supply disruptions, or the need for transitioning countries to reduce costs.

Similarly, portfolio prioritisation (which vaccines to introduce with the highest health impact) is an increasing priority in Gavi 5.0/5.1, but there has been less new vaccine uptake than anticipated. As per estimates in December 2020 reporting to the Board, 15 out of 26 new vaccine introductions planned for 2020 were delayed due to COVID-19.[clxvi]

Demand materialisation and optimisation are also key challenges affecting the market health of the four antigens rated as unacceptable under S4.1 (Rota, HPV, cholera, malaria) as well as many other antigens which are assessed under S4.1 as "acceptable with risks".

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[96] Partnership of Gavi market-shaping partners: Gavi Secretariat, UNICEF-SD, WHO-IVB, & BMGF-VDCP (Gavi's Market Shaping Strategy 2021-2025).

[97] Unacceptable market health is defined by the Square partners via a rigorous balanced scorecard process encapsulating 4 parameters. The scorecard assessment is applied to each antigen supported by Gavi. See Annex 9 for further details.

2 **Finding 2.21: Until recently, there was insufficient downstream/country support for evidence-based market shaping decision making on vaccine uptake and switches. However, the Secretariat has recently strengthened support for healthy demand, especially during 2023, with scope for further expansion.** KIs report a lack of country capacity to take decisions on new vaccine uptake and switches. The Secretariat has consequently expanded its resources by creating a framework with common language on how to compare new vaccine options, together with updating of roadmaps to ensure that target outcomes include demand side targets. A significant advance in supporting country capacity has been the "Brown Bag" webinars initiated by the vaccine programmes team, supporting an evidence-based review of e.g., serotype relevance, cold chain requirements, and programmatic implications of portfolio optimisation.

Demand health is where the market shaping and introduction and delivery goals come together, with links between the vaccine programmes and market shaping teams well established at the antigen level (e.g. with the vaccine programmes team engaged in the antigen roadmap development process). A more recent example of coming together was the launching of an Alliance working group to discuss and work on cross-antigen and cross-country demand health topics jointly between markets and programmes teams.

However, the Secretariat's approach to viewing demand health across portfolios, with country engagement and strategic implementation perspectives is still evolving. Square partners acknowledge that demand health is a newer area of work, likely to require new forums for communication across the programmatic, vaccine programmes and market-shaping teams, new policies related to how these teams work together, more cohesive targets that are collectively created across the two teams, and remapping of roles and responsibilities, along with improved communication of vaccine choices to countries.[98] Further work is needed on other more systemic areas e.g., the influence of Gavi co-financing and budget allocation policies on country vaccine uptake, and switch decision-making processes and outcomes.

2 **Finding 2.22: Gavi's proposal to engage in more market shaping efforts prior to final Board approval of vaccines on the pre-VIS longlist has the potential to address gaps in the vaccine market shaping value chain**. As has been shown for over a decade[clxvii] in sectors other than vaccines, a wide variety of push and pull levers can be tailored to address specific market shortcomings throughout the R&D process to access value chains. The vaccine sector in comparison is relatively weak in the market shaping architecture that sits at the interface between late-stage R&D and product access, introduction, and scale. This is partly because market shaping activities at Gavi normally only start once the Board has approved a new vaccine programme under VIS. Recognising this gap, there is a proposal under development ("long-horizon market shaping") for a larger investment to be considered for 6.0. [clxviii] This proposal acknowledges that pre-VIS market shaping can have a positive impact on averting market failure, preparing markets for optimised programme launches, and ensuring improved responsiveness and faster access to a vaccine in the event of an outbreak or epidemic. For example, when Gavi intervened exceptionally before a vaccine programme was approved as was the case for Ebola, malaria and Hexavalent.[clxix] Such an evolution in Gavi's market shaping focus would support earlier intervention with market shaping pull mechanisms while at the same time would require revisiting roles and responsibilities between Gavi Secretariat teams (e.g., policy/VIS, global health security, market shaping) and external (e.g., CEPI, BMGF) teams. Care would need to be taken to not undermine the objectivity of the VIS process by pressure to validate Gavi's pre-VIS investments.

[98] For example, the Gavi website communicates the antigen offering, eligibility and the application for each, but the communication could be structured more along the lines of, for example, 'Because of the high impact of these antigens, we highly recommend these four first. After those, here is a menu depending on the region you are in' Countries could click and see the fiscal implications and potential health impacts.

1 **Finding 2.23: Gavi's demand health influence is limited, due to the current co-financing policy, the country finance allocation methodology, and country control over choice of vaccine suppliers and product presentation.** Several challenges make Gavi's ability to influence supply and demand alignment more problematic: i) growing number of programmes and vaccine presentations, some having large price differentials with no meaningful programmatic or biological benefit compared to the less expensive alternative; ii) a tendency for countries to prefer higher-value vaccines and those produced by multi-national corporations; iii) higher-priced vaccines such as malaria and HPV included on Gavi's Board approved antigen menu; and iv) insufficient attention to encouraging uptake of lower priced vaccines, or reduced dosing schedules, where comparable options exist. These issues limit Gavi's ability to influence demand health and achieve VfM.

The co-financing policy does not incentivize price sensitivity, except for countries in the preparatory and accelerated transition phases. For initial self-financing countries, there is no price sensitivity, as countries pay US$ 0.20 per dose regardless of the cost of the vaccine. However, for countries in preparatory and accelerated transition, there is price sensitivity as the co-financing share increases with time and GNI. Therefore, these countries have incentives to take up less expensive (comparable) alternatives and potentially disincentives to take up newer more expensive vaccines.

The vaccine programmes team is increasing support to country vaccine portfolio decision-making. However, **insufficient encouragement for countries to take up lower priced (comparable) vaccines or reduced dosing schedules to maximize Gavi resources and sustainability remains.** Gavi's investment cases are based on projections of vaccine introduction and support at country level, as well as anticipated co-financing levels. Reductions in dosing schedules or prices paid (for countries on the transition pathway) affect Gavi budget utilisation and co-financing levels, unless compensated by either a similarly sized new uptake of additional antigens, or a change in the co-financing policy to maintain a country's fiscal contributions. Budget utilisation and co-financing levels are measured by Gavi; countries efforts to optimise vaccine portfolios for best value-for-money vaccines are not.

No limitations posed by Gavi's country or vaccine allocation formula. As opposed to cash support, for which there are country ceilings, there is no country maximum limit for vaccine support. Gavi eligible countries apply for vaccine support as justified by epidemiological considerations and cohort size, but the level of support is not impacted by whether other vaccine programmes are supported by Gavi and there is no cap on the vaccine price per dose. In other words, if a country opts for introducing a malaria vaccine and requires Gavi support, this will not impact or reduce the support it can receive for other eligible vaccines. Therefore, in theory, a large volume country could introduce several vaccines at once, including expensive malaria vaccines, and absorb a disproportionate percentage of Gavi resources. This is in contrast with the Global Fund's allocation methodology whereby disease grant ceilings for each country are intended to facilitate allocative efficiency across countries, equity in financing distribution, and incentives for countries to maximise their funds to achieve targeted coverage levels within a budget ceiling. Gavi has a prioritisation mechanism,[99] but due to sufficient funding, applying the mechanism has not been necessary since 2009.

With a few exceptions,[100] countries have complete control over the choice of vaccine supplier and product presentation. The Gavi product menu available for financing in a particular strategic cycle is based on vaccine programmes approved by the Board as eligible for funding.[101] With so many new presentation options now available (e.g., 12 for Rota) some KIs suggest that demand health could be

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[99] https://www.gavi.org/programmes-impact/programmatic-policies/prioritisation-mechanism.

[100] Cold chain equipment and Covid vaccines are examples of product categories handled differently; countries can list top 3 choices, but ultimately the product allocated will depend on a number of other factors and may not be the top choice.

[101] Gavi's Product Portfolio Management Principles also dictate which WHO Pre-qualified products can be made available to countries through the Gavi menu

improved if some categories could be "culled" to encourage countries to choose the most cost-effective options available.[102] The proliferation of options has led to difficulties in aligning supply with demand in some product categories, and one consequence has been slow introductions when the supply of a preferred product is less than the unconstrained demand. With HPV, Gavi had a transaction heavy process of deciding at each step how to ration the HPV vaccine. Some countries had to wait three to five years because they opted for the GSK vaccine. Now that the largest countries are coming on board, the introductions in these countries will be phased over 2-3 years. The same issue could likely occur with the malaria vaccine.

2 **Finding 2.24: Gavi's entry into supporting African and regional manufacturing, in response to global imperatives,[clxx] includes a 4-pronged strategy approved by the Board in 2022.** In December 2022, following advocacy by the G7 and a call from the African Union for Gavi to support increased African production of vaccine doses by 2040, the Board approved a new regional manufacturing strategy with a particular focus on Africa. The strategy involves close partnership with the African Union, including Africa Centres for Disease Control and Prevention, to help analyse and provide assurance on future levels of demand and sets out recommended actions that local, regional, and international partners will need to engage in to develop sustainable African vaccine manufacturing.

2 **Finding 2.25: The African Vaccine Manufacturing Accelerator (AVMA) proposal recently approved by the Board defines the incentive amounts, their duration and structure, eligibility requirements (antigens and value chain stage), together with further work.** A capitalisation fund of up to US$ 1 billion will support time-limited incentive payments with funding deriving from the US$ 2.6 billion remaining funds from COVAX.[clxxi] The aim is for a legacy of at least four African vaccine manufacturers operating sustainably in international markets, delivering more than 0.8 billion doses over ten years. Furthermore, the focus is on ensuring localisation of three drug substance (DS) antigen platform technologies and supporting routine production capacity such that its repurposing could potentially yield 0.7 billion annual doses, filled and finished in an emergency. Antigen eligibility appropriately focuses on those facing a constrained market: cholera, malaria, hexavalent and measles-rubella. Achieving positive impact depends on i) whether the broader enabling environment will effectively de-risk African supplier investments (the risk of waiting until prequalification to provide a first "prize" reward is that African firms with limited access to financial markets may not have the ability to fund R&D all the way to the prequalification stage[clxxii]), ii) the management of potential unintended consequences, notably other suppliers raising their prices as a response to the subsidy, and iii) the evolution of demand for African vaccines.

2 **Finding 2.26: Initially delayed, Gavi's Vaccine Innovation Prioritisation Strategy work on the innovation market shaping pillar[clxxiii] has now picked up pace and supports Gavi's immunization coverage and ZD goals.** Under 5.0, Gavi has the mandate for earlier involvement in the development pathway to support vaccine delivery innovations such as microarray patches, barcoding and thermostability. After initial delays due to the pandemic and operationalising a newer area of work, the pace has picked up, demonstrating clear strategies, action plans, alignment, and collaboration with partners. There are now nine such innovations in development, with two new products having received licensure for controlled temperature chain. These delivery innovations are supportive of Gavi's coverage and ZD priorities, given the focus on product characteristics that align to the contexts in which these populations live.

[102] As a comparison, the Global Fund menu for some product categories is limited to those which the Global Fund has assessed as most cost effective; countries are required to submit a justification and get special approval if they want to procure outside of the recommended options.

2.2.7 Is SG4 as originally articulated still relevant for the second half of the Gavi 5.0/5.1 Strategy period?

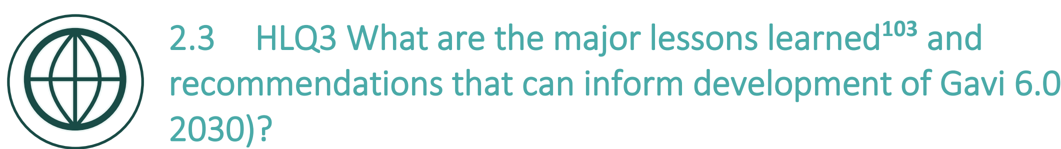
1 **Summary finding**: Gavi's market shaping work has changed during Gavi 5.0 with new areas and differential levels of urgency and pace applied to different pillars. Most emphasis has been on the AVMA and improving processes and tools for developing partner-aligned strategic approaches to market shaping. The "innovation" and "demand health" pillars were initially delayed but are now making good progress. The SG4 targets for Gavi 5.0 will likely be met, and there could be even better results with emphasis on improving demand health and enabling market shaping earlier in the vaccine R&D value chain.

1 **Finding 2.27: The scope of Gavi's market shaping work has changed since the outset of 5.0, with some new areas, and differential levels of urgency and pace applied to different pillars of the market shaping strategy. Given the pandemic, it is difficult to imagine a counterfactual scenario with a different level of emphasis on the market shaping goal. However, some of the areas that have received less attention to date will now require a major lift during the remainder of 5.1.** Efforts to align partners around strategic approaches to market shaping have been a major emphasis during this strategic period, largely reflected in the antigen roadmaps which are important to guiding partner activity and informing UNICEF's procurement strategies. The other major emphasis during Gavi 5.0/5.1 has been the AVMA (see Section 2.2.5 above) an important new initiative which has required continuing Gavi efforts to refine the approach.

Due to Alliance capacity constraints during the pandemic, progress on the "innovation" and "demand health" pillars of the market shaping strategy, initially delayed, are now making impressive gains. There has been slower progress on demand health, a newer focus under 5.0 that has taken some time to operationalize, and because supply constraints as well as the pandemic led to delayed vaccine introduction and switch activity, to which this pillar is linked.

1 **Finding 2.28: The SG4 indicators will likely be met, but more emphasis is needed to improve areas where market health remains weak. Strengthening efforts on pre-VIS market shaping and influencing demand health could allow Gavi to achieve more.** Market shaping work serves as an important enabler of the other SGs - new vaccine introduction, scaling to high, equitable coverage and future financial and programme sustainability. The SG4 indicators are however an incomplete reflection of 5.0/5.1 work and their "achieved" status may deflect attention from recurrent challenges relating to certain antigens experiencing repeated "market health" issues, due to misalignment of supply and demand. For many reasons detailed earlier, work to improve demand health is urgent. Although Alliance efforts to support countries to make evidence informed decisions are increasing, the full range of Gavi levers is not yet being deployed to bring about VfM-based portfolio prioritisation and optimisation. This has implications for delivering on Gavi 5.1 market shaping strategy objectives - the demand health side objectives under the market shaping strategy may not be fully delivered under Gavi 5.1 without cross-Secretariat and Alliance collaboration, and evolution of wider Gavi approaches which affect demand materialisation, demand predictability and balanced demand.

Similarly, Gavi's market shaping work is constrained in terms of what it can achieve upstream under the current business model. Discussions are underway about how Gavi can intervene earlier to avert a market failure, prepare markets for optimised programme launches, and ensure improved responsiveness and faster access to a vaccine in the event of an outbreak or epidemic.



2.3 HLQ3 What are the major lessons learned[103] and recommendations that can inform development of Gavi 6.0 (2026–2030)?

1	**HLQ3 summary finding:** Gavi appears to have identified the important themes and drivers for 6.0. The operating environment for 6.0 will likely continue to be marked by significant economic disruption and social fragility across and within countries. Gavi will need systems and processes and capacity to offer the timely, flexible and tailored support which will be needed in in the next strategic cycle.

2.3.1 What new and emerging themes or drivers/factors could impact Gavi's mission, and are critical to inform Gavi 6.0?

Our findings for this EQ are derived from the thematic studies carried out as part of the MTE, and from a review of Gavi's analysis of trends in the external environment as part of the 6.0 design process.[104] Our findings corroborate many of the risks and trends that have already been identified by the Alliance during the planning process for 6.0, for example, the need for a new eligibility, transition and sustainability model.

1 **Finding 3.1: The first three years of the Gavi 5.0/5.1 period were marked by an unprecedented level of disruption caused by COVID-19 and the economic and social shocks associated with the pandemic. Although the pandemic has eased, Gavi's operating environment will likely continue to be marked by turbulence and uncertainty during the remainder of 5.1 and in 6.0, and Gavi needs to ensure that its systems and processes can respond to different country contexts with timely, flexible programming.** The key drivers likely to impact Gavi's mission – climate change, natural disasters, migration, wars, misinformation/vaccine hesitancy and financial crises, to name but a few - need little explication as they are well known to the Gavi Board. We focus therefore on the implications of a few key drivers, gleaned from our document and literature reviews, KIIs and thematic studies.[105]

The direct and indirect effects that **climate change, conflict and population growth** will have on Gavi's mission are becoming clearer. As just one example, a recent study[clxxiv] predicts that climate change and demographic growth may place an additional five billion people at risk from malaria by 2040 (one billion of whom will be in Africa). This could have profound implications for Gavi's financing model (see below), but also for supply chains if malaria becomes a problem for high income countries (HICs).

One pressing implication is that the Global Health initiatives (GHIs) need to have organisational models which allow for quick adaptation and fast response to shocks as well as opportunities (such as new technologies). The model also needs to differentiate, in their policies and programmes, between the varied ways in which climate crises will play out between regions, countries and within

[103] As previously noted, identification of lessons relies on examples of attempts to implement solutions to known problems and reflection on whether these have worked or not. Unfortunately, Gavi's monitoring systems are insufficiently granular to generate the required evidence. We have, though, identified five general lessons learned

[104] The pre-read for the Gavi 6.0 Board/PPC virtual workshop on 10 October 2023 includes a summary of trends shared at the Board retreat in March 2023, in which only one of the references was from 2023. Our Horizon Scanning has added value by looking at literature published up to November 2023, bringing in some aspects of the external environment that were not included in the pre-read.

countries. This will put a premium on implementation of ongoing Secretariat organizational and process reforms designed to speed up decision making and improve results. Allied with this is the hardly new, but even more urgent need to work with partners at global, regional, and country level to develop resilient and responsive health systems. A fragmented approach, where each agency focuses on its own area of expertise, to the detriment of a coordinated and integrated approach, will no longer suffice (if it ever did).

1 **Finding 3.2: While international support for Gavi's mission remains high, the actual volume of financial support for 6.0 has yet to be established in the face of multiple competing priorities, and replenishment for 6.0 may be less straightforward than for 5.0**. There are also expectations of improved effectiveness and coordination amongst the GHIs,[clxxv] with a major Gavi donor recently committing, in relation to forthcoming replenishments of Gavi, the Global Fund and WHO, "to work with partners to drive reform across the global health architecture".[clxxvi] External KIs also noted the need for more transparency, particularly on programme implementation, suggesting that the investment case for Gavi 6.0 will need to show substantial progress on organizational and process reforms.

2 **Finding 3.3: Vaccine nationalism and hesitancy may again feature in future pandemics, and as with COVID-19, impede vaccine access and delivery for LICs in a future pandemic.** An International Monetary Fund study concluded that such disparities were overwhelmingly due to the lack of access in low-income countries and only marginally the result of vaccine hesitancy.[clxxvii][clxxviii] As a case in point, malaria will likely impact many high- and upper-middle-income countries by 2040, which could dramatically increase high-income country demand for malaria vaccines, with the potential for increased vaccine nationalism, making the efforts to develop African vaccine and other regional manufacturing particularly relevant.

2 **Finding 3.4: Political commitment and advocacy are clearly important to ensure long-term social and political support for vaccines and to counter misinformation** – a recent news article noted that in Afghanistan, the Taliban, who were previously deeply opposed to polio vaccinations, now support them, with positive results.[clxxix] However, as noted below, vaccine advocacy alone is unlikely to be sufficient to raise or even maintain domestic spending on vaccines during a fiscal crisis when policy makers must juggle various priorities.

1 **Finding 3.5: Sustainability of immunisation financing is not assured.** As we note in Annex 11, Gavi's successful co-financing policies are a poor proxy for future sustainability. Many Gavi-eligible countries will experience increasing fiscal challenges and declining health expenditures in upcoming years due to increased debt distress and macroeconomic shocks, including COVID-19. Per capita government health spending is projected to decline annually from 2019 to 2027 in 41 LICs and LMICs.[clxxx] Deteriorating economic conditions are not necessarily a prelude to falling vaccine investments, since total domestic vaccine expenditures are only a small part of total government public health expenditures and since these investments have very high returns, governments may protect them against cuts. However, negative trends in general and health expenditures may also impact the sustainability of domestic immunisation financing. Our analysis of drivers highlights the positive effect of domestic political commitment to progress on Gavi indicators and equally, insufficient resources allocated to immunisation comes out as one of the strongest barriers. As noted already, the two are related when allocation of resources to immunisation competes with more immediate needs.

As a case in point, we found that in-country vaccine spending is vulnerable to cuts, particularly for the domestic resources (e.g., transport, fuel) needed to deliver vaccines in hard-to-reach areas. This may particularly impact ZD children, where the costs of reaching them can be significantly higher (Annex 11). But it will also impact all countries as new and more expensive vaccines such as for malaria are approved, or if the Alliance moves forward on more life course vaccines. A recent article highlights the considerable differences between expected per capita health expenditures and

projected needs.[clxxxi] Many countries are similarly ill-prepared for the next pandemic or other health crisis. A recent literature review could not identify any explicit publicly available frameworks for reallocating budgets in the wake of emergencies.[clxxxii]

In Annex 11, we discuss how the next set of transitioning countries face unique financial challenges. These countries will see steeply increased costs per dose for RI vaccines after transition (potentially exacerbated by currency devaluation). While large countries may have some bargaining power, that will not be the case for the smaller countries. At present, the economies in 20% of these transitioning countries are contracting, 50% are stagnating, and 60% are at high risk of, or already in debt distress. There is a serious risk that short-term fiscal needs may take precedence over investments (particularly in marginalized populations) with long-term gains such as vaccines. We have noted previously the key importance of Gavi's market shaping work and the need to accelerate and deepen this work. We also advocate that Gavi should work more closely with its core partners to pay extra attention to the overall financing and economics of vaccine procurement and delivery in the context of a country's overall health financing envelope.

1 **Finding 3.6: Country focus has long been a Gavi policy, but many KIs, including Board members and country representatives, noted the tensions between "countries decide" and centrally determined global initiatives and funding levers.** We do not advocate for a decentralized Secretariat, but there appear to be multiple opportunities in 6.0 to work with partners and countries to increase differentiation and delegation and improve policies (e.g., for financing mechanisms for future pandemics[clxxxiii] based on common understanding of risk and country challenges).[106] This could significantly ease Alliance transaction costs as well as improve impact and effectiveness.

[106] A recent Lancet paper notes a gap in scenarios developed by and for LICs on region-specific projections of the burden of infectious illnesses, especially for areas in which weak health systems and socioeconomic factors create enhanced barriers. Weber, Eartha, et al. "The use of environmental scenarios to project future health effects: a scoping review." The Lancet Planetary Health 7.7 (2023): e611-e621. https://www.thelancet.com/journals/lanplh/article/PIIS2542-5196(23)00110-9/fulltext.

3 Conclusions & recommendations

3.1 Conclusions

Conclusion 1

During the first three years of Gavi 5.0/5.1, a period of exceptional disruption and uncertainty, the Alliance can claim some notable achievements and organisational reforms, including helping countries contain some of the backsliding in RI coverage while delivering nearly 2 billion COVID-19 vaccine doses and increasing the breadth of protection. There was substantial growth in Gavi's scope during Gavi 5.0/5.1. This included expanding the vaccine portfolio, vaccine cohorts, and the channels needed to reach them, MICs engagement, new partnerships, programmes, and staff, while minimising COVID-19-induced major disruptions to co-financing commitments and RI supplies. Secretariat leadership initiated much-needed reforms such as Operational Excellence, EVOLVE, Full Portfolio Planning (FPP), the country programme monitoring and performance management framework (CPMPM), differentiation to reduce administrative bottlenecks and burdens on Gavi supported countries, increasing flexibility, speeding up decision making and enhancing country voice. The successful implementation of these reforms requires major changes in organisational culture throughout the Alliance – the Board, core partners, and Secretariat. Within the Secretariat, this includes clear definitions of accountability, increased delegation, prioritisation, and greater risk appetite.

Strengths

- Gavi's action to mitigate the impact of COVID-19 on RI appears to have contributed to preventing more substantial backsliding.
- Gavi projects full utilisation of the 5.0/5.1 budget, which is remarkable in the context of COVID-19-related operational constraints. This demonstrates that with clear priorities (and in a crisis), the Gavi model can deliver exceptional results. If the efficiency and Operational Excellence drives referred to in Conclusion 4.3 are successful, Gavi will be well-positioned to fulfil its core functions in Gavi 6.0.

Challenges

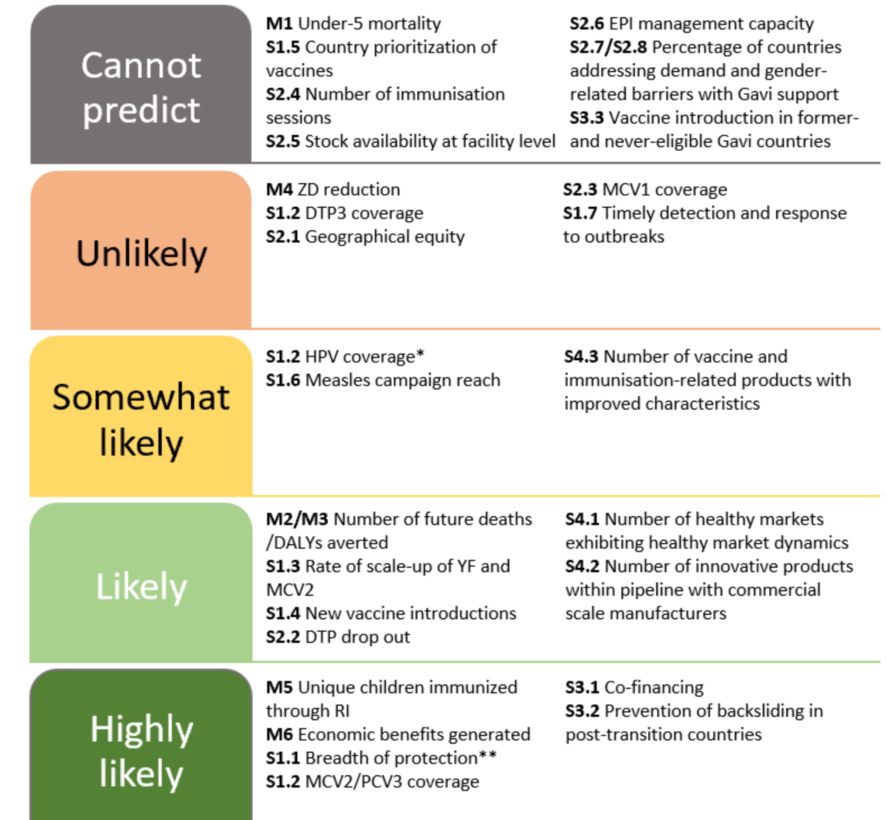
- Delivery on cash grants, which are slower to programme and harder for countries to absorb in addition to other sources of non-Gavi external funding, will be challenging during the remainder of Gavi 5.1. Constrained fiscal space and debt distress may also slow disbursements where domestic resources are needed for implementation.
- Continued results on Gavi 5.0/5.1 implementation delivered to date (and by extension for Gavi 6.0) will depend on a range of factors discussed in the following conclusions. Chief amongst these are challenges related to transition, sustainability (Conclusions 5 and 6), and responding to uncertainty in Gavi's operating environment (Conclusion 7).

Conclusion 2

Some, but not all, strategic goals 1-3 will be met by 2025 while most strategic goal 4 targets will be achieved.

There are several caveats regarding our analysis of the plausibility of achieving Gavi 5.0/5.1 coverage targets. The first concerns the confidence which can be placed on the relatively small annual changes which occur in WUENIC data. Both the numerator (number of immunisations) and the denominator (target population) are subject to enumeration errors, but WUENIC data is not presented with confidence limits and does not necessarily correspond with that from household surveys. Second, there is a one-year time lag before official coverage data becomes available, with for example, 2023 coverage estimates will only be available in July 2024. Our analysis therefore reflects data only up to 2022, two years into implementation of the Gavi 5.0/5.1 strategy. Third, some Gavi strategy indicators (SIs) are lacking targets or data points. With these caveats, the likelihood of Gavi-supported countries achieving 5.0/5.1 targets, in ascending order, is depicted in Figure 8.

Figure 8: Plausibility of achieving Gavi 5.0 targets.



* pending introduction by countries such as India and Nigeria which will substantially change the overall weighted average coverage

** flatlining in core countries

Strengths

- Based on current metrics, SG1 and SG3 are mostly on track, suggesting that Gavi is well placed in 6.0 to continue with its core mandate of sustainable access to vaccines.
- Whilst SG2 appears off track, intervention level activity suggests emphasis on ZD has translated to action within the Secretariat (see Conclusion 4 for findings on Alliance

Challenges

- More focus is needed on sustainability, both in terms of metrics, programming, and coherence (Conclusion 6).
- With varied results – core and post-transition countries are struggling more than other segments – the need for differentiation is clear (see Conclusion 4).

partners). This is likely a good sign for Gavi 6.0.

- Gavi is trying concurrently to address multiple, shifting, complex priorities.
- Greater focus is needed on pre-Vaccine Investment Strategy (VIS) market shaping and demand health.

Conclusion 3

Gavi's contribution to the 5.1 strategic goals through 5.0/5.1 programming will not be visible until mid-2025, but likely will make a positive contribution. The contribution from Gavi 4.0 appears strong but recalibrating 5.0 strategic priorities has had limited impact. Measuring Gavi's contribution to the SGs is problematic due in part to issues with country and partner monitoring/reporting arrangements, the staggered nature of grant making, delays in Gavi 5.0/5.1 operationalisation, indicator choice (including lack of output indicators and the focus of SG3 and SG4 indicators) and missing data points – although resolving these issues is not straightforward. Despite recent improvements, such as the Balanced Scorecard, management systems for planning and tracking contributions to the SGs are insufficient to enable learning, course correction and prioritisation of work. There are also issues of timely access to available data, which can make it difficult for external observers to reach appropriate judgements.

Strengths

- The high degree of continuity between Gavi 4.0 and 5.0/5.1 seems set to be a positive feature of contribution to results.

Challenges

- COVID-19 impeded the first two years of Gavi 5.0/5.1 implementation, exacerbated by a range of internal factors (Conclusion 4), which are likely to continue into 6.0 without action.
- Due to reporting lags and the staggered nature of the grant-making process, the impact of Gavi 5.0/5.1 on immunisation will not be visible in WUENIC reporting until mid-2025. This is well understood, but difficult to address.
- Gavi 5.0/5.1 programming will be finalised only in 2024, with consequent overlaps into the 6.0 period. This places practical constraints on what can be done in Gavi 6.0, and goals should be set accordingly.
- Tracking progress at the level of outputs is conceptually complex and probably unrealistic. Designing SMART[107] indicators for measures such as increased capacity, innovation, political commitment, and collaboration would be challenging. Measurement would be burdensome both for countries and the Secretariat and would not always translate across different contexts.

[107] Specific, measurable, achievable, relevant, and time-bound indicators that are used in monitoring and evaluation.

Conclusion 4

Gavi is making concerted efforts to achieve the 5.1 goals. Maintaining progress requires tackling how the Alliance influences country immunisation programming, while respecting country ownership. It also requires accelerating and deepening the ongoing, much-needed internal reforms to streamline Gavi's systems and processes. Progress in implementing Gavi 5.0/5.1 is covered under Conclusion 2. Successful implementation for the remainder of Gavi 5.1, and by extension Gavi 6.0, will depend on implementation of the multiple ongoing reform processes described under Conclusion 1. These reforms will likely take time and will also be influenced by the grant making cycle, which in turn reflects varying country planning cycles. Therefore, it is probable that the reform process will not be fully implemented until well into the Gavi 6.0 period. As priorities, the recent evaluations of the operationalisation of Gavi's strategy and Gavi's contribution to reaching ZD children and missed communities both highlight the urgent need to reduce complexity and transaction costs for countries, simplify processes, and speed up grant approvals and disbursements.

The current operational model, involving multiple centrally determined donor requirements and funding levers, imposes burdensome administrative costs on countries, can impede country voice, and may also be incompatible with domestic budgetary systems, even when aligned with country planning cycles. This issue, while hardly unique to Gavi, requires re-examination to provide greater scope for country priorities, ensure consistency with country budget mechanisms and planning cycles, and account for different levels of need and institutional capacity. Success also depends on effective partnerships, both within the Alliance and with governments and CSOs.

Country voice and support for country priorities are underpinning principles, but there can be tensions between delivering Alliance strategic priorities and ensuring country ownership. We recognise that reform is challenging in a complex multi-country and multi-agency partnership, but the need for dynamic, data-driven, context specific solutions coupled with greater data accessibility to improve oversight on performance is urgent. We note that Gavi is acting on these important agendas, including through EVOLVE and efforts to strengthen the overall functioning of the Alliance.

4.1 Partnerships

Strengths

- Alliance partners play a pivotal role in the operationalisation of Gavi strategies, including ensuring Gavi can reach marginalised populations and work in fragile countries.

Challenges

- The Alliance has experienced significant headwinds during Gavi 5.0, mostly linked to the pressures from COVID-19. Efforts to "reset" Alliance relationships are commendable. Nevertheless, there is work to do going into Gavi 6.0 to mitigate tensions and ensure shared expectations around roles and responsibilities, capabilities, performance, and accountability, based on mutual trust and effective communication.
- The Civil Society and Community Engagement Framework (CSCE) provides a steer on the three fundamental pillars of Gavi's relationship with CSOs - service delivery, demand generation and advocacy. However, efforts to increase and

	expand CSO and non-core partner engagement have created some tensions with core partners and country governments.
4.2 Country ownership and country-level capacity	
Strengths • Gavi is committed to country ownership and has taken steps in 5.0/5.1 to strengthen country engagement and capacity. These efforts have been met with some success and need to be continued into 6.0.	**Challenges** • The differentiated engagement model is key but needs further refinement to ensure that it better reflects Secretariat and country capacity and needs. The approach for Gavi 5.0/5.1 and 6.0 should ensure support is available where needed, with decisions delegated to the appropriate level. • In countries suffering from fiscal space limitations, the expanding Gavi funded vaccine programmes and presentation options warrants reconsidering the balance between country choice and market health needs. • Delivering against Gavi's strategic priorities whilst ensuring country ownership can be challenging.
4.3 Complexity of Gavi systems and processes	
Strengths • Gavi recognises that complex processes and slow decision-making need urgent resolution. The varied root causes are now largely on Gavi's radar. • The Operational Excellence initiative provides a critical and thoughtful approach to diagnosing and identifying solutions, but at this early stage of implementation, we cannot assess the likelihood of success. These initiatives will continue to be important throughout the remainder of Gavi 5.1 and into 6.0.	**Challenges** • The challenges associated with Gavi's complex systems and processes have been known since at least 2016. The measures proposed in EVOLVE and Operational Excellence (which address personnel and culture) will require effective change management efforts well into Gavi 6.0. • Solutions to key barriers have been identified previously, including by other evaluations. These barriers have proven hard to address, in part because other issues such as COVID-19 took priority. There has, however, been little tracking of efforts to address these barriers and this is a key gap to fill in Gavi 5.1 and 6.0. • The impetus to add new levers to support new initiatives, or resolve immediate crises, can be strong, overriding efforts to simplify processes. Reaching agreement with the Board on a revised, simplified model with clear monitoring could help reduce the internal and external drivers of complexity.

- Countries struggle to engage with Gavi processes, exacerbating existing country level capacity constraints.
- Operational reporting weaknesses may reduce accountability and transparent prioritisation, as well as opportunities for learning and course correction.

Conclusion 5

Resilient and strong health systems are essential for vaccine programme sustainability. Gavi has a long history of investments in aspects of health systems strengthening (HSS) such as supply chain and cold storage, which have also helped strengthen primary health care (PHC). Gavi recognises that strong PHC systems are essential to ensure equitable access to vaccines, to achieve the ZD agenda (with opportunities to integrate the ZD approach into the wider PHC system), and for sustainability. Gavi is for the first time developing a health systems strategy for Gavi 6.0, an important and timely initiative, even if history suggests that implementation, requiring enhanced cooperation with partners, will be challenging. The strategy will likely recognise that a key element is to articulate how Gavi investments will strengthen health systems, and how these investments will provide more specific programmatic support. The recent Future of Global Health Initiatives (FGHI) process noted that "building greater alignment, particularly around HSS and a more sustainable global health ecosystem, is even more urgent as the world faces increasing epidemiological and demographic changes and global health inequities."[clxxxiv] Gavi can point to several recent examples of enhanced HSS collaboration with key partners such as the Global Fund and the World Bank.

The MTE found few Gavi-supported interventions to improve, for example, budget efficacy at country level (see also Conclusion 6), market intelligence on, and transparency of vaccine prices for MICs, or support to supply and procurement performance in countries nearing/after transition, despite the pivotal role of these interventions for sustainability. Without clear attention to these issues, countries may be unable to introduce new vaccines, or even sustain existing investments.

Strengths

- Gavi is developing a new health systems strategy for Gavi 6.0 which has the potential to provide clearer strategic direction, greater cooperation with partners, and mechanisms to evidence HSS results.
- Gavi's market shaping work has picked up pace in the first part of Gavi 5.0/5.1 and is set to continue through 2025. Secretariat capacity/ processes on healthy demand have been strengthened.

Challenges

- It is important to prepare and implement a holistic health systems strategy for Gavi 6.0 which, working with core partners, supports strong PHC and vaccine delivery systems, including for transition countries.
- Supporting supply and procurement performance in countries nearing/after transition and improving market intelligence data for MICs and never-eligible Gavi countries as part of a comprehensive approach to sustainability and transition.

Conclusion 6

Notwithstanding increased momentum towards 5.1 goals, there are serious concerns around transition and sustainability as some countries may again backslide during a time of increasing global social, political, and economic fragility. The co-financing model created over 15 years ago to assist vaccine introductions in lower-income countries has been successful – from 2008 to 2023, Gavi countries paid approximately US$ 1.7 billion in co-financing.[clxxxv] However, as more countries transition out of Gavi support, Gavi's footprint and impact will decline, even while large numbers of children remain unvaccinated. The Alliance recognises that it cannot reach the SDGs and global vaccination targets, or effectively support new life course vaccines, without engaging key former and never-Gavi-eligible MICs, where a significant proportion of un- or under-vaccinated children reside.

With the increasing number of Gavi financed vaccines, additional supplier presentations, challenges balancing country product preferences with available supply, more countries moving towards transition, or already self-financing vaccines, and more countries in economic distress, the challenge is to prioritise and optimise vaccine portfolios to achieve value for money (VfM) and security of supply. The current eligibility, co-financing and transition model/pathway insufficiently addresses affordability, sustainability of RI and new introductions for low-income countries (LICs) and transitioning/transitioned countries lacking medium-term access to Gavi-similar vaccine prices, and so no longer fit for purpose.[108] In preparation for Gavi 6.0, Gavi is reviewing the Eligibility, Transition and Co-financing (ELTRACO) policies through an informal Board task force, which aims to better take into consideration countries with specific and different profiles, as well as countries with more challenging fiscal/ financial environments.

Strengths

- Countries have maintained co-financing levels, despite economic headwinds.
- The MICs approach has proved a welcome innovation, with important learning.

Challenges

- Immunisation portfolios are becoming more expensive, while countries face constrained finances. Better financial and economic monitoring with partners is key both to identify and mitigate risks, and to monitor the broader sustainability of Gavi's model.
- Experience to date with implementing the MICs approach has identified scope for adaptation, including improving transparency in vaccine pricing, HSS support, revised transition criteria, and more defined partnership working arrangements.
- Transition for the next cohort is problematic as some countries lack the stability, health system maturity, or financial capability to sustain RI gains. We understand that Gavi is intending to address these challenges in the 6.0 design process.

[108] Gavi-similar prices are negotiated on behalf of transitioned countries for some antigens and for a specific duration – in theory these engagements will not need renegotiation since UNICEF tiered pricing and better market health in general should ensure access to affordable vaccines for in- and transitioned countries. However, these actions, while necessary, may not be sufficient considering the increasing financial fragility in these countries.

- The current allocation model, co-financing policy, and policies on country vaccine choice do not prioritize VfM and vaccine programme sustainability.

Conclusion 7

We agree with the Gavi analysis of the barriers to vaccine uptake during 6.0, including conflict, climate change and natural disasters, vaccine hesitancy, weak health systems, and economic disruption. The extent to which the Alliance can overcome them depends crucially on the success of current efforts to deal with longstanding barriers to operational efficiency and effectiveness. Economic, social, and political turbulence will likely be the norm, placing a high priority on streamlined processes, decision-making and accessible data. While international support for Gavi's mission remains high, the actual volume of financial support has yet to be established in the face of multiple competing priorities. Recent Board papers and evaluations have also noted the trade-offs between the "core" Gavi 5.1 agenda and further expansion and deepened engagement. These trade-offs are real, but this is not a binary choice, given rapidly shifting demands on the Alliance. It will be vital to maintain attention to implementing the core Gavi 5.1 agenda efficiently and effectively, while judiciously focusing on new initiatives and innovations which can substantially reduce the global burden of infectious disease. Balancing these trade-offs and establishing clear criteria for prioritisation between competing demands and limited resources, both in the Secretariat and in-country, as well as clear accountability within the Alliance, will be key to successful outcomes for Gavi 6.0. At the same time, ensuring that Gavi has the right systems and mechanisms to develop tailored approaches and to adapt to changes in its operating context will be critical to its effectiveness.

Strengths

- Gavi is aware of and is planning to address risks that may affect Gavi 5.1 results. Gavi's analysis of risks is comprehensive and of high quality.

Challenges

- Gavi has limited control or influence over the many exogenous factors which can affect performance. How these will affect Gavi's operations will vary across and within countries and cannot be easily predicted. Gavi's capacity to respond will depend on its business risk appetite, a "differentiated approach to materiality[109]", and to a considerable extent, overcoming internal barriers to greater efficiency and effectiveness.

[109] Key informant quote

3.2 Recommendations

Since many recommendations apply to the final stages of Gavi 5.1 and the forthcoming Gavi 6.0, they are not divided between the two strategic periods. Where the recommendations are specific to either one, this is noted. Our recommendations are consistent with and build on those in the recent evaluations of Gavi's contribution to reaching ZD and missed communities and the operationalisation of Gavi's strategy. They also reflect feedback from participants at the 15 February 2024 Gavi co-creation workshop, whom we thank for their constructive suggestions and assistance. The Alliance is already working on some of the areas covered by our recommendations and a summary of these actions can be found in Annex 16.

For each recommendation, the type of action is described using the following three terms:

- **CONTINUE**: choose to prioritise this area of existing work in Gavi 5.1 and into 6.0;
- **ADAPT:** make modifications to existing work to respond to experience and analysis from MTE and/or other evaluations; and
- **STOP:** stop development or implementation of processes or initiatives in highlighted areas.

Recommendation	Conclusion
1 ***Build on the momentum which now exists in Gavi 5.1 to achieve Gavi's four strategic goals and continue this focus in 6.0.*** a. Since it is likely that Gavi 5.1 and 6.0 will run concurrently for a period, ensure that ongoing Gavi 5.1 programmes are not "buried" under new 6.0 initiatives when 6.0 starts in 2026. **[ADAPT]**	Conclusions 1, 2, 3, 7
2 ***To enhance Gavi's responsiveness and impact during Gavi 5.1 and in advance of 6.0, accelerate, test, and monitor organisation-wide implementation of Operational Excellence initiatives and agreed strategy operationalisation evaluation recommendations.*** a. Prioritise and accelerate the reforms to operational culture identified by EVOLVE and the strategy operationalisation evaluation to reduce country transaction costs and increase responsiveness to crises and changing contexts.[110] In that context, sharply reduce the current 21.4 months (as of January 2024) duration between initiating the FPP process and disbursement.[clxxxvi] **[CONTINUE/ADAPT]** b. Manage the risk that Operational Excellence is seen as a 'silver bullet' for all organisational challenges by ensuring that it outlines clear and realistic goals and benchmarks to measure progress. **[ADAPT]** c. Initially, focus the Target Operating Model[111] on those reforms (e.g. simplified processes) that are particularly useful in fragile/conflict settings, and which assist implementation of strategic priorities (e.g. contracting of CSOs in support of RI service delivery, demand generation, advocacy and the overall ZD agenda). **[CONTINUE]** d. Consolidate the current 17 funding levers and limit the addition of new levers to reduce country transaction costs and operational complexity. Building on analysis in the MTE, identify the internal and external drivers of multiple funding levers as well as the barriers to consolidation, and resolve issues prior to implementation of Gavi 6.0. Plan the consolidation	Conclusions 4 (4.3), 7

[110] As previously noted, the need for operational reforms has been apparent since at least 2016.
[111] The EVOLVE Target Operating Model has identified a set of reforms including end-to-end view with differentiated paths, simplified processes, clear roles and responsibilities, automation, focus on activities that add value, rebalanced effort across the grant management cycle, data-driven decision-making, removal of duplicated work, consolidation of funding levers, and integrated platforms.

Recommendation	Conclusion
of levers to harmonize with country processes and preferences. For example, adopt a new funding lever only if existing funding mechanisms (even when revised) would not work **AND** if affected countries agree that the new lever can be easily accommodated in country processes, including the FPP. **[STOP]** e. Put in place change management processes[112] to ensure that Operational Excellence reforms are fully implemented before Gavi 6.0 starts, since previous organisational reform efforts have met with mixed success. Ensure sufficient processes, human and financial resources, and structures are in place to underpin implementation, and that the drivers and barriers to reforms are well understood.[113] Ensure that all relevant parts of the Secretariat (operational, country, financial) are on board. Map the potential impacts of reforms on all country segments (core, high impact, and fragile) and stress test these reforms by piloting in different settings. **[CONTINUE]** f. Monitor these reform processes against agreed benchmarks and regularly inform the Board on progress and bottlenecks. **[ADAPT]**	
3 ***Review the country engagement model, including the differentiated approach, so that Gavi support is better aligned with national immunization priorities and support mechanisms are sufficient and appropriate for country needs, capacity, and potential for impact.*** a. Accelerate work with countries and partners to ensure that sustainable national immunisation strategies (NIS) are in place and empower countries to align Gavi support with their NIS. In addition, develop country-level strategic goals, aligning programmes where needed with other global health institutions. **[ADAPT]** b. In alignment with EVOLVE proposals, differentiate country engagement based on a composite of indicators such as performance, capacity, fiduciary and programmatic risk, and potential impact, rather than by segment. For example, in a high performing country with good vaccination coverage and low fiduciary risk, empower the country to choose priorities from a menu of Gavi support. At the same time, manage tensions between country ownership and centrally determined priorities[114] through effective policy and technical advice to support and influence countries to identify relevant Gavi support (see Recommendation 3c).[115] **[ADAPT]**	Conclusions 3, 4 (4.1, 4.2), 7

[112] E.g. covering leadership (including setting ambitious goals and sticking to agreed plans if/when challenged), planning and oversight, involvement of stakeholders, communication, training, metrics).

[113] Our mandate did not include an organisational, or governance review and the 2019 McKinsey organizational review was not shared with us. However, it is clear from available evidence and our analysis, that Gavi systems, processes, structures, resources, and governance can be better aligned - a review to ensure their coherence, and their mutual reinforcement would be strategic.

[114] Giving more choice to countries would require Gavi to manage implications (in terms of reduced control over delivery against global commitments) and consider new ways to report on the portfolio of diverse country choices (see recommendation 8).

[115] We recognise that Gavi already offer countries a menu of vaccine support plus HSS and TCA grants. But we also note that centrally determined priorities form part of application review processes through both official requirements, e.g., the EAF envelope can only be used for activities that are identified as critical to reaching ZD children and missed communities, and unofficially through application materials and IRC review processes, e.g., encouraging the inclusion of ZD and gender-related activities. This creates tension between country ownership and global objectives. This recommendation seeks to address this tension by placing greater emphasis on facilitation of tailored programmes from a menu of Gavi support options.

Recommendation		Conclusion
	c. Delegate decision making and accountability for country programmes and priorities to the senior country managers (SCMs).[116] Empower them to take, after appropriate consultation with relevant internal and external stakeholders, effective and timely decisions on country priorities and decisions, up to agreed financial ceilings, on actions such as reallocations.[117] Identify and address internal and external barriers to decentralisation and delegated authority, and assess current competency gaps and take appropriate actions (e.g. training, talent placement, other resources) to ensure that SCMs and their teams have the necessary resources and capacity to support successful implementation of tailored country programmes.[118] **[ADAPT]** d. Define criteria for adoption of new initiatives which are "off-plan" (not foreseen in the country NIS) (see Recommendation 2b). **[ADAPT]**	
4	***Identify clear roles and accountabilities with core partners to help achieve Gavi's strategic goals, especially in challenging areas such as gender and expanded partnerships. Identify/implement suitable mechanisms to track Gavi-funded partner implementation of Gavi 5.1 and incorporate into 6.0.***[119] a. Ensure appropriate governance mechanisms are in place at global, regional, and country levels to facilitate alignment, communication and coordinated action between and within Alliance partners. This could, for example, build on successful examples of engagement of regional-level core partners under the MICs approach. **[CONTINUE]** b. Agree terms of reference with core and extended partners (at each geographic level as appropriate) which specify partner roles and accountabilities to achieve the SGs and delivery of Gavi 5.1 and 6.0. These agreements should specify how individual partners will use Gavi funds to support identified strategic priorities and goals and include benchmarks to monitor progress, along with regular reporting to the Board. Ensure that the necessary partner capacity and capability exists, particularly at country level, and identify any remedial measures needed. Consider periodic independent assessment of processes and performance to identify any needed course correction. **[ADAPT]** c. Use country-led joint appraisals to monitor progress regularly in all countries. **[ADAPT]**	Conclusions 4 (4.1), 7

[116] SCMs play an important role in the interface between countries and the Secretariat, but their real decision authority appears quite limited despite their senior status, in part due to the multi-layered decision/approval processes documented by EVOLVE and the consensus decision making culture within the secretariat.

[117] Currently it appears that SCMs have little financial decision-making authority as all reallocation and reprogramming must be approved by Regional Heads or senior management. We note the recent delegation of authority for programmatic approvals from CEO/CFO to the MD and Directors of CPD but argue that this authority should be delegated to the SCMs up to an agreed dollar amount.

[118] This critical change in organizational culture was also identified in the EVOLVE process.

[119] Gavi's impact depends crucially on how the Alliance partners work together. We recognize that the structure of the Alliance makes these discussions challenging, but clarity on roles and responsibilities of core partners will be very important for the successful implementation of 6.0. We understand that there are ongoing discussions amongst the core partners which touch on these issues.

	Recommendation	Conclusion
5	***In consideration of increasing fragility and vulnerability in many Gavi countries[120], revise the eligibility, transition, and co-financing model in 6.0 to enhance financial and programmatic sustainability.*** In this context: a. Focus on financial sustainability, including through ongoing work with core partners and other institutions to better understand and mitigate the impact of domestic financial constraints on achievement of Gavi 5.1/6.0 priorities and objectives. Ensure that the impact of fiscal constraints and the availability, or unavailability, of domestic resources is factored into the design of all future initiatives. **[ADAPT]** b. Ensure a comprehensive definition and approach to sustainability by factoring in key components of programmatic sustainability such as equity, gender, and regulatory/legal enabling environments at global, regional, and national levels. **[CONTINUE/ADAPT]**. c. To maximize programmatic and financial sustainability, identify criteria in Gavi 6.0 (e.g., fragility, indebtedness, PHC capacity, and legal and regulatory frameworks) to determine the speed of transition for eligible countries and eligibility for MICs support for never-eligible countries. **[ADAPT]** d. In the context of major changes in the vaccine market (e.g., expanding vaccine portfolios and higher costs), promote access to and affordability of vaccines in MICs and nearing/post-transition countries by: i) supporting supply and procurement performance (see Recommendation 9g); ii) improving vaccine market intelligence data relating to MICs and never-eligible Gavi countries; and iii) giving prominence to identifying new and innovative sources of financing (i.e. not domestic) for never-eligible MICs and transitioning countries. **[ADAPT]**	Conclusions 2, 5, 6, 7
6	***Design a health systems strategy in time for Gavi 6.0 describing how Gavi, with its partners, will invest in building viable country PHC systems. This is essential for equitable and sustainable immunisation and the ZD agenda.*** The strategy should reflect the recent Lusaka agreement which incorporates a programmatic sustainability objective,[121] and also reflect on past efforts (dating back at least 15 years) to harmonize partner investments in health systems, including managing the associated high transaction costs. **[ADAPT]**	Conclusion 5
7	***Build on experience in Gavi 5.1 to specify the range of Alliance technical/ advisory support to MICs to promote sustainable transition for former-eligible countries and sustainable adoption of new vaccine programmes for both former- and never-eligible countries.*** This is particularly important since the majority of ZD children live in MICs, and MICs have a high disease burden which could be reduced by vaccines in the research and development (R&D) pipeline. **[ADAPT]**	Conclusions 6, 7

[120] See also recommendation 9a.
[121] The Lusaka agenda captures consensus around five key shifts for the long-term evolution of GHIs, including Gavi – and the wider health ecosystem – and highlights several near-term priorities to catalyse action. The five shifts are: make a stronger contribution to PHC by effectively strengthening systems for health; play a catalytic role towards sustainable, domestically financed health services and public health functions; strengthen joint approaches for achieving equity in health outcomes; achieve strategic and operational coherence; and coordinate joint approaches to product research and development and regional manufacturing to address market and policy failures in global health.

Recommendation	Conclusion
8 ***Establish appropriate monitoring systems for Gavi 6.0 which provide timely evidence of country progress towards the strategic goals, and Gavi's contributions to such progress. Explore whether these systems can be redesigned to be less transaction heavy for countries, while allowing Gavi access to key data to assess progress and contribution. Document rationale for configuration of internal systems, including trade-offs,[122] and periodically review sufficiency, relevance, and effectiveness of monitoring arrangements with the Board.*** In this context, address two key issues repeatedly raised by external evaluations (and well-known to Gavi): a. Methodological issues on measuring results and predicting future trends. WUENIC data is the main data source to estimate coverage, but its limitations include long time lags and large data confidence limits. Consider further efforts to strengthen country health management information systems and complementary investments in survey data (including rapid surveys). [ADAPT] b. Strengthen monitoring of Gavi's contribution to observed and future results. This could include strengthening internal reporting mechanisms[123] including reporting by partners to track activity against plans and delivery against Gavi's ToC outputs and outcomes. It could also include portfolio-level monitoring approaches adopted by other institutions such as the World Bank. [124] [ADAPT]	Conclusion 3, 4 (4.2)
9 ***Continue to improve the supply and sustainability of affordably priced vaccines by expanding efforts and overcoming constraints in areas requiring enhanced efforts and coordination across the Secretariat and partners (e.g. demand health, long horizon market shaping, and vaccine programme sustainability).*** In this context: a. Continue the effective deployment of existing market shaping tools which facilitate innovation, competition, and demand consolidation (e.g. support to Vaccine Innovation Prioritisation Strategy (VIPS) work, WHO Prequalification and national regulatory authorities, and UNICEF procurement tenders) and a partner-aligned strategic approach to market shaping (principally through the antigen roadmap process). Improve the efficiency of data sharing amongst Square partners,[125] clarify roles and responsibilities, and enhance the processes and tools used for market shaping including aligning the level of effort with expected impact and the content and timing of the output with its anticipated use. [ADAPT] b. Continue work to refine plans for the African Vaccine Manufacturing Accelerator (AVMA), while mitigating risks to achieving impact. Further	Conclusions 5, 6

[122] There are trade-offs between comprehensive monitoring of data which enables Gavi to report on implementation and contribution to SGs and the associated transaction costs for countries and partners in comprehensive reporting on Gavi programmes. Monitoring systems nevertheless need strengthening (e.g. joint appraisals and reporting by partners on implementation) so that evidence is periodically collected against agreed country level outputs and outcomes which can be incorporated into a portfolio level overview.

[123]The importance of activity and output level monitoring is heightened in cases where Gavi interventions require a longer time to show results than a Gavi strategic cycle. The utility of the CPMPM as a tool to estimate contribution is somewhat limited since the indicators in the CPMPM do not closely match the SIs.

[124] https://scorecard.worldbank.org/en/scorecard/home

[125] Partnership of Gavi market-shaping partners: Gavi Secretariat, UNICEF-SD, WHO-IVB, & BMGF-VDCP (Gavi's Market Shaping Strategy 2021-2025).

Recommendation	Conclusion
design decisions would benefit from economic modelling from the perspective of individual firms targeted by the AVMA, as well as from the overall market perspective of the targeted antigens. **[CONTINUE]** c. In the context of unprecedented expansion in the menu of Gavi supported vaccine products and presentations, further strengthen/expand efforts on demand health. This should include: i) better ways of communicating vaccine choices to countries and mechanisms for supporting NITAGs with vaccine product portfolio management decisions as well as new forums for communication across the programmatic and market-shaping teams; ii) remapping of roles and responsibilities; iii) new policies related to how the market-shaping and programmatic teams work together; and iv) more cohesive demand health targets that are collectively created across Secretariat teams. **[ADAPT]** d. Heighten corporate attention to measurement of demand health attributes (e.g., percent of unconstrained demand met within a certain timeframe and number of product switches to more appropriate presentations) as distinct metrics. **[ADAPT]** e. Review the influence of the co-financing policy, budget allocation model, and policies enabling country control over the vaccine supplier and product presentation on vaccine demand materialisation, portfolio optimisation, VfM, and sustainability. Analyse the impact of a switch to a country budget ceiling allocation model and/or altering the policies on country choice of vaccine supplier and product presentation on: i) allocative efficiency at the overall Gavi portfolio level; ii) VfM decision-making at country level regarding vaccine programme choices; and iii) leverage to influence market health. Revise the co-financing policy to incentivize VfM in all countries, not just countries in transition. **[ADAPT]** f. Where justified by Gavi's comparative advantage and market needs, intervene with pull mechanisms earlier (in the Gavi pre-VIS to vaccine introduction cycle) to avert market failure, prepare markets for optimised programme launches, and ensure improved responsiveness and faster access to vaccines in the event of an outbreak or epidemic. **[ADAPT]** g. Implement the agreed 2020 procurement and supply strategy evaluation recommendations to: i) support supply and procurement performance in nearing/post transition countries and improve vaccine market intelligence data relating to MICs and never-eligible Gavi countries; and ii) strengthen M&E of operational activities. The latter should balance transaction costs and utility (accountability and lesson learning) while addressing antigen roadmap data confidentiality by identifying meaningful, but non-sensitive measures which can be shared. **[ADAPT]**	

3.3 Lessons learned

This section details lessons[126] that Gavi could draw upon for the Gavi 6.0 strategy, based on the experience of developing and implementing Gavi 5.0/5.1, under two main headings: i) adaptability and flexibility; and ii) monitoring and tracking implementation. These lessons are based on findings from the MTE and not necessarily drawn from Gavi's own analysis.

On being able to adapt and be flexible

1. After COVID-19, it is a given that Gavi can adapt and respond fast to an emerging crisis. However, in a less crisis-driven environment, there are conflicting drivers at work. For example, the need for simplification of Gavi systems reflects country demands for lower transaction costs and less burdensome processes. However, donors, with accountability to different stakeholders, may make demands which increase complexity and transaction costs. Although there has been some progress during Gavi 5.0/5.1, in practice there has been too little reform over the past decade. Much more needs to be done to tackle the barriers which are inherent in a large, complex organization with diverse stakeholders, each reporting to separate governing bodies. Overcoming these barriers is complex and requires determined change management from top to bottom of the organisation, and explicit agreement with the Board around associated implications and/or trade-offs.
2. Rapid reprioritisation may be needed during these times of crisis, alongside appropriate adjustment of expectations. This places a premium on effective (flexible and responsive) partnerships – with core and extended Alliance partners, with country stakeholders, and within the Secretariat. Defining roles and responsibilities and aligning expectations around revised priorities based on mutual trust and effective communication is key. Sufficient resources will be needed to manage these processes, which need to be functioning in advance of the next crisis.
3. Gavi's ability to identify required changes and to execute those changes depends on the extent to which the SCMs, whose capacity may be stretched across multiple countries, have the necessary delegated authority, resources, capabilities, and partnerships in place to affect change.
4. Models that have worked for Gavi in the past may not work as well in the contexts that are likely to predominate in Gavi 6.0 – for example, fragility and conflict, both between and within countries, and the majority of ZD children living in MICs. This makes it particularly relevant for Gavi 6.0 to focus on eligibility, transition and sustainability, market shaping, and HSS.

On monitoring progress and tracking implementation

5. Monitoring strategic implementation and results and using this information for course-correction and engagement with stakeholders necessitates high-quality systems that provide relevant, timely and publicly accessible data. Establishing the minimum set of information required and balancing this with acceptable transaction costs of collection/collation/accessibility is a difficult balancing act, involving choices and trade-offs. This is a longstanding challenge that is best addressed through explicit documentation of goals and decisions.
6. The results of implementing a five-year strategy may only be realised during the subsequent strategic period, resulting in a challenge to accountability and reporting to stakeholders on

[126] The DAC definition of a lesson requires that lessons highlight strengths or weaknesses in preparation, design, implementation; and we note, in this regard, overlap with strengths and challenges identified for each conclusion in the Executive Summary.

progress. Managing expectations of what can be achieved in a five-year phase is important, especially if going beyond Gavi's existing 'core business', as is the use of long-term indicators spanning multiple strategy periods.

7. Setting goals in terms of measurable targets and consistent indicators across all contexts provides challenges for country ownership, and Gavi is not alone in experiencing the resulting tensions between accountability to donors and the principle of country ownership. Gavi will need to be mindful that a move towards country ownership may weaken its ability to commit to global targets and donor-specific requirements. The next replenishment cycle should factor these challenges into its investment case and funding levers.

Annexes (separate volume)

Annex 1: Request for proposal (ToR) as received from Gavi
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Annex 3: Key aspects of MTE methodology
Annex 4: Bibliography and list of key informants
Annex 5: Supporting evidence for HLQ1
Annex 6: Supporting evidence for HLQ2
Annex 7: Use of Forcefield Analysis and Current Reality Tree
Annex 8: Summary of questions for MTE arising from strategy operationalisation evaluation analysis and other key evaluations
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Annex 10: Thematic study – MICs
Annex 11: Thematic study – RM
Annex 12: Thematic study – Innovation
Annex 13: Stakeholder engagement
Annex 14: Line of sight
Annex 15: Strengths and weaknesses
Annex 16: Supporting information for recommendations

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